Occupational therapy lifestyle intervention REVEAL(OT) added to multidisciplinary chronic pain treatment at a Danish pain centre

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Occupational therapy lifestyle intervention REVEAL(OT) added to multidisciplinary chronic pain treatment at a Danish pain centre

Svetlana Solgaard Nielsen

Ph.D.-thesis

This thesis has been submitted to the Graduate School of Health Sciences,

University of Southern Denmark

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The REVEAL(OT) intervention

(Redesign your Everyday Activities and Lifestyle with Occupational Therapy)

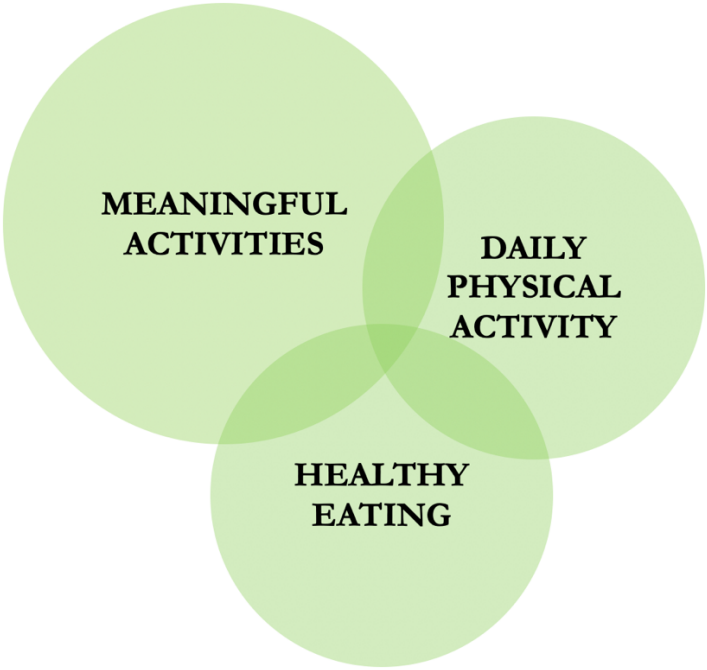

Illustration above: from Colourbox, licenced

Illustration below: The three-fold focus in the REVEAL(OT)-intervention, from the author

Declaration by the author

This thesis contains my original work and materials developed for the current research project. The thesis includes no materials written by another person, unless a reference to another source is provided. Publications produced within the project inclusive submitted manuscripts can be seen in the following. The co-author contribution is clearly stated in a separate section. Collaborators and their contribution in different research phases, including survey conduct, statistical assistance, data management and financial support, are listed below.

Herewith, I declare that copyright holders of the reproduced materials used in this thesis have been asked for permission when relevant, and the copyright reside with those.

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/Svetlana Solgaard Nielsen, December 2021

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Abbreviations and acronyms

The readers will meet the following abbreviations:

- ACT, Acceptance and Commitment Therapy
- AMPS, the Assessment of Motor and Process Skills
- Appx., approximately
- BMI, Body Mass Index
- CBT, cognitive-behavioural therapy
- CCPA, Controlled Cuff Pressure Algometry
- Cf., confer
- CI, confidence interval
- CMO, Context-Mechanism-Outcome
- CMOP-E, the Canadian Model of Occupational Performance and Engagement
- CONSORT, the Consolidated Standards of Reporting Trials
- COPM, the Canadian Occupational Performance Measure
- COVID-19, coronavirus disease 2019 (2019-nCoV acute respiratory disease/ 2019-nCoV ARD)
- CPPF, the Canadian Practice Process Framework
- E.g., for "exempli gratia" in Latin (for example)
- EQUATOR, Enhancing the QUAlity and Transparency Of health Research
- Et al., for "et alia" in Latin (and others)
- EU, the European Union
- FIM, the Functional Independence Measure
- HBM, the Health Belief Model
- HRQoL, Health-Related Quality of Life
- IASP, The International Association for the Study of Pain
- ICD-11, the International Classification of Diseases, 11th version
- I.e., for "id est" in Latin (in other words)
- IMMPACT, the mission of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
- IPA, the Impact on Participation and Autonomy
- LIFE-H, the Assessment of Life Habits
- MAS, the Milliken Activities of Daily Living Scale
- Max., maximum
- MCAR, missing completely at random
- MCID, minimally clinical important difference
- MCP, the Multidisciplinary Pain Centre
- Min., minimum
- MRC, the British Medical Research Council

- NADA, the National Acupuncture Detoxication Association
- OBQ, the Occupational Balance Questionnaire
- OPHI-II, The Occupational Performance History Interview-II
- OTU, the Occupational Therapy Unit
- P., page
- PFPA, the Pain and Functional Performance Assessment
- POP, the Assessment of Pain and Occupational Performance
- PRECIS-2, PRagmatic Explanatory Continuum Indicator Summary-2
- PROSPERO, the International Prospective Register of Systematic Reviews
- PSEQ, the Pain Self-Efficacy Questionnaire
- QQ-plot, quantile-quantile plot
- QST, quantitative sensory testing
- RoB, Risk of Bias
- RCT, randomised controlled trial
- REVEAL(OT), "**R**edesign your **Eve**ryday **A**ctivities and **L**ifestyle with **O**ccupational **T**herapy"
- SD, standard deviation
- TENS, Transcutan Electric Stimulation
- TIDieR, Template for Intervention Description and Replication
- USA, the United States of America
- USC, the University of Southern California
- VAPAIN, Validation and Application of a patient relevant core outcome set to assess effectiveness of multimodal PAIN therapy
- VAS, visual analogue scale
- WHO, the World Health Organisation
- WMA, the World Medical Association
- YLD, years lived with disability

List of publications

Paper I Svetlana Solgaard Nielsen, Søren T. Skou, Anette Enemark Larsen, Alessio Bricca, Jens Søndergaard, Jeanette Reffstrup Christensen. The effect of occupational engagement on lifestyle in adults living with chronic pain – A systematic review and meta-analysis. Occupational Therapy International, in review - ID 7082159

Paper II Svetlana Solgaard Nielsen, Søren T. Skou, Anette Enemark Larsen, Jens Søndergaard, Jeanette Reffstrup Christensen. Associations of health-related quality of life with sociodemographic characteristics, health, pain, and lifestyle factors, and motivation for changing lifestyle in adults living with chronic pain: a cross-sectional exploratory study. Scandinavian Journal of Pain, vol., no., 2021, pp. 000010151520210062. https://doi.org/10.1515/sjpain-2021-0062

Paper III Svetlana Solgaard Nielsen, Jeanette Reffstrup Christensen, Jens Søndergaard, Vicki Oldenschläger Mogensen, Anette Enemark Larsen, Søren T. Skou & Charlotte Simonÿ (2021) Feasibility assessment of an occupational therapy lifestyle intervention added to multidisciplinary chronic pain treatment at a Danish pain centre: a qualitative evaluation from the perspectives of patients and clinicians, International Journal of Qualitative Studies on Health and Well-being, 16:1, DOI: 10.1080/17482631.2021.1949900

Paper IV Svetlana Solgaard Nielsen, Søren T. Skou, Anette Enemark Larsen, Romanas Polianskis, Wojciech Zbigniew Pawlak, Henrik Bjarke Vægter, Jens Søndergaard, Jeanette Reffstrup Christensen. Programme development and feasibility study of an occupational therapy lifestyle management programme added usual care for adults living with chronic pain. Scandinavian Journal of Occupational Therapy, in review – ID 215315438

Preface

This Ph.D.-project was carried out between January 2019 and December 2021 when I was affiliated as a Ph.D.-student with the Faculty of Health Sciences at the University of Southern Denmark and the Department of Physiotherapy and Occupational therapy at Naestved, Slagelse and Ringsted Hospitals in Region Zealand. The experimental part of this Ph.D.-project was conducted in collaboration between the Occupational Therapy Unit, the Multidisciplinary Pain Centre at Naestved Hospital, Region Zealand and the University of Southern Denmark. This Ph.D.-project was originally planned to contain a feasibility study with subsequent randomised controlled trial. Early in the process I realized that the feasibility phase needed to be prolonged due alterations in clinical practice and the uncertainties in the intervention design that followed herewith.

This thesis follows so called "funnel model" starting from a broader perspective on chronic pain treatment and narrowing down to the Ph.D.-project presentation from its development phase to feasibility test and evaluation. In the development phase, I present and reflect on two studies that improved the evidence base for the project – a systematic review with a meta-analysis and a survey. Presenting the occupational therapy lifestyle intervention REVEAL(OT), I start with the protocol for the randomised controlled trial that illustrates the initial research activities planned. Later, I describe the iterative feasibility process with continuous intervention development and reflect on the research decisions informed by the participants feedback and alterations in the clinical practice. The evidence from two other studies representing the feasibility phase will illustrate that.

Finally, I summarise the cumulative research experience both in general and for each study involved, reflect on my choices as a researcher and propose alternative solutions when relevant. With this approach, I attempt to reveal and discuss the potential of occupational lifestyle-oriented approach added to the standard multidisciplinary treatment of chronic pain.

Kind regards,
Svetlana Solgaard Nielsen

Summary in English

Introduction: Interventions addressing daily activities and lifestyle seem relevant for people living with chronic pain. Previous research showed that occupational therapy lifestyle management could benefit the chronic pain population. However, its effectiveness needs further investigation. Occupational therapy intervention REVEAL(OT) - Redesign your EVEryday Activities and Lifestyle with Occupational Therapy - targeting meaningful activities, daily physical activity and eating habits (Clinicaltrials.gov reg. NCT03903900) was developed as an add-on to multidisciplinary cognitive-behavioural therapy-based treatment at a Danish pain centre. No occupational therapy lifestyle management was previously included in the current treatment. Before initiating a full-scale randomised controlled trial (RCT), the intervention for feasibility.

Objectives: Based on knowledge derived from the development and feasibility evaluation process of the occupational therapy lifestyle intervention REVEAL(OT) added to standard multidisciplinary chronic pain treatment, this Ph.D.-project aimed to prepare an RCT that would investigate in the intervention effectiveness. Besides the presentation and methodological discussion of the research process represented in four scientifical studies, this Ph.D.-thesis attempted to set the REVEAL(OT) intervention in a broader perspective of non-pharmacological chronic pain treatment.

Methods: The REVEAL(OT) development and evaluation process followed the Medical Research Council (MRC) recommendations allowing a multifactorial iterative approach to intervention development and conduct. The research complied with the principles of The World Medical Association's (WMA) Declaration of Helsinki.

In the intervention development phase, a systematic review with a meta-analysis investigated the effect of interventions including occupational engagement on lifestyle factors. In a survey, the associations between quality of life, health, pain, and lifestyle factors in the target population was investigated, inclusive motivation for initiating lifestyle changes as a part of chronic pain treatment. A qualitative mid-term evaluation with eight outpatients and four clinicians involved in the REVEAL(OT) using focus group methodology gained in-depth opinions on their participation derived from the data-driven thematical analysis and inspired to further intervention improvement.

In total, the REVEAL(OT) went through three feasibility rounds between January 2019 and June 2021 and included eight groups (40 adults, 85.0% females, 46.6±10.9 (23-64) years old, average pain duration = 10 (9.3) years). Structural adjustments between the feasibility rounds reflected the

outpatients and clinicians' feedback. Primary outcomes were predefined research progression criteria based on "the traffic light" system (the red-amber-green method), including recruitment rate, participant retention, program adherence, assessment procedure acceptance, patients' self-perceived relevance, timing, and mode of delivery, adverse and the fidelity of delivery. No comparator or blinding was applied. Secondary outcomes included were self-reported health-related quality of life (EQ-5D-5L, HRQoL) and occupational performance and satisfaction (The Canadian Occupational Performance Measure, COPM).

Results: Research progression criteria for feasibility regarding program adherence; patients' self-perceived relevance, timing, and mode of delivery; assessment procedure acceptance; and adverse events were overall feasible. Recruitment rate, participant retention and fidelity of delivery needed to be optimised before a randomised controlled trial. We found no improvement in HRQoL, mean = .04 (SD .16; 95% CI -.03; .12) assessed in 23 pre-post reports but significant change in the COPM scores, mean occupational performance = 1.80 (SD 1.44; 95% CI 1.25; 2.35) and mean satisfaction with occupational performance =1.95 (SD 2.34; 95% CI 1.06; 2.84), assessed in 29 pre-post reports. The recommended COPM cut-off for minimal clinically important difference (MCID) was 13.8% and 24.1%, respectively.

Conclusion: Occupational engagement included in chronic pain interventions can support lifestyle improvements in adults. Interventions targeting pain, sleep, lifestyle and daily activities are needed to improve quality of life and health in people living with chronic pain. The REVEAL(OT) added to the multidisciplinary chronic pain treatment strengthened acceptance of living with chronic pain in adult chronic pain patients and empowered them for initiating lifestyle changes. The REVEAL(OT) satisfactory fulfilled its research progression criteria regarding programme adherence; patients' self-perceived relevance, timing, and mode of delivery; assessment procedure acceptance; and adverse events, and thus was overall feasible. However, the recruitment, participant retention and delivery strategy of the REVEAL(OT) programme need optimisation before initiating an RCT. Improved interdisciplinary treatment delivery context will benefit the intervention feasibility.

Summary in Danish

Introduktion: Interventioner med fokus på hverdagsaktiviteter og livsstil er relevante for mennesker som lever med kroniske smerter. Selvom tidligere forskning har vist, at livsstilsorienteret ergoterapi kan gavne kroniske smertepopulation, er evidensen stadig mangelfuld.

Ergoterapeutisk intervention REVEAL(OT) - Redesign dine EVEryday Activities and Lifestyle with Occupational Therapy - har fokus på meningsfulde aktiviteter, spisevaner og daglig fysisk aktivitet (Clinicaltrials.gov reg. NCT03903900). REVEAL(OT) blev udviklet og lagt oveni den eksisterende multidisciplinære kognitive adfærdsterapi-baserede behandling på et dansk smertecenter, hvor der tidligere ikke var et ergoterapeutisk livsstilsorienteret tilbud. Vi testede om interventionen var mulig at gennemføre som forberedelse til et fuldskala randomiseret kontrolleret forsøg (RCT).

Formål: På basis af den evidens som blev genereret under udviklingen af REVEAL(OT), havde nærværende Ph.D.-projekt til formål at forberede et RCT, som ville undersøge effekten af den ergoterapeutiske intervention. Med afsæt i fire videnskabelige publikationer, havde denne Ph.D.-afhandling til formål at sætte REVEAL(OT) i et bredere perspektiv som et nyt ikke-farmakologisk behandlingstilbud til kroniske smertepatienter.

Metoder: Den iterative udviklings- og evalueringsprocess af REVEAL(OT) fulgte anbefalingerne for komplekse interventioner fra den Britiske Medical Research Council og forskningsprincipperne fra Declaration of Helsinki fra World Medical Association. I interventionsudviklingsfasen undersøgte vi effekten af aktivitetsinvolvering (occupational engegement) på modificerbare livsstilsfaktorer i et systematisk review med meta-analyse. Associationerne mellem livskvalitet, sundhed, smerte og livsstilsfaktorer blandt kroniske smertepatienter blev undersøgt ved et spørgeskema i samme forskningsfase. Her undersøgte vi også deres motivation for at foretage livsstilsændringer. Midtvejs i studiet foretog vi en kvalitativ evaluering via tre fokusgruppeinterviews med i alt otte ambulante patienter og fire klinikere, der alle var involveret i REVEAL(OT). Fokusgruppeinterviewsene afdækkede deres meninger og holdninger i forhold til at deltage i REVEAL(OT) og hjalp til at interventionen blev yderligere forbedret.

REVEAL(OT) gennemgik tre feasibility-runder mellem januar 2019 og juni 2021. I alt deltog otte interventionsgrupper (40 voksne, 85.0 % kvinder, 46,6±10,9 (23-64) år gamle, gennemsnitlig smertevarighed = 10 (9,3) år). Interventionen blev justeret til mellem feasibility-runderne på baggrund af patienternes og klinikernes feedback.

Til evalueringen anvendte vi foruddefinerede progressionskriterier for rekruttering, fastholdelse, programoverholdelse, accept af undersøgelsesproceduren, patienternes selvevaluerede relevans, timing og leveringsform, uønskede hændelser og overensstemmelse af den leverede intervention med planen. Hvorvidt progressionskriteriernes var opfyldt blev evalueret via rød-gul-grøn ("trafiklys" system) metode. Der var ingen kontrolgruppe og ingen blev blindet. Ændringer i selvrapporteret livskvalitet (EQ-5D-5L) og aktivitetsudførelse og tilfredshed (The Canadian Occupational Performance Measure, COPM) før- og efter interventionen blev målt som et led i feasibility-evalueringen.

Resultater: Progressionskriterierne for programoverholdelse; patienternes selvevaluerede relevans, timing og leveringsform; accept af undersøgelsesproceduren; og uønskede hændelser havde tilfredsstillende niveau. Interventionsstrategierne for rekruttering, fastholdelse og planmæssig levering krævede optimering. Selvom vi ikke observerede ændringer i livskvalitet (23 patientrapporter), gennemsnitlig ændring = .04 (SD .16; 95% CI -.03; .12), opnåede deltagerne en signifikant ændring i COPM-scorer (29 patientrapporter) for aktivitetsudførelse, gennemsnitlig ændring = 1.80 (SD 1,44; 95% CI 1,25; 2,35) og tilfredshed med aktivitetsudførelsen, gennemsnitlig ændring = 1,95 (SD 2,34; 95% CI 1,06; 2,84). Den mindste klinisk relevante forskel for COPM-scorer (MCID) lå på henholdsvis 13,8% og 24,1%.

Konklusion: At inddrage aktivitetsengagement kan være med til at understøtte en sundere livsstil hos voksne som lever med kroniske smerter. Der er behov for interventioner der fokuserer på smerte, søvn, livsstil og daglige aktiviteter for at forbedre livskvalitet og helbred på trods at kronisk smerteproblematik. REVEAL(OT) lagt oveni den tværfaglige smertebehandling har styrket patienternes accept af livet med kroniske smerter bland voksne patienter og opmuntret dem til en sundere livsstil. REVEAL(OT) viste sig at være mulig at gennemføre ved at opfylde progressionskriterierne for programoverholdelse; patienternes selvevaluerede relevans, timing og leveringsform; accept af undersøgelsesproceduren; og forekomsten af uønskede hændelser. Rekruttering, fastholdelse og leveringsstrategi for REVEAL(OT) bør optimeres yderligere inden opstart af en RCT. Interdisciplinær karakter i leveringen vil styrke interventionens gennemførbarhed.

Background

Occupational therapy and science understand humans as occupational beings and differentiate the terms ”occupations” and ”activities” while both have been used interchangeably in other fields of science (77). This thesis will operate with the definition of ”occupations” as a set of consistently and regularly performed context-bound meaningful activities where people engage themselves while pursuing personal goals and which determines a person’s lifestyle (68, 78). Hence, promoting performance and participation in meaningful activities within the lifestyle-oriented occupational therapy intervention described and explained in this thesis will pursue improved occupational engagement in the participants to enhance their self-perceived health and quality of life (79).

The recipients of the experimental treatment will be described in specific parts of this Ph.D.-thesis as ”participants” in the intervention participation context, ”patients” in the context of the tertiary chronic pain treatment system, and ”clients” in the context of client-centred occupational therapy. The background section will start with the broader perspective on the phenomenon of chronic pain and its treatment to present the reader for the current context entered by the REVEAL(OT) intervention before taking the occupational therapy perspective.

Chronic pain phenomenon

Pain is a vital mechanism serving human safety, preventing us from heavier tissue damage or other adverse effects of an action. According to The International Association for the Study of Pain (IASP), pain is defined as “an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage” (1). Though, not all sorts of pain are biologically appropriate for human health and well-being. Therefore, it is important to distinguish acute and subacute pain from chronic pain. While acute and subacute pain serves our survival in a potentially dangerous situation or accompanies a healing process, chronic pain does none of those (2). Despite symptomatic similarities between acute, subacute and chronic pain, they require different treatment approaches.

Pain experts have been uncertain about the time of chronic pain onset, where some sources operate with six months of persistent pain as the time limit whereafter chronicity emerges. However, the IASP

group's latest evidence confirms that the transformation from acute to subacute and further to chronic pain can happen just in three months of a persistent pain sensation (3). On average, about every fifth individual may suffer from chronic pain globally, while its prevalence may reach 40% in several countries (4). Furthermore, chronic pain is the primary cause of disability and is one of the most frequent reasons for seeking medical assistance and withdrawing from the labour market (4, 5).

Chronic pain is an overarching term for a variety of its subcategories. Recently, a new classification of chronic pain has been developed and included in the revised version of the International Classification of Diseases (ICD-11) as a result of cooperation between the World Health Organization (WHO) and the IASP (6). In the latest revision, a new chronic pain category of primary chronic pain has emerged, marking a new paradigm in our understanding of chronic pain and underpinning the duality of the chronic pain phenomenon that may be primary, or secondary. While secondary chronic pain has an underlying disease or other identifiable origins, primary chronic pain does not appear to be linked to any other specific health condition (3). This new classification reflects chronic pain as an independent disease that may not include other sick health states.

The pain experience is always personal and often may not be visible to others unless it is caused by bodily damage or has apparent symptoms. Therefore, people living with primary chronic pain conditions, such as fibromyalgia or migraine/ headache with no somatic origin or visible symptom declaration, may perceive a stigma attached to the fatigue, attention deficit, recurrent contacts with healthcare services or taking frequent sick days (7). Sigma may not only impair self-confidence, worsen mental health and awake a "give up" attitude in an individual living with chronic pain but also increase the inequality in healthcare for "difficult patients" (8). On the other hand, new comprehension of chronic pain as an independent disease may promote the recognition of the needs of those who suffer from it and provide them with necessary treatment opportunities.

With its 30.3% prevalence for the global population (9), chronic pain is considered a heavy societal burden. Chronic pain demanded up to $635 billion in annual treatment coverage in the USA in 2010 and over 18 billion euro in Austria in 2016 (10, 11). Productivity losses because of chronic pain were mainly associated with early retirement, work absence and sick leave (11, 12). On the personal plan, chronic pain was among the ten most severe causes of years lived with disability (YLD) across 188

countries in 2013 (13). Appropriate and effective treatment of chronic pain may reduce the high healthcare expenses and negative individual consequences of long-term pain conditions.

Chronic pain treatment

According to the IASP Declaration of Montreal from 2010, access to pain management has the status of a fundamental human right (14). The declaration called for attention to the major deficits in various aspects of pain management in general, e.g., its accessibility, pain knowledge and education, lack of national treatment policies, noncomprehensive training programmes, and restricted medicine availability, and underscored stigmatising of individuals living with chronic pain.

Bio-psychosocial focus

The understanding of pain mechanisms evolved from a reductionistic view on it as a mainly biological process within the nervous system that dominated until the 19th century to a holistic perspective including biological, psychological, sensory and social components (15). Melzack and Wall have taken the integrative perspective on chronic pain as the result of mind-body interplay in their Gate Control Theory of Pain that based its explanation of chronic pain phenomenon on the interaction of physiological and psychosocial mechanisms (16, 17). According to The Gate Control Theory, substantia gelatinosa in the dorsal horn of the spinal cord mediates and controls the intensity of afferent nociceptive impulses letting those pass to the brain where higher cortical functions may become responsible of how the impulses are being perceived and interpreted (18). Hence, we began to distinguish nociception (the mechanisms in pain receptors and fibres) from pain as a subjective sensory experience.

The ICD-11 has anchored chronic pain duality that can be a disease caused by an objective bio-mechanic event or an illness originating from subjective experience (6). Today, pain experts worldwide agree that no cure would eliminate chronic pain but learning how to cope and live with it is essential (19). In this term, the bio-psychological focus on chronic pain calls for a holistic approach to its treatment. It emphasises adopting effective self-management strategies as a cornerstone in promoting health and well-being in people living with chronic pain.

Multimodality in chronic pain treatment

Each individual living with chronic pain may experience a unique complexity of its manifestations, demanding tailored treatment options offered by the primary, secondary and tertiary healthcare sectors (20). While the primary healthcare sector will often cover the patient needs emerging from acute pain conditions, the secondary healthcare sector will cover the sub-acute phase supporting an effective rehabilitation process after an injury, and the tertiary healthcare sector will focus on specialised prevention of permanent disability. Prevention of permanent impairment caused by chronic pain requires a well-coordinated multimodal treatment approach delivered by teams of healthcare professionals (20-22).

A variety of treatment modalities offered to people living with chronic pain allow every individual to try, comprehend and adopt the chronic self-management strategies that match individual's personal life situation and individual capacities. In the literature, the multimodal treatment of chronic pain, including at least two healthcare professions in its delivery, has been interchangeably called multidisciplinary or interdisciplinary (23). Stanos and Houle (2006) have encouraged a differentiated use of the terms saying that multidisciplinary chronic pain treatment rather implies its structural composition (24). A variety of treatment options itself does not guarantee the treatment effectiveness if the treatment approach is not mutually coordinated and only represents diverse components (23). Besides the authors named above (23, 24), many others urged the implementation of interdisciplinary multimodal chronic pain treatment, which would enhance the benefits of specialised chronic pain treatment (25-27). Multimodal chronic pain treatment in the Danish public tertiary healthcare system has been delivered by eleven pain centres that traditionally employ physicians (anaesthesiologists), nurses, psychologists, physiotherapists and social workers. In contrast, greater involvement of occupational therapists has been urged in the Danish Health Authority in its report from 2020 on pain management in Denmark (28).

Pharmacological and non-pharmacological treatment

Pharmacological pain relief includes prescription of opioids, i.e., morphine-like natural or synthetic drugs with analgesic properties, that are useful in treating acute and sub-acute pain (29). However, long-term opioid consumption may cause dependency with multiple adverse sequelae for an

individual's physical, mental and social life. The latest report on worldwide opioid consumption showed that in 2019, 19.6% of the world population, mainly concentrated in Europe and North America, consumed 87.2% of the total amount of morphine for pain relief (30). The report ranked Denmark number nine internationally and number six among European countries in the average consumption of eight most consumed opioids per million inhabitants per year (30). This tendency of high opioid consumption in wealthy countries and inequalities in this area between those and low-income countries has existed for the last couple of decades.

The recent evidence still reports on the so-called "opioid epidemic" because medications are still a preferrable treatment solution for pain relief in many countries (31, 32). Anyhow, pain patients often consider medications as unsatisfactory and insufficient because they can only temporarily alleviate pain and have multiple side effects (33). Among common side effects of opioids are sedation, dizziness, nausea, vomiting, constipation, physical dependence, tolerance and respiratory depression which negatively impact daily functioning and quality of life (34). Therefore, health care professionals urge non-pharmacological alternatives for pain alleviation as the first-choice treatment of chronic pain because of no drug addiction risk and better sustainability of the effect in the long term.

Several factors associated with chronic pain, such as genetics, female gender, old age, low socioeconomic status, ethnicity and culture, or injury exposure, are unmodifiable. However, there are still other potentially amendable factors for a healthcare intervention (35). The latter are pain, multimorbidity impact, mental vulnerability (e.g., anxiety, depression and catastrophising beliefs) and lifestyle (e.g., smoking, alcohol consumption, overweight and obesity, physical activity, sleep quality and stress), work ability and sun exposure for adequate D-vitamin production (35). Of the above-named modifiable factors, only pain is potentially amenable for pharmacological treatment, while the rest of the list calls for non-pharmacological methods of impact. The non-pharmacological methods such as exercise, acupuncture, CBT, mindfulness, massage, mind-body practices and multidisciplinary approach were recently found most beneficial (36). However, non-pharmacological interventions are often complex because of the various interacting components involved (37). Although non-pharmacological approaches in chronic pain treatment have been highly demanded, the evidence gaps regarding novel treatment options may set a barrier for their implementation.

Lifestyle-oriented approach

Lifestyle has a narrow connection to the chronic pain phenomenon (35). Referring to Melzack and Wall's Gate Control Theory of Pain (16), Gatchel (2007) suggests that negative psychosocial states such as hopelessness and anxiety, as well as lifestyle factors such as lack of physical activity, poor sleep quality, unhealthy eating habits and smoking, may undermine the inhibitory mechanisms of the gate control system and amplify pain sensation (15).

Viewing chronic pain as a lifestyle-related illness emerged from the mechanisms of negative reinforcement of physical deconditioning resulting from pain catastrophising and avoidance behaviour, the mechanism explained by the fear-avoidance model (Figure 1) (38-40).

According to the fear-avoidance model (40), the self-perceived negative affect (conditioned stimuli, CS) from an actual or previous experience of bodily threat, or even an observation of such (unconditioned stimuli, US) may lead to response including increased arousal, attention to the sources of pain, withdrawal, fear and avoidance behaviour. The response, initially automatic and immediate (unconditioned response, UR), becomes conditioned (CR) and generalised to novel nonthreat life situations (GS) associated with the negative affect (CS). Vlaeyen et al. (2016) find that the mechanisms may also explain the sedentary lifestyle and other lifestyle-related challenges in people living with chronic pain (40). However, the chain of the negative responses can still be redirected towards recovery through prioritising value-based goals as a transformational key tool (40). Emerging evidence has also focused on approaching systemic cytokine-mediated inflammation and oxidative stress in chronic pain interventions as an underlying cause of chronic pain onset (41), which also supports the lifestyle-oriented approach. Moreover, recent evidence urged interventions simultaneously targeting multiple lifestyle factors in an intervention, based on the expectation of systemic improvement in health and well-being (42).

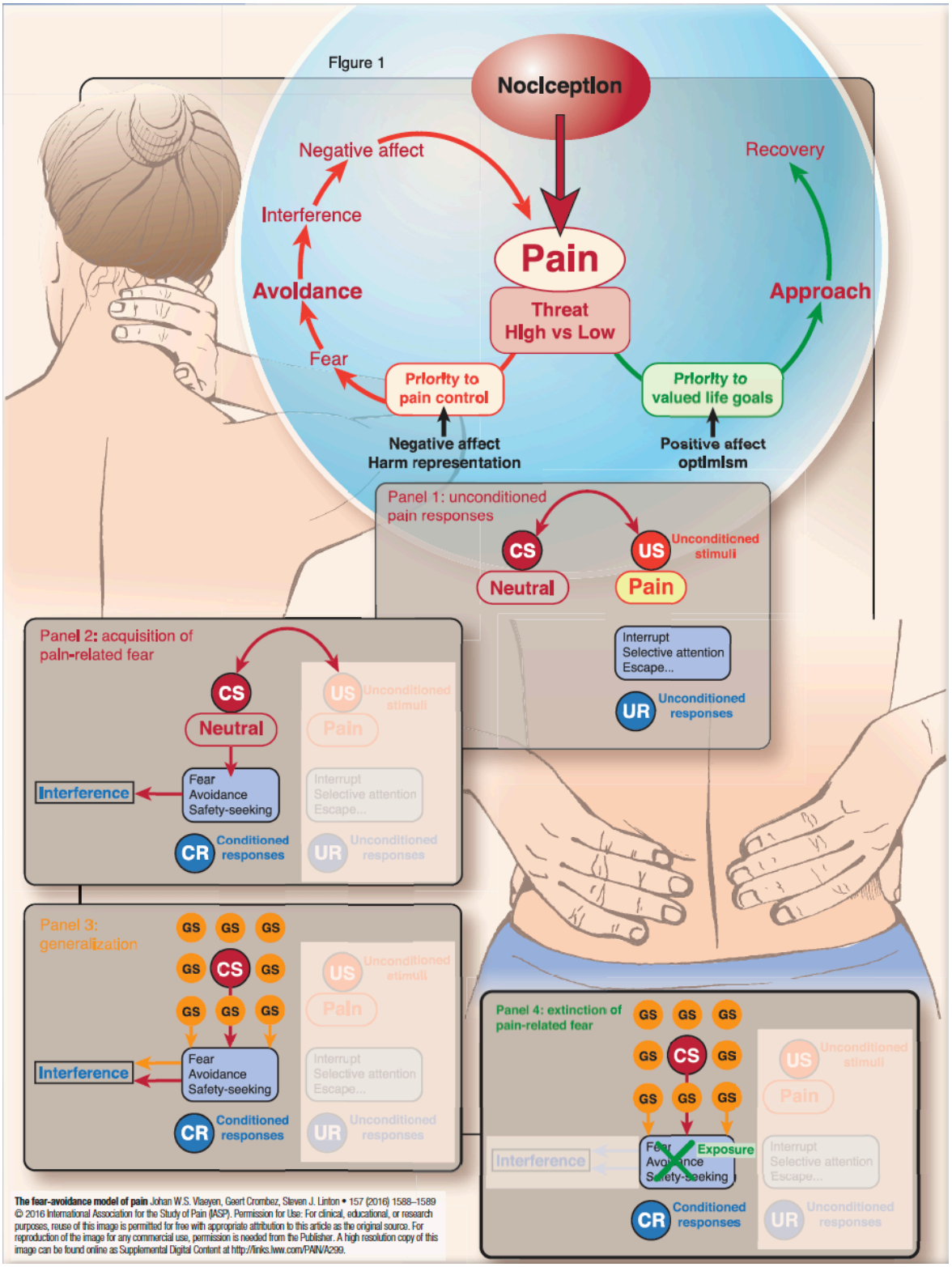

Figure 1. Fear-avoidance model (permitted by IASP for educational, clinical and research purposes when attributed to the original source: Vlaeyen JWS et al. The fear-avoidance model of pain. PAIN. 2016;157(8):1588-1589) (40)

I could not find examples of systematic addressing lifestyle in people living with chronic pain within Denmark's multidisciplinary public healthcare system. Though, physical activity, nutrition and stress have been addressed in self-management courses "Learn to Tackle" ("Lær at tackle", in Danish) offered by the Danish municipalities (43). This self-management concept has been based on the programme Chronic Disease Self-Management (CDSMP) developed by the researchers from Stanford University (USA) (44, 45). The Committee for Health Information (Komiteen for Sundhedsoplysning, in Danish) administrates these courses aimed at people living with chronic pain, anxiety and depression, chronic disease and workers with disability. Participation in the self-management courses if free and does not demand a general practitioner's referral. Instructors delivering the courses may or may not be graduated healthcare professionals. Thus, the public tertiary chronic pain care in Denmark needs to pay more attention to lifestyle-related challenges in people living with chronic pain. One of possible solution could be the inclusion of novel non-pharmacological treatment options targeting lifestyle through value-based approaches that promote recovery processes.

Occupational therapy approach to chronic pain treatment

The IASP recommended the inclusion of occupational therapists and occupational therapy assessment and intervention methods in chronic pain treatment, i.e., in multidisciplinary pain centres (46). Occupational therapy is declared an equal player in healthcare teams working with people living with chronic pain, both internationally (47) and in Denmark (28).

Occupational therapy links human behaviour, health and well-being with occupations (48, 49). Successful and satisfactory engagement in meaningful and purposeful occupations determines an individual's good quality of life, where meaningfulness is considered particularly important (50).

Difficulties in daily life in people living with chronic pain emerge from physical, emotional, cognitive, and environmental obstacles for successive and satisfactory occupational performance, i.e., in self-care, work, leisure and social relations (49, 51). Müllersdorf (2002) categorised the occupational performance disruptions and needs in chronic pain population as "occupational performance limitations", "need for education", "need to regain activities" and "adjustment difficulties" (52). According to Skjutar et al., occupational therapists working with chronic pain reported that their

clients experienced disturbed occupational engagement, knowledge deficit of pain mechanisms and pain coping strategies, occupational imbalance, physical and environmental strains, and pain-induced stress and depression (53). Severe memory problems were also seen in the chronic pain population (54). Even when people living with chronic pain may appear to perform well enough, they may perceive dissatisfaction with the time spent in performing occupations due to the experience of "crip time" (as an opposite to straight or natural time continuum) (55). This experience may cause frustration, messy daily structure, productivity loss and even make one feel having no future (55).

Occupational therapy intervention involves active and complex (non-linear) interrelations between occupational therapist's professional and behavioural characteristics; client's resources, needs and behaviour; intervention contents; situational context; and the environment (56). Using a client-centred and holistic approach, occupational therapists working in chronic pain management aim to enable occupational participation and enhance occupational engagement in individuals or groups whose occupational performance is negatively affected by chronic pain (49, 57).

Core focus area for occupational therapy in chronic pain management is reducing barriers for occupational engagement that clients may experience in mobility, self-care, work, leisure and social life while using the client's individually-valued significant activity (49, 57, 58). Thus, occupational therapy also supports an individual's occupational identity, including values, beliefs, roles, and interests (49). As summarised by Lagueux et al., the roles of occupational therapists in chronic pain management belong to (a) activities and participation, (b) bodily functions, (c) structures and environmental factors, and (d) personal factors in their clients (57). Occupational therapy roles and methods can be seen in Appendix 1.

The Canadian Model of Occupational Performance and Engagement (CMOP-E), focusing on interactions between the core domains Person, Environment, Occupation and Engagement, has been applied to chronic pain management (59, 60). A thorough assessment of occupational needs and wishes is essential at starting occupational therapy chronic pain intervention (58). Occupational therapists use activity analysis, occupational interviews, observations, and standardised function tests to evaluate occupational participation and identify occupational issues (49, 57). The most used occupational therapy assessment tools applied to chronic pain management are the Canadian Occupational Performance Measure (COPM), the Performance History Interview (OPHI-II), and the

Assessment of Pain and Occupational Performance (POP) (57). The following assessment tools have also been seen in the evidence, e.g., Functional Independence Measure (FIM), the Milliken Activities of Daily Living Scale (MAS), the Assessment of Motor and Process Skills (AMPS), the Assessment of Life Habits Questionnaire (LIFE-H), the Impact on Participation and Autonomy (IPA), and the Pain and Functional Performance Assessment (PFPA) (57).

Occupational therapy intervention methods for enabling occupational engagement in chronic pain treatment were previously reviewed in the evidence (49, 57, 58, 61). Hence, Laqueux et al. (2018) have recently categorised those using the intervention taxonomy developed by McColl and Law that classified the interventions according to their primary focus on either person, environment or occupation (57). Though the occupational therapy intervention methods would not always be eligible for such sharp focus differentiating, the overview proposed by the authors may help to systematise the occupational therapy approaches in this field, also depicted by other researchers (49).

Thus, occupational therapists conduct training, skill development, and education of their clients using a variety of intervention methods, e.g., improvement of body mechanics, postures and positioning; energy conservation techniques; exercising; mindfulness; CBT and other behavioural approaches; pain coping strategies; coordination and strengthening training; desensitisation and sensory re-education; and active movement and mobilisation techniques (49, 57). Working with tailored occupational goals (inclusive goal setting, monitoring and evaluation) may also belong to this category of person-oriented occupational therapy intervention methods (49). Less frequently were seen publications reporting on occupational therapy interventions including methods such as electrical stimulation and acupressure (57). Occupational therapy intervention methods for environmental support at home and work included ergonomics, i.e., using assistive devices and environmental modifications (49, 57). For enabling occupation through task adaptation and occupation development, occupational therapists used methods such as pacing and graded activity; activity adaptation and therapeutical activity; vocational training; sleep hygiene; and graded in vivo exposure (49, 57); as well as integrative (mind-body) medicine techniques, e.g., yoga and Tai chi (57).

Occupational therapy role in multidisciplinary teams is to enable individuals to achieve satisfying performance and participation in daily activities, reduce pain and fatigue-induced discomfort, and enhance the quality of life (49). In any case, occupational therapy may add to the combined effect of

multidisciplinary chronic pain treatment on an individual living with chronic pain because of the wide variety in personal preferences and needs, which a multiarray impact has a potentially better chance to meet (58).

However, the following publications witnessed challenges among occupational therapists entering the area of chronic pain management. Though most occupational therapists meet clients living with chronic pain and express a need for improvement in pain-induced occupational engagement disruptions, uncertainty may exist among occupational therapists about core occupational therapy roles and appropriate methods for chronic pain intervention (62). Occupational therapists reported on paucity in pain training during their undergraduate education as one of the barriers for their greater involvement in the field of chronic pain management, yet growing professional competence over time (62). When working in multidisciplinary teams, occupational therapists may also adopt a reductionistic bio-mechanical paradigm from other team members (62). Another frequent obstacle for professional confidence may be too wide use of bottom-up approach (i.e., relying on the client's own decisions) in working with people living with chronic pain, which may reduce an impact on occupation (57). Finally, lack of evidence on the effect of occupational therapy in chronic pain treatment can be both the result of its rather limited inclusion in the multidisciplinary chronic pain treatment facilities or still modest involvement in chronic pain research (63).

Some of the tendencies mentioned earlier were revealed two or more decades ago. In 2011, Robinson et al. again raised the question of whether occupational therapy adequately meets the chronic pain population's needs (64). Recently, evidence again reported on the persistent conflict between the bio-mechanical and occupational perspectives within occupational therapy in the field of chronic pain treatment (57). The researchers have seen the potential for further development of occupational therapy impact on chronic pain, particularly in multidisciplinary teams, where occupational therapists may affirm themselves as specialists in enabling occupational engagement (57). The IASP in its Curriculum Outline on Pain for Occupational Therapy encourages the improvement of pain education and training of occupational therapists to promote their involvement as multidisciplinary team members (65).

The evidence urges occupational therapists working with people living with chronic pain to comprehend chronic pain as a bio-psychosocial phenomenon, have fidelity to the occupational

therapy philosophy and the central role of occupation, balance bottom-up and top-down treatment approaches, be attentive to the patient narratives and focus on sustainable improvement in occupational performance and participation (57, 61, 64). Occupational therapy also needs an improvement of the evidence base with more controlled studies investigating the effectiveness of occupational therapy treatment services for people living with chronic pain (57, 58, 61). All in all that may help occupational therapy establish a strong professional position in chronic pain management.

Occupational therapy lifestyle management of chronic pain

From occupational therapy and occupational science perspective, human occupational performance in daily life defines an individual's lifestyle (66). Thus, our daily occupational choices regarding self-care, productivity, and leisure will form one's occupational lifestyle. At the same time, a health-related lifestyle will depend on one's habits regarding physical activity, eating, smoking, drinking alcohol, adequate sleep hygiene, and stress-free daily scheduling. Therefore, cooperation with occupational therapists on appropriate lifestyle management through value-based occupational choices and health-related modifiable lifestyle factors would benefit people living with chronic pain and promote their physical, mental, emotional and social well-being (52, 53).

One of the well-established occupational therapy lifestyle management programmes is the Lifestyle Redesign®-programme developed at the University of Southern California (USA) to guide people with various health issues in creating meaningful and health-promoting habits and routines (67). The programme has improved older adults' physical functioning, occupational performance, and health throughout different study phases from pilot to long-term follow-up (68-71). The intervention has also proved its cost-effectiveness (72). The results of the programme applied to chronic pain management were also encouraging. A retrospective one-group cohort in 45 adults with chronic pain diagnoses, e.g., low back pain, myalgia and complex regional pain syndrome, significantly improved their occupational performance and satisfaction, energy levels, general health, quality of life, pain self-efficacy, physical and social functioning, and reduced their role limitations and fatigue (73). Recent mixed methods study from Canada concluded that 15 adults living with fibromyalgia significantly improved their occupational engagement in meaningful activities, life balance, mental health, and pain self-efficacy (74). They also benefitted from focusing on daily activities and strengthening of the sense of belonging (74). Although the evidence revealed examples of the

positive impact of occupational therapy lifestyle management applied to the chronic pain population, further investigations are still needed in the effectiveness of lifestyle-oriented occupational therapy included in chronic pain treatment.

Aims

Project rationale

The prevalence of chronic pain in society is high and calls for further inclusion of novel non-pharmacological treatments, e.g., those addressing lifestyle. Occupational therapists improve occupational engagement and lifestyle in people living with chronic pain by addressing their occupational problems related to self-care, productivity, and leisure, and thus, thus enhancing their health, well-being, and quality of life (57, 58). However, while occupational therapy lifestyle management, e.g., creating meaningful and healthy habits in a self-determined value-based way, has shown promising results (75), this treatment option has not been offered at the multidisciplinary pain centres in Denmark. A lifestyle-oriented occupational therapy programme was added to the standard multidisciplinary chronic pain treatment and evaluated for feasibility to provide the Danish chronic pain patients referred to a multidisciplinary pain centre with occupational therapy lifestyle management and prepare a randomised controlled trial (RCT) to investigate the effectiveness of this approach. The programme was adopted to the current multidisciplinary clinical practice using an iterative pragmatic, eclectic approach.

Significance of the project

The project would deliver new knowledge on the development and feasibility of the REVEAL(OT) intervention informed by international evidence and applied to adult chronic pain patients referred to standard multidisciplinary treatment at a Danish hospital. This new knowledge would strengthen the current chronic pain treatment practice with a lifestyle-oriented occupational therapy approach. Moreover, the project would generate new evidence on how lifestyle-oriented occupational therapy as a new non-pharmacological treatment modality can support the current standard treatment by creating meaningful, healthy habits in adults living with chronic pain. The results would also inform future research activities to estimate the effectiveness of the occupational therapy lifestyle-oriented approach. In a longer perspective, the project may help to nuance the current standard treatment approach and thus, improve the treatment opportunities for people living with chronic pain.

Objectives

This Ph.D.-project aimed to develop and evaluate for feasibility a lifestyle-oriented occupational therapy intervention REVEAL(OT) added to the current standard treatment for adults referred to a Danish pain centre where neither lifestyle management nor occupational therapy has previously been included. Subsequently, the evidence generated throughout the research process should inform the preparation of a future RCT that would investigate the effectiveness of the REVEAL(OT). The results derived from different stages of the research are presented in four research papers (Figure 2). The research papers contributed to a better understanding of the lifestyle-oriented occupational therapy approach, setting the REVEAL(OT) in a broader perspective of nonpharmacological treatment for adults living with chronic pain.

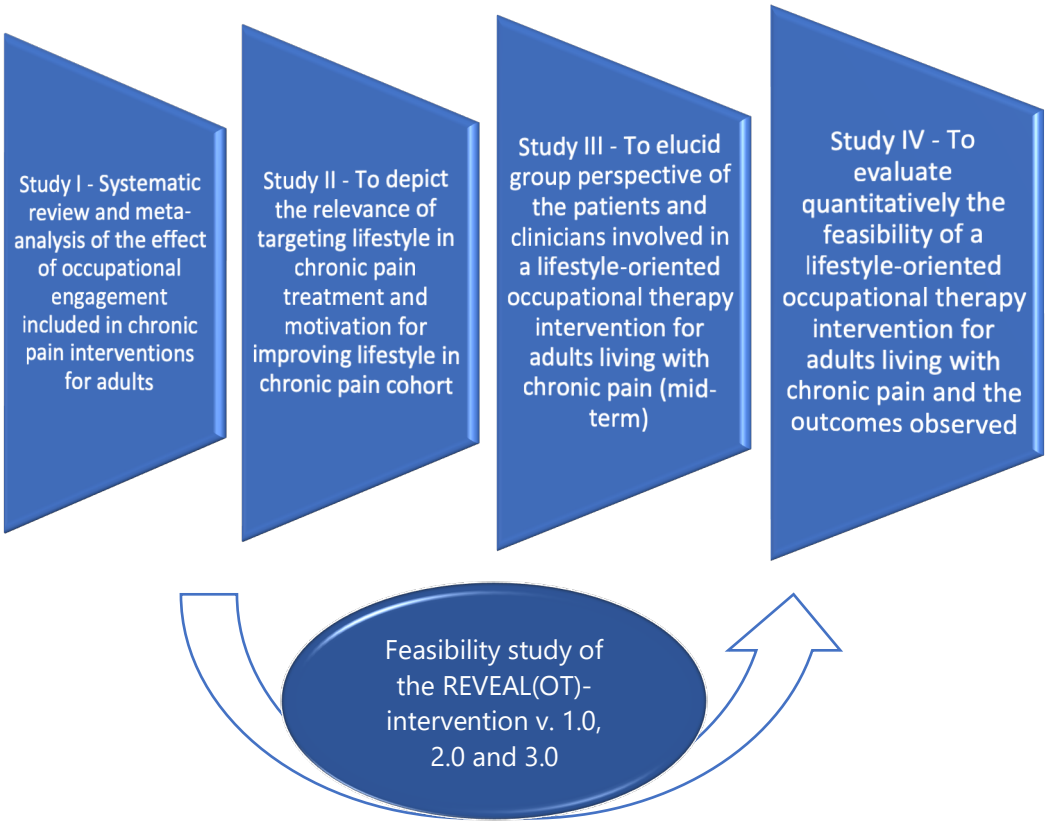

Figure 2. Studies included in the Ph.D.-project

Studies I and II pursued to explore the evidence base and the target population characteristics to inform the development of an occupational therapy lifestyle intervention REVEAL(OT) (Redesign your

Everyday Activities and Lifestyle with Occupational Therapy) to be added the existing standard treatment. Finally, Studies III and IV evaluated the intervention's feasibility, including three feasibility rounds corresponding to the REVEAL(OT) versions 1.0, 2.0 and 3.0. The author of this thesis was the principal researcher of the project.

I will demonstrate and evaluate the research process from the intervention development to its feasibility study in the following. Finally, I will discuss the knowledge gained and consider implications for further research.

Methods

The MRC guidance

The following presentation of the process for development and feasibility test of the REVEAL(OT) intervention will refer to recommendations for development and planning complex interventions proposed by the British Medical Research Council (MRC)), Figure 3 (76). The guidance is particularly beneficial when interventions of a multifactorial character are to be developed. The new MRC framework from 2021 (77) (Figure 4) within this field was launched after the feasibility study, and thus, was not a part of the reasoning process.

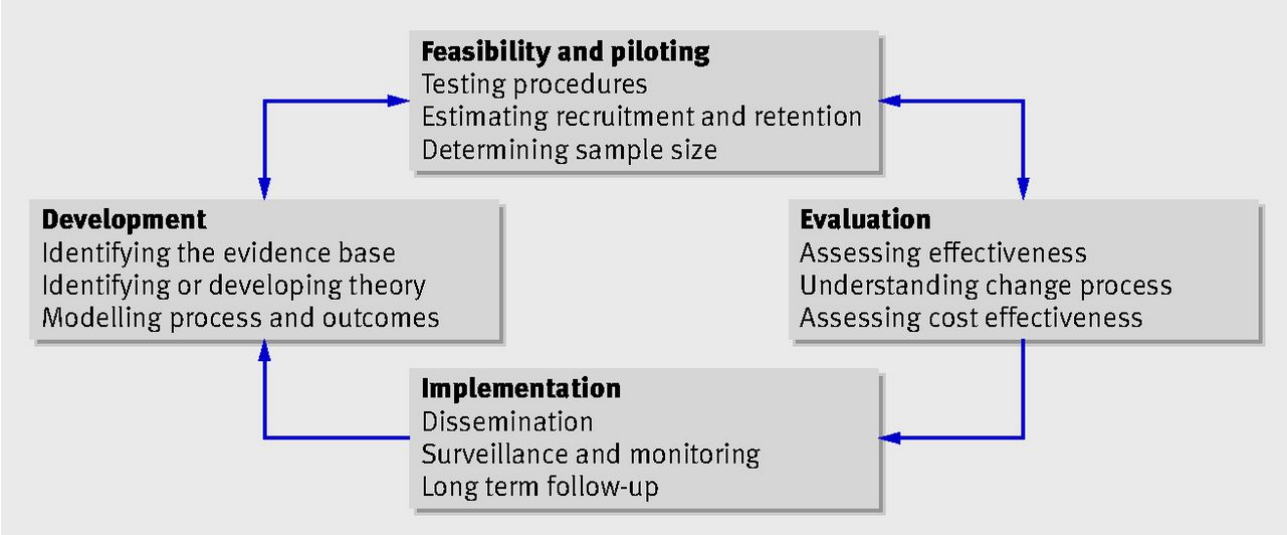

Figure 3. The outline of the MRC guidance for development and planning complex interventions (Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/; From: Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M et al. Developing and evaluating complex interventions: the new Medical Research Council guidance BMJ 2008; 337 :a1655 doi:10.1136/bmj.a1655) (76)

The REVEAL(OT) added to the existing standard treatment can be described as a complex healthcare intervention because it had a variety of interaction factors involved such as:

- The intervention content targeting both meaningful activities and modifiable lifestyle factors

- Complexity of stakeholders involved
- Complexity of behaviours in the chronic pain patients and the intervention deliverers
- Variety of outcomes
- Tailored approach that demanded a certain degree of flexibility in the delivery.

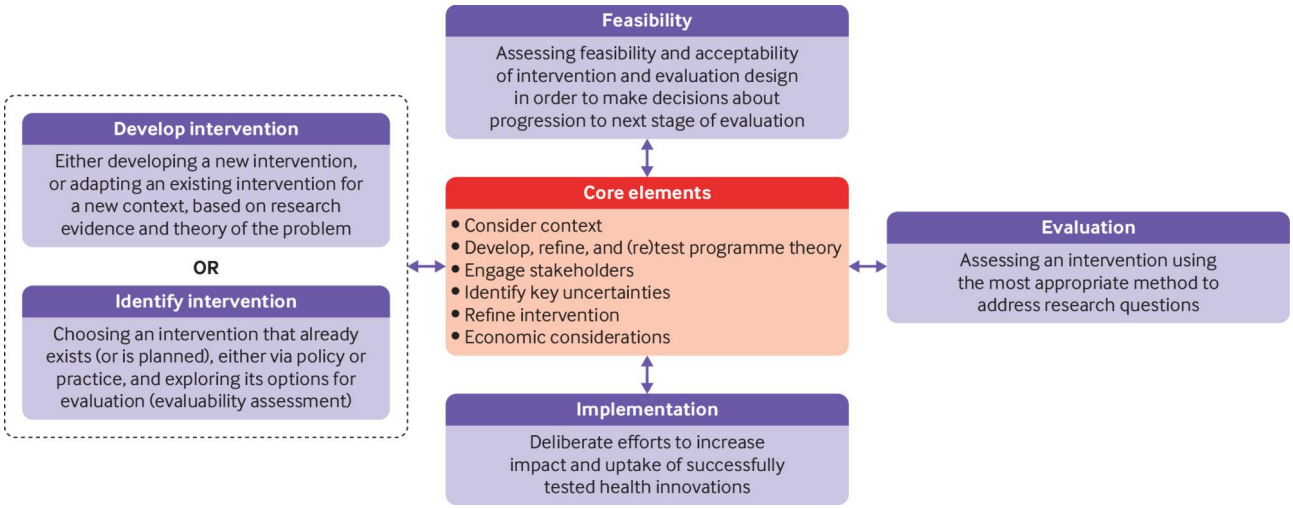

Figure 4. The new framework for developing and evaluating complex interventions, 2021 update of Medical Research Council guidance (Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/; From: Skivington K, Matthews L, Simpson S A, Craig P, Baird J, Blazeby J M et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance BMJ 2021; 374 :n2061 doi:10.1136/bmj.n2061) (77)

Pragmatic, eclectic approach to the complexity depicted above opened up for using various research designs in this Ph.D.-study to help answer the research questions emerging from the clinical and research practice (78). Both quantitative and qualitative methodology was applied iteratively, which matched the research needs at the different stages of the project.

Development of the REVEAL(OT) started with identifying relevant evidence, developing its theoretical base and determining the intervention process and outcomes. Studies I and II supported the development phase, while studies III and IV evaluated the REVEAL(OT) feasibility and informed its adjustments. Initially, I intended to complete the Development – Feasibility – Evaluation – Implementation circle during the author's Ph.D.-study. An RCT protocol has been developed

(Appendix 2) and approved by relevant authorities (see Ethical considerations) to frame the forthcoming feasibility evaluation. The RCT planned to randomise 228 adults living with chronic pain to the intervention group receiving the REVEAL(OT) added to the current standard treatment and compare it with controls that would only receive occupational therapy. The intervention group was hypothesised to achieve significantly more considerable improvements in self-perceived health-related quality of life (HRQoL) as the primary outcome for the RCT one year from baseline (primary endpoint), compared to controls. Other outcomes, i.e., occupational performance and participation, occupational balance, pain self-efficacy and lifestyle anthropometrics, were hypothesised to show between-group improvements, synergetic with the primary outcome.

Before the RCT, 48 chronic pain outpatients were to test the study design and procedures for feasibility. Though, the feasibility phase needed certain refinements that demanded more time than was initially anticipated. Last but not least, the COVID-19 pandemic and the lockdown for all non-acute treatment activities in the Danish healthcare system from March to August 2020 postponed the research process. Feasibility phase in healthcare interventions must not be rushed because it has a crucial impact on the upcoming research activities and, if forced, lead to wrong decisions (76, 79).

Ethical considerations and project approvals

The project followed the principles of The World Medical Association (WMA) described in the WMA Declaration of Helsinki, the European Union's (EU) General Data Protection Regulation (GDPR) and the Danish Data Protection Act (80-82). The project received ethical approval from the Regional Committee on Health Research Ethics (Reg. nr. SJ-703) and was registered at the Data Protection Authority for Zealand Region, Denmark (REG-052-2018). Five revisions of both applications were made due to changes in the recruitment procedure and the time points for baseline assessment and the intervention start that followed organisational amendments in the standard treatment. In addition, detailed participant information documents were developed, revised if necessary and attached to the project applications for approval. The feasibility study registration number on Clinicaltrials.gov, NCT03903900 (Appendix 3) would follow throughout all the research steps.

The project operated with data from patient journals and PainData, the Danish national quality and research database for chronic pain patients (The Danish Data Protection Agency reg. nr. 14/44319),

added several questions for the project needs (83). Cooperation with the PainData data manager and the inclusion of the project-related questions into the existing standard admittance procedure at the MPC allowed us to avoid duplicating questionnaire assessments.

The project contained no obvious risks of adverse effects. All the assessment procedures were pilot tested by the proncipal investigator and the occupational therapists in the intervention. Certain discomfort under the cuff-algometry test (see the Assessment protocol section for details) could have occurred. However, the algometry test used standard procedures that could not be changed, and the discomfort would rather be unlikely (minimal), expected and unavoidable. Detailed instruction to the assessors and calm assessor behaviour and communication would help prevent the discomfort under the test. By any injury related to the project participation, the patients had their right to seek compensation according to the regular healthcare policy rules.

Decision-making process

The PRECIS-2 tool was applied to the REVEAL(OT) intervention development (84). Since the research sought to adapt the REVEAL(OT) to the current treatment practice, I was interested in knowing how the intervention will work in the specific clinical setting, which determined the pragmatic character of the intervention (85). The PRECIS-2 tool helped categorise and explain the intervention rationale by placing the domains: eligibility criteria, recruitment, setting, organisation, flexibility (delivery), flexibility (adherence), follow-up, primary outcome, and primary analysis on a scale from 1 (very explanatory) to 5 (very pragmatic). Explanation of the REVEAL(OT) rationale in tabular form can be seen in Appendix 4. The PRECIS-2 tool also provides a graphical illustration of the project rationale on the PRECIS-2 wheel (Figure 5).

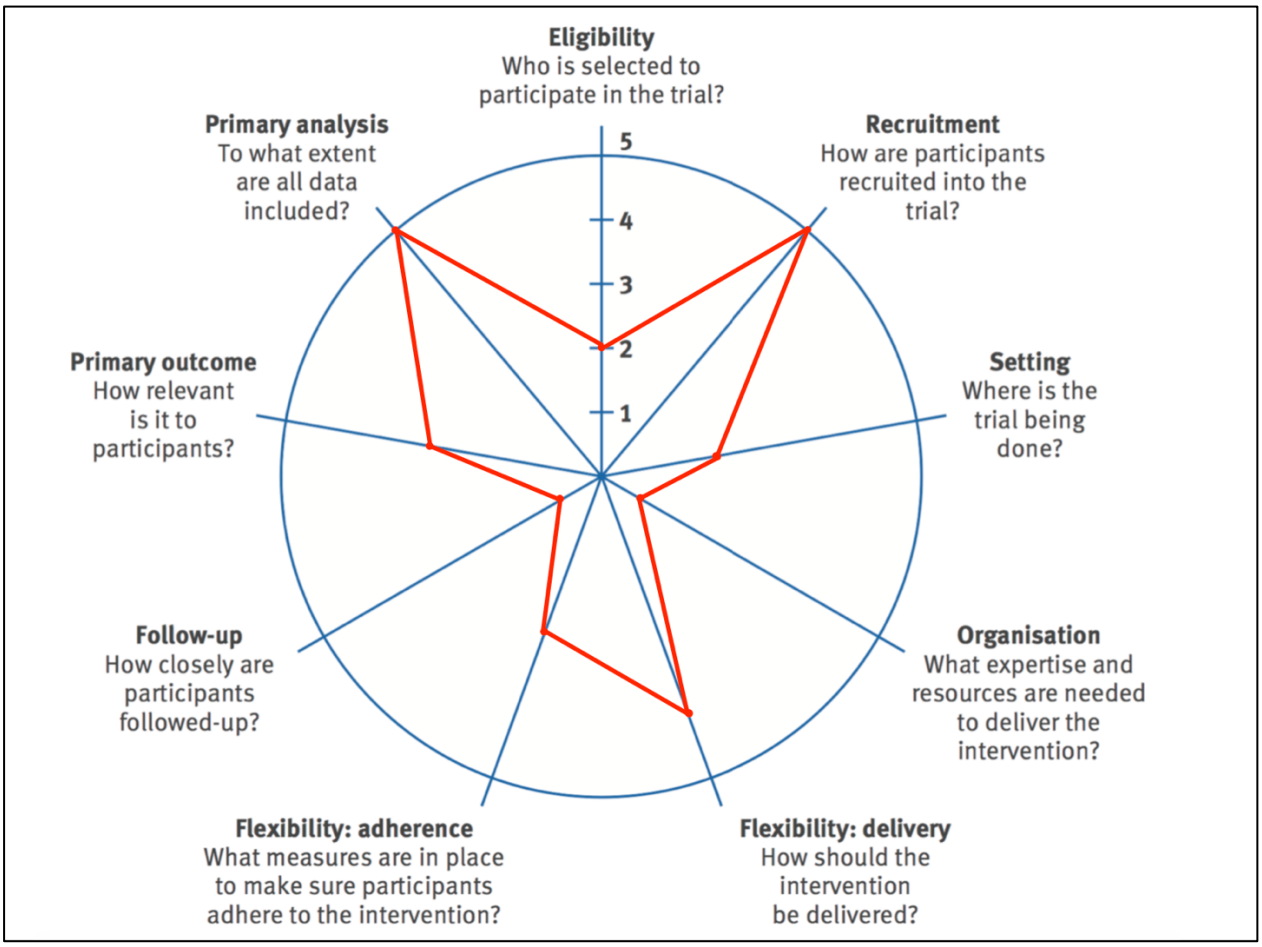

Figure 5. The PRECIS-2 wheel for REVEAL(OT)

Intervention development

I approached the REVEAL(OT) programme development considering both the MRC methodological guidance (76, 86), international evidence, our current research findings and the existing clinical practice in the decision-making process. The research process report will follow the CONSORT (Consolidated Standards of Reporting Trials) group extension on reporting randomised pilot and feasibility trials (87) exclusive the randomisation step, which is not relevant for one-arm experimental studies. In addition, the template for intervention description and replication (TIDieR) proposed by the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network (88) will inform the intervention description (Appendix 5).

Clinical settings

Two clinical sites, the Occupational Therapy Unit (OTU) and the Multidisciplinary Pain Centre (MPC) at Naestved hospital in Region Zealand, cooperated on this research project. Region Zealand is one of the five regions in Denmark with four somatic hospitals and one psychiatric hospital delivering healthcare to 837.225 people (per April 1th, 2020) living on an area of 7.274 square kilometres (89). Most towns in the region are located between 25 km (e.g., Ringsted and Praestoe) and 108 km (e.g., Nakskov) from Naestved Hospital (90).

Since opening its doors in 2014, the MPC operated with the bio-psychosocial approach to chronic pain and offered cognitive-behavioural therapy (CBT) treatment to 800-1000 chronic patients annually. The treatment used to be delivered by physicians, nurses, physical therapists, psychologists, and social worker. After an admittance consultation, the standard treatment course at the MPC used to start with preparatory psychoeducation in groups up to appx. 40 participants (5 weeks, 1-1,5 hour/week) where each health professional represented at the MPC was responsible for one session each. Afterwards, each patient was referred to a consulting nurse and a physician and followed an individual treatment plan. The personal treatment plan may include medication adjustments, CBT-based consultations, manual techniques (e.g., transcutaneous electrical nerve stimulation (TENS), NADA ear acupuncture and group courses on specific aspects (e.g., mindfulness, positioning in bed,

pain management for men and fibromyalgia group for women). The clinical supervisor for the project estimated the average total treatment course length to be appx. eight months.

The OTU used to deliver occupational therapy primarily to inpatients with lung, cancer and neurological diseases. Chronic pain was a voluntarily prioritised focus area for the OTU. Before this project started, the OTU delivered brief occupational therapy for groups of max. five chronic pain patients (three 2-hours group sessions, once á week) upon a referral from the MPC, if revealed occupational problems. Thus, the OTU's capacity allowed occupational therapy for appx. 2-3% of the entire chronic patient cohort referred to the MPC.

To this description, I would like to add that both clinical sites were located separately from each other, although belonging to the same hospital, a nuance that revealed its importance during the qualitative mid-term evaluation in Study III.

Programme theory

Logic model

The logic model for the REVEAL(OT) was developed to assist the research practice regarding the project's planning, implementation and description (91). The logic model (Appendix 6) helped me comprehend the intervention complexity incorporating relevant theoretical perspectives, pragmatic considerations and empirical evidence. Together with the results from the feasibility study, the logic model would assist in answering the question on how mechanisms of action (M) interact with context (C) in the generation of outcomes (O) – CMO construction for the intervention (92). Furthermore, the logic model served as an active tool for programme theory development and intervention planning, allowing relevant amendments within the research continuum (93).

In the logic model taxonomy, the process-oriented iterative approach that focused on causality between the intervention impact and the outcomes and allowed continuous refining in response to the demands emerging from the clinical practice was determined most beneficial for the REVEAL(OT) feasibility study (93). I anticipated that the novel character of the add-on intervention planned might demand continuous learning and adapting the intervention to the existing chronic pain treatment in

an iterative process. Hence, the study should inform me about the best compatible intervention version as an add-on to the standard treatment in the future RCT.

The following will describe the components included in the programme theory for the REVEAL(OT) intervention will be described. After that, the intervention mechanism anticipated will be visually summarised.

Occupational therapy theory and occupational science concepts

The transformative power of occupational engagement

Occupational therapy pursues to improve health and well-being in humans by promoting occupational engagement (48). The REVEAL(OT) aimed to encourage occupational engagement with the three-fold focus on meaningful activities, healthy eating and daily physical activity to improve quality of life in people living with chronic pain. Cooperating with the participants in client-centred manner, occupational therapists supported the participants in making value-based occupational choices within the three-fold focus and fulfilling the occupational goals following a stepwise process (94). The gradual, tailored approach to working with personal occupational goals in the REVEAL(OT) attempted sustainable change in the participants' health behaviour that could be self-managed post-intervention (95).

The REVEAL(OT) pursued to activate the transformative capacities of occupation through synergy between the occupational dimensions Doing, Being, Becoming, and Belonging that impact and determine human health and well-being (96, 97). Wilcock understands Doing as the central element linking occupation and health through occupational engagement that incorporates physical, mental and sociocultural determinants of individual occupational performance (96, 98). In the occupational therapy practice framework CMOP-E, doing is an expression of occupational engagement (99). At the same time, Creek (2010) embedded it as a more everyday life-close character of one's lived experience (100). Being is all about being true to oneself and personal values emerging from reflecting on own life choices and the world around us (96, 98). Some occupational scientists considered Being the cumulative set of individual abilities and skills (99) and the determinant for doing (101, 102). Becoming represents the continuous process of self-actualisation in social interaction with others, expressing ourselves and pursuing self-determined goals (96, 98).

Representing systematic behaviour change over time (99), becoming has been metaphorically described as river flow in the Kawa model (103). Belonging adds to the sociocultural dimension of occupational engagement, expressing the act of sharing values, interests, commitment or obligation (96, 98) with a tight connection to the institutional dimension in occupational engagement (99). The presence of all four models is characteristic for occupational therapy practice (97)

Although all four occupational dimensions were present in the REVEAL(OT), the programme approached the Doing dimension particularly. Learning from own and others' experiences, gaining inspiration for pursuing personal meaning, finding alternative ways of performing habitual routines, planning value-based activities and completing personal goals should have empowered the participants for the transformation towards a better quality of life and healthier lifestyle. Through the process of "learning by doing" that, according to Dewey (104), helps embody the new knowledge in a person, the REVEAL(OT) helped create knowledge on occupational performance and participation in the participants (105). This new knowledge was directly transferable to the everyday practice both within and after the intervention, and thus, prompted continued practising on the participants' own.

Meaningful occupational engagement implies performing a combination of different occupations, and thus, inevitably connected with the concept of occupational balance (106, 107). Appropriate occupational balance, i.e., individually tailored and well-organised patterns of occupational performance, is health-promoting (98, 108).

Improvement in occupational performance has previously correlated with self-perceived self-efficacy in people living with chronic pain (109-111), which may positively affect overall human functioning. Activating the transformative power of occupation, the REVEAL(OT) could expect bringing certain synergy effects in multiple life areas and dimensions in the human system. From my point of view, this synergetic effect was allowable and not considered contaminating the standard treatment but instead added occupational dimension supporting the cumulative treatment effect.

Lifestyle Redesign®-programme

The REVEAL(OT) gained its inspiration from the Lifestyle Redesign®-programme that pursues creating healthy habits by promoting occupational engagement (67). The REVEAL(OT) also adopted the methods such as didactic presentation, peer exchange, direct experience and personal

exploration, pursuing sustainable health behaviour changes (67). The didactic presentations were relatively brief, leaving more space for peer support, reflection and personal experiment in practice, promoting occupational doing aspect (96). The REVEAL(OT) complied with the conceptual considerations of the Lifestyle Redesign®-programme regarding the occupation's curative features (112-114). Meaningfulness in occupational choices was pursued through joyful, pleasurable and satisfactory experiences aligned with the sense of coherence and immersion in the occupation (115), promoting Flow in occupational performance (115, 116).

Lifestyle Redesign® developers allow using the programme materials for inspiration in other interventions. Several topics from Lifestyle Redesign®-programme such as the role of occupation in promoting health and well-being in humans (Module 1), benefits of active lifestyle and energy expenditure in various activities (Module 3), inflammation management (Module 4), benefits of healthy eating, portion size, food labels (Module 5), time management (Module 6), and thriving-promoting activities and hobbies (Module 10) inspired the REVEAL(OT) contents. Several materials supporting learning activities such as determining personal values, daily schedule revision, interests' check, food lable quiz and individual storytelling to accumulate personal experience gained throug the intervention participation when ending a group (117) were modified for group work in the REVEAL(OT). No sessions from Lifestyle Redesign® programme were adopted directly. The different target group and setting in the Lifestyle Redesign®-manual (older American community-dwelling adults) allowing much longer intervention duration and its higher intensity (group meetings 2-hours a week during 6-9 months supplied by individual sessions) (117) called for modifications, to adapt the relevant topics to the specific clinical settings.

The REVEAL(OT) was framed to last 3-4 months, corresponding with appx. 50% of the average treatment course length at the MPC gives space for other treatment options of relevance. Pursuing a more compact structure for the REVEAL(OT), I entirely omitted the topics such as medications, hormones, sexuality, stress management and relationships, because the standard treatment at the MPC included those. I also omitted the topics related to ageing, community mobility, home and community safety and navigating health care because of their primary relevance for an older audience and the project timeframe.

Psychological theories and concepts

Widely used in healthcare interventions, the Health Beliefs Model (HBM) belongs to the social learning theory approach to changing health behaviour (118, 119). HBM explains human health behaviour through individual perception of risk susceptibility (i.e., threat to disease), risk severity (i.e., fear of a harm onset), benefits of action, barriers for action, cues to action (i.e., action prompts) and self-efficacy (i.e., odds for success). The self-perceived barriers and benefits of action were found the strongest HBM variable predicting health behaviour (120). The HBM informed the REVEAL(OT) programme theory in terms of disrupting fear, removing barriers, and promoting the desire for meaningful occupational engagement in the participants. Peer support and contacts with occupational therapists should enhance this mechanism of impact. According to the social learning theory, we can learn new healthier behaviour by communicating and observing others performing occupations close to the individual zone of proximal development, which secures personal progress (121). Value-based occupational choices were to promote pleasurable experiences with meaningful, joyful, and satisfactory occupational performance, complying with the recovery-promoting actions in the fear-avoidance theory presented in the introduction of this thesis (40). Self-determination, autonomy, and stronger self-esteem fuelled by this process may activate the brain's rewarding mechanisms with elevated production of serotonin, dopamine, and endorphins. Thus, improving mood without medication lets one seek repeated enjoyable occupational performance experiences. Prochaska & DiClemente Stages of Change Model (Figure 6) supported the client-centred approach in the REVEAL(OT) delivery (122). Every participant's readiness for change determined the therapeutic reasoning in the intervention providers (123).

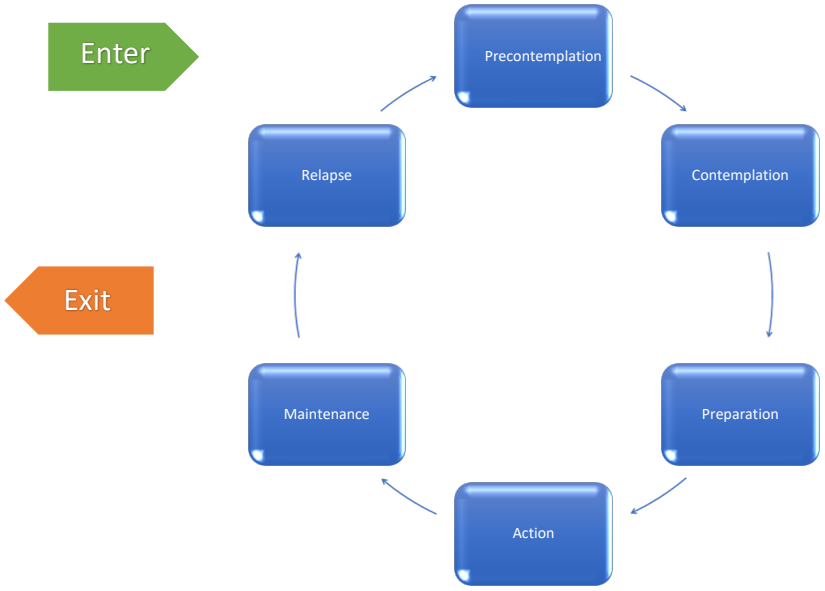

Figure 6. Prochaska & DiClemente Stages of Change Model

Pedagogical approach

Experiential learning is described in Kolb's learning cycle model (Figure 7). The model operates with the terms such as concrete experience, reflective observation, abstract conceptualisation and active experimentation one step at a time, which supported both the intervention methods adopted from the Lifestyle Redesign®-programme and the theoretical psychological background of the REVEAL(OT) connecting theory with practice (124).

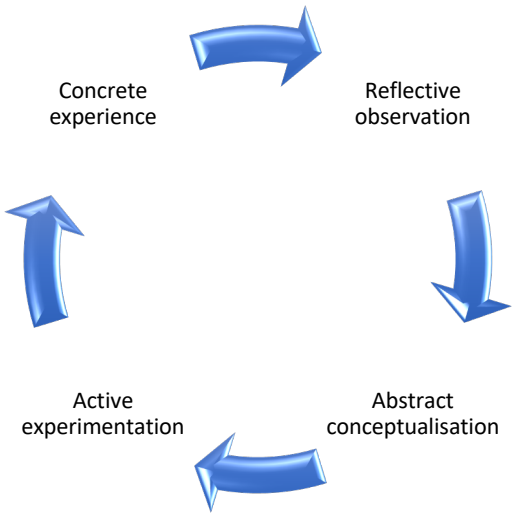

Figure 7. Kolb's learning cycle model for experiential learning

Impact on lifestyle factors through nutritional and physical activity recommendations

At the time of writing this thesis, the updated versions of physical activity guidelines for adults from the World Health Organisation (125) and healthy nutrition advice from the Danish population from the Ministry of Food, Agriculture and Fisheries in Denmark (126), published respectively in Autumn 2020 and Winter 2021, were launched in Denmark. Therefore, when the REVEAL(OT) was conducted, the older documents were due, and the handout material was already produced. The updates comprised an amendment of 10 minutes bouts for accountable physical activity to any physical activity considered accountable and seven healthy nutrition advices instead of the previous ten (127). Both versions of the recommendations can be seen in Appendices 7 and 8, respectively. I considered the updates important for motivating the participants to do physical activity (128) and attached the updates as supplemental materials, which allowed us to avoid re-printing the patient handbooks, thus, additional costs.

The Canadian Practice Process Framework

The Canadian Practice Process Framework (CPPF) should help the intervention providers strengthen client-therapist contact and integrate the existing societal, practice and the interpersonal context in the intervention delivery process (60). The CPPF pursues occupational enablement through eight action points: initiate, set the stage, assess/evaluate, agree on a plan, implement the plan, monitor/modify, evaluate outcomes, and conclude/exit. Occupational enablement assisted by CPPF would help the participants reach their occupational goals stepwise, which would secure appropriate adaptation and sustainability of new health behaviours (129). I have been aware that interconnecting contexts improve feasibility in complex health interventions (76, 91).

Summary of theoretical assumptions in the REVEAL(OT) programme

Figure 8 represents the CMO mechanism of the REVEAL(OT) described above.

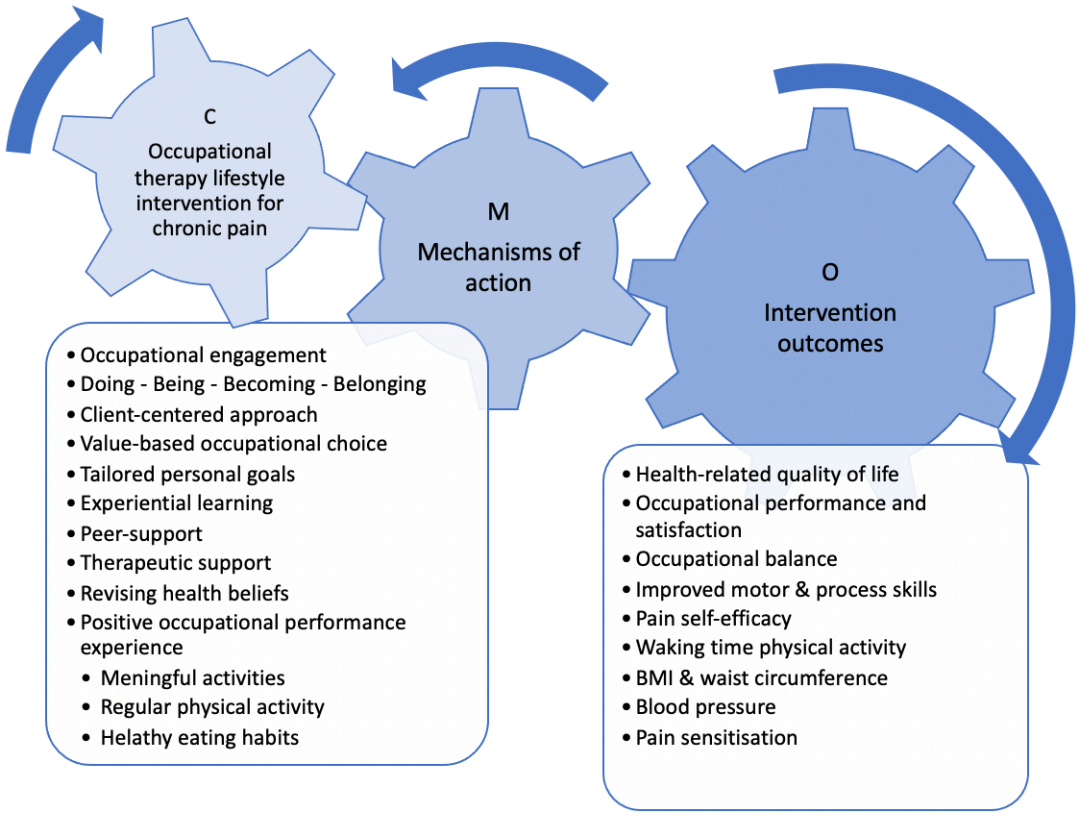

Figure 8. CMO construction of the REVEAL(OT) intervention

Improving the evidence base

The iterative character of the intervention development and feasibility testing contained parallel research activities aimed to improve our knowledge (Figure 9). The need for further investigation in everyday life, lifestyle and motivation of the target population raised the following questions:

- Which effect has promoting occupational engagement on lifestyle in people living with chronic pain?
- How do sociodemographic characteristics, pain, health and lifestyle status associate with quality of life in chronic pain population, and what is their motivation for initiating lifestyle changes?

Answers to these questions would help us determine the intervention's relevance and further tailor its content and outcomes, improving the evidence base.

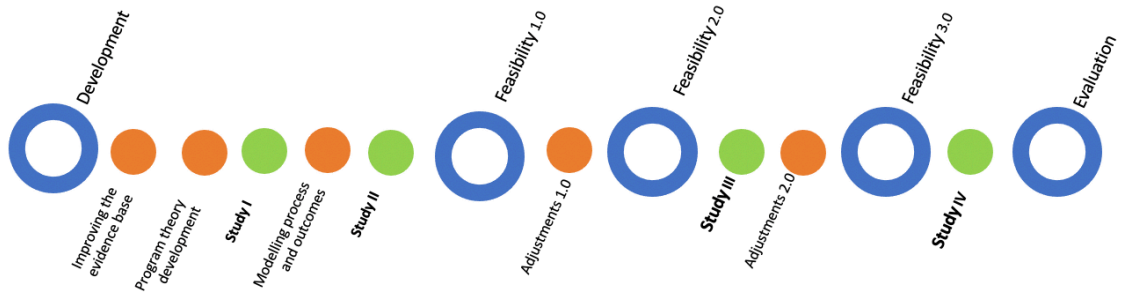

Figure 9. The research process continuum

Effect of promoting occupational engagement on lifestyle: a systematic review and meta-analysis - Study I

Recent scoping review urged further research that would estimate the effect of occupational therapy in chronic pain (57). However, the effect of promoting occupational engagement on modifiable lifestyle factors in chronic pain population has not previously been studied in a systematic review.

Aim - Study I

This systematic review (PROSPERO reg. CRD42020159279, Appendix 9) aimed to investigate the effectiveness of occupational engagement included in chronic pain interventions on modifiable lifestyle factors in adults living with chronic pain (130). See also Appendix 10 for the manuscript inclusive appendices. The results of this study would help us tailor the REVEAL(OT) intervention and determine relevant outcomes. Moreover, the review would potentially improve the evidence base on the effectiveness of occupational therapy impact on chronic pain. PRISMA guidelines for reporting systematic reviews guided the reporting of this systematic review (131).

Methods - Study I

Following the positivist paradigm in answering our research question (132), I made a comprehensive literature search in databases Ovid MEDLINE, Embase, PsycINFO, CINAHL, Cochrane, Scopus, Web of Science, OTseeker, ClinicalTrials.gov, and OpenGray supplemented by monitoring the web-engine Google Scholar (first three pages with relevant hits), citations and references of key articles.

Peer-reviewed publications in English, German, Italian, Swedish, Norwegian or Danish on randomised controlled trials (RCTs) for chronic pain population (≥18 years old) with primary chronic pain diagnoses classified by the World Health Organisation (WHO) in the International Classification of Diseases for mortality and morbidity statistics (ICD-11) (2) were eligible. In addition, mixed chronic pain diagnoses were allowed for inclusion if the treatment programme was not diagnosis-specific.

Outcomes of interest were body anthropometrics, e.g., body weight in kilograms (kg; continuous), Body Mass Index (BMI; interval) and waist circumference in centimetres (cm; continuous); physical

activity level measured in hours and minutes (continuous) or a number of walking steps (continuous); alcohol consumption in units per week (continuous); cigarettes smoked per week (continuous); self-perceived sleep quality level (ordinal); and self-perceived stress level (ordinal).

Eligible interventions had to include an occupational engagement component, i.e., relevant assessment tools and/or explicit authors' reports on performing meaningful and purposeful daily activities as a part of the intervention strategy. Eligible interventions could: a) be delivered by occupational therapists or multidisciplinary teams; b) have individual, group, or mixed approaches; and/or c) operate with non-pharmacological treatment methods, alone or in combination with pharmacological treatment. Comparators were interventions not involving occupational engagement as an active component of the impact, i.e., with no planned practising of daily occupations during the intervention period or no intervention.

EndNote X8 software (Clarivate Analytics), released 8 November 2016, and Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) available at www.covidence.org were used. The EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network template for intervention description and replication (TIDieR) guided the data extraction (88). Any disagreement between the two researchers who performed the data sourcing, sorting and extraction were subject to discussion until consensus.

One of my co-authors and I evaluated methodological quality by the Cochrane Risk-of-bias tool (133). Then, I performed a meta-analysis calculating standardised mean difference (SMD) converted to Hedges' g to detect corrected (unbiased) effect sizes when two or more studies reported on an outcome of interest. The Cochrane group recommendations (para. 9.5.2.) assisted heterogeneity evaluation (134), and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group recommendations (135) guided the interpretation of the results from the meta-analysis.

Results - Study I

A total of 9152 items was identified. Of those, 211 articles on RCTs that included occupational engagement in chronic pain interventions and assessed modifiable lifestyle factors such as physical

activity, body anthropometrics, alcohol consumption, smoking tobacco, stress and sleep were found eligible and read in full text (Figure 10).

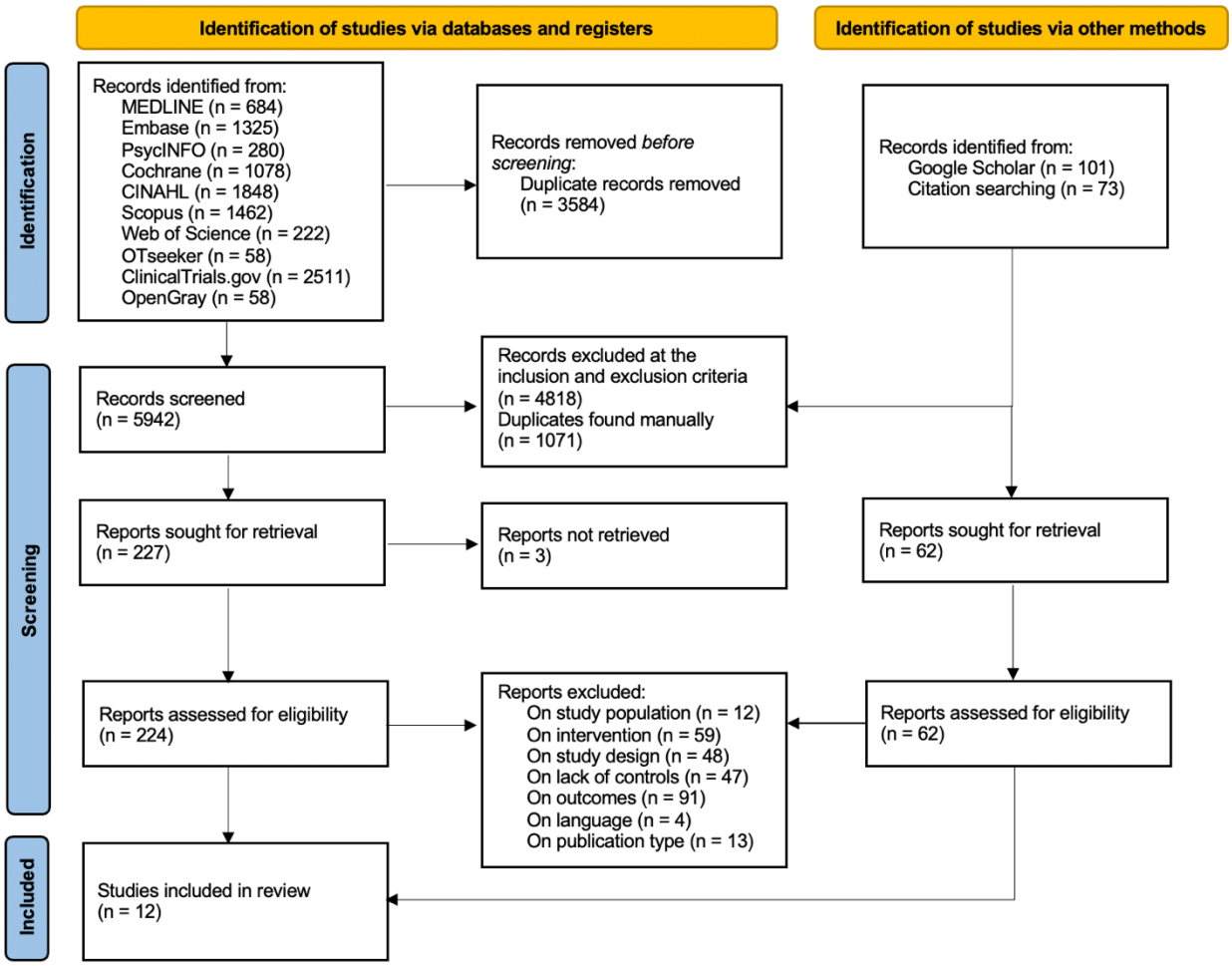

Figure 10. PRISMA Flowchart, Study I (131)

The eleven RCTs comprising 995 adults matched the inclusion criteria. The RCTs assessed physical activity level, sleep quality, stress and body mass index (BMI). No eligible RCTs on smoking and alcohol consumption were found. Only the physical activity and sleep outcomes allowed for meta-analysis (Table 1). The meta-analysis suggested a moderate increase in sleep quality after multidisciplinary self-management of fibromyalgia, including occupational engagement, up to 6 months after intervention discharge, and little to no effect on physical activity level. The methodological quality and total certainty of the evidence was low.

Table 1. Summary of findings, Study I

Occupational engagement component included in chronic pain treatment of adults compared with other or no treatment					
Patient or population:	Adults with primary chronic pain				
Intervention:	Using occupational engagement				
Comparison:	No occupational engagement component				
Outcomes	**Comparator**	**Anticipated absolute effect (95% CI)**	**Number of participants (studies)**	**Quality of the evidence (GRADE) a**	**Comments**
(A) Physical activity level, SD units: two different instruments used - (a) 6-point ordinal scale; (b) pedometer-driven walking step count; and c) activity diary. Low scores mean lower physical activity level.	Other treatment (brief advise/ information leaflet/ standard physiotherapy/ fibromyalgia education).	At 6-12-weeks from baseline: SMD 0.55 higher (0.09 lower to 1.19 higher) g; (b) Observed significant increase in physical activity participation (walking steps) in the intervention group compared to controls.	298 (5)	⊕⊕○○ c d e f (Low)	As a rule of thumb, 0.2 SD represents a small effect, 0.5 a moderate effect, and 0.8 a large effect. Further research is likely to change our estimate. Our confidence of the effect estimate is limited.
		At 3-12-months after intervention: (a) SMD 0.14 higher (0.15 lower to 0.44 higher) g; (b) Observed significant increase in physical activity participation (n registered activities) in the intervention group compared to controls.	257 (4)	⊕⊕○○ c e f (Low)	
(B) Sleep quality, SD units: four different instruments used - (a) 9-point ordinal scale*, high scores mean low quality of sleep; (b) 10-point ordinal scale, high scores mean high quality of sleep; (c) 0-5-item Likert scale, high scores mean high quality of sleep; and (d) 30-390-point interval scale, high scores mean high satisfaction with sleep quality/good quality of	Other treatment (consultation with walking advise) or no treatment (waiting list, usual care allowed).	At 10-12-weeks from baseline: SMD 0.09 lower(0.45 lower to 0.27 higher) h.	300 (4)	⊕⊕○○ c e f (Low)	As a rule of thumb, 0.2 SD represents a small effect, 0.5 a moderate effect, and 0.8 a large effect. Further research is likely to change our estimate. Our confidence of the effect estimate is limited.
		At 3-6-months after intervention: (a) SMD 0.35 higher (0.08 lower to 0.61 higher) h; (b) Observed significant increase in sleep quality after a behavioral intervention compared to an educational intervention and controls.	266 (3)	⊕⊕○○ c e f (Low)	
(C) Stress level, 4-point ordinal scale used. Lower scores mean stress decrease.	Other treatment (waiting list with non-specified usual care, treatment regimens may vary).	At 14-weeks from baseline: mean 0.93 lower (standard error 0.30), p<0.00.	305 (1)	⊕○○○ c e (Very low)	We are very uncertain of the effect estimate.
(D) BMI, calculated from weight (kg) divided by height (m2).	Other treatment (Fibromyalgia education).	At 12-weeks after intervention: mean 1.1 higher (5.3 lower to 2.9 higher).	84 (1)	⊕○○○ b e (Very low)	We are very uncertain of the effect estimate.

Abbreviations: CI, confidence interval; d, day; MD, mean difference; n, number; SD, standard deviation; SMD, standardized mean difference

** In Soares (2002), adjusted for direction*

a Quality rated from 1 (very low quality) to 4 (high quality)

GRADE Working Group grades of evidence

High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

b Evidence limited by inconsistency
c Evidence limited by imprecision
d Evidence limited by heterogeneity
e Evidence limited by small sample size
f Evidence limited by risk of bias (suspicion of selective reporting bias)
g Based on Hedges'g interpretation of effect sizes

Conclusions - Study I

Occupational engagement in daily activities included in multidisciplinary interventions for chronic pain treatment may increase physical activity in the short term and sleep quality in the long term. However, the overall evidence quality was low, not allowing for firm conclusions. Further investigations of strong methodological quality are needed to estimate the effect of chronic pain interventions including occupational engagement on lifestyle.

Survey of the outpatient characteristics and their motivation for changing lifestyle - Study II

To further improve the evidence base and model the intervention outcomes, I performed a survey in chronic pain outpatients referred at the MPC (see Appendix 11 for full text inclusive appendices) (136).

Aim - Study II

This survey aimed to explore the associations between HRQoL and health, pain, and lifestyle factors, and motivation for lifestyle changes, in the outpatients referred to the MPC from December 2018 to March 2019.

Methods - Study II

The positivist approach was used in this investigation, quantifying the opinions on the matter of the investigation and deriving associations expressed in numbers from the data (132). A convenient sample of outpatients completed a questionnaire on HRQoL (EQ-5D-5L), health, pain, lifestyle factors (BMI, physical activity, smoking, alcohol, physical fitness, eating, sleep, and stress), and motivation for lifestyle changes. I used multiple linear regression analyses to assess associations between HRQoL and the independent variables.

Results - Study II

The total of 144 participants (age mean 50 years, 81% females) had ≥2 body pain sites (93%), BMI≥25 (64%), sedentary lifestyle (43%), and multiple (n≥2) elevated metabolic risk factors (58%) (Table 2). High frequencies of overweight, obesity, sedentary lifestyle, pain in multiple body sites, and multiple lifestyle-related risk factors were observed in the study population.

Table 2. Sociodemographic and pain-related characteristics of the sample, Study II

Variable (sample size, n)[a]	Value (mean (SD); frequency (range))
Females	
In responders (n=144)	117 (81%)
In nonresponders (n=145)	101 (70%)
Age, years	
In responders (n=144)	50 (13; 19-81)
In nonresponders (n=145)	50 (13; 26-94)
Age groups, years old (n=144)	
18-24	3 (2%)
25-34	20 (14%)
35-44	22 (15%)
45-54	50 (35%)
55-64	29 (20%)
65-74	17 (12%)
≥75	3 (2%)
Highest achieved education level (n=139)[b]	
Primary and lower secondary school	32 (23%)
Secondary school	10 (7%)
Vocational education	34 (24%)
Short-cycle higher education	28 (20%)
Medium-cycle higher education	30 (22%)
Long cycle higher education	5 (4%)
Employment status (n=139)	
Employed[c]	33 (24%)
Unemployed[d]	59 (43%)
On disability pension	20 (14%)
Retired	21 (15%)
Students/ trainees	6 (4%)
Body pain sites (n=126)	
0	3 (2%)
1	6 (5%)
2	21 (17%)
3	3 (2%)
4	9 (7%)
5	7 (6%)
≥6	77 (61%)
Body pain spreading, % of the body (n=126)	
Up to 25	77 (61%)
25-50	28 (22%)
50-75	12 (10%)
Over 75	9 (7%)

Body pain location[e] (n=126)	
Low back	65 (52%)
Lower spine	44 (35%)
Thoracic spine	32 (25%)
Shoulders/ upper arms (front/ back)	28 (22%)
Head (front/ back)	27 (21%)
Knees (front/ back)	27 (21%)
Feet (dorsal/ plantar)	27 (21%)
Abdomen	26 (21%)
Back	26 (21%)
Hands (dorsal/ palmar)	25 (20%)
Neck	19 (15%)
Chest	13 (10%)
Elbows/ forearms (front/ back)	10 (8%)
Thighs/lower legs (front/ back)	8 (6%)
Major body pain sites (n=125)	
Low back	34 (27%)
Knees (front/ back)	12 (10%)
Neck	11 (9%)
Feet (dorsal/ plantar)	10 (8%)
Shoulders/ upper arms (front/ back)	9 (7%)
Thighs/lower legs (front/ back)	8 (6%)
Head (front/ back)	7 (6%)
Abdomen	7 (6%)
Thoracic spine	7 (6%)
Lower spine	7 (6%)
Hands (dorsal/ palmar)	6 (5%)
Back	4 (3%)
Elbows/ forearms (front/ back)	2 (2%)
Chest	1 (1%)
Pain intensity in the most painful body site[f] (n=122)	8 (2; 3-10)
Taking opioids for pain relief[g] (n=138)	70 (51%)

[a] *The total n of the reports in each question category is provided*
[b] *The categories refer to the Danish Educational Nomenclature (137)*
[c] *Employee or self-employed (full or part-time)*
[d] *At-home staying and on sick leave*
[e] *The sum of the frequencies does not give 100%, one participant may have had more than one body pain site*
[f] *Pain intensity in most painful body site on 0-10 NRS-scale within the last month*
[g] *As a regimen or pro necessitate*

Most participants experienced moderate to extreme levels of the problems (scores≥3) in pain/discomfort (94%), usual activities (81%), and mobility (61%) (Figure 11). Most participants (62%) experienced poor health (EQ-VAS score 0-50), considered lifestyle important for HRQoL (72%) and expressed moderate to very high motivation for changing lifestyle (92%) (Table 3).

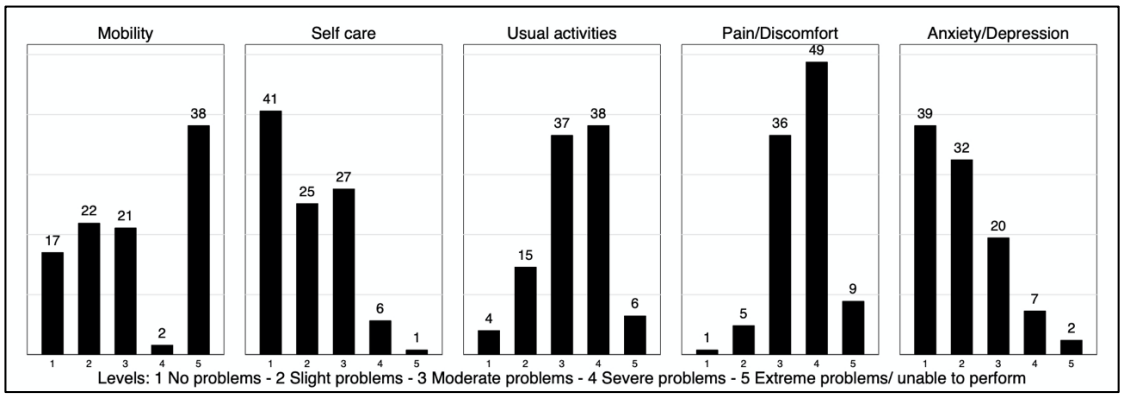

Figure 11. Levels of problems affecting health-related quality of life, Study II

Table 3. HRQoL, health and lifestyle in the participants, Study II

Variable (sample size, n)[a]	**Value (mean (SD); frequency (range))**
BMI (n=113)	
Underweight (BMI<18.5)	4 (4%)
Normal weight (BMI≥18.5<25)	36 (32%)
Overweight (BMI≥25<30)	25 (22%)
Obese (BMI≥30<40)	42 (37%)
Severely obese (BMI≥40)	6 (5%)
Physical activity weekly, minutes (n=113)	
0	20 (18%)
<150	28 (25%)
≥150<300 (min. recommended)[b]	21 (18%)
≥300<600	26 (23%)
≥600	18 (16%)
Smoking (n=113)	47 (42%)
Alcohol consumption[c] (n=113)	
None	82 (73%)
Low risk[d]	30 (26%)
Moderate risk	1 (1%)
Physical fitness (n=113)	
Very good	1 (1%)
Good	9 (8%)
Neither good/nor poor	36 (32%)
Poor	36 (32%)
Very poor	30 (26%)
Don't know	1 (1%)
Eating habits (n=113)	

Very healthy	3 (3%)
Healthy	31 (27%)
Neither healthy nor unhealthy	63 (56%)
Unhealthy	11 (10%)
Very unhealthy	3 (3%)
Don't know	2 (1%)
Stress (n=113)	
Very low	10 (9%)
Low	20 (18%)
Neither low nor high	46 (40%)
High	20 (18%)
Very high	11 (10%)
Don't know	6 (5%)
Sleep (n=113)	
Very good	2 (2%)
Good	6 (5%)
Neither good/nor poor	37 (33%)
Poor	36 (32%)
Very poor	32 (28%)
Presence of multiple metabolic risks[e] (n=113)	66 (58%)
Importance of lifestyle for quality of life (n=112)	
Very important	37 (33%)
Important	44 (39%)
Neither/nor	22 (20%)
Slightly important	1 (1%)
Very slightly important	1 (1%)
Don't know	7 (6%)
Motivation for changing lifestyle[f] (n=112)	
Very highly motivated	29 (26%)
Highly motivated	46 (41%)
Moderately motivated	28 (25%)
Low motivated	3 (3%)
No opinion	6 (5%)
HRQoL	
EQ-5D Index score[g] (n=122)	0.397 (0.254; -0.196 -0.824)
EQ-5D Profile[h] (n=122)	
Only level 1 or 2 items	2(2%)
Several level 3 items, no level 4 or 5	25(20%)
Min. one level 4 or 5 item	95(78%)
Health (EQ-VAS score 0-100) (n=121)	45 (24; 1 - 95)
1-25	32 (26%)
26-50	44 (36%)
51-75	35 (29%)
76-95	10 (8%)

[a] *The total n of the reports in each question category is provided;*
[b] *Corresponding to the WHO recommendations on physical activity for adults (138);*
[c] *No reports in the category "Don't know";*
[d] *Corresponding to the limits for low risk (≤7 units/week for women; ≤14 units/ week for men) and moderate risk (above the low risk limits), The Danish Health Authority (139);*
[e] *Risky health behaviour in multiple (n≥2) lifestyle areas, such as BMI≥25; Physical activity weekly, minutes <150; Poor or very poor Fitness; High or very high stress; Smoking "yes";*
[f] *No reports in the category "very low motivated"*
[g] *Scores >0="worse than death"; 1= "perfect health"*
[h] *Index 11111=full health; 55555=worst health*

Participants in this survey had significantly lower self-evaluated HRQoL than the general population (*P*=0.000; diff. -0.492 (95%CI -0.520; -0.464) from the same geographical region and comparable at age (n=15.700; age mean 47; SD 16; range 20-79) (Figure 12). Maximal cumulative HRQoL-scores observed in the study cohort (EQ-5D Index score max.=0.824) were below the mean value for the general population (EQ-5D Index score mean=0.889; SD 0.154).

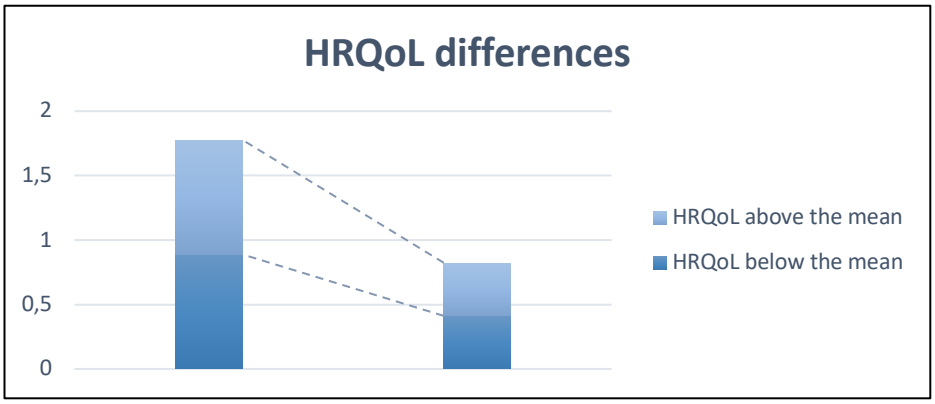

Figure 12. HRQoL differences in the general population and study sample, Study II

Poorer HRQoL in the study population was significantly associated with higher pain intensity in the most painful body site (ß=-0.316, P=0.001) and very poor sleep quality (ß=-0.410, P=0.024). Serious-to-extreme problems in usual activities such as work, study, housework, family life and leisure were associated with significantly poorer self-evaluated health (ß=-0.328, P=0.030).

Conclusions - Study II

Further interventions addressing pain alleviation, sleep quality, prevention of problems in usual activities, and promotion of healthy lifestyle, e.g., physical activity and healthy eating, are needed to improve health and quality of life in people living with chronic pain.

Modelling intervention process and outcomes

New knowledge learnt from the Studies I and II

The new knowledge obtained from Study I and II confirmed the relevance of the lifestyle-oriented focus in the REVEAL(OT) and appropriateness of occupational therapy, pain and lifestyle-related outcomes, with HRQoL as the primary outcome for the intervention. The study population represented high frequencies of pain spreading, sedentary lifestyle, overweight and obesity and multiple metabolic risks, together with moderate to high motivation for improving lifestyle during their chronic pain treatment. HRQoL in the study population was significantly lower than in the general Danish population and significantly associated with high pain intensity, very poor sleep and serious problems with usual activities. The study population revealed no challenges regarding smoking tobacco or alcohol consumption.

Our findings suggested that an intervention targeting sedentary lifestyle, serious problems with usual activities, eating habits and sleep quality would be relevant and attractive for adults living with chronic pain referred to the MPC. Occupational engagement could support a more physically active lifestyle and is anticipated to benefit sleep in the long term. Though, certain cautiousness in the interpretation of the results was needed because the survey design only allowed conclusions on the sample included and low certainty of evidence in the systematic review.

Feasibility study of the REVEAL(OT)

Protocol for the feasibility study

Study design

This small-scale pretest-posttest one-group feasibility study of the REVEAL(OT) intervention evaluated research progression criteria to inform a future RCT. The feasibility study was guided by the scientific background; settings; eligibility criteria; outcome measures and ethical considerations for the RCT (Region Zealands reg. SJ-703/ REG-052-2018, cf. Appendix 2).

1). No randomisation or controls were used in the study because feasibility testing of the procedures planned didn't require any of those. No procedures were blinded either in the participants or assessors. The participants followed the treatment activities planned for the intervention group in the RCT from recruitment to intervention discharge.

Participants

Adults ≥18<65 years old with chronic pain diagnosis ≥ 3 months were considered eligible. Those who had acute/ sub-acute pain; cancer-related pain; unstable medicine intake over the past four weeks; daily opioid intake >30 mg; headache/migraine; currently diagnosed depression; current substance misuse; severe psychiatric diagnosis; poor Danish speaking skills and participating in other CNMP-treatment programmes were excluded from participation. Severe psychiatric diagnoses are defined as a mental illness involving distortion in thinking and perception and leading to significant social and occupational dysfunction, e.g., schizophrenia or other primary psychotic disorders corresponding with the diagnosis codes 6A20-24/ 6A2Y in the ICD-11 (6). Self-reported inability to walk outdoors the distance of min. 100 m became an additional exclusion criterion because the feasibility study revealed that some of the planned programme content was not compatible with an inability to walk outdoors.

Recruitment

The project participants were enrolled from the outpatient cohort referred to the MPC. After initial screening for age and interest performed by the MPC team at the initial admittance consultation, a trained project assistant delivered detailed written and oral information (Appendix 12) to the candidates for participation and, if still interested, approved those for eligibility. All the participants signed informed consent (Appendix 13) and received a personal intervention plan (Appendix 14) before participation.

Sample size

No formal sample size calculation for the feasibility study was performed (140). I considered the minimum of 12 participants sufficient for monitoring the progression criteria determined (140, 141), according to the rationale about feasibility, means and variance precision and regulatory recommendations (142). I considered max. total of 48 participants sufficient for this feasibility study. The number represented 21% of the sample for the future RCT and was dividable with six (the max. group size in the intervention).

Intervention

In total, three versions of the REVEAL(OT) -1.0, 2.0 and 3.0 - were developed and tested for feasibility.

Intervention contents

To achieve an appropriate combination between standard treatment at the MPC and the REVEAL(OT) impact on meaningful activities, healthy eating and daily physical activity, I determined minimal doses of the standard treatment at the MPC in co-operation with the head of the clinical unit. The minimal dose of the standard treatment was estimated to include (duration and average frequency of the total n sessions provided) psychoeducation, 1-1,5 hour/ 5 weeks (100%), 2 consultations with a physician (appx. 30 min., 50%); 2-4 consultations with a nurse (appx. 1 hour, 25-50%), 1 consultation with a physiotherapist (appx. 1 hour, 50%), and 1 consultation with a social worker (appx. 1 hour, 50%). Consultations with psychologists (n=7 in total) were excluded from the minimal dose calculation because those were usually prescribed to a few patients at the later stages of the treatment.

Regarding the standard treatment contents, consultations with a physician would include medication adjustment and pharmacological/non-pharmacological treatment planning. Consultations with nurses would content working with max. 2 goals related to the topics such as sleep, fatigue, resource management, social relations/ isolation, pacing, respiration, catastrophising, stress, acceptance of chronic pain, sexuality, communication, and CBT. Consultation with a physiotherapist would content physical inspection and consultation on improving in relevant bodily aspects (inclusive optional home exercise programmes and advice on physical activity). Finally, consultation with a social worker would content advise on the job situation. In regular clinical practice at the MPC, various aversions from the average treatment doses were present.

The REVEAL(OT) was comparable in the number of contacts with health professionals with the standard treatment during a similar period. The REVEAL(OT) consisted of 2-4 individual sessions of 1 hour and 4-8 group sessions of 2 hours over 12-15-weeks (at n=2 individual sessions per programme, up to 7 phone- or video-based individual contacts were provided). Max. six patients were admitted pr. group. At baseline, the patients identified their occupational problems related to productivity, self-care and leisure activities that inspired further goal setting. Besides the assessments at baseline and follow-up, session topics covered: introduction to the course, occupation for health and well-being, benefits of daily physical activity, meals and eating habits, occupational balance and time management, productivity/ domestic activities (in-home), productivity/ activities out-of-home, ergonomics, Flow experience, hobbies and leisure, goal setting, goal evaluation, home visits, and ending the group.

The programme featured contacts with occupational therapists at least every second week. Lifestyle diaries for monitoring occupational performance, healthy eating, and physical activity (outdoors walking wearing pedometer for step counting) were implemented to help the patients train and transform the new knowledge into their everyday lives. In addition, the programme offered home visits aimed at home ergonomics. The patients could borrow and try a variety of assistive devices such as ergonomic chairs, seats and lumbar cushions, swivel pads, kitchen utensils, bath benches, bath brushes with ergonomic handles, and sliding layers. Emerging questions and issues were discussed with the MPC team. The REVEAL(OT) intervention was protocolised (cf. Appendix 2) and manualised (see Supplementary materials). A patient handbook was developed (Appendix 15).

Assessment protocol (Appendix 16) inclusive patient assessment files (Appendix 17) were developed to secure homogeneous performance of the assessments planned. After the intervention discharge, the patients continued with their planned standard treatment at the MPC.

Intervention development process

The iterative approach to the REVEAL(OT) development as a pragmatic intervention has again demonstrated its relevance in modelling the treatment doses throughout the feasibility phase. Not only the REVEAL(OT) was up to be improved. The standard treatment also went through several changes in the clinical practice. For example, the admittance consultation at the MPC changed its format from an appointment in-clinic to the online format, which demanded changes in the recruitment procedure and seeking new approvals from the research project.

The REVEAL(OT) in its versions 1.0 and 2.0 started upon the admittance at the MPC and ran parallel with the preparatory psychoeducation course. Informed by the participants' feedback, the number of sessions and intensity in the REVEAL(OT) 2.0 were reduced (from every week to every second week to ease participation in the parallel treatments. The REVEAL(OT) 3.0 continued with sessions in-clinic every second week but moved its start after the psychoeducation course and added video/ phone consultations. The intervention's focus and session format of 2-hours for the group sessions and 1 hour for individual consultations remained unchanged throughout the feasibility phase. Changes in the structure of the REVEAL(OT) 1.0-3.0 throughout the iterative intervention development process were visualised (Figure 13).

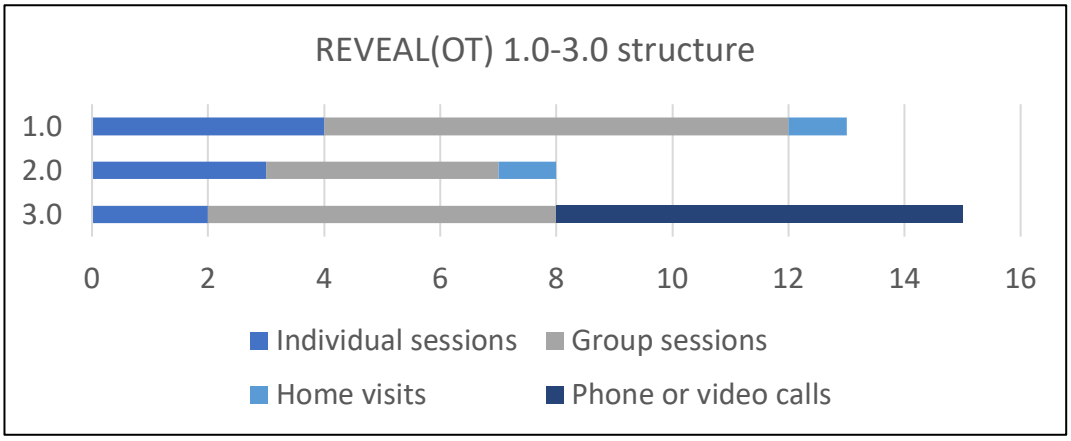

Figure 13. Structure of the REVEAL(OT) 1.0, 2.0 and 3.0

Treatment doses in the REVEAL(OT) 1.0-3.0 were represented by applying its manualised contents to the occupational therapy intervention taxonomy based on the Person-Environment-Occupation model (143), with reference to previous evidence on the occupational therapy methods in chronic pain treatment (57) (Table 4). The treatment doses were measured in time quotes (hours) dedicated to each taxonomy element.

Table 4. Treatment doses in the REVEAL(OT) 1.0-3.0

Main focus	**Type of impact***	**n (%) hours delivered per feasibility round**			
		Hours, total	1.0	2.0	3.0
Person	Training[1]	28.7	13.6 (47.4)	7.4 (25.8)	7.7 (26.8)
	Education[2]	53.0	13.2 (24.9)	25.6 (48.3)	14.2 (26.8)
	Skill development[3]	27.9	7.3 (26.2)	12.4 (44.4)	8.2 (29.4)
		109,6			
Occupation	Task adaptation[4]	19.8	6.4 (32.3)	7.4 (37.4)	6.0 (30.3)
	Occupational development[5]	105.8	37.3 (35.2)	28.1 (26.6)	40.4 (38.2)
		125,6			
Environment	Environmental modification[6]	17.8	7.7 (43.3)	4.1 (23.0)	6.0 (33.7)
	Support provision[7]	46.9	14.5 (30.9)	15.0 (32.0)	17.4 (37.1)
	Support enhancement[8]	0	0	0	0
		64,7			

** According to the occupational intervention taxonomy as described in McColl & Law (2013) (143): [1] Enhancing performance of physical, psychological, cognitive, and social components, i.e., exercise and practice with no explicit occupational outcome; [2] Learning more about chronic pain, options for improvement, ways of preventing difficulties or improving occupational performance and function; [3] Improving the performance of specific, purposeful tasks/ the building blocks of occupation; [4] Modifying a task to permit it to be accomplished in a different manner given personal limitations; includes proximal adaptations and adaptive media; [5] Optimising participation in integrated occupations, such as vocational training, leisure programs, activities of daily living; [6] Modifying the non-human environment to enhance function. May include distal adaptive equipment, cueing, accessibility; [7] Provision of physical or psychological support by the therapist to enhance occupational performance; [8] Enhancing the ability of the family/caregivers and support system to provide support for occupational performance.*

Intervention providers

Two graduated (BSc) occupational therapists (further "intervention therapists") with over 14-years of working experience led the REVEAL(OT), providing individually tailored support to promote the transfer of the new knowledge and experiences to the patients' everyday life and maintain the intervention impact. The principal researcher (MSc) received a continued educational online course

in occupational lifestyle management (Life Management Series: Introduction to Lifestyle Redesign® and Lifestyle Redesign® for Chronic Pain and Headache Management) provided by The USC Mrs. T.H. Chan Division of Occupational Science and Occupational Therapy at the University of Southern California, USA (further USC). Certificates are provided in Appendix 18. The knowledge was disseminated to the intervetnion therapists.

Educational activities were planned to improve the assessor-qualifications of the intervention therapists and the principal researcher who were to perform the in-clinic assessments in the feasibility study. The assessor team participated in a workshop on the Canadian Occupational Performance Measure (COPM) interviewing technique by A. Enemark Larsen, occupational therapist and Ph.D. (the University College Metropol, Copenhagen, Denmark). The intervention therapists also took a brush-up course in the Assessment of Motor and Process Skills (AMPS), which allowed them to renew their AMPS licenses (see Outcomes section for more information on the AMPS). Detailed assessment protocol and supporting materials, i.e., the AMPS manual, evidence supporting the nutritional advice and physical activity recommendations for adults from the Danish Health Authority and testing equipment user manuals, were available at hand. The assessment protocol was updated in case of amendments. The intervention therapists received supervision by the principal researcher once a week or on-demand, online and by email. All questions were answered. All the intervention providers had access to the electronic patient journaling system (Sundhedsplatformen) in Region Zealand and the projects' Sharepoint site with all the materials. Relevant co-workers could obtain external access to the materials in the project on demand by contacting the principal researcher.

Intervention facilities

The intervention facilities at the OTU included a training room for group sessions, a training kitchen and an assessment room. The training room could accommodate (at no social distance restrictions) up to 19 persons, the kitchen room for up to 7 persons, and the assessment room for up to 3 persons (including an intervention therapist or assessor). In addition, caretakers were welcome to attend the baseline and follow-up assessments and home visits. At the same time, that was not allowed under the group sessions because of the programme's patient confidentiality rules and conceptual consideration.

Intervention mode of delivery

Following occupational therapy methods relevant for chronic pain treatment, according to Laqueux et al. (2018) (57), were applied to the REVEAL(OT):

- Tailored goal setting and work
- Body mechanics/postures and positioning
- Energy conservation/joint-sparing techniques
- Relaxation
- Ergonomics for home (work) inclusive assistive devices
- Environmental modification
- Pacing/ graded activity
- Activity adaptation

Each group session started with a brief didactic presentation. Pursuing occupational enablement in the participants, the intervention therapists followed the CPPF-informed approach (60) illustrated in Figure 14.

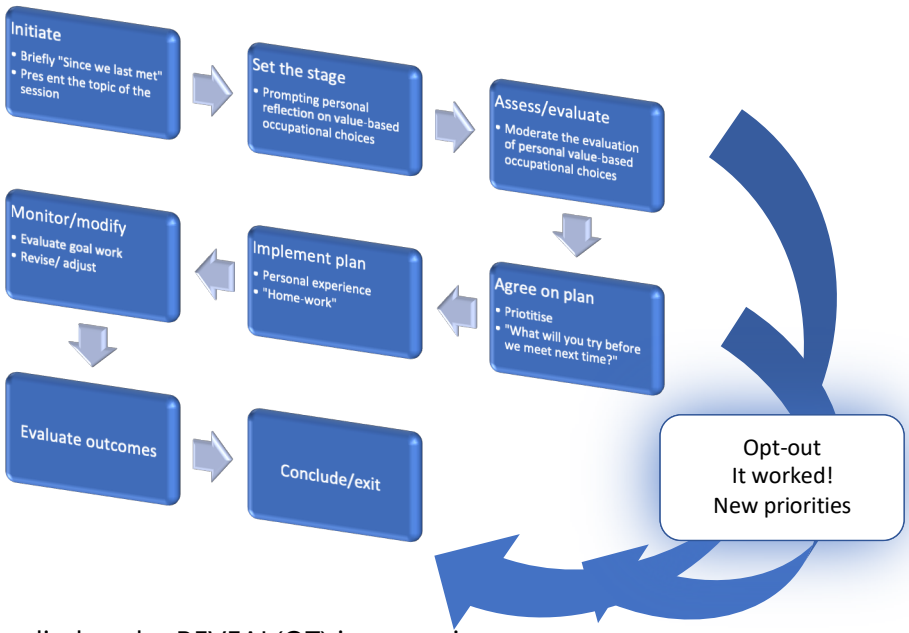

Figure 14. CPPF model applied to the REVEAL(OT) intervention

The repetitive use of the CPPF-model should strengthen the participants' skills on a stepwise approach to personal goals to prepare successive self-management after the intervention discharge.

Intervention outcomes

Primary outcomes

Predefined research progression criteria based on the green-amber-red light system were the primary outcomes of the REVEAL(OT) feasibility study (Table 5) besides the participant' and clinicians' feedback. In this progression criteria, the green level means "continue, no changes needed", the amber level means "solve, improvements needed" and the red level means "no further action, major changes needed" (144). Feasibility outcomes helped us evaluate whether the intervention was perceived relevant and appropriate in terms of timing and form for delivery, the assessment procedures were acceptable, retention and adherence among the participants, as well as the fidelity of delivery in the intervention providers, were satisfactory, and if severe adverse events occurred. Evaluating the recruitment rate would help us anticipate if the determined sample size estimate for the future RCT (n = 228) could be reached in a realistic timeframe. Adverse events were defined as unpleasant experiences during follow-up, causing discontinuation from the trial.

Table 5. Research progression criteria for feasibility outcomes

Feasibility outcomes	**Evaluation source**	**Decision/ action to be taken**		
		Continue	**Solve**	**Stop**
Recruitment rate	n recruited per month (n/ group)	n ≥ 3 (5)	n = 2 (2)	n = 1 (1)
Participant retention	Completion rates	≥ 80%	< 80 ≥ 75%	< 75 %
Program adherence to >75% of sessions	Adherence rates	≥ 75%	<75 ≥ 50%	< 50%
Patients' self-perceived relevance, timing and mode of delivery	Patient evaluations (positive)	≥ 75%	< 75 ≥ 50%	< 50 %
Assessment procedure acceptance	Patient evaluations	≥ 75%	< 75 ≥ 50%	< 50%
Adverse events, % discontinued	Patient journals and PainData	0%	≥ 1%	≥ 10%
Fidelity of delivery	Process evaluations	≥ 90%	< 90 ≥ 50%	< 50%

Note. NA, not applicable

The following materials were used to monitor the feasibility outcomes:

- recruitment registration scheme with dates for contacts, appointments and reasons for withdrawal
- attendance registration scheme for evaluation of retention and adherence in the participants
- evaluation forms for evaluation of patients' self-perceived relevance, timing, and mode of delivery (Appendix 19)
- process evaluations checklists for evaluation of fidelity of delivery in the intervention providers inclusive registration of the patients' acceptance of the assessment procedures (Appendix 20)
- adverse events registration (patients' feedback and automatic alerts in the patient electronic journal system supplied by self-reports from the PainData questionnaire).

Secondary outcomes

Sociodemographic characteristics

The participants' age, gender, weight, height, marital status, educational level, alcohol and tobacco consumption, and employment status were collected through the Danish clinical pain registry PainData (52). For this feasibility study, the standard PainData questionnaire was supplied with additional questions assessing, e.g., HRQoL, occupational balance and pain self-efficacy.

Outcome evaluation

Feasibility studies usually have preliminary character and cannot predict treatment effects (145). The secondary outcomes in this feasibility study were informed by the recommendations proposed by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) (146, 147) and the VAPAIN consensus statement (148). The secondary outcomes were related mainly to the core outcome domains such as pain, physical activity, satisfaction with social roles and activities, productivity (paid and unpaid), health-related quality of life, and patient's perception of treatment goal achievement. Adverse events were included in the primary outcomes for this research. Participant disposition was not accessed because all interested outpatients that fulfilled the inclusion criteria were considered eligible for the intervention. Monitoring outcomes in this feasibility study aimed to inform further modelling of outcomes included in the future RCT.

HRQoL: Difference in self-reported HRQoL (scored by EQ-5D-5L Index, EuroQol reg. ID 28126, Appendix 21) was the primary outcome for the future RCT (37, 38). EQ-5D-5L questionnaire assessed problems in mobility, self-care, usual activities, pain/ discomfort, and anxiety/ depression ranged on a 5-point categorical scale from 1="no problems" to 5= "extreme problems" (EQ-5D values) and self-perceived health on a 0–100-point visual analogue scale where 100 was the best imaginable health (EQ-5D VAS) (23-25). This outcome measure would allow a later cost-effectiveness analysis.

Occupation, pain and lifestyle-related outcomes: The following outcome categories were related to occupational engagement (A), an impact on lifestyle (B), and accumulated systemic improvement (C):

A. Self-reported Occupational Performance and satisfaction (COPM) (40, 41), observed Motor and Process Skills (AMPS) (34, 42), self-reported Occupational balance (OBQ) (43);
B. Physical wake-time activity (actigraphy units) (45); BMI (weight and height scale), waist circumference (measuring tape), and blood pressure (sphygmomanometer) (35);
C. Pain Self-efficacy (PSEQ) (44) and quantitative sensory testing (QST) measured by Controlled Cuff Pressure Algometry (CCPA).

For a complete overview of the outcomes included in the RCT and their assessment methods, please see Appendix 2 or Appendix 4 in Study IV.

Analysis plan

The quantitative analysis was planned to include descriptive statistics for study sample sociodemographic characteristics of the sample, means and standard deviations (SD) for continuous variables and frequency distributions for categorical variables. Feasibility outcomes were to be analysed descriptively for frequencies of the research criteria fulfilled and compared with the predefined satisfactory estimates in the green-amber-red light system. Differences in secondary outcomes changes before-after the intervention were to be calculated from means or proportions and SD using t-test statistics. Microsoft® Excel software, version 16.53 and Stata© 17.0 (Stata Statistical Software: Release 21. College Station, TX: StataCorp LLC) should support the statistical analyses. The statistical significance level at 5% should assist the interpretation of the results.

Preliminary results from the REVEAL(OT) 1.0-2.0

Preliminary evaluation of the results in 13 participants after feasibility 2.0 revealed significantly improved Canadian Occupational Performance Measure scores for occupational performance (1,57 [95% CI: 0.8; 2.4], p=.0004) and satisfaction (1.25 [95% CI: 0.17; 2.34], p=.0133). No significant changes in occupational performance function (Assessment of Motor and Process Skills) and bio-impedance were detected (see Supplementary materials, S8).

Participants expressed satisfaction with their participation, but adherence to some procedures, e.g., completing the online questionnaire, was difficult for some participants and demanded efforts to monitor adherence to the plan. Hence, uncertainties remained regarding the self-perceived outcomes of the intervention and nuanced knowledge of retention and adherence obstacles. Therefore, an in-depth investigation of the patients' and clinicians' experiences from their involvement in the REVEAL(OT) was necessary because the analysis of the evaluation forms alone could not inform further research decisions.

Mid-term qualitative feasibility evaluation - Study III

Aim - Study III

This study (full text inclusive appendices provided in Appendix 22) aimed to investigate perspectives of patients and clinicians involved in the occupational therapy lifestyle-oriented programme REVEAL(OT) 1.0-2.0 added to the standard multidisciplinary chronic pain treatment (149).

Methods - Study III

Focus group interview methodology was applied to generate evidence on the participant experiences with the REVEAL(OT) added to the current multidisciplinary chronic pain treatment. Considering both the patients and clinicians involved in the REVEAL(OT) for participants in the intervention process, I applied interpretivist epistemology and hermeneutic phenomenological approach to the investigation (132, 150). All the patients who took part in the REVEAL(OT) 1.0-2.0, the MPC team and intervention therapists were welcome to participate (see the participant information and consent letters in Appendices 23-26). Three focus group interviews were conducted, two with eight patients

and one with four clinicians, who participated voluntarily. The patients' focus groups included a mix of participants in the REVEAL(OT) 1.0 and 2.0. However, I could not establish differential participation because of the participants' timing preferences.

The focus group interviews lasted 90 to 120 minutes. An interviewer (extern) and observer (principal investigator) strived to establish an open and trustful atmosphere promoting free group communication. Two semi-structured interview guides (for patients and clinicians) were used (Appendix 27 and 28). Both interview guides followed a similar approach, which included few main questions with a broad focus to prompt unrestricted refelction and additional questions to encourage balanced participation in the discussion (151). I welcomed explicitly any relevant information, including criticism and negative or missing experiences.

Moreover, I urged the clinicians involved in the focus group interviews to collect any relevant comments regarding the REVEAL(OT) among their colleagues who could not participate. Ergonomic sitting chairs, food and beverages were available for the participants in the focus group interviews. The interviews were recorded and transcribed verbatim by an extern assistant not affiliated with the current research.

In the semantic data-driven analysis, two authors followed the six phases proposed by Braun and Clarke (152): getting familiarised with the data, comprehending the entire transcribed text and gaining an overall understanding of the data (Phase 1); independently generating initial codes and discussing discrepancies in formulating the codes (Phase 2), e.g., the word "partner" was preferred over "spouse" or "husband", because formalities were less important in this context; searching, reviewing, defining and naming the themes emerged from the initial codes (Phases 3-5) where the focus was placed on the contributive role of each code to either occupation, person or environment in chronic pain treatment (57), which allowed for a similar approach to both the patients' and clinicians' perspectives (Appendix 29); understanding and discussing the findings and elaborating on a cumulative report (Phase 6). Selected citations added transparency to the results. I considered this inductive approach to reflexive thematic analysis appropriate for the interpretation of the individual participant experiences because it allowed me to look at the data from my point of view as principal researcher and act "a translator" of the new knowledge into current research process (153).

Results - Study III

No markable differences in patient characteristics or experiences from participants in the REVEAL(OT) 1.0 versa 2.0 were observed. The cumulative analysis revealed two themes: "Increased patient acceptance of living with chronic pain" and "Empowering patients to make lifestyle changes".

The patients reported satisfaction with the intervention and a greater acceptance of living with chronic pain through increased understanding of pain mechanisms, more effective daily planning and improved social interaction in different ways, e.g.:

> *"I'm aware now that there are other ways to handle things. I appreciate it deeply"; "I look at myself with new eyes, so I think that is the most important output of being here"; "The most important thing for me was to find space for myself… and say "no" to what I can't or don't want or have the capacity for (…) That it is okay not to be able to cope with all that I was used to before. It has helped me, indeed"*.

One of the clinicians explained the mechanism of change which the growing acceptance in the patients may start:

> *"When they begin to communicate in a new way and express their needs in terms of pain, then they show more respect for their pain condition and get more skilled in setting clear limits. One's social environment can handle that much more easily!"*

Restarting habitual interests, prioritising joyful occupations for improved occupational balance, and lifestyle modifications empowered the patients for changing lifestyle. Important empowering factors in working with lifestyle goals were frequent contacts with occupational therapists and peer support.

> *"It has been fantastic to understand that it is okay to peel some potatoes and then relax and sit and knit, and then to return and make some meatballs or whatever. (…) Because you manage those pain flares better"*.

The clinicians saw the relevance of including occupational therapy in chronic pain treatment. Still, they pointed out structural challenges and the need to intensify the cooperation and patient-related communication between the MPC and OTU. In addition, both patients and clinicians expressed the

need to reduce information and treatment load to ease the participation in both the standard and the add-on treatments.

Conclusion – Study III

Study III concluded that the patients and clinicians found the lifestyle-oriented occupational therapy programme relevant and beneficial for acceptance of living with chronic pain and changing lifestyle, but further improvements were needed to reduce information and treatment load and a higher degree of interdisciplinary cooperation and communication between the clinical units involved.

Completing the feasibility phase

With the knowledge earned from Study III, I planned the REVEAL(OT) 3.0 entry *after* the psychoeducation course and sessions in-clinic every other week, followed by phone calls for monitoring the goal work every opposite week. Patient handbooks were used instead of handouts. Administrator access to registration and completion records for the PainData questionnaire was provided to the principal researcher. The ethical and legal authorities approved all the amendments.

COVID-19 pandemic impacted further research activities. The first attempt of conducting the REVEAL(OT) 3.0 failed due to COVID-19 lockdown. The COVID-19 restrictions at Naestved hospital, launched in March 2020, affected the recruitment routines and intervention schedule. The initial screening had to be conducted online, and no group-based psychoeducation could be delivered in a quarantine period. Many patients were discharged because of stop in all non-acute hospital activities. Discharge from the standard treatment meant also discharge from the add-on treatment in the REVEAL(OT). Our second attempt to conduct the REVEAL(OT) 3.0 after the lockdown period started in September 2020 and was still embossed by the COVID-19 effects but manageable.

Feasibility evaluation of the REVEAL(OT) 1.0-3.0 - Study IV

Aim - Study IV

This study (full text inclusive appendices provided in Appendix 30) aimed to evaluate the feasibility of the REVEAL(OT) intervention, its pre-post outcome measures and the adjustment needs, to determine further research steps before initiating an RCT (154).

Methods - Study IV

The intervention design, settings, participants, recruitment procedures, intervention contents, delivery and outcomes were previously described (cf. pp. 65-74). According to the research objectives, this study evaluated the intervention feasibility from the positivist perspective (132) using the green-amber-red system ("traffic light" method) of the research progression criteria (155), cf. Table 5, pp. 72, to evaluate the feasibility parameters. Statistical methods were used for pre-post comparison of the intervention outcomes.

Data collection

The recruitment rate was registered in the projects' SharePoint database inclusive details regarding, e.g., allocation, reasons for withdrawal or non-eligibility. Participant retention and program adherence were registered in group attendance forms, patient journals and appointment schedules for the OTU. Program adherence to the intervention contents was monitored additionally in detail on personal goal work template (Appendix 31) developed to support the participants and intervention therapists in systematic working with prioritised goals. The participants independently filled out the patient evaluation forms for self-perceived relevance, timing, and mode of delivery (cf. Appendix 19) that asked about the following:

1. Was the scheduling of the session appropriate?
2. Was the timeframe for the session appropriate?
3. Were the session contents relevant?
4. Were the intervention contents easy to comprehend?
5. Was the form for delivery (individual or in-group) appropriate?
6. Were you satisfied with your participation in the session?

While the patient evaluation forms in the REVEAL(OT) 1.0-2.0 were based on a 3-item Likert scale ("Agree", "Disagree" or "Don't know"), those for the REVEAL(OT) 3.0 contained a 6-items Likert scale ("Fully agree", "Agree", "Neither/ nor", "Disagree", "Definitely disagree" or "Don't know"), both inclusive comment boxes for other options and details. Evaluating the phone/video sessions, the participants reported their feedback orally to the intervention therapists, who registered their answers and comments.

The intervention therapists completed process evaluation checklists for the fidelity of delivery after each session delivered (cf. Appendix 20). The bullet-listed process evaluation checklists for the manualised intervention contents allowed a rapid check of actions performed in each session, including direct feedback from the participants. During supervision, the intervention therapists and principal investigator evaluated the needs for further steps to be taken upon the participants' feedback, e.g., providing supplementary materials or additional demonstration of assessments procedures.

Adverse events were defined as unpleasant experiences during follow-ups, such as an increase in medication and occurrence of depression, morbidity and mortality causing discontinuation from the trial. Data on adverse events were collected from the PainData questionnaire, automatic alerts in the patient electronic journal system and patients' feedback. Phone calls clarified the causes for untimely discontinuation from participation.

Outcomes

Outcomes were monitored by assessing the effect outcomes within two weeks before and after the occupational therapy lifestyle programme. Study IV reported on HRQoL as the primary outcome for the RCT and occupational performance and participation as the outcome that guided the goal work during the intervention. Other outcomes evaluated in the feasibility study (cf. Appendix 2 or Appendix 4 in Study IV)) were to be reported in a separate publication.

HRQoL: From the EQ-5D data on problems in mobility, self-care, usual activities, pain/ discomfort, and anxiety/ depression derived from the PainData registry (20), I calculated the cumulative HRQoL score (EQ-5D Index) using the Danish EQ-5D Crosswalk value set (26). The EQ-5D Index ranging from -0.594 to 1 considers all states below zero being "worse than death", while 1 = "perfect health" (27).

COPM: The Canadian Occupational Performance Measure (COPM) assessment helped identify and prioritize personal occupational problems related to self-care, productivity, and leisure on a 10-point scale according to their self-perceived importance, performance, and satisfaction with the performance (higher scores mean higher importance, performance and satisfaction) (28). The COPM assessment as an outcome is valid, reliable and sensitive to change, i.e., in chronic pain studies (29).

Analysis

Feasibility outcomes were analysed descriptively for frequencies of the research criteria fulfilled and compared with their predefined satisfactory estimates in the green-amber-red system. Data on self-perceived relevance, timing and mode of delivery from the 6-items evaluation forms in the REVEAL(OT) 3.0 were collapsed to match the 3-items evaluation forms in the REVEAL(OT) 1.0-2.0. Hence, the answers "Fully agree" and "Agree" were categorised as "Agree", and "Neither/nor", "Not agree" and "Definitely not agree" as "Not agree". The category for indefinite answers ("Don't know")

remained unchanged. The participant comments supported the interpretation of the results. Only adverse events causing discontinuation from the intervention were eligible for comparison with the predefined research criteria. Still, all adverse events were evaluated for their relevance for further improvements in the intervention. Fidelity of delivery in the intervention providers was analysed considering a delivery failure if any session had at least one deviation from the process evaluation. The delivery failures were analysed for frequency and described using additional comments and observations on possible reasons.

All the participants who completed baseline and follow-up assessments were included in the secondary outcome analysis. Differences in change pre-post intervention in HRQoL and COPM in the intervention completers were assessed using paired t-tests. The percentage of participants who achieved the MCID for the COPM performance and satisfaction (min. 3 or 3.2-points difference in any direction, respectively) (32, 33). Statistical analyses were performed using Microsoft® Excel software, version 16.53 and Stata© 17.0 (Stata Statistical Software: Release 21. College Station, TX: StataCorp LLC). The 5% significance level guided the interpretation of the statistical results.

Results – Study IV

From January 2019 to October 2020, 174 outpatients were referred to the OTU regarding participation in the REVEAL(OT) (Figure 15). Several outpatients were either not interested in participation (n=54) or not reachable by phone (n=17) despite several attempts (min. 5 per outpatient). Of the 103 outpatients assessed for eligibility, n=57 were included.

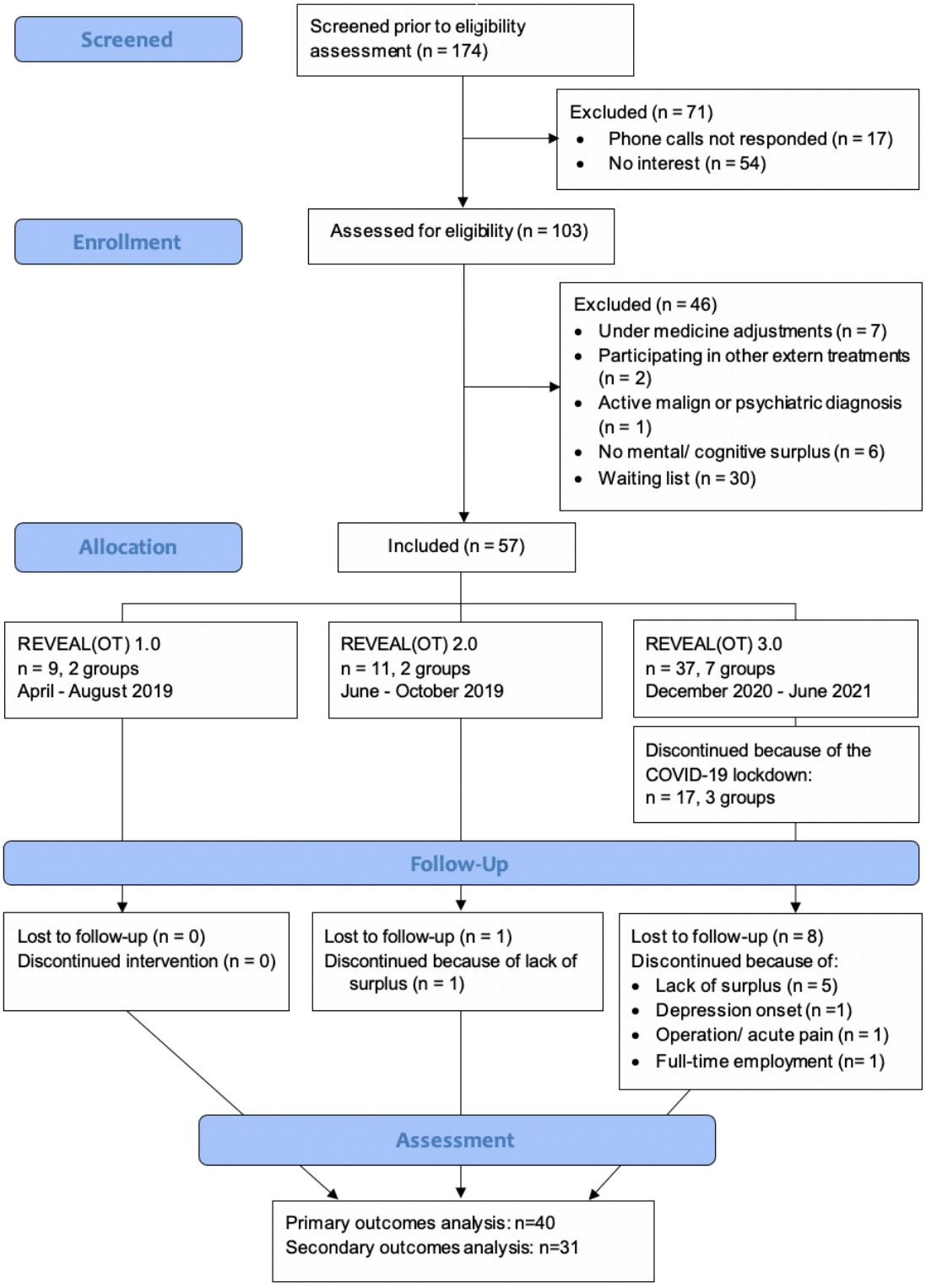

Figure 15. CONSORT study flow diagram

Participant characteristics

The 40 chronic pain outpatients (85.0% females, mean age 46.6±10.9 (23-64) years, average pain duration of 10 years (9.3; range 0.7-39)) participated (Table 6). No significant differences were observed between the completers, discontinued due to the lockdown (age, p-value=0.7967; gender, p-value=0.7530) or nonparticipants (age, p-value=0.7174; gender, p-value=0.0522). There were 17.4% more males in the nonparticipants.

Table 6. Sociodemographic and health-related characteristics of the participants, Study IV

Variable	**Value (mean (SD) Frequency (range)**
Females	
Study sample (n=40)	34 (85.0%)
Discontinued groups (n=17)	15 (88.2%)
Not included (n=117)	81 (69.2%)
Age, years	
Study sample (n=40)	46.6 (10.9; 23-64)
Discontinued groups (n=17)	47.4 (10.3; 22-63)
Not included (n=117)	45.8 (10.7; 22-63)
Age groups, years old (n=40)	
18-24	1 (2.5%)
25-34	6 (15.0 %)
35-44	9 (22.5%)
45-54	12 (30.0 %)
55-64	12 (30.0%)
Years with pain (n=35)	9.7 (8.7; 0.7-29.9)
<5	13 (37.1%)
5-9	8 (22.9%)
10-14	3 (8.6%)
15-19	6 (17.1%)
≥20	5 (14.3%)
Self-evaluated health, EQ-5D-VAS 0-100 (n=36)	48.6 (20.2; 6-90)
0-24	5 (13.9%)
25-49	17 (47.2%)
50-74	11 (30.6%)
75-100	3 (8.3%)

Feasibility evaluation

Recruitment rate

Despite the recruitment rates reached the green level in the REVEAL(OT) 2.0 and 3.0, and the mean number of participants per group was acceptable (n=5), some groups were small, and the recruitment criteria n≥3 participants per month did not guarantee a min. n=5 participants in all groups. Therefore, the overall research progression criteria for recruitment rate was downgraded to the amber level.

Moreover, with this recruitment intensity and one year from baseline to the primary endpoint in the RCT planned, one therapist could deliver the REVEAL(OT) programme in its version 3.0 to mean n=20 outpatients (4 groups) annually or n=40 (8 groups) in 1,5 years. Thus, from 6 to 11 research sites should be involved in the future RCT estimated to include 228 participants. Of the total n outpatients referred to the intervention, 30 (17.1%) remained on the waiting list because no vacant place or appropriate group was available. Running two or more groups at a time could be considered at a research site if clinical capacities allow.

Participant retention

Main reasons for dropout (n=9 of 40; 22,5% dropout rate) were mental or cognitive surplus deficit (n=6). Prevalence in surplus deficit occurrence increased in the COVID-19 pandemic period (n=5), reportedly because of the increased caretaking load and fear of the disease. In total, n=31 (77.5%) completed the feasibility study, corresponding with the amber level for research progression for retention. In the non-pandemic-exposed groups (REVEAL(OT) 1.0 and 2.0), retention reached 90.9% and 100% accordingly. Please see the graphical overview of retention in the REVEAL(OT) 1.0-3.0 in Appendix 5 to Study IV.

Participant retention to the in-clinic assessments was higher (n=31 of 40) than the online questionnaires returned (n=23 of 31). Efforts were made to secure the questionnaire completion, i.e., a mean of 5 attempts per participant, including phone calls, digital posts and messages. However, n=8 (25.8%) had missing questionnaire data at baseline, follow-up, or both. Information memorising issues were reported as the reason. Remarkably few participants initiated a contact themselves to

solve challenges with completing the assessments at home, in contrast with the assessments in-clinic. Additional time and electronic devices were available for completing the questionnaire in-clinic, but few participants had surplus to stay longer than the regular assessment session time that varied 2 - 2.5 hours. In the REVEAL(OT) 3.0, the completion rate improved along with the administrator access to the online questionnaire for the principal researcher, which allowed for better control with the completion.

Programme adherence

Before intervention discharge (n=31) or discontinuation (n=9), the participants attended 412 (83.9%) sessions of 492 available in total, with mean=83.5 (range 38.5-100) sessions attended per participant (Appendix 32). In total, 77.5% attended ≥75% of the programme delivered, placing the research progression criteria for programme adherence on the green level.

Patients' self-perceived relevance, timing, and mode of delivery

Of the 343 evaluation forms in total, 97.0% (91.9-100) of the participants responded positively to the questions (Table 7), placing the research evaluation criteria on the green level. Several participants proposed the revision of the intervention schedule (5.8%), e.g., adding afternoon groups or extended sessions for more peer discussion and therapist contact (4.1%). Long transportation time was also challenging in a few.

Table 7. Patient evaluation of self-perceived relevance, timing, and mode of delivery

Item	Reports of the total n=343 and in feasibility rounds, n (%)		
	Agree	Disagree	Don't know
a) Was the scheduling of the session appropriate?			
Total	315 (91.9)	20 (5.8)	8 (2.3)
1.0	73 (92.4)	2 (2.5)	4 (5.1)
2.0	70 (89.6)	4 (5.7)	4 (5.7)
3.0	172 (92.5)	14 (7.5)	0 (0)
b) Was the timeframe for the session appropriate?			
Total	328 (95.6)	14 (4.1)	1 (0.3)
1.0	76 (96.2)	2 (2.5)	1 (1.3)
2.0	70 (89.7)	8 (10.3)	0 (0)
3.0	182 (97.8)	4 (2.2)	0 (0)
c) Were the session contents relevant?			
Total	336 (98.0)	0 (0)	7 (2.0)
1.0	73 (92.4)	0 (0)	6 (7.6)

2.0	77 (98.7)	0 (0)	1 (1.3)
3.0	186 (100)	0 (0)	0 (0)
d) Were the intervention contents easy to comprehend?			
Total	342 (99.7)	0 (0)	1 (0.3)
1.0	78 (98.7)	0 (0)	1 (1.3)
2.0	78 (100)	0 (0)	0 (0)
3.0	186 (100)	0 (0)	0 (0)
e) Was the form for delivery (individual or in-group) appropriate?			
Total	333 (97.1)	0 (0)	10 (2.9)
1.0	69 (87.3)	0 (0)	10 (12.7)
2.0	78 (100)	0 (0)	0 (0)
3.0	186 (100)	0 (0)	0 (0)
f) Were you satisfied with participation in the session?			
Total	397 (100)	0 (0)	0 (0)
1.0	79 (100)	0 (0)	0 (0)
2.0	47 (100)	0 (0)	0 (0)
3.0	186 (100)	0 (0)	0 (0)
Total mean %	97.0	1.7	1.3

Assessment procedure acceptance

The research criteria for assessment procedure acceptance were 95.0%, corresponding with the green level. Of the 40 participants, n=2 (5%) declined participation in specific assessments such as cuff-algometry test because of discomfort (n=1) or wearing an actigraphy-unit because of allergy (n=1). In addition, most participants reported tiredness or exhaustion after the assessment rounds.

Adverse events

No serious adverse events led to discontinuation from the intervention, placing the research criteria on the green level for adverse events. Adverse events were registered in n=8 (20%) participants with reasons such as depression (n=2), short hospitalisation for observation of heart (n=1) and gut (=1), hospitalisation (anticipated, no date at baseline) for knee operation (n=1), emergency room visit (n=1), leg pain after cuff-algometry (n=1) and consulting a psychiatrist (n=1). None of the events was associated with the intervention. One of the depression cases was diagnosed after intervention discharge, and therefore not discontinued.

Fidelity of delivery

Of 233 (80.1%) process evaluations collected, 39 (16.7%) contained 45 amendments to the planned contents. Of those, 22 (48.9%) were not timely completed online questionnaires; 9 (20.0%) were

excessive session time used; 9 (20.0%) changes in test order (of practical reasons); 3 (6.7%) difficulties in following the session plan due to concentration deficit (all in the participants from the COVID-19 pandemic-exposed groups); and 2 (4.4%) declined participation in tests (cuff-algometry and actigraphy, described above). All the amendments related to single actions within a session. However, when counting any sessions with an amendment for delivery failure, the fidelity of delivery with 194 correctly performed sessions was 83.3%, placing the research criteria on the amber level. According to the intervention therapists' feedback, the fidelity of delivery demanded high flexibility in contact with the participants, i.e., due to many sudden amendments to the schedule.

Summary of feasibility outcomes

The primary outcomes for the study were summarised (Table 8) and attached comments on relevant research actions.

Table 8. Research progression criteria summary

Research progression criteria	**Total**	**Feasibility rounds**			**Evaluation**	**Considerations and comments**
		1.0	**2.0**	**3.0**		
Recruitment rate (mean n recruited (referred) per month; n per group)	5.7 (17.5) 5 (4-6)	6.7 (28.0) 5 (4-5)	4.3 (13.3) 5 (5)	6.7 (27.3) 5 (5^{1}-6)	Amber/ Solve	Recruitment n≥3 per month did not guarantee a min. n=5 in all groups, despite mean n=5 per group; With the current recruitment intensity, the recruitment must begin at least ≥2 months before baseline assessment
Participant retention[2] (n, %)	31 (40) 77.5%	9 (9) 100%	10 (11) 90.9%	12 (20) 60.0%	Green/ Continue	The lockdown negatively affected participant retention; solutions allowing the intervention to continue during force major situations shall be considered; follow-up assessment completion must be secured
Program adherence to >75% of sessions, % mean (range)	77.5% (38.5-100)	77.8% (57.1-92.9)	81.8% (44.4-100)	75.0% (38.5-100)	Green/ Continue	Adherence ≤50% of the sessions can occur in few participants and needs attention; self-assessments demand a more effective procedure

Patients' self-perceived relevance, timing and mode of delivery (% mean)	97.0% (91.9-100)	94.5% (87.3-100)	96.3% (89.6-100)	98.4% (92.5-100)	Green/ Continue	Continuous monitoring is useful; personal preferences may appear; sufficient time for peer discussions shall be provided; afternoon groups may be relevant for some participants
Assessment procedure acceptance (n, %)	38 (40) 95.0%	9 (9) 100%	9 (11) 81.8%	20 (20) 100%	Green/ Continue	The assessment procedure may need the assessment load reduction; further evaluation of the outcomes observed may support the improvements; assessment performance requires closer monitoring for timely completion
Adverse events (% caused discontinuation)	0%	0%	0%	0%	Green/ Continue	Several participants experienced discomfort from cuff-algometry, though none was at health risk or discontinued
Fidelity of delivery (% evaluations collected; n, % contents delivered as planned)	80.1% 194 (233) 83.3%	60.7% 28 (37) 75.0%	100% 14 (23) 60.9%	100% 152 (173) 87.9%	Amber/ Solve	The peer support component may barrier the fidelity of delivery, exceeding the protocolized time of delivery; the intervention providers need flexibility, e.g., extra calendar space for new appointments/ other problem solving

Note. [1] One participant stopped after baseline assessment; [2] Exclusive n=17 discontinued involuntarily due to the COVID-19 lockdown

Accept of randomisation

At the entry to the REVEAL(OT) 3.0 programme, I asked the participants (n=37) whether they would accept participation in an RCT and the risk of not receiving the experimental content. Of those, 97.3% accepted, while n=1 declined.

Patient-reported outcomes

One of the 24 participants who returned complete online questionnaires assessing the HRQoL was excluded because of deviations from the treatment plan (higher doses of the standard treatment

received before starting in the REVEAL(OT)). In the 23 reports, no significant difference in HRQoL was observed (Figure 16 and Table 9).

The pre-post difference in COPM scores (cf. Table 9) showed a significant trend for change in occupational performance 1.80 (95% CI 1.25; 2.35), $p<0.001$, and satisfaction with an occupational performance by 1.95 (95% CI 1.06; 2.84), $p<0.001$, indicating an overall positive trend for successful and satisfactory resolution of self-reported occupational problems. Only 13.8% of the participants reached the recommended clinical important difference (MCID) cut-off of ≥3 for COPM occupational performance and 24,1% (MCID≥3.2) for satisfaction. However, in the REVEAL(OT) 3.0, MCID was 27.3% and 45.5%, respectively.

Conclusion – Study IV

Overall, the research progression criteria were feasible regarding programme adherence, patients' self-perceived relevance, timing, mode of delivery, assessment procedure acceptance, and adverse events. However, participant recruitment, retention and delivery strategy of the REVEAL(OT) needed further optimization. No improvement in HRQoL and significant change in occupational performance and satisfaction was detected.

Table 9. Pre-post differences in Health-Related Quality of Life and COPM scores

Outcomes	n	Baseline	Follow-up	Mean diff.	SD	95% CI		Median (range)	p-value	MCID[1]
HRQoL	23	.429	.472	.04	.18	-.03	.12	.051 (-.210; .432)	.2494	-
COPM, Performance	29	3.36	5.10	1.80	1.44	1.25	2.35	1.5 (-1.2; 5.4)	<0.001**	13.8%
COPM, Satisfaction	29	2.55	4.40	1.95	2.34	1.06	2.84	1.9 (-1.4; 8.8)	<0.001**	24.1%

Note. Abbreviations: CI, confidence interval; COPM, The Canadian Occupational Performance Measure; MCID, Minimal Clinically Important Difference; n, number; SD, standard deviation
[1] ≥3 pct. for performance; ≥3.2 pct. for satisfaction
* p-value <.05, **, p-value <.001

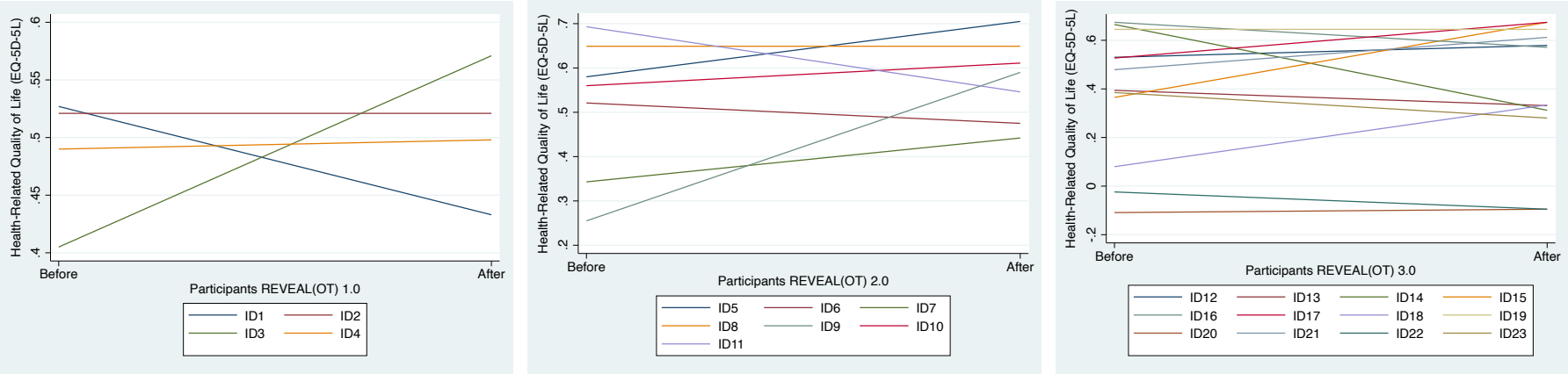

Figure 16. Health-Related Quality of Life pre-post intervention

Discussion

This thesis presented a research project aimed at developing and feasibility evaluation of a lifestyle-oriented occupational therapy intervention REVEAL(OT) added to the current standard treatment for adults living with chronic pain referred to a Danish pain centre to prepare a full-scale randomised controlled trial. Through a pragmatic approach, every step in this research pursued to reflect on the complexity of the existing clinical practice and generate new knowledge that would answer whether the REVEAL(OT) is designed and conducted in a feasible way (78). An eclectic approach where quantitative and qualitative research methods supported each other allowed to meet the emerging research needs and support the decision-making with both quantified and in-depth knowledge (78, 156). This pragmatic eclecticism helped tackle the complexity in the existing clinical reality the REVEAL(OT) intervention was embedded. The iterative research process was represented in four scientific publications (130, 136, 149, 154). In the following, I will discuss the main results from the four studies and afterwards share methodological considerations on reliability and validity in each of those separately for later to conclude on the entire research project findings.

Viewing the research actions performed from the perspective of developing and evaluating complex interventions (76, 77, 91), Study I and II identified "active ingredients" in the REVEAL(OT), while Study III and IV described its conduct and qualitative and quantitative evaluation (132, 154). The systematic review with a meta-analysis (Study I in this thesis) took a positivist view on the effect of occupational engagement included in chronic pain interventions targeting lifestyle (130, 132). The positivist perspective was prioritised because the evidence on the occupational therapy effectiveness in chronic pain treatment is still scarce, and more studies would strengthen the evidence base (57, 61, 157).

Transforming health through occupational engagement

Study I suggested the effect of including occupational engagement in chronic pain interventions on physical activity in the short term and on sleep quality in the long term (130). Both factors are significant health risks in people living with chronic pain (42). Low methodological quality in the RCTs included in the review reduced the evidence certainty to low-very low. Knowing the benefits of

physical activity in chronic pain (158), I expected a more significant effect size in our meta-analysis. The effect power may have remained on the suggestive level (135) because of other treatments as a comparator. No treatment as a comparator could likely enhance the effect size. Although I could not make firm conclusions on the effect size, the findings added important consideration on occupational therapy potential for promoting health behaviour changes, not only in people with overweight and obesity (75) but also in specialised tertiary chronic pain rehabilitation at a hospital.

The systematic review included any RCT that reported on occupational engagement as a component in its experimental contents, irrespectively, which health profession has delivered the intervention (130). Moreover, many interventions in the study sample practised a holistic approach. Insufficient physical activity in more than 30% of the global population is concerning (159). Therefore, I would wish that this review added confidence to occupational therapists to join the battle with a sedentary lifestyle and think metabolic health along with occupational engagement. The dual focus may not necessarily possess a reductionistic view on health but still be holistic and create a synergic impact on health.

Wilcock (2001) raised criticism of occupational marginalisation when moralising and stigmatising people for their lack of control (98) which may be easy to fall into when advising on lifestyle. This perspective seems congruent with the recent evidence that explicitly pronounced the need for a holistic approach to lifestyle in chronic pain (42). Occupational therapists are educated to identify what brings joy into people's life. Particularly the accent on the joyful character of physical activity and choosing what people like to do was considered a powerful promoting factor for living an active lifestyle (160). This systematic review added an argument to the relevance of occupational therapy lifestyle management in chronic pain treatment and illustrated that more interventions oriented on personal value-based occupational choices should be carried out and evaluated.

Though, it can be argued that health behaviour change is not on the list of occupational therapy methods applied to chronic pain treatment (57) and may instead belong to the scope of other healthcare disciplines, e.g., dietitians or psychologists. However, strengthening the body has been included in the energy conservation strategies used by occupational therapists (161) and thus, can still be considered an occupational therapy-relevant area of impact. In addition, patients participating in the mid-term evaluation of the REVEAL(OT) reported the empowering effect of the collaboration

with occupational therapists when initiating lifestyle changes (149). Although occupational therapists will probably approach lifestyle differently than other healthcare disciplines, multimodality may benefit people living with chronic pain, providing a variety of treatment options and enhancing the odds for a person to find those "that work" (23).

Adjusting intervention focus

This research confirmed the relevance of targeting physical activity and assessment of body anthropometrics in the REVEAL(OT) (130). Targeting sleep would also be relevant, but anyhow, the feasibility study would not be able to assess the effect in the long term. Additionally, the standard treatment contained an impact on sleep. Not to disturb the current clinical practice, the intervention therapists involved the participants in planning and asked if they had any additional needs regarding this subject to be covered within the REVEAL(OT) (77). Still, the primary impact on sleep remained in the standard treatment.

Continuing with the positivist approach, Study II quantified patient-reported HRQoL, health, pain, lifestyle and motivation to initiate lifestyle changes (132, 136). The study found that serious-to-extreme problems in usual activities were associated with poorer self-evaluated health in the participants, confirming the relevance of occupational therapy impact in people living with chronic pain, other evidence has identified (49, 57, 157). In addition, the prevalence of metabolic risks in the chronic pain population detected in Study II also confirmed the other evidence (35, 42, 57).

Moreover, the study population surprised with its significantly lower level of self-perceived HRQoL compared to the general Danish population from the same geographical region (162), together with poor self-evaluated health. From the associations detected, it wouldn't be possible to say whether lifestyle was the reason for the poor evaluation or vice versa, i.e., poor health and quality of life in chronic pain harmed lifestyle. Anyhow, high pain levels and very poor sleep quality were significantly associated with a decline in HRQoL, while serious problems in usual activities were significantly associated with poor health (136). The high motivation for initiating lifestyle changes within chronic pain treatment course was surprising. Still, it confirmed that many may have reached at least the pre-contemplation phase in Prochaska & DiClemente Stages-of Change Model, indicating their readiness for such an impact. The study concluded that pain alleviation, sleep quality improvement, prevention

of serious occupational disruption in everyday life, and optimising physical activity level is vital for promoting health and quality of life, severely impaired in the chronic pain population (35). As in Study I (130), these results spoke into the relevance of targeting occupational engagement in chronic pain treatment. Studies I and II confirmed the relevance of focus chosen for the REVEAL(OT) intervention and motivation in the target population to get involved in lifestyle-oriented goal work during chronic pain treatment (130, 136).

In this thesis and current project, I used the expression "meaningful activities and lifestyle" when describing the REVEAL(OT) focus. The expression should clarify the simultaneous involvement of the core concept of occupational therapy of engagement in meaningful activities and focus on physical activity and healthy eating. However, the mix of professional and common terminology may question the expression's credibility. The expression may appear confusing, giving the impression that both terms are "weighted" equally from the perspective of occupational therapy lifestyle management when they are not. According to Fidler (1996), meaningful activities *are* lifestyle because they are what we do on a daily basis, which forms our lifestyle (66). The current experimental focus could have been described as value-based occupational engagement, which would impose any occupational choice and meaningful or purposeful doing, representing fundamental human rights (163). I needed both expressions to illustrate the intervention focus on occupational engagement *and* health behaviour for academia, professional communities and layperson audience (164).

Both occupational engagement and lifestyle are constructs involving action (165, 166). Every act of doing or not doing determines one's health and well-being through lifestyle-related choices (96). The doing-aspect in the REVEAL(OT) cohort seemed imperative for whether a participant perceived the deconditioning processes caused by chronic pain reverse into recovery processes. For example, those who actively engaged in goal work, peer support, and research activities also had "a good story to share", e.g., at focus group interviews in Study III (149). Those who met up for focus group interviews were anticipated more resourceful (or capable of doing) than those who withdrew. However, the entire REVEAL(OT) cohort had initially confirmed their participation. In Study III that followed the hermeneutic phenomenological approach, two major themes emerged from the multiple realities constructed by the "knowers" (150): "Increased patient acceptance of living with chronic pain" and "Empowering patients to make lifestyle changes" (149). Patients' examples of

changes in their lives pointed to improved ability to cope with everyday obstacles. Personal capabilities matching the situational requirements in occupations is a powerful mechanism for empowerment and personal development (115). Otherwise, people may avoid the occupational situation when those do not match. However, the hermeneutic phenomenological approach helped comprehend important outcomes to pursue in the REVEAL(OT) included in a multidisciplinary context.

Co-operating with chronic pain patients

The REVEAL(OT) demonstrated how occupational therapists could co-operate with adults living with chronic pain on stepwise improvements in their lifestyle, targeting meaningful activities, regular physical activity and healthier eating habits through value-based occupational engagement (154). The occupational therapy holistic approach appeared compatible with the biopsychosocial approach in the multidisciplinary chronic pain treatment. Previously, several researchers illustrated the conceptual interrelations between the Biopsychosocial Model developed by Mosey (1974) and occupational therapy theory (167-169). This Ph.D.-project added the standard treatment an occupational therapy perspective based on core concepts of Doing, Being, Becoming and Belonging that informed the REVEAL(OT) programme theory (96, 98).

The findings presented in this Ph.D.-thesis illustrated that the biopsychosocial model's biological, psychological and social components could be tackled by lifestyle-oriented occupational therapy through the dimension of Doing and improved occupational engagement. While the biological component became supported through more physical activity and healthier eating, psychological strength may have grown from *being* empowered to initiate lifestyle changes, and the social interactions improved through communication with intervention therapists, peers, and personal environments (149). *Becoming* competent in fulfilling personal goals may have made one perceive oneself as the person one wants to be and *belong* to a group of people competent in managing their own lives. The positive change in occupational performance identified in Study IV could be an expression for the accumulated treatment effect (154). The REVEAL(OT) intervention needs an investigation in a controlled randomised study design to ensure this effect. Nevertheless, the observation is encouraging, mainly because it confirms that the negative influence of chronic pain on occupational engagement is potentially reversible with lifestyle-oriented occupational therapy.

Decisions on doing or not doing are informed by both the biological needs and the sociocultural context (170, 171). The rationale for not doing in some participants may have been stronger than its healthier alternative. In this term, any avoidance in the study cohort can be considered a declaration of a mismatch in project demands and the participants' personal capacities, which shall be solved to support programme adherence in a future RCT.

During the feasibility study, intervention therapists attempted a differentiated approach, beneficial for vulnerable populations such as people living with chronic pain (149). Vulnerability imposed by long-term complex chronic pain may result in the need for lifestyle improvement on one hand. On the other hand, difficulties in acting towards it may emerge, which justifies the differentiation. Intervention therapists demonstrated the prerequisites necessary for tackling the complexity of the chronic pain population. Still, it seemed that more continued education would benefit future occupational therapy involvement in this field, e.g., guided by the IASP curriculum for occupational therapists (65) or inspired by the USC Life Management Series (www.chan.us.edu).

Besides the differentiated approach, the REVEAL(OT) targeted several lifestyle factors in the same intervention, which has been urged by other evidence (42). All those factors inevitably enhanced the complexity of the intervention. When preparing an RCT, the intervention components and its impact mechanism had to be controlled (79). Thus, the complexity should be explained in terms of its meaning for the intervention. The protocolised intervention contents structured the intervention. Still, the research process made obvious that alterations may still emerge, irrespectively of planning and retests. For example, any change in the standard treatment compromised the intervention plan and demanded a decision on how the project could adopt the new clinical reality (76).

Intervention complexity

The feasibility process illustrated that pre-planned flexibility in the intervention design would benefit its further investigation in an RCT design. Though, flexibility increases the intervention complexity (76), which needed to be reduced according to both the patients and clinicians participating in Study III (149). An individual intervention approach could have reduced the complexity. Still, it might have compromised the peer-interaction component that was reported to be an essential factor in promoting acceptance of living with chronic pain in the patients (149). Another possibility to reduce

the complexity could be a less comprehensive intervention design because simple intervention design is more accessible for the participants (79). Occupational therapy operates with various methods, less comprehensive than the REVEAL(OT) programme, that could be applied to the existing standard multidisciplinary chronic pain treatment (49, 57, 58, 172, 173). Though, it would not let us investigate in the novel lifestyle-oriented approach that many people living with chronic pain need and seem to be motivated for (42, 136).

The contextual complexity has even increased towards the last feasibility round because of the COVID-19 pandemic making the need for a more flexible intervention design even more apparent (154). The REVEAL(OT) intervention seems to share this knowledge with other healthcare interventions conducted in the last couple of years. The growing number of telehealth initiatives that demonstrate better adaptive features than on-site interventions witness the benefits of remote intervention participation (174-176).

Context received growing attention when the new MRC framework for developing and evaluating complex interventions was published in September 2021 (77). A complex intervention's interaction with its context may have crucial importance for its ability to change clinical practice (77). However, no assessment of the contextual feasibility of the REVEAL(OT) was performed. Thus, whether REVEAL(OT) has improved the existing treatment of chronic pain remained unclear.

Complex intervention can experience the effect of contamination between treatments (177). Composing the REVEAL(OT) programme theory, I was determined not to let it disturb but support the existing evidence-based clinical practice. I supposed that the REVEAL(OT) targeting meaningful activities and lifestyle added mainly to the behavioural component in the CBT (178). Occupational performance contains both micro, meso and macro perspectives (179), and isolating what people do from their thoughts, emotions, bodily reactions and social interactions would be impossible. However, the REVEAL(OT) was not working with the background for occupational performance and participation but its operational dimension.

To access possible treatment contamination, I would need to know the outcomes of the standard treatment, e.g., as proposed by the IMMPACT and VAPAIN consensus (148, 180). This knowledge is currently limited. Biopsychosocial chronic pain treatment appears heterogeneous regarding delivery,

assessment and reporting (47, 181). An RCT would be able to detect possible contamination by assessing the same set outcomes in the intervention and control groups. Patient distribution (or phenotyping) included at the recruitment stage to the RCT would improve the study sample representativeness and support interpretation of the treatment effect (182).

Before an RCT, it must be considered whether information and treatment load could still be too high from the perspective of the current need for lowering infection pressure on the society. The pandemic effects were anticipated to play a role in dropout from the study because of lowered surplus for attending the programme in this patient group with an initially elevated level of vulnerability (183, 184). An early survey of the COVID-19 psychological effects in 1210 respondents witnessed that 53.8% considered its negative impact moderate to severe. In general, social isolation may increase mortality by about 30% (185). Multiple negative effects of the pandemic on health and well-being in the society, i.e., growing prevalence of depression, anxiety, poor sleep, stress and pain, may persist in long-term (186). Enforced close-proximity with relatives under lockdown may cause personal autonomy disruption (187). Social disruption under lockdown may increase self-perceived injustice and cause maladaptive cognitive appraisal (i.e., the feeling that one does not matter anything to others) (188). Additionally, disturbance in the everyday routines with paused leisure-time opportunities, difficulties in the performance of domestic shores out-of-house, distant work and home-schooling of children may have added to the mental load (189).

Interdisciplinary context

As another contextual aspect demanding attention, improvements in multidisciplinary co-operation and communication proposed by the patients and clinicians in Study III added to the discussion about multidisciplinary versa interdisciplinary character of chronic pain treatment (23). Both terms have been used interchangeably in the literature, which may sound confusing. The term "multidisciplinary" has been used in this thesis and previous publications. Gatchel (2014) argues that the multidisciplinary treatment is delivered by several (more than one) healthcare professionals that may or may not be situated in the same setting but do not adequately interact with each other, while the interdisciplinary impact is characterised by a common philosophy of rehabilitation, daily communication on-site and active patient involvement (23).

Successful chronic pain treatment shall be interdisciplinary in its nature, i.e., first and foremost, be delivered from the same clinical facilities allowing close co-operation between the disciplines involved (1). The lack of interdisciplinarity was pointed out in Study III that highlighted the presence of occupational therapists "under the same roof" with the MPC team as a crucial factor for successful integration of the REVEAL(OT) (149). However, attempts to establish a closer location failed due to various systemic aspects. Investigating in feasibility, I could have started by clarifying possible systemic obstacles for integrating a new treatment modality, which can also be relevant to consider during feasibility evaluation (77).

Further steps

No clear guidance exists for when the feasibility phase is to stop (190). The iterative feasibility testing and evaluation from the positivist perspective in Study IV showed that most research progression criteria for feasibility were met, indicating the REVEAL(OT) overall feasibility. The significant change in the COPM scores for occupational performance and satisfaction observed in the waste majority of the participants in Study IV was encouraging (154). The results may have implied that the REVEAL(OT) managed to activate transformative processes in the participants to a certain degree and demonstrated occupational therapy capability in meeting the need for multiarray lifestyle focus. If the REVEAL(OT) lasted longer, the MCID percentages reached would maybe have been higher. However, no improvement in HRQoL was detected. More time in intervention would probably also be necessary to bring this outcome to a significant level. Only sustainable changes would benefit health, not rapid changes with consequent relapse (191, 192). Anyhow, long-term effects cannot be measured in feasibility studies (79). Thus, it would be interesting to investigate whether the improvements would be maintained over time, e.g., one year after baseline as determined by the primary endpoint for the future RCT. Though, this feasibility study's outcomes shall be interpreted cautiously due to the risk of skewness caused by the high dropout rates. A supervised maintenance period and long-term follow-up would be appropriate to include in further studies to monitor the progression (193).

However, critical factors for clinical trials such as recruitment, retention and the fidelity of delivery still needed optimisation (154). Some examples of further actions to improve the REVEAL(OT) design and conduct can be the following. First, having all healthcare disciplines involved working from the

same location (149), must be present to secure interdisciplinary treatment delivery (23). Second, deeper investigation in the treatment contamination and contextual disturbances would have a nuanced understanding of the intervention impact (91). Third, an enhanced level of flexibility in the REVEAL(OT) would be beneficial, e.g., approached through telemedicine (194). Forth, the assessment plan should allow better control of timely questionnaire completion to prevent missing data (195). Finally, it would be interesting to study its societal impact on the occupational therapy position in the current chronic pain treatment practice in Denmark (28). At the long term, it would also be relevant to investigate whether the REVEAL(OT) encouraged the Danish occupational therapists to get more involved with chronic pain treatment (62).

Methodological considerations, Study I

Performing systematic reviews is a complex and time-consuming process (134). Reliability of Study I was strengthened by following the structured approach proposed by the Cochrane group and PRISMA reporting guidelines for systematic reviews (131, 134). If following the same strategy, other researchers would probably obtain similar results because the inclusion criteria were based on standard terminology on primary chronic pain diagnoses derived from ICD-11 and modifiable lifestyle factors. The comprehensive literature search qualified through collaboration with a university librarian possessed a low risk of missing relevant items. The Covidence software assisted in sorting the items, alerts helped us monitor newly published articles, and the tools developed by the Cochrane group assisted in evaluating the evidence quality. The standardised methods helped us keep the working process transparent, organised and documented, improving its replicability and reproducibility (196). The workload would probably be reduced if there were few lifestyle factors and only the general term "chronic pain" was included in the literature search. Neither any of the relevant lifestyle factors could be excluded because of the evidence on the associations between chronic pain and physical activity (197), overweight and obesity (198), smoking (199), alcohol consumption (200), sleep (201) and stress (202).

However, the occupational engagement component could be interpreted differently because no firm definition exists in occupational science (203). Occupational engagement consists of several components such as meaning, self-determination, individual capacities, motivation and personal

responsibility (165). The terminological complexity and the risk of interpretational inconsistencies of the term among different researchers may have impaired the reliability of the study. By explicating value-based occupational choice as the leading criteria in the study eligibility evaluation, I attempted to enhance the reliability in Study I.

Occupational engagement belongs to core concepts in occupational therapy and occupational science, relevant to any health condition, e.g., primary and secondary chronic pain. Narrow focus on primary chronic pain in the systematic review may have caused loss of potentially relevant evidence and limited the study's validity, e.g., when excluding diagnoses such as osteoarthritis where lifestyle improvement is also highly relevant (204, 205). A broader focus may have changed the sample size, and thus the effect estimates, e.g., regarding physical activity level. The narrowed focus may also have reduced the external validity of the results, which, even when relevant, would be less applicable to other than primary pain diagnoses (206).

Lack of body-mind interventions in the study sample could also compromise the study's validity. Interventions such as yoga belong to the scope of occupational therapy (57) and have previously been included in the review of systematic reviews on physical activity in adults with chronic pain (158). Including additional terms regarding body-mind interventions on our literature search could have helped identify more relevant studies.

Investigating the differentiated effect of chronic pain treatment might have improved the transferability of the results to specific patient subgroups and, thus, the clinical relevance of the research (182). However, none of the studies included in Study I attempted assessment of the differentiated effect. Therefore, lack of effect differentiation shall be considered when interpreting the study results regarding their external validity.

Besides the research objectives for the study, the selection and deselection of publications identified depended on the information available in those (207). Reporting gaps in the identified publications, e.g., not sufficiently explicated study characteristics or lack of lifestyle-related outcomes, and the focus on RCTs for the meta-analysis purposes, may have given the additional loss of potentially relevant evidence, thus compromising the validity. Another review methodology would allow us to accumulate more evidence across the identified publications. Anyhow, a comprehensive scoping

review on occupational therapy in chronic pain treatment has recently been published and, along with earlier evidence, urged further effect studies in the field (57, 58, 61). Thus, conducting another scoping or literature review would not sufficiently improve the total evidence quality in the area, which made us prioritise the systematic review design.

Our search for Gray literature revealed emerging research on lifestyle in chronic pain. Continuous monitoring of new relevant publications would be appropriate for possible replication of this systematic review in the future, following the Cochrane recommendations (208, 209), to attempt a firm effect estimation of including occupational engagement in chronic pain interventions.

Methodological considerations, Study II

In terms of Study II reliability, a cross-sectional survey was an appropriate study design because it allowed a broad and rapid screening of the target population for their health, pain, quality of life, lifestyle and motivation for lifestyle changes (210). However, I was aware that the results would only tell us about the target population at that specific point of time. Deviations from the picture obtained may occur if variables change at a retest, and the strength of the associations identified may depend on the sample characteristics and size (211).

I knew from the clinical practice at the MPC that the outpatients could be challenging to involve in research. In this investigation, I chose EQ-5D-5L for measuring health and HRQoL, which was anticipated easy to complete (212). I also attempted not to overload the participants and provided the option for voluntary (not forced) answers together with the options "don't know", being aware that both would elevate the risk of missing data, which I otherwise aimed to avoid (195). Otherwise, I feared not reaching a sufficient response rate within the planned time frame, mainly because of our agreement with the external assessors involved.

I could not use call back to the participants because of the anonymous character of the survey. Thus, I attempted to give the questionnaire a straightforward form to support the completion (213). Thus, the questionnaire content one question on each page (online version) or space between the questions (paper version), comment boxes and visual support, e.g., body chart illustrating body pain areas and 0-10 VAS for pain intensity. I offered assistance by phone, email or in person. The efforts

made to improve the response rate could have compromised the accuracy of the assessment when help was given (214). Different assistants could have tackled their role differently, though all were taught not to prompt any choices while completing the questionnaire. However, no interrater-induced issues were observed. Internal consistency of the responses and their correlation with the underlying constructs was secured by using exact questionnaire composition in both electronic and paper forms.

Although the study reached a 50% response rate, some dropout was observed. The partly completed questionnaires revealed missing data classified as MCAR (missing completely at random), which had no pattern, pointing to progressive exhaustion in the participants rather than a systematic error (195). Little's Test of Missingness was not performed because the missing rows were easy to inspect visually. Multiple sources report the prevalence of fatigue and cognitive deficit in the chronic pain population, while high demands can cause them discomfort and lead to withdrawal (215-218). This observation indicated that probably the most vulnerable participants remained silent, which impaired the reliability of the results. Moreover, I discovered that continuous support for cognitive functioning would probably also be necessary at the later research stages.

Prevalence of women in the study sample corresponded with the international evidence on gender distribution in the chronic pain population (219-223). Moreover, I observed that males withdraw from the survey more often than women, which may have skewed the results. Self-reported retrospective data may contain recall, misreporting and social desirability bias, particularly regarding lifestyle-related contents (224). However, the tendencies observed in Study II appeared characteristic for the study population, which strengthened this survey's generalisability and informative value for further research activities.

Construct validity of Study II was attempted secured using standardised assessment tools relevant for answering the research questions. Though, using a combination of valid measurements for the same variable would allow for evaluation of the criterion validity of the survey. For example, SF-36 that previously showed better sensitiveness could be used along with EQ-5D-5L for HRQoL assessment (225). However, it would have increased the assessment load. Thus, the EQ-5D-5L was prioritised as a briefer HRQoL measure for the future RCT.

Findings in Study II were congruent with the REVEAL(OT) intervention's focus. Thus, this explorative investigation informed us that the REVEAL(OT) should target physical activity, sleep quality, eating habits and problems in usual activities and was a useful information source for the intervention development process (77). However, the high motivation to initiate lifestyle changes in the study population, independently of gender or age, was surprising. Although initial motivation may be crucial for starting lifestyle changes, many other factors may still impact true readiness to change (226, 227). Assessment of readiness to change could be included in this survey, enhancing the content validity of the survey and providing more relevant information about the target population. The assessment could also be included in the assessment protocol for feasibility study, which would have been natural because Prochaska & DiClemente Stages of Change Model (228, 229) was a part of the programme theory for the REVEAL(OT). Several questionnaires have been used internationally for the purpose, e.g., the Readiness to Change Questionnaire (RCQ) (230, 231). However, no validated tools in Danish were identified. Moreover, additional tools would increase the assessment load, which became reasons for not including the readiness to change assessment in the feasibility study.

Methodological considerations, Study III

Evaluating the quality of Study III, I will use the same terminology as for the quantitative studies in this thesis to improve the consistency in the presentation. Although the terms such as credibility or trustworthiness are used to be applied to qualitative research, reliability and validity may also be applicable (232). When evaluating the reliability of Study III, I would like to note that focus group interviews pursued investigation in opinions of a purposely selected group rather than a representative sample of the whole population (233). Study III, with its interpretative context-specific character informed by hermeneutic phenomenology (150), focused on those patients and clinicians who had an experience with both the standard and the add-on treatments. All the outpatients and clinicians involved in the REVEAL(OT) were invited to participate in the three focus group interviews to promote the reliability of the data collected. Of the total number involved, approximately 40% of the outpatients (n=8, two focus group interviews) and 25% of the clinicians (n=4, one focus group interview) participated. The number of participants recruited was lower than the theoretical saturation of >10-12 representatives (234). Most authors recommend a minimum of six participants

per focus group (235-237). Though, the recruitment rates in percentage from the total appeared appropriate.

However, I would distribute the outpatients who participated in each version of the REVEAL(OT) - 1.0 or 2.0 – to different focus groups. That would have let me better evaluate the differentiated impact of the intervention. Anyhow, the scheduling task would exceed our timeframe. Moreover, planning may burden the study cohort and lead to withdrawal which would be critical for the reliability and validity and compromise the transferability of the results. Study III did neither match the recommendation of minimum two groups per category of participants in the case of the clinicians (238). Anyhow, the workload at the MPC didn't allow a higher number of representatives. I haven't found it reasonable to distribute those into two groups with only four clinicians involved. If I did, the focus groups would instead become dyadic interviews, interactive like focus group methodology but containing two people's conversation and not a group discussion (239).

Furthermore, I would wish to recruit representatives from all the health professions involved in the intervention to secure reliable and valid results. Though, nurses who were the largest clinician group at the MPC could not participate in the investigation due to the workload. Knowing that, I sent an information letter on the focus group interview to all the members of the MPC team and explicitly asked to submit any comments to the principal investigator or a colleague who consented to participation. I have not received any direct feedback from nurses. To fill this gap, I could have repeatedly asked nurses for feedback, allowing for triangulation and additional control of reliability and validity of the study (240). Though, that was considered inappropriate because of the timeframe for the study that had to comply with the external moderator's Master thesis workflow. The external moderator played an important role in this investigation, allowing the principal researcher to act as an observer and promote as free discussion in the focus groups as possible (241).

Thus, particular sampling bias in both patients and clinicians may have affected the external validity of this investigation, illustrating that barriers to research participation must be considered in further research planning, allowing better inclusion of vulnerable subgroups (242). It was new for me to comprehend vulnerability as a universal human feature that may appear in any social group or person (243). Healthcare workers, particularly nurses, appeared as a vulnerable group in research because of lack of time or organisational circumstances, making additional motivational incentives necessary

(244) to promote participation and enhance the external validity of the results. The inclusive character of this investigation imposed no scientific or ethical but rather practical or self-perceived barriers in the potential participants, which may still lead to knowledge gaps (245). All in all, more comprehensive stakeholder involvement could better inform the REVEAL(OT) development and evaluation, preventing ineffective decisions (77, 246).

Another potential source of skewed results could be the analysis method chosen for the data derived from our focus group interview. The authors have also pointed out that many other thematic analysis approaches could be used (152). Researchers performing traditional text analysis, opposite computerised text analysis, can unintentionally misinterpret the data, "reading between lines" (247). However, I believe that a fully computerised text analysis may be challenged by comprehending the themes that emerged from both patients and clinicians' points of view because of the language inconsistencies between the groups. On the other side, our inductive data-driven approach to the data was prone to a high abstraction level when performing empirical data summary (248). Our understanding of the chronic pain phenomenon and human occupation could also play a role in generating initial codes and defining the themes (249). Finally, I could argue that I also have used an abductive approach to data when identifying specific areas of further improvement in the intervention (250), which may have reduced the limitations named earlier and enhanced the credibility of the results (251).

Methodological considerations, Study IV

Study IV concluded on the overall feasibility of the REVEAL(OT) regarding the research progression criteria such as programme adherence, patients' self-perceived relevance, timing, and mode of delivery, assessment procedure acceptance and adverse events, demanding further optimization in participant recruitment, retention and delivery strategy (154). In addition, a significant change in occupational performance and satisfaction was observed (154).

The REVEAL(OT) was designed as a pragmatic healthcare intervention adopted to the specific clinical setting. Although clinical reality has informed many research decisions, the intervention had several components determined in a rather explanatory than the pragmatic manner, which the PRECIS-2 wheel illustrated (cf. Figure 5, pp. 43) (84). The domains setting, flexibility (adherence) and primary

outcome were on the middle of the explanatory-pragmatic continuum, and eligibility and follow-up were based on predefined criteria or procedures, thus pure explanatory.

A review of 616 trials conducted over the last two decades tells us that pragmatism increased mainly in the domains of eligibility, setting, intervention delivery and primary outcome (252). In this term, the REVEAL(OT) followed the tendency only regarding flexibility in delivery understood as a tailored approach to each participant. Otherwise, the intervention providers, who also performed the assessments, were trained to follow the protocolised intervention contents and assessment procedures as planned. Thus, I attempted to avoid the interrater-induced reliability issues as much as possible (253), i.e., by using objective evaluation criteria allowing for counting and rating actions performed using same-style check-off forms.

Consistency in measurements was secured by using clearly defined variables and assessment methods, most of which were objective, which may have benefited the reliability level (253). Thorough training for the assessors preceded assessment performance to eliminate errors. At the same time, the participants performed self-assessments where attrition risk was high, impairing the internal validity in the evaluation of the intervention outcomes (224). Thus, the outcomes ought to be interpreted cautiously.

The construct validity of the outcome assessments planned for the RCT was secured using the IMMPACT recommendations (180) to ensure the diagnosis appropriateness and comparability with other chronic pain studies. HRQoL as the primary outcome for the RCT was chosen because it was considered relevant for both the multidisciplinary clinical practice and generally for all chronic pain patients (also the controls who will not receive the REVEAL(OT) intervention), according to the IMMPACT (180). The COPM was determined an important occupational therapy outcome because it correlated with self-efficacy, which may illustrate the coping levels in an individual (109, 110).

The construct validity of the feasibility assessment informed by the red-amber-green method (144) was easy to interprete and effective, allowing quantification of the data collected and visualising the results. However, the limits of the research progression criteria were defined using a pragmatic approach, thus being context-dependent to certain degree. Although the existing evidence was considered when taking pragmatic decisions, the REVEAL(OT) would fail to match the pooled

retention rate of 90% in physical exercise trials identified by a recent systematic review (254) or manage 8-10 participants per group, which was the standard group size in the Lifestyle Redesign®-programmes (67). Naturally, the red-amber-green research progression criteria should only inform the lowest acceptable limits within each category. An as high as possible degree of their fulfilment was attempted.

Regarding content validity in feasibility assessment, the context-related feasibility dimension has not been studied in the current feasibility evaluation. Inspection of the intervention design with the PRECIS-2 tool (84) showed that the domain of organisation-imposed changes in the current clinical practice at both the MPC and OTU. Thus, a certain degree of context disturbance caused by the REVEAL(OT) may be expected (77). Investigation of the disturbance degree would provide us with additional information on the intervention acceptance and overall utility in the current healthcare context (255). Undoubtedly, greater involvement of all kinds of relevant stakeholders' opinions would have improved its feasibility evaluation (77).

Otherwise, instead of the feasibility study design, I could have decided to conduct a pilot study, testing randomisation and effectiveness trends of the REVEAL(OT). According to Treweek (2015), randomisation was not the main issue in complex interventions while that were feasibility outcomes, i.e., recruitment and retention that can extend the planned duration of an RCT (79). Moreover, I still wouldn't measure long-term effects in a pilot study (79). Adjusting sample size for the future RCT will still be better allowable in a pilot controlled trial. Additionally, the outcomes observed in this feasibility study shall still be confirmed at the further research because the differentiated loss to follow-up may have compromised those (79). Randomisation would also allow measuring a degree of contamination in treatment (190) which can be relevant since the REVEAL(OT)'s had the add-on character. Though, such evaluation would probably be only applicable to the local clinical settings because a recent systematic review found wide methodological and statistical heterogeneity in interdisciplinary chronic pain interventions (256), which may reduce the generalisability of the results. Thus, the internal validity of Study IV was satisfactory, allowing the identification of areas for further improvement. The external validity (generalisability) of the results is suggested as appropriate because of similarities with the target chronic pain population but still limited to the specific clinical setting. Future research is needed to improve generalisability.

Conclusion

This thesis provided the perspective on occupational therapy lifestyle management applied to multidisciplinary chronic pain treatment. Using lifestyle-oriented occupational therapy intervention REVEAL(OT) as an example from the Danish clinical practice, this thesis described and explained the iterative process of the REVEAL(OT) development and feasibility evaluation informed by the Medical Research Council guidance on developing and evaluating complex interventions, to inform the preparation of a full-scale RCT. Four scientific publications accumulated the evidence generated in the research process.

This research added to the evidence on the application of occupational engagement in chronic pain interventions as a beneficial tool for promoting physical activity and improving sleep quality. Low HRQoL level, significant associations between HRQoL and pain, poor sleep and severe problems in usual activities, multiple metabolic health risks together with high motivation for initiating lifestyle changes in chronic pain cohort revealed by this research confirmed the need for a lifestyle-oriented approach in multidisciplinary chronic pain treatment, to prevent deconditioning and improve health and quality of life.

Relevance of the REVEAL(OT) focusing on value-based choices regarding meaningful activities, daily physical activity and healthy eating and added to the standard multidisciplinary chronic pain treatment at a Danish Pain centre was confirmed by patients and clinicians involved. The REVEAL(OT) was beneficial for better acceptance of living with chronic pain and empowerment for initiating lifestyle changes in adults living with chronic pain. The REVEAL (OT) confirmed its overall feasibility with satisfactorily fulfilled research progression criteria regarding programme adherence; patients' self-perceived relevance, timing, and mode of delivery; assessment procedure acceptance; and adverse events. However, its recruitment, participant retention and delivery strategies would need optimisation before initiating an RCT. Improved interdisciplinary context for the REVEAL(OT) delivery would benefit the intervention feasibility. An RCT is needed to investigate the effectiveness of the lifestyle-oriented occupational therapy approach in multidisciplinary chronic pain treatment.

Perspectives

In this thesis, the development and feasibility evaluation of the occupational therapy lifestyle intervention REVEAL(OT) was described, explained and discussed in the tertiary healthcare system but should not be limited to such. The feasibility study cohort had, on average, 10-years long experience with chronic pain. Already in primary care at chronic pain onset, occupational therapists could provide an earlier lifestyle-oriented impact on prescription from general practitioners. Early occupational therapy would empower people living with chronic pain to cope with everyday obstacles. Hence, the negative effect of chronic pain on humans, such as occupational identity loss and deconditioning, would get captured at an earlier point. That may enhance its reversibility and thus, reduce chronic pain treatment costs in the long term. Otherwise, occupational therapy could also be offered on a post-tertiary (quaternary) basis, helping transfer new skills and knowledge in specialised rehabilitation into everyday life.

Implications for clinical practice and research

With the various perspectives on how occupational therapy lifestyle approach can be applied, I would propose the following general recommendations for clinical practice and research:

(i) Occupational engagement included in chronic pain treatment can benefit the acceptance of living with chronic pain and improvement in lifestyle in adults living with chronic pain, with potential for sustainable changes in health behaviour, but needs further investigation

(ii) Inclusion of new treatment modalities in existing multidisciplinary chronic pain treatment needs a coordinated systemic interdisciplinary approach

(iii) Further research on the impact of occupational therapy lifestyle management on people living with chronic pain, inclusive estimation of its effectiveness and cost-effectiveness, is needed.

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Appendix1

Occupational therapy roles and methods in chronic pain treatment

Occupational therapy in chronic pain treatment: roles and methods

(Adopted from Lagueux É, Dépelteau A, Masse J. Occupational Therapy's Unique Contribution to Chronic Pain Management: A Scoping Review. Pain Research and Management. 2018;2018:19.

Occupational therapy roles

Occupational therapy methods

Occupational therapy methods	
For training, skill development and education of a person	Body mechanics/postures and positioning Energy conservation/joint-sparing techniques Relaxation training/stress management Exercises/fitness program Mindfulness Cognitive behavioral therapy/behavioral approaches Coping strategies Coordination/dexterity, strengthening tasks Desensitization techniques/sensory reeducation Active movements/mobilization techniques Biofeedback Functional splinting Oedema modalities Proprioceptive neuromuscular facilitation/reeducation Thermal modalities Graded motor imagery Mirror visual feedback Stress loading Breathing techniques Electrical stimulation Massage/acupressure Mental imagery/visualization

For environmental support	Ergonomics for home and work, inclusive assistive devices Environmental modification
For enabling occupation through task adaptation and occupation development	Pacing/ graded activity Activity (task) adaptation/therapeutically activity Vocational training Sleep hygiene Graded in vivo exposure Yoga/Tai chi

Appendix 2

Protocol for a randomised controlled trial

Research initiative of Activity Studies and Occupational Therapy

Research Unit of General Practice

Department of Public Health

PROTOKOL

Lifestyle-oriented occupational therapy intervention for patients with chronic non-malignant pain – A randomized controlled trial

Ergoterapeutisk livsstilsintervention til patienter med kroniske non-maligne smerter - et randomiseret kontrolleret forsøg

V. 1.5, rev. 05.08.2020

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Project resumé

Introduction: About 20-30% of the Danish population suffer from chronic non-malignant pain. Current evidence suggests that a bio-psychosocial treatment delivered by multidisciplinary teams is the most effective treatment of chronic non-malignant pain. However, evidence is still missing on the optimal multimodal treatment combination as well as the additional effect of specific treatment modalities. **Methods:** The project will involve 276 chronic pain patients referred to the Multidisciplinary Pain Centre, Zealand, Denmark (n=228 for an RCT, and n=48 for a feasibility study, to inform the RCT). The two-arm RCT will randomize 228 patients to either a lifestyle-oriented intervention added to the current multimodal treatment, or the current treatment only. Quality of life (EQ-5D-5L) will be the primary outcome. Occupational performance, occupational balance, meaningful activity participation, pain self-efficacy and lifestyle will be the secondary outcomes. **Analysis:** Differences in change in the primary and secondary outcomes between the groups from baseline to the intervention discharge and 1-year follow-up will be analysed by repeated measures mixed model. **Ethics and dissemination:** The study is ethically approved at The Regional Committee on Health Research Ethics and the data protection authorities for Region Zealand (Denmark). The results will be reported in peer-reviewed journals and presented at conferences.

Keywords: *pain rehabilitation, health behaviour, QoL, value-based activity choice, in-home environments*

Project description

Background

About 20-30% of the Danish population suffer from chronic non-malignant pain (CNMP), making CNMP a serious health issue (1). The pharmacological treatment of CNMP is often experienced by patients as insufficient (2, 3). The ability of opioids to cause drug dependency and worsen the pain in the long-term, together with growing opioid consumption in many world countries, inclusive Denmark, call for proper alternatives in the treatment of CNMP (4, 5).

Many health professionals highlight non-pharmacological multimodal treatment as the central treatment of CNMP (6, 7). Current evidence suggests that the bio-psychosocial approach delivered by multidisciplinary teams is the most effective, and potentially cost-effective in long term, in treatment of CNMP (8, 9). However, evidence is still missing on the optimal CNMP-treatment composition, amount or duration, as well as the effectiveness of particular treatment components in different patient subgroups (10). The evidence is prompting new studies to identify differential effects of the evidence-based CNMP-treatment (10).

An increased understanding of the role of neural sensitisation processes in CNMP and brain plasticity has suggested a potential reversibility of the negative side-effects of CNMP on the patients' lives, and highlighted that a whole-person lifestyle approach should be included in treatment of CNMP (11, 12). Changing lifestyle in combination with cognitive behavioural therapy has beneficial effects on metabolic health and physical activity in high risk groups, e.g. obese health care workers (13). Lifestyle changes and supervised exercises improve pain and quality of life (QoL) in patients with osteoarthritis, with maintained effect at 1 year follow-up (14, 15). Improvements in lifestyle in CNMP-patients are considered to be as relevant as in other chronic non-communicable diseases, i.e. hypertension, diabetes, stroke and obesity. (16, 17). However, the effectiveness of a lifestyle approach as part of bio-psychosocial treatment of CNMP has not yet been thoroughly investigated.

The occupational therapy (OT) program Lifestyle Redesign® (The University of Southern California, USA) has demonstrated effectiveness in changing the lifestyle of adults through holistic, system-based approach (18-21). Several studies has confirmed that Lifestyle Redesign® is also successful in improving QoL, physical and social functioning and self-efficacy in adults, as well as being cost-effective in older adults (22-24). A retrospective cohort study on Lifestyle Redesign® for CNMP proposed further investigations in the method, using better control of bias and comparison to controls not receiving the OT component (24). Thus, there is a need to investigate, whether the lifestyle-

oriented OT approach as a part of multidisciplinary rehabilitation would improve quality of life and overall health in adults with CNMP.

Aim

The aim of this RCT is to investigate effectiveness of a lifestyle-oriented OT intervention added to the current multimodal treatment for adults with CNMP. The impact of OT on QoL through improved occupational performance and participation, and healthier lifestyle will be evaluated.

Hypothesis

This study hypothesises that adults receiving multimodal CNMP treatment including lifestyle-oriented OT program will achieve significant larger improvements in QoL 1 year from baseline, compared to controls receiving the multimodal CNMP treatment without the OT component. The secondary outcomes related to occupational performance and participation in meaningful everyday activities, pain self-efficacy and lifestyle are hypothesized to show between-group improvements, synergetic with the primary outcome. The trial will explore differentiated effects of both treatments on various patient subgroups from the sample.

Rationale of the study

The study will eliminate the knowledge gap regarding how a lifestyle-oriented approach can complement the established evidence-based treatment of CNMP. The lifestyle OT approach, with its focus on everyday activities, activity roles, daily routines and habits, has the potential benefit the target group, appealing to those, who learn best by doing. Furthermore, the lifestyle OT approach has the potential to improve the existing rehabilitation practice, allowing patients to tackle CNMP in a new, innovative way, which is close to their everyday life and environments.

Methods

Design

This is a protocol for a two-arm randomized controlled trial (1:1 allocation ratio) of lifestyle-oriented OT intervention as a part of multimodal treatment at the Multidisciplinary Pain Centre (MPC), Naestved, Slagelse and Ringsted Hospitals, Zealand. The protocol is guided by SPIRIT statement (Standard Protocol Items: Recommendations for Interventional Trials) (25) and registered at ClinicalTrials.gov (NCT03903900). The trial results will be reported according to the CONSORT statement (26, 27).

Study setting

The Multidisciplinary Pain Centre (MPC) at Naestved, Slagelse and Ringsted Hospitals has been operating with the bio-psychosocial model for CNMP-treatment since 2014, and is currently admitting about 800 outpatients á year. At the MPC, the patients receive individually composed treatment combinations, in terms of content, duration and frequency, delivered by physicians, nurses, physical therapists, psychologists and a social worker. The MPC is cooperating with The Department of OT at the Hospital. OT groups for max. 5 participants (2 hours once á week at 3 weeks) have been established 3-4 times á year. Thus, only about 2-3% of the MPC's patients are currently receiving OT.

Participants and eligibility criteria

The participants will be enrolled from the outpatient cohort referred to the MPC on regular basis (by family physician etc.) and fulfilling the eligibility criteria below.

Inclusion criteria: age ≥ 18<65yo, CNMP-diagnose present ≥ 3 mths at admission.

Exclusion criteria: acute/ sub-acute pain; cancer-related pain; instable medicine intake over the past four weeks; daily opioid intake >30 mg; headache/migraine; currently diagnosed depression; current substance misuse; severe psychiatric diagnosis; poor Danish speaking skills and participating in other CNMP-treatment programs. Severe psychiatric diagnoses are defined as a mental illness involving distortion in thinking and perception, and leading to significant social and occupational dysfunction, e.g. schizophrenia and schizotypal, delusional, schizoaffective or psychotic disorders, or psychosis (coded as F20-F29 in ICD-10 2016, Chapter V) (28, 29). Self-reported inability to walk the distance of min. 100 m will be an additional exclusion criterion.

Allocation, randomization and blinding

All 18-65 years old outpatients admitted at the MPC will be provided with the detailed written information on the project sent digitally. The outpatients will confirm during a phone-based visitation session conducted by the MPC-team whether they have an interest in participating in the lifestyle-oriented occupational therapy intervention and will accept their contact information (without patient journal access) to be passed on to the principal investigator in terms of recruitment. Those who give their accept will receive a phone call from an educated project assistant to clarify eligibility. An appointment for provision of the detailed oral information on the aim, risks and anonymity in the project will be set for those who consider participation in the project. At least one week thinking time will be given. All the questions will be answered. If needed, an additional thinking time will be available. The informed consent on participation in the project will be received before the inclusion at an appointment in accordance with the treatment plan or, if preferred, by post. Relatives and friends

to the potential participants will be welcome to participate at any appointment prior to the intervention start. Those signed the informed consent on the project participation will receive an electronical ID-based letter with the project appointment plan and an invitation for the baseline assessment. The assessment rounds will take place in a separate meeting room.

The informed consent will give the principal investigator and his representative direct access to information from the patient records that are necessary for the project implementation and control of data throughout the process. After the informed consent is obtained, patient journal data will be assessed at baseline, the intervention discharge and 1-year follow-up, to ensure that any changes in patients' status, e.g. changes in medication consumption, new diagnoses or drop out, are recorded correctly.

The patients confirming their participation will be randomly allocated in 1:1 ratio to either intervention, or control group. To ensure treatment balance in the groups, a computer-generated randomization schedule with permuted blocks of 4 patients stratified by age and gender will be prepared by an independent statistician. The randomization schedule will ensure similar distribution of study participants having neuropathic vs. non-neuropathic pain origin according to the diagnosis prior to referral to the MPC. Allocation will be conducted by an independent researcher not affiliated with the trial, using opaque sealed envelopes with allocation numbers prepared by a recruitment administrator. The envelopes will be kept confidentially by the recruitment administrator, until informed consent and baseline assessments have been obtained.

The intervention group will participate in OT lifestyle-oriented intervention combined with the regular treatment at the MPC. The control group will receive the regular treatment at the MPC. Due to the treatment character, the participants cannot be blinded to treatment. The recruitment administrators, outcome assessors and statistician are blinded to group assignment. To reduce risk of interpretation bias, blinded results from the analyses (Group A compared with Group B) will be presented to all authors. An agreement on two alternative written interpretations will be achieved, before the data manager unblinds the randomization code (30). The project flow is outlined in Appendix, Figure 1.

Intervention and controls

Cognitive Behavioural Therapy (CBT) has been the major treatment approach at the MPC. The regular multimodal treatment at the MPC starts with an in-group preparatory psychoeducation course (1hour á week in 5 weeks) delivered by the health professionals represented at the MPC (nurses, physiotherapists, psychologists, social advisors and physicians). An individual treatment plan after the psychoeducation course may include medication adjustments, consultation, education, exercises and

homework. Every individual treatment composition is agreed by the patient and the multidisciplinary team. Group treatments are available through the MPC's Pain School, mindfulness course, positioning group course, pain treatment group for men and fibromyalgia group for women. The transcutaneous electrical nerve stimulation (TENS) and acupuncture is offered when relevant.

The original Lifestyle Redesign®-program will be adapted to complement the regular treatment at the MPC. The intervention will be composed as a bridge-building approach between the outpatient treatment facilities and the patients' at-home environments including client-centred education, discussion, personal reflection and skills training in relation to various everyday topics inspired by Lifestyle Redesign®-programme (31) (Appendix, Figure 2). The intervention therapists will be trained before the intervention start and supervised during the intervention once a week, or upon demand.

The experimental group will receive the OT lifestyle-oriented intervention as an added treatment modality to the regular treatment. The intervention will be initiated after the participants have been through the preparatory psychoeducation course, parallel with the individual treatment part at the MPC. The intervention will vary 15 weeks and consist of 5 group sessions of 2 hours and 3 individual sessions of 1 hour, both led by occupational therapists. All the sessions will find place every other week and supported with phone calls, thus weekly contacts with occupational therapists will be provided. The groups will be composed of max. 6 participants. The participants will have contact with an occupational therapist at least every other week, either individually or in-group. Group sessions will include information and discussion on topics linked to meaningful occupations, healthy eating and daily physical activity in relations to chronic pain. The participants will be inspired to practice value-based choice on everyday basis, in terms of revision and changing prioritized health behaviour and habits. Skills training in Activities of Daily Living and homework will be provided to prompt a healthier lifestyle and help a smoother transformation of the new knowledge to the home-environment. The individual sessions will be planned in cooperation with every individual patient according to the actual needs, inclusive an opportunity for home-visits, in terms of in-home ergonomics and use of assistive devices. Concerned individual demands, max. 2 additional individual OT sessions can be provided on agreement. The intervention plan will be presented in the intervention manual developed for the study. Cooperation with the multidisciplinary team at the MPC and inter-sectoral units will be provided according to the patient's needs and on interdisciplinary basis. Subsequently, the intervention group will continue with the regular treatment. The control group will receive the regular multimodal treatment at MPC, without the OT component.

Assessment and outcomes

The outcome measures in this trial will be based on the recommendations for chronic pain clinical trials from the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) and include the core chronic pain outcome domains, such as participants' rating of overall improvement, pain intensity, physical functioning and emotional functioning (32, 33). Validated OT tools investigating occupational performance and balance will be included (34-36). Monitoring of lifestyle parameters and activity levels will be conducted. Demographic characteristics will allow detection of potential confounders. For overview of outcomes in this study, see Appendix, Figure 3.

Socio-demographic characteristics

The data on the participants' age, gender, weight, height, marital status, educational level, alcohol and tobacco consumption, and employment status will be collected.

Primary outcome

Differences in self-reported health-related QoL (scored by EQ-5D-5L Index) will be the primary outcome for the study (37, 38). IMMPACT considered quality of life (QoL) being especially important in assessment of treatment effects in chronic conditions (32). The patients will evaluate their subjective health state in domains Mobility, Self-care, Usual activities, Pain/ Discomfort and Anxiety/ Depression on a 5-point Likert scale from 1= having no problems, having slight problems, having moderate problems, having severe problems and 5= being unable to do/having extreme problems. The outcome measure will allow a later cost-effectiveness analysis.

Secondary outcomes

Inclusion of physical, emotional and social outcomes is recommended, when evaluating QoL and treatment effect (39). With the aim to investigate in A. impact of OT on quality of life through improved occupational performance and participation, and B. healthier lifestyle, the additional effects of the intervention which will be evaluated:

A. Self-reported *Occupational Performance and satisfaction* (COPM) (40, 41), observed *Motor and Process Skills* (AMPS) (34, 42), self-reported *Occupational balance* (OBQ) (43) and *Pain Self-efficacy* (PSEQ) (44) to investigate meaningful everyday activities, participation and coping capacity;
B. *Physical wake-time activity* (actigraphy units) (45); *BMI* (weight and height scale), *waist circumference* (measuring tape), and *blood pressure* (sphygmomanometer) (35) will be measured by verified methods, to evaluate lifestyle-associated conditions and risks.

Adverse effects

Adverse effects (AE) will be defined as undesirable experience during follow-up, such as an increase in medication, and occurrence of depression, morbidity and mortality causing discontinuation from the trial. AE will be registered in the generic questionnaire by asking the participants at all follow-ups. Those, untimely discontinued from the trial will be contacted by phone in terms of the discontinuation causes. For all AEs, the date of occurrence, duration and potential consequences will be assessed.

Other outcomes

Quantitative sensory testing (QST) is recommended in chronic pain trials as the methods is capable to show, how treatment affects somatosensory pain perception, and thus, brain plasticity mechanisms (46, 47). As chronic pain patients are a highly heterogenic target group, QST methods would also support patient phenotyping and identification of treatment effect (48, 49). Controlled Cuff Pressure Algometry (CCPA) will be used in the study as a standardized QST method is applicable to various chronic pain conditions and able to identify general pain sensibility in an individual, based on deep tissue somatosensory pain response (50, 51). To minimize the assessment load, other QST methods will not be used in the trial.

Other outcomes of interest, such as sleep, pain localization, pain intensity and pain catastrophizing, will be assessed through the Danish clinical pain registry implemented at the MPC (52). For this trial, the registry questionnaire for the MPC will be supplied with additional questions concerned general health (EQ-VAS). BMI will also be assessable through the registry.

The data will be collected by external and blinded outcome assessors (occupational therapists, physical therapists, nurses and physicians). The OT assessments (COPM, AMPS and OBQ) will be performed by graduated occupational therapists with appropriate qualifications. Physical wake-time activity cycles will be obtained as self-assessment. Adherence to treatment will be assessed by registration of sessions attended or missed by each participant. Phone calls will be used to establish compliance and prevent missing data.

Endpoints

The improvements in QoL, occupational performance and participation, pain self-efficacy and lifestyle parameters are expected to reach significant levels 1 year (T2) from baseline (T0) as the primary endpoint of the study. The improvements are also expected to be seen at the intervention discharge (T1), appx. 6 months from baseline.

Feasibility study

A small-scale pretest-posttest feasibility study was conducted prior to the project, to try out the procedure of the assessment and inform the design and conduct of the occupational therapy lifestyle intervention added to multidisciplinary bio-psychosocial treatment. The feasibility study was guided by the scientific background; settings; eligibility criteria; outcome measures and ethical considerations for the main study. The pretest-posttest study followed the participant activities planned for the intervention group from the recruitment to the intervention discharge, inclusive the assessments at baseline and post-discharge. The feasibility study participants were given an additional information regarding the study.

The feasibility study will be evaluated in quantitatively (by analysis of differences in changes before-after the intervention) and qualitatively (by focus group interviews for max 16 participants and max 16 health professionals affiliated with the MPC and the Department of Occupational Therapy at the Naestved Hospital). The research activities will run in October - December 2019.

Statistical considerations

Sample size

The minimally important difference (MID) in the primary outcome (EQ-5D-5L) among patients with various chronic pain conditions has previously been found (MID mean 0.074, range 0.011 – 0.140) (53). The study will be powered to detect this difference between the intervention and control group in the primary outcome (EQ-5D-5L) from baseline to 6-months and 1-year follow up. Assuming SD pooled=0.156, power=90% and alpha level=0.05, 95 participants in each group are needed to detect this difference. A total of 228 participants will be recruited for the RCT to account for a potential loss to follow up of 20% detected previously in chronic pain conditions (54, 55). The sample size for the RCT corresponds with 28,5% of the MPC's annual patient admittance and seems to be achievable within about four months.

A total of 48 participants will be recruited for the feasibility study (56). The sample for the feasibility study will be achievable within one month. Thus, 276 patients will be involved both in the feasibility study and the RCT.

Analysis

Continuous data will be described by mean and standard deviations, and categorical data will be summarized as frequency and proportions. Between-group difference in change in the primary and secondary continuous outcomes from baseline to follow-up will be compared using repeated measures mixed model, with patients as random effect, visit (baseline, 6 months and 1 year) and treatment arm

(lifestyle-oriented OT added regular treatment, or regular treatment only) as fixed effects, and with adjustment for baseline imbalance. The primary endpoint will be defined as the change from baseline to 1 year after baseline. Analyses for all randomized participants will be conducted according to the intention-to-treat principle. Per protocol and as treated analyses for the primary outcome will be performed. Between-group comparison of the occurred adverse events will be conducted by Poisson regression model with a robust error variance. Null hypothesis on no difference between the groups will be tested by X^2-test, Fisher's exact test or Mann-Whitney-U-test for categorical outcomes. Statistical significance will be defined as $p > 0.05$.

Timelines

The trial will be conducted in 2019-2020 as part of Ph.D.-study. The Ph.D.-study will be conducted during consecutive 3 years, from January 2019 until December 2021.

Risks, adverse effects and discomfort

The trial does not have any obvious risks of adverse effects for the participants. No biological samples will be obtained and/ or stored. Some participants may also feel some discomfort caused by mechanical pressure, when tested with CPPA. The procedures for the assessment will not distinguish from the regular use of the equipment. Thus, the discomfort may be considered as minimal, expected and unavoidable. All the participants will be supervised by educated health professional assessors during assessment procedures. The intervention and the control groups will both receive evidence-based treatments that would potentially improve their overall health and QoL. Thus, any possible risks for the participants can be considered as minimal and unlikely, while multiple benefits will be expected, for both the actual, and the future CNMP-patients. By an injury, the patients will be able to seek the Patient Compensation.

Data privacy and ethical concerns

The project follows the principles of The World Medical Association (WMA) described in the WMA Declaration of Helsinki (57). The ethical approval of the project was obtained from The Regional Committee on Health Research Ethics in Region Zealand (Denmark) (SJ-703). The project was also reported to data protection authorities in Region Zealand (REG-052-2018). The project is conducted in compliance with the European Union's (EU) General Data Protection Regulation (GDPR) and the Danish Data Protection Act (58, 59). The project data may be used in other statistical and scientifical projects approved by the internal (regional) data protection authorities or the Danish Data Protection Agency, after a written permission from the main investigator for the current project is obtained. Other

projects must report on data transmission from this project in their protocols. The transmitted data must be protected for identification of the individuals behind, e.g. by dissemination of the results. After ended research, all transmitted data must be destroyed or archived.

The project will operate with data from patient journals and quality and research database PainData modified for the specific project needs (52). Co-operation in terms of the modifications is established with the Data Manager and developer of PainData from the University Hospital Odense. PainData in its original version is approved as a quality and research database by The Danish Data Protection Agency (Reg. nr. 14/44319). The project protocol will be registered at www.clinicaltrials.gov.

Dissemination of the results

The information on various development stages of the project and its results will be disseminated through publications in international scientific journals and conference presentations. All the significant, non-significant and/ or inconclusive results will be explicated and published. All the results will be available at www.clinicaltrials.gov.

Funding

Naestved, Slagelse and Ringsted Hospitals' Research Fund (Denmark) supported the development of study protocol and intervention manual for the project with 150.000 DKK given to the Department of Physical and Occupational Therapy, Næstved, Slagelse and Ringsted Hospitals. Danish Association of Occupational therapists supported the project with 120.000 DKK to cover the tution fees for Ph.D.-students at the University of Southern Denmark for Svetlana Solgaard Nielsen.

Project funds will be raised by funding proposals, i.e. to The Region Zealand Research Fund, The Danish Association of Occupational therapists and The Danish Rheumatism Association. The raised funds will cover the salaries for project personnel (project leader, intervention therapists, extern assessors, student assistants and a secretary) and consultants (a statistician and experts, i.e. in Pain Data and COPM), transportation costs for intervention therapists (i.e. home-sessions), materials (i.e. hand-outs, minor purchase for AMPS-tests and ADL-skills (Activities of Daily Living skills) training, assistive devices, and tape and water resistant film for actigraphy units) and patient benefits i.e. compensation for transportation costs between home and treatment facilities.

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Appendix

Figure 1. The project flow chart

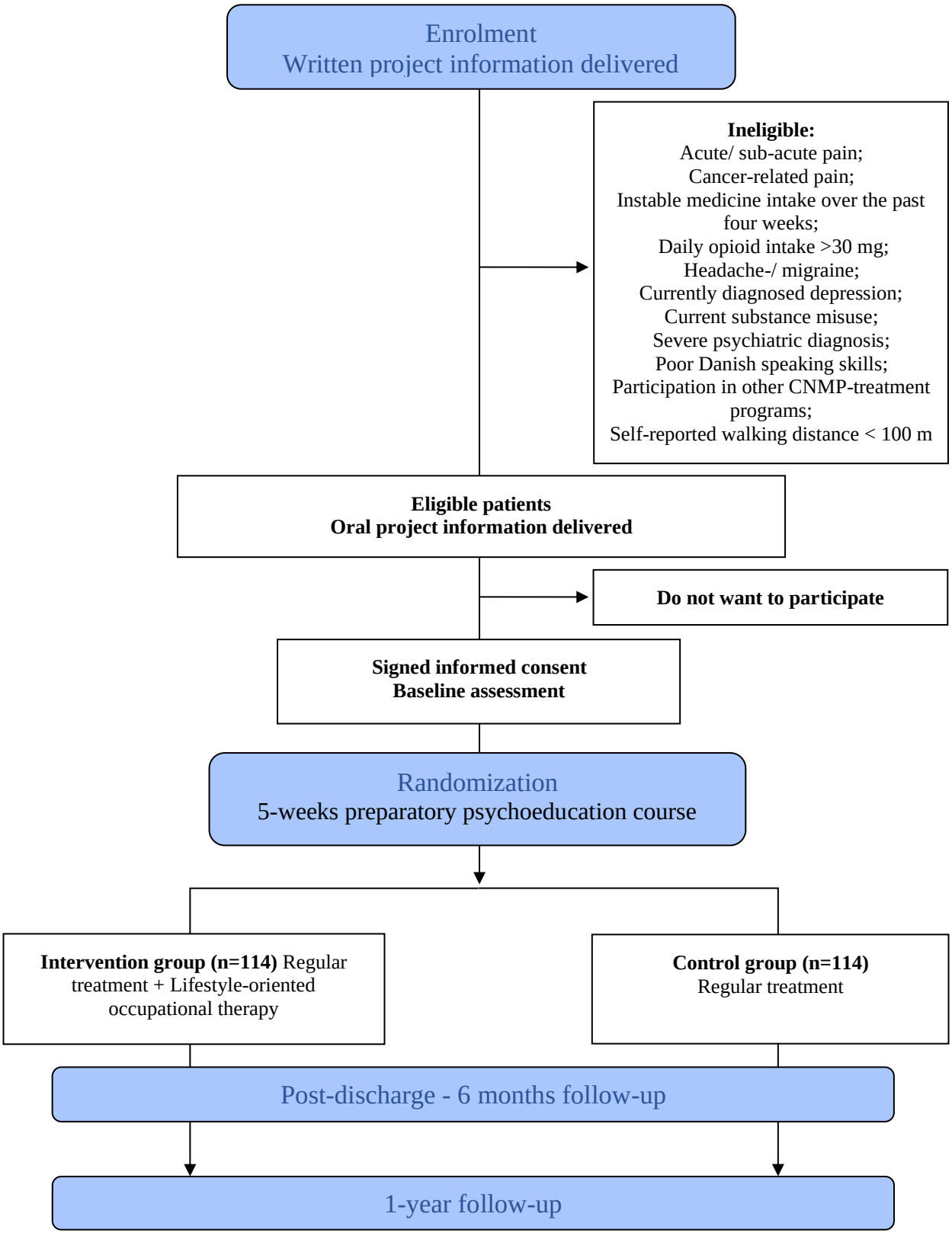

Figure 2. Lifestyle-oriented occupational therapy intervention content

Overview of the Lifestyle-oriented occupational therapy program	
Group sessions (mandatory)	Individual sessions
✓ Meaningful activity and its impact on health ✓ Occupational balance and value-based activity choice ✓ Energy management ✓ Time management/ "Time geography" ✓ Self-care and sleep ✓ Household management ✓ Ergonomics at home and workplace ✓ Movement and well-being ✓ Eating routines. Preparing and enjoying meals ✓ Transportation and exploring the environments ✓ Socialization	✓ Identification of Values, Roles, Interests and Habits ✓ Individual goal setting ✓ ADL & I-ADL* on day- and week-basis ✓ Activity levels on day- and week-basis ✓ Ergonomic advise ✓ Applied energy and time management ✓ Social relations ✓ Executing ADL routines ✓ Accompanied basic physical activity

- *ADL (Activities of Daily Living) refers to personal care, e.g. bathing, dressing, eating etc.; I-ADL (Instrumental Activities of Daily Living) refers to the daily attributes of an independent lifestyle, e.g. doing laundry, shopping, cooking etc.*

Figure 3. Data collection, measures, and endpoints

Parameter	Tool	Present in the Danish pain registry	Endpoints[1] T0	T1	T2
Socio-demographic variables:					
• Age, gender, civil status, education		X	X	-	-
• Employment		X	X	X	X
• Adverse events	Generic questionnaire	X	X	X	X
QoL	EuroQOL (EQ-5D-5L Index)	X	X	X	X
QoL	EuroQOL (EQ-5D-5L, EQ-VAS)	X[2]	X	X	X
Occupational performance and satisfaction	The Canadian Occupational Performance Measure (COPM)	-	X	X	X
Occupational performance, Motor & Process Skills	The Assessment of Motor and Process Skills (AMPS)	-	X	X	X
Occupational balance	The Occupational Balance Questionnaire (OBQ)	-	X	X	X
Pain Self-efficacy	Pain Self Efficacy Questionnaire (PSEQ)	X[2]	X	X	X
Pain intensity	NRS (Numeric Range Scale) 0-10	X	X	X	X
Pain catastrophizing	Pain Catastrophizing Scale (PCS)	X	X	X	X
Pain localization	Body drawing	X	X	X	X
Sleep quality	Karolinska Sleep Questionnaire (KSQ)	X	X	X	X
Physical wake-time activity	Actigraphy units (4 days, monitored at-home)	-	X	X	X
BMI	Weight and height scale	X	X	X	X
Waist circumference	Measuring tape	-	X	X	X
Blood pressure	Sphygmomanometer	-	X	X	X
Pain sensitisation	CCPA (Controlled Cuff Pressure Algometry)	-	X	X	X

[1] Endpoints: baseline (T0) and follow-up at 6 months (T1) and 1 year (T2) from baseline
[2] Added to the original version of The Danish pain registry questionnaire

Appendix 3

ClinicalTrial.gov registration

View Protocol Section

Study Identification

Unique Protocol ID: SJ-703

Brief Title: Redesign of Everyday Activities and Lifestyle With Occupational Therapy for Chronic Pain Patients (REVEAL(OT))

Official Title: Redesign of Everyday Activities and Lifestyle With Occupational Therapy for Chronic Pain Patients - A Feasibility Study of an Occupational Therapy Intervention Added a Multidisciplinary Biopsychosocial Treatment at a Danish Pain Centre

Secondary IDs:

Study Status

Record Verification: September 2021

Overall Status: Completed

Study Start: April 15, 2019 [Actual]

Primary Completion: August 1, 2021 [Actual]

Study Completion: September 15, 2021 [Actual]

Sponsor/Collaborators

Sponsor: Slagelse Hospital

Responsible Party: Principal Investigator
Investigator: Svetlana Solgaard Nielsen [svetlana s. nielsen]
Official Title: BSc/MSc in Health (Occupational Therapy)
Affiliation: Slagelse Hospital

Collaborators: University of Southern Denmark
Danish Association of Occupational Therapist
Region Zealand
Odense University Hospital

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved Approval Number: SJ-703
Board Name: Research Ethics Committee in Region Zealand
Board Affiliation: Region Zealand
Phone: 57 87 52 83 Email: rvk-sjaelland@regionsjaelland.dk
Address:
Region Sjælland Alléen 15, 4180 Sorø, Denmark

Data Monitoring: Yes

FDA Regulated Intervention: No

Study Description

Brief Summary:

About 20-30% of the Danish population suffers from chronic non-malignant pain. Current evidence suggests that a bio-psychosocial treatment delivered by multidisciplinary teams is the most effective treatment of chronic non-malignant pain. However, the evidence is still missing on the optimal multimodal treatment combination as well as the additional effect of specific treatment modalities.

A lifestyle-focused intervention is considered to be a relevant supplement to the multidisciplinary treatment of chronic non-malignant pain. Occupational therapy (OT) has previously demonstrated effectiveness in changing the lifestyle of adults through a holistic, systems-based approach. To our knowledge, the method has not previously been approved as a part of the multidisciplinary treatment of adults with chronic non-malignant pain.

The aim of this study is to evaluate the feasibility of the lifestyle-oriented OT intervention added to the current treatment for adults with chronic non-malignant pain, to inform the design and conduct of the future RCT.

Detailed Description:

Methods

Design

The feasibility study is designed as a mixed-methods single-arm case series pretest-posttest study. The feasibility of the planned intervention course and the assessment procedures will be evaluated. Forty-eight adults aged 18-65 will receive the lifestyle-oriented OT intervention for 15 weeks in addition to the current multidisciplinary CNMP treatment. The participants will complete assessments for Quality of Life (EQ-5D-5L), Occupational performance (COPM, AMPS), Occupational balance (OBQ), Pain-related Self-efficacy (PSEQ), Physical wake-time activity (actigraphs), BMI (weight and height scale), Waist circumference (measuring tape), Blood pressure (sphygmomanometer), and Central pain sensitization at baseline and upon OT intervention discharge. Adverse events (AE) will be registered.

Satisfaction with the add-on OT treatment among the participants and the multidisciplinary team members will be investigated through qualitative research methods. All the steps of the OT intervention will be evaluated by the participants qualitatively and quantitatively throughout the course. Focus group interviews with the participants and the multidisciplinary team inclusive OTs will be conducted upon the end of the OT intervention.

Ethical standards

The feasibility study follows the principles of The World Medical Association (WMA) described in the WMA Declaration of Helsinki. Ethical approval was obtained from the Research Ethics Committeé (SJ-703) and the Data Protection Authority (REG-052-2018) in Zealand Region, Denmark. The feasibility study is conducted in compliance with the European Union's (EU) General Data Protection Regulation (GDPR) and the Danish Data Protection Act.

Recruitment

The participants are enrolled from the outpatient cohort referred to the MPC as usual (e.g. by family physician etc.). All the admitted outpatients are approved for eligibility by a trained project assistant. Detailed written and oral information on the project, and invitation to participate, is provided to the outpatients who meet the inclusion and exclusion criteria. Informed consent on participation is obtained.

Sample

A total of 48 participants is estimated as sufficient for the feasibility study. All the participants are the citizens living in the Zealand Region, Denmark.

Intervention

The participants attend a lifestyle-oriented OT intervention combined with the current treatment at the MPC. The current treatment at the MPC may include medication adjustments, consultation, education, exercises, and homework, with Cognitive Behavioural Therapy (CBT) being the major approach. The patients start the treatment course with a 5-weeks (1,5 hour á week) compulsory group-based psychoeducation course delivered by the MPC's health professionals, e.g. physicians, nurses, physiotherapists, psychologists, and a social worker. The treatment continues afterward as individual treatment sessions by relevant health professionals. Every individual treatment composition is agreed upon by the patient and the multidisciplinary team. Group treatments are available through the MPC's Pain School, mindfulness course, positioning group course, pain treatment group for men and fibromyalgia group for women. The transcutaneous electrical nerve stimulation (TENS) is offered when relevant.

A lifestyle-oriented OT intervention is developed to complement the current treatment at the MPC. Inspired by the Lifestyle Redesign®-concept (USA), the OT intervention includes client-centered education, peer exchange, personal reflection and practicing in-vivo. The OT intervention is delivered by graduated OTs during the 15 weeks and runs parallel with the individual treatment at the MPC, after the psychoeducational course. The OT intervention has a three-fold focus on meaningful daily occupations, physical activity, and eating habits and routines. The OT intervention provides outpatients with an OT contact once a week, in-person every other week and by phone in the opposite weeks. The in-person contacts contain two 1-hour individual sessions and five 2-hours group sessions. One of the in-person individual sessions may be offered as a home visit in terms of an evaluation of home environments, when relevant. The groups are composed of six participants that will meet at the OT Department at Naestved Hospital.

The intervention manual is developed for the study. The trained intervention OTs receive supervision from the project leader during the intervention once a week, or upon demand. Cooperation with the multidisciplinary team at the MPC and inter-sectoral units on local communities across Zealand Region will be provided on an interdisciplinary basis and according to the participant's needs.

Data collection procedures

The project operates with data from patient journals and the Danish quality and research database PainData (approved by The Danish Data Protection Agency as a quality and research database, Reg. nr. 14/44319). The original questionnaire in PainData is supplied with additional questions for the specific project needs. Upon the recruitment and before the baseline assessment, the participants receive electronic access to the PainData and fill in the questionnaire. Thus, demographic and pain-related data, self-reported Quality of Life (QoL), Occupational balance, Pain Self-efficacy, and AE are registered in PainData.

After being admitted to the MPC and recruited to the project, the participants meet for the baseline assessment round that varies 2,5 hours, inclusive breaks. The participants complete the assessment of Occupational performance, Weight, Height, Waist circumference, Blood pressure, and Central sensitization. The participants are provided actigraphy-units (actimetry sensors) for home monitoring of rest-activity cycles. Detailed instructions for home monitoring is provided. The post-discharge assessment round follows the same procedure and is carried out after the ended OT intervention, approximately 5-6 months from the treatment start at the MPC.

The assessment of Occupational performance is performed by graduated OTs with appropriate qualifications. Physical wake-time activity cycles are obtained as self-assessment. Adherence to treatment is assessed by the registration of sessions attended or missed by each participant. Phone calls are used to establish compliance and prevent missing data. Qualitative data from the interviews are collected and transcribed. The transcription process is conducted by two undependable researchers.

Measures

The outcome measures in this trial are based on the recommendations for chronic pain clinical trials from the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) and include the core chronic pain outcome domains, such as participants' rating of overall improvement, pain intensity, physical functioning, and emotional functioning. Validated OT tools investigating occupational performance and balance will be included. The monitoring of lifestyle parameters and activity levels is conducted. Demographic characteristics allow the detection of potential confounders.

Adverse Events

Adverse events (AE) are defined as undesirable experiences during follow-ups, such as death, life-threatening disease, hospitalization, disability or permanent damage (or any need for prevention of those), and other serious health issues with a need for medical or surgical treatment. AEs are registered in the generic questionnaire in the Danish quality and research database PainData. Those untimely discontinued from the study receive a phone call in terms of the discontinuation causes. For all AEs, the date of occurrence, duration, and potential consequences are assessed.

The study course does not have any obvious risks of adverse effects for the participants. Any possible risks for the participants can be considered as minimal and unlikely, while multiple benefits will be expected, for both the actual and the future CNMP-patients. By an injury, the patients are able to seek the Patient Compensation.

Analysis

Data analysis will inform further decisions on a subsequent randomized controlled trial and adjustments in the OT intervention, and improvements of the multidisciplinary team cooperation during a treatment course. Explorative analysis of quantitative and qualitative data will examine the possible effects of the intervention and shortcomings. Whether the study population is normally distributed or not, quantitative methods, such as paired-samples t-test or Wilcoxon signed-rank test, will be used to estimate gain scores from the treatment.

Qualitative data will be analyzed through the following steps to ensure rigorous analysis of the qualitative data: i) mutual coding manual developed during the coding process; ii) iterative coding process where similarities and differences will be identified; iii) research group discussion and agreement during the analysis process; and iv) triangulation of quantitative and qualitative data on acceptability and satisfaction by the treatment.

Dissemination

All the significant, non-significant and/ or inconclusive results will be explicated and published.

Conditions

Conditions: Chronic Pain

Keywords: Activities of daily living
Occupational performance
Quality of life
Health behaviour change
Healthy eating
Physical activity
Occupational Therapy

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: N/A
Interventional Study Model: Single Group Assignment
Number of Arms: 1
Masking: None (Open Label)
Allocation: N/A
Enrollment: 40 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Intervention group Adults with chronic pain (n=48) matching the inclusion and exclusion criteria will be included.	Behavioral: Lifestyle-oriented Occupational Therapy added to current treatment of chronic non-malignant pain The participants are recruited from the outpatient cohort admitted at The Multidisciplinary Pain Center (MPC) at Naestved Hospital (Zealand Region, Denmark). The participants receive both, the current treatment based on Cognitive Behavioural Therapy (CBT) and delivered by physicians, nurses, physical therapists and a social worker as usual care, and a lifestyle-oriented Occupational Therapy intervention. The Occupational Therapy intervention targets meaningful daily occupations, physical activity, and eating habits and routines. The intervention is delivered by graduated occupational therapists once á week during the 15 weeks after the initial 5-weeks compulsory psychoeducation course at the MPC. The intervention contains in-person contacts with OTs every other week (e.g. two 1-hour individual sessions at the hospital and/ or at-home and five 2-hours group sessions) and seven phone consultations in the opposite weeks.

Outcome Measures

Primary Outcome Measure:

1. Change in Quality of Life (EQ-5D-5L Index) from baseline to post discharge

   The participants will evaluate their subjective health state in domains Mobility, Self-care, Usual activities, Pain/ Discomfort and Anxiety/ Depression on a 5-point Likert scale from 1= having no problems, having slight problems, having moderate problems, having severe problems and 5= being unable to do/having extreme problems.

   [Time Frame: Baseline and 6 months from baseline]

Secondary Outcome Measures:

2. Change in Occupational Performance and satisfaction from baseline to post discharge

   Obtained by The Canadian Occupational Performance Measure (COPM), Self-reported The COPM is an interview-based OT tool that measures occupational performance in all areas of life and throughout different life stages. The COPM will help the client to identify the issues related to self-care, leisure and productivity, to assess a degree of importance of those for the individual, to prioritize the occupational issues, and to detect changes in self-perceived occupational performance from one point of time to another. The COPM will provide basis for setting intervention goals.

   [Time Frame: Baseline and 6 months from baseline]
3. Change in Motor and Process Skills from baseline to post discharge

   Obtained by The Assesment of Motor and Process Skills (AMPS), Observed The AMPS is an OT tool that helps to evaluate the overall ability to perform domestic or instrumental activities of daily living (ADL), as well as motor and process skills, in an individual. Motor skills are defined as the observable actions that have been made by an individual during an ADL-performance. Process skills are defined as the observable operations, an individual has made in terms of organizing and proceeding his or her occupational performance.

   [Time Frame: Baseline and 6 months from baseline]
4. Change in Occupational balance from baseline to post discharge

   The Occupational Balance Questionnaire, Danish version (OBQ-DK), Self-reported The OBQ is an OT-tool that consists of 13 items and six-steps ordinal scales (from 1 to 4; min. 13 - max. 52) expressing certain amount and variation of occupation in an individual, and defining personal satisfaction with those. A higher score means a better outcome.

   [Time Frame: Baseline and 6 months from baseline]
5. Change in Pain Self-efficacy from baseline to post discharge

   Obtained by Pain Self Efficacy Questionnaire (PSEQ), Self-reported The PSEQ is a 10-item (0-6 scores; min. 0 - max. 60) questionnaire that helps to assess how confident an individual is with his or her activity performance, e.g. household chores, socializing and work, while in pain. The PSEQ can be applied to all pain presentations. A higher score means a better outcome.

   [Time Frame: Baseline and 6 months from baseline]
6. Change in Physical wake-time activity from baseline to post discharge

   Obtained by actigraphy units (actimetry sensors) all around the day (24 hours) in 4 days To monitor rest-activity cycles, and thus everyday amount of physical activity, actimetry sensors will be worn by the participants for a period of four days

   [Time Frame: Baseline and 6 months from baseline]
7. Change in BMI from baseline to post discharge

   Weight and height measures will be obtained by not-wearing shoes or heavy clothes Considering the evidence on common presence of co-morbid obesity in chronic pain conditions, the BMI will be measured by validated weight scale (Tanita DC-360S) and height scale (SECA), to monitor weight changes throughout the intervention. The BMI is defined as a person's weight in kilograms divided by the square of the person's height in meters (kg/m2).

   [Time Frame: Baseline and 6 months from baseline]

8. Change in Waist circumference from baseline to post discharge

   Obtained by a measuring tape (SECA) WC will be measured by measuring tape wrapped around the waist, parallel to the floor and not twistet, with one layer of thin clothes between the body and the measuring tape, and the bottom edge of the measuring tape aligned with the top of the hip bone. WC as the specific measure to detect the amount of abdominal fat, is found to effectively support BMI assessment and identify the risk of metabolic syndrome in a person.

   [Time Frame: Baseline and 6 months from baseline]

9. Change in Blood pressure from baseline to post discharge

   Obtained by Sphygmomanometer (MicroLife BPA3L Comfort) According to the evidence, chronic pain may cause hypertension, and thus, higher cardio-metabolic risks. BP was measured by a sphygmomanometer, with an inflatable rubber cuff wrapped around the left arm.

   [Time Frame: Baseline and 6 months from baseline]

Other Pre-specified Outcome Measures:

10. Change in Quantitative sensory testing (QST) for somatosensory pain perception

    Controlled Cuff Pressure Algometry (CCPA) unit, with two cuffs applied under the knees CCPA will be used in the study as a standardized QST method is applicable to various chronic pain conditions and able to identify general pain sensibility in an individual, based on deep tissue somatosensory pain response. To minimize the assessment load, other QST methods will not be used in the trial.

    [Time Frame: Baseline and 6 months from baseline]

Eligibility

Minimum Age:	18 Years
Maximum Age:	65 Years
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	

Inclusion Criteria:

- Age ≥ 18<65yr, chronic non-malignant pain diagnosis present ≥ 3 mths at the inclusion

Exclusion Criteria:

- Acute/ sub-acute pain; cancer-related pain; unstable medicine intake over the past four weeks; daily opioid intake >30 mg; headache/migraine; currently diagnosed depression; current substance misuse; severe psychiatric diagnosis; poor Danish speaking skills and participating in other CNMP-treatment programs. Severe psychiatric diagnoses are defined as a mental illness involving distortion in thinking and perception, and leading to significant social and occupational dysfunction, e.g. schizophrenia and schizotypal, delusional, schizoaffective or psychotic disorders, or psychosis.

Both, new eligible patients, and those who fulfill the eligibility criteria after an initial opioid intake adjustment course, will be considered.

Contacts/Locations

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Study Director
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▼Locations:

Denmark

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IPD Sharing Statement

Plan to Share IPD: No

References

▼Citations:

Links:

Available IPD/Information:

Additional Notes: NOTE: Site Recruitment Status is not shown on ClinicalTrials.gov unless Overall Recruitment Status is "Recruiting"

Record Summary

Appendix 4

PRECIS-2 tabular REVEAL(OT) presentation

	Domain	Score	Rationale
1	Eligibility criteria	2	Inclusion criteria: age ≥ 18<65yo, CNMP-diagnose present ≥ 3 mths at admission. Exclusion criteria: acute/ sub-acute pain; cancer-related pain; instable medicine intake over the past four weeks; daily opioid intake >30 mg; headache/migraine; currently diagnosed depression; current substance misuse; severe psychiatric diagnosis; poor Danish speaking skills and participating in other CNMP-treatment programs. Self-reported inability to walk the distance of min. 100 m will be an additional exclusion criterion.
2	Recruitment	5	The participants will be enrolled from the outpatient cohort referred to the MPC on regular basis (by family physician etc.)
3	Setting	2	The Multidisciplinary Pain Centre (MPC) at Naestved, Slagelse and Ringsted Hospitals
4	Organisation	1	Both clinical units involved adjusted their usual practice to include the REVEAL(OT) intervention. New practices included: instruction and supervision of occupational therapists providing the intervention on the intervention delivery; education of the multidisciplinary team assisting recruitment; multidisciplinary collaboration between team members in the current treatment and occupational therapists
5	Flexibility (delivery)	4	The REVEAL(OT): - Protocolised - Compliance with treatment monitoring based on self-reports - Certain number of visits but semi-flexible if sick days, etc. - No allowance for other simultaneous pain interventions but control dependent on self-reports - Exclusion if stop in usual care
6	Flexibility (adherence)	3	- Adherence control - Population prone to have multiple sick days and delayed respons
7	Follow-up	1	- Follow-up assessment procedure matches baseline - Evaluations at all visits - Focus group interviews for qualitative evaluation
8	Primary outcome	3	The primary outcome of health-related quality of life is relevant to participants and clinicians involved in chronic pain treatment across healthcare disciplines
9	Primary analysis	5	The study includes different quantified feasibility outcome measures. Several feasibility evaluation forms use open-ended questions and allow for inclusion of the perspectives of the participants in the evaluation. Mid-term qualitative evaluation investigated opinions of the patients and clinicians.

Appendix 5

TIDieR-informed REVEAL(OT) presentation

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	p. 3	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	p. 5	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	p. 7-9	Appendix 4 Appendix 6
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	p. 6 p. 8	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	p. 6	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	p. 5-7	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	p. 4	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	pp. 10-11	Figure 1 Appendix 3
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	p. 5	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	p. 6	Appendix 3
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	pp. 11-15	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	pp. 12-14	Table 3

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Appendix 6

The logic model for the REVEAL(OT) intervention

System Characteristics:	**Resources**	**Activities**	**Mechanisms of Change**	**Short and Long term Outcomes**
• Occupational therapy (OT) in multidisciplinary treatment of chronic non-malignant pain • Non on Danish regional pain centres have OT lifestyle management implemented • OT as add-on treatment to usual care • Project base: Multidisciplinary Pain Centre in Naestved (CBT as the main treatment approach; No continuous focus on lifestyle) • Evidence for relevance of lifestyle-oriented treatment in chronic pain (lifestyle affects quality of life, occupational performance and health) • Existing OT expertise in lifestyle management (USA)	Identify the programmes that work Investigate in the local needs in the patients and clinicians Appropriate scheduling of the OT intervention added to usual care (non-interfering with usual care) Estimate for the eligible participants' flow (power estimate correction?) Recruiting assistance needed from the pain centre' stuff Geography and transportation: Possible alternative ways of the intervention delivery Available facilities and tools High motivation for working with lifestyle changes in the target population	Investigation in the usual care composition Investigation in the patients' needs and expectations Development of the intervention delivery competences in the intervention OT's Condensing the intervention contents to the main areas of focus – to reduce the treatment load and the costs) Three-fold focus 1) Meaningful activities (i.e., occupations); 2) Healthy eating; 3) Daily physical activity	**Intervention methods:** Didactic presentation, Peer-feedback, Self-reflection, and Practicing **Therapeutic methods:** - Tailored value-based goal work support - Body mechanics/postures and positioning - Energy conservation/joint-sparing techniques - Relaxation training/stress management - Ergonomics for home (work) inclusive assistive devices - Environmental modification - Pacing/ graded activity - Activity (task) adaptation/therapeutically activity **Theories and frameworks:** - OT theory of the transformative power of occupational engagement - OT concept of Doing, Being, Becoming, and Belonging - OT lifestyle management (Lifestyle Redesign®) - Fear-avoidance theory - Operant learning theory - Social learning theory - The Health Beliefs Model: disrupting threats and barriers & promoting self-efficacy and the desire for action - Behaviour change techniques taxonomy - Kolb's learning cycle: concrete experience, reflective observation, abstract conceptualization and active experimentation - Stages of Change Model: meeting one at his/ her stage; taking a step/ few steps further - Recommendations on physical activity for adults (World Health Organisation and Danish Health Authority) - Nutritional advice for the Danish population (Danish Health Authority on basis of the World Health Organisation recommendations for Europe) - The Medical Research Council framework for development of complex interventions	**In short term:** - Making healthier choices - Re-focusing (from pain through meaningful doing to better quality of life) - Re-gaining one's important roles/ being more for the others **In 1-3 years:** ↑ Quality of life ↑ Overall health ↑ Occupational performance ↑ Occupational participation ↑ Occupational balance ↑ Pain self efficacy ↑ Social functioning ↑ Physical activity level ↓ Body mass & waste circumference (if BMI≥30) ↓ Pain spreading ↓ Pain intensity **In 5-10 years:** OT lifestyle-oriented program as a part of the usual multidisciplinary treatment of chronic non-malignant pain

Implementation: stepwise co-operation with stakeholders (patients/ health professionals/ decision makers) a) locally (Naestved-Slagelse-Ringsted + Holbaek-Koege-Roskilde), b) regionally (Region Zealand) and c) nationally (DK)

Appendix 7

Danish healthy nutrition advises

Kostrådene 2013 (”De ti kostråd”)

1. Spis varieret, ikke for meget og vær fysisk aktiv
2. Spis frugt og mange grøntsager - spis 600 gram om dagen, mindst halvdelen skal være grøntsager. Spis grøntsager til alle dine hovedmåltider og frugt og grøntsager som mellemmåltider. Vælg grove grøntsager som løg, ærter, broccoli, blomkål , rodfrugter og bønner
3. Spis mere fisk - I alt skal du have 350 g fisk om ugen, heraf 200g fed fisk, som laks, ørred, makrel sild. Spis fisk mindst 2 gange om ugen som hovedret og flere gange om ugen som pålæg
4. Vælg fuldkorn- spis mindst 75 g om dagen.
   Vælg fuldkorn først, gå efter fuldkorsmærket, når du køber ind. Vælg rugbrød eller anden fuldkornsbrød til madpakken og vælg fuldkornsris eller -pasta .
5. Vælg magert kød og kødpålæg - vælg kød og kødprodukter med max 10% fedt og spis højst 500 g tilberedt kød om ugen fra okse, kalv, lam eller svin.
   Spiser du federe udskæringer, så hæld stegefedtet fra.
6. Vælg magre mejeriprodukter- vælg skummet-, mini- eller kærnemælk, 1/4 -1/2 liter mælkeprodukter om dagen er passende
   Vælg surmælksprodukter som yoghurt med maks. 0,7 % fedt, og vælg ost med maks. 17 % fedt (30+)
7. Spis mindre mættet fedt - Vælg planteolier og flydende eller blød margarine i stedet for smør, smørblandinger og hård margarine.
   Skrab brødet eller lad vær med at bruge fedtstof og maden i olie i stedet for smør og smid fedtstoffet væk.
8. Spis mad med mindre salt - Køb madvarer med mindre salt, det meste salt får vi fra forarbejdede madvarer som brød, kødprodukter, ost og færdigretter - vælg produkter med nøglehulsmærket.
   Smag på maden før du salter.
9. Spis mindre sukker - Skær ned på de søde sager og drikke både til hverdag og på fridage. Drik maks. en halv liter sodavand, saft, juice eller energidrik om ugen.

10. Drik vand - drik vand i stedet for sodavand og saft. Hvis det ikke er varmt er det som regel nok, at drikke 1 -1,5 liter væske om dagen

De officielle Kostråd 2021

1. Spis planterigt, varieret og ikke for meget
2. Spis flere grøntsager og frugter
3. Spis mindre kød – vælg bælgfrugter og fisk
4. Spis mad med fuldkorn
5. Vælg planteolier og magre mejeriprodukter
6. Spis mindre af det søde, salte og fede
7. Sluk tørsten i vand

Supplerende:

- Begræns madspild
- Gå efter Nøglehullet

References:

Ministry of Food, Agriculture and Fisheries. The Official Dietary Guidelines – good for health and climate 2021 [Internet]. Ministry of Food, Agriculture and Fisheries of Denmark, Danish Veterinary and Food Administration; 2021 [cited 2021 June 20]. Available from: https://altomkost.dk/fileadmin/user_upload/altomkost.dk/Publikationsdatabase/De_officielle_Kostraad_2021/Danish_Official_Dietary_Guidelines_Good_for_Health_and_climate_2021_PRINT_ENG.pdf.

Tetens I, Andersen LB, Astrup A, Gondolf UH, Hermansen K, Jakobsen MU, et.al. The evidence base for Danish advice on diet and physical activity (Evidensgrundlaget for danske råd om kost og fysisk aktivitet) [Internet]. 1st ed. DTU Fødevareinstituttet; 2013 [cited 2021 June 20]. Available from: www.food.dtu.dk.

Appendix 8

WHO recommendations on physical activity for adults 18-64 years old

Anbefalinger for fysisk aktivitet for voksne (18-64 år)

- Fysisk aktivitet (moderat til høj intensitet) mindst 30 minutter om dagen og ud over almindelige daglige aktiviteter. De 30 minutter kan deles op i sekvenser á mindst 10 minutter.
- Fysisk aktivitet med høj intensitet mindst 20 minutters mindst 2 gange om ugen

Fysisk aktivitet i større omfang vil medføre yderligere fordele for sundheden.

Revideret anbefaling for fysisk aktivitet for voksne 2019

Varigheden af fysisk aktivitet med moderat til høj intensitet á mindst 10 minutter afskaffes.

References

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Danish Health Authority. Physical activity – Handbook for prevention and treatment (Fysisk aktivitet - Håndbog om forebyggelse og behandling), 4th edition. Sundhedsstyrelsen; 2018 [cited 2021 Aug 08]. Available from: https://www.sst.dk/da/sundhed-og-livsstil/fysisk-aktivitet/anbefalinger/~/media/6B3A4AE698BC42139572C76C5854BA76.ashx

Saint-Maurice PF, Troiano RP, Matthews CE, Kraus WE. Moderate-to-Vigorous Physical activity and all-cause mortality: do bouts matter? J Am Heart Assoc. 2018;7(6):e007678.

Appendix 9

PROSPERO registration

Systematic review

1. * Review title.

Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

The effectiveness of occupation-focused and occupation-based interventions that target changes in lifestyle and health behavior in adults with chronic non-malignant pain – A systematic review

2. Original language title.

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

Effekten af aktivitetsbaserede og aktivitetsfokuserede interventioner til fremme af ændringer i livsstil og sundhedsadfærd blandt voksne med kroniske ikke-cancerrelaterede smerter - Et systematisk review

3. * Anticipated or actual start date.

Give the date when the systematic review commenced, or is expected to commence.

01/10/2018

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

01/04/2020

5. * Stage of review at time of this submission.

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.
Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.
This field should be updated when any amendments are made to a published record and on completion and publication of the review. If this field was pre-populated from the initial screening questions then you are not able to edit it until the record is published.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here (e.g. Funded proposal, protocol not yet finalised).

6. * Named contact.

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

Svetlana Solgaard Nielsen

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Mrs Nielsen

7. * Named contact email.

Give the electronic mail address of the named contact.

ssolgaard@health.sdu.dk

8. Named contact address

Give the full postal address for the named contact.

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

The University of Southern Denmark; Naestved, Slagelse and ringsted Hospitals (Region Zealand), Denmark

Organisation web address:

www.sdu.dk; https://www.regionsjaelland.dk/sundhed/geo/slagelsesygehus/Afdelinger/Reumatologisk-afdeling/forskning-progrez/Sider/default.aspx

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country are now mandatory fields for each person.**

Mrs Svetlana Solgaard Nielsen. The University of Southern Denmark; Naestved, Slagelse and Ringsted Hospitals
Assistant/Associate Professor Jeanette Reffstrup Christensen. The University of Southern Denmark

12. * Funding sources/sponsors.

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

Svetlana Solgaard Nielsen, PhD Student, The University of Southern Denmark

Grant number(s)

13. * Conflicts of interest.

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country are now mandatory fields for each person.**

Professor Soeren Thorgaard Skou. The University of Southern Denmark; Naestved, Slagelse and Ringsted Hospitals
Professor Jens Soendergaard. The University of Southern Denmark

15. * Review question.

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS where relevant.

What is the evidence of the effectiveness of occupation-focused and occupation-based interventions that target changes in lifestyle and health behavior in adults with chronic non-cancer pain?

16. * Searches.

State the sources that will be searched. Give the search dates, and any restrictions (e.g. language or publication period). Do NOT enter the full search strategy (it may be provided as a link or attachment.)

Databases: MEDLINE, Embase, PsycINFO, CINAHL, Cochrane, Scopus, ClinicalTrials.gov, Web of Science, and OTseeker; Grey literature: Google Scholar and OpenGrey. Last search 02.12.2019. The records will be collected using Endnote software, and screened using Covidence software

17. URL to search strategy.

Give a link to a published pdf/word document detailing either the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search strategies), or upload your search strategy.Do NOT provide links to your search results.

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Changes in lifestyle and health behavior among adults with chronic non-malignant pain

19. * Participants/population.

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

The participants in the included studies must be ? 18 or older and have ? 3-months chronic pain experience.

Pain conditions commonly described as chronic pain, persistent pain and long-term pain will be eligible.

Children, adolescents, and pregnant or postpartum women will be excluded.

There will be included specific categories of chronic pain defined according to the latest version of the International Classification of Diseases (ICD-11) of the World Health Organization (WHO), e.g. a) Chronic primary pain, e.g. musculoskeletal or neuropathic pain of unclear etiology, widespread pain (e.g. fibromyalgia), generalized pain syndrome, complex regional pain syndrome, facial pain, visceral pain, temporomandibular disorder, burning mouth, headache/migraine, and unspecified pain; b) Chronic postsurgical and posttraumatic pain with neuropathic component; c) Chronic peripheral neuropathic pain caused by a nerve trauma or neuro-anatomical distribution of the pain; and d) Chronic headache and orofacial pain.

Chronic cancer pain; postsurgical and posttraumatic pain with recurrent malignant or inflammatory component; central neuropathic pain and peripheral neuropathic pain caused by stroke or diabetic neuropathy; and nociceptive musculoskeletal pain with infectious, autoimmune or metabolic etiology, or caused by cartilage structural changes, will be excluded.

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

The eligible interventions will focus on meaningful activities of daily living and be occupation-focused (e.g. use meaningful occupation as a subject for clinical advice or education) or occupation-based (e.g. use meaningful occupation as a treatment-by-doing tool). The eligible occupation-focused and occupation-based

interventions may be: a) both delivered on mono- or multidisciplinary basis; b) use both individual, group or mixed approaches; c) operate with various non-pharmacological treatment methods, e.g. education, peer-exchange, skill training, personal reflection, exercise and assistive technology use. The eligible interventions must have a control group.

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Other or no treatment

22. * Types of study to be included.

Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.

i) all experimental studies (e.g. RCT, NRCT); ii) all observational studies (e.g. case control, cohort, cross-sectional)

23. Context.

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

The inclusion and exclusion criteria are defined according to the target group of adults with chronic non-malignant pain typically assigned multidisciplinary pain centers in Denmark, to inform the design and conduct of an occupation-based and occupation-focused intervention som an add-on treatment modality to usual care

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

Changes from baseline to the last available follow-up in lifestyle-related parameters, such as a) physical fitness measured by verified methods, e.g. bio-impedance anthropometrics (body weight in kg, muscle mass, body fat mass and/or body fat percent); b) physical activity and exercise measured by time used; c) BMI measured by the body mass in kg divided by the square of the body height in meter (kg/m2); d) waist circumference measured in cm; f) alcohol consumption measures by the number of alcohol units a week; e) smoking cessation measured by the number of cigarettes smoked a week; f) self-perceived sleep quality measured by nominal (yes-no), ordinal (quality levels) or numerical (visual analogue scale scores) variables ; and g) self-perceived stress measured by nominal (yes-no), ordinal (stress levels) or numerical (visual analogue scale scores) variables.

* Measures of effect

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Differences in changes pre-post intervention

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state ‘None’ or ‘Not applicable’ as appropriate to the review

Self-perceived changes in occupational performance, occupational participation, and lifestyle-related habits and routines from baseline to the last available follow-up measured by nominal (yes-no), ordinal (levels of self-perceived change) or numerical (visual analogue scale scores) variables.

* Measures of effect

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Differences in changes pre-post intervention

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Study selection

Two reviewers will independently screen records for eligibility criteria and select studies for inclusion in the systematic review. Covident software will be used in data selection and management process. When unclear eligibility, full-text assessment of the articles from the literature search will be conducted. The eligible studies will be assessed in full text by both authors (SSN and JRC) independently. Any disagreements will be solved by consensus.

Data extraction

The data extraction will be performed by the first author and validated by the co-author. Standard extraction form proposed by JBI will be used. The data extraction form will be piloted to check applicability on the first three studies from the alphabetical list of the study sample. The extraction form will contain data on study details, authors, year and country of conduct, study design and methodology, objectives, study settings/ context, baseline characteristics and number of the participants, appraisal instrument and rating, assessed outcomes of interest, study results/ findings, and comments. Study investigators will be contacted by e-mail or phone for unreported data or additional details, if necessary. Any disagreements will be solved by consensus.

27. * Risk of bias (quality) assessment.

Describe the method of assessing risk of bias or quality assessment. State which characteristics of the studies will be assessed and any formal risk of bias tools that will be used.

Both reviewers will perform independent assessment of methodological quality of the retrieved studies using the standardized critical appraisal checklists for experimental, quasi-experimental, case control, cohort, and cross-sectional studies developed by JBI. Study characteristics, such as presence and methods of randomization, treatment allocation, blinding, and risk of bias will be assessed at study level. Any disagreements will be solved by consensus.

28. * Strategy for data synthesis.

Provide details of the planned synthesis including a rationale for the methods selected. This **must not be generic text** but should be **specific to your review** and describe how the proposed analysis will be applied to your data.

The minimum of two studies will be required for synthesis. Data on the main and additional outcomes will be synthesized and summarized in tabular form. The findings will be the subject for narrative analysis.

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

If the sample size is big enough and expresses sufficient heterogeneity, subgroup analyses for anticipated differences in participant characteristics, such as a) chronic pain category (ICD-11); b) pain location; and c) age group (adults 18-65 yo vs. older adults 65yo), will be conducted using appropriate logistic regression methods.

30. * Type and method of review.

Select the type of review and the review method from the lists below. Select the health area(s) of interest for your review.

Type of review

Cost effectiveness
No

Diagnostic
No

Epidemiologic
No

Individual patient data (IPD) meta-analysis
No

Intervention
No

Meta-analysis
No

Methodology
No

Narrative synthesis
No

Network meta-analysis
No

Pre-clinical

No

Prevention
No

Prognostic
No

Prospective meta-analysis (PMA)
No

Review of reviews
No

Service delivery
No

Synthesis of qualitative studies
No

Systematic review
Yes

Other
No

Health area of the review

Alcohol/substance misuse/abuse
No

Blood and immune system
No

Cancer
No

Cardiovascular
No

Care of the elderly
No

Child health
No

Complementary therapies
Yes

Crime and justice
No

Dental
No

Digestive system
No

Ear, nose and throat
No

Education
No

Endocrine and metabolic disorders
No

Eye disorders
No

General interest
No

Genetics

No

Health inequalities/health equity
No

Infections and infestations
No

International development
No

Mental health and behavioural conditions
No

Musculoskeletal
No

Neurological
No

Nursing
No

Obstetrics and gynaecology
No

Oral health
No

Palliative care
No

Perioperative care
No

Physiotherapy
No

Pregnancy and childbirth
No

Public health (including social determinants of health)
No

Rehabilitation
Yes

Respiratory disorders
No

Service delivery
No

Skin disorders
No

Social care
No

Surgery
No

Tropical Medicine
No

Urological
No

Wounds, injuries and accidents
No

Violence and abuse
No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.
English

There is not an English language summary

32. * Country.

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.

Denmark

33. Other registration details.

Give the name of any organisation where the systematic review title or protocol is registered (such as with The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

Give the citation and link for the published protocol, if there is one

Give the link to the published protocol.

Alternatively, upload your published protocol to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

The review results will be disseminated at international conferences for occupational scientists and

therapists, and other health care professionals.

Do you intend to publish the review on completion?

Yes

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

occupational performance and participation

activities of daily living

health behavior modifications

rehabilitation

37. Details of any existing review of the same topic by the same authors.

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38. * Current review status.

Review status should be updated when the review is completed and when it is published. For newregistrations the review must be Ongoing.
Please provide anticipated publication date

Review_Ongoing

39. Any additional information.

Provide any other information the review team feel is relevant to the registration of the review.

40. Details of final report/publication(s).

This field should be left empty until details of the completed review are available.

Give the link to the published review.

Appendix 10

Study I manuscript inclusive appendices

The effect of occupational engagement on lifestyle in adults living with chronic pain – A systematic review and meta-analysis

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[4] Department of Therapy and Midwifery Studies, Faculty of Health Sciences, University College Copenhagen, Sigurdsgade 26, 2200 Copenhagen N, Denmark;

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Alessio Bricca, PhD, Postdoc, E-mail: abricca@health.sdu.dk

Jens Søndergaard, MD, PhD, Professor, E-mail: jsoendergaard@health.sdu.dk

Jeanette Reffstrup Christensen, OT, PhD, Associate Professor, E-mail:

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E-mail: ssolgaard@health.sdu.dk; Phone: 0045 51252255

Abstract

Background: Healthy lifestyle is important to decrease health risks in individuals living with chronic pain. From an occupational therapy perspective, human health and lifestyle are linked to occupational engagement, i.e., performance and participation in meaningful everyday activities. This study aimed to investigate the effect of including occupational engagement in chronic pain interventions on lifestyle.

Methods: In this systematic review (PROSPERO reg. CRD42020159279), we included randomised controlled trials (RCTs) on interventions involving occupational engagement and assessing physical activity, body anthropometrics, alcohol consumption, smoking, stress, and sleep. We sought the databases Ovid MEDLINE, Embase, PsycINFO, CINAHL, Cochrane, Scopus, Web of Science, OTseeker, ClinicalTrials.gov and OpenGray, the web engine Google Scholar and citations and references of relevant publications. We evaluated methodological quality with the Cochrane Risk-of-bias tool 2.0, determined the overall evidence certainty using the GRADE methodology, and performed meta-analysis when two or more trials reported on the outcome.

Results: Of the 9526 items identified, 286 were full text screened. We included twelve articles with eleven RCTs comprising 995 adults and assessing physical activity, sleep quality, stress, and Body Mass Index. Sufficient data for meta-analysis was only available for physical activity and sleep quality. The meta-analysis suggested a moderate increase in physical activity after behavioural interventions for fibromyalgia and musculoskeletal pain (SMD=0.69 [0.29; 1.09]) and a small increase in sleep quality up to 6 months after multidisciplinary self-management of fibromyalgia (SMD=0.35 [95% CI 0.08; 0.61]). The overall certainty of the evidence was deemed low.

Conclusion: Including occupational engagement in chronic pain interventions may increase short-term physical activity and long-term sleep quality. Due to the few available RCTs

including occupational engagement in chronic pain treatment for adults living with chronic pain further high-quality RCTs are needed and will likely change the conclusion.

Keywords: activities of daily living, health behavior, occupational therapy, pain management

The Effect of Occupational Engagement on Lifestyle in Adults Living with Chronic Pain: A Systematic Review and Meta-analysis

1. Introduction

Chronic pain is associated with a higher risk of lifestyle challenges such as inactivity, sleep disturbance, unhealthy eating, excessive tobacco smoking, alcohol misuse, and mental stress [1]. An unhealthy lifestyle can further reduce health and increase the risk of comorbidity, thereby calling for interventions to improve lifestyle factors such as physical activity, weight, diet, alcohol consumption, tobacco use, stress and sleep [2]. From the occupational therapy perspective, an important part of a healthy lifestyle is occupational engagement in meaningful and purposeful everyday activities that are beneficial for lifestyle factors [3]. By engaging people living with chronic pain in occupations that promote a healthier lifestyle, occupational therapy could help initiate lifestyle changes and improve health and well-being.

A recent scoping review underscored the unique role of occupational therapy in chronic pain treatment, highlighting the need for further research on the effectiveness of interventions targeting occupational issues in people living with chronic pain [4]. We also know that occupational therapy can be useful in weight-loss interventions for adults [5], but whether occupational engagement included in chronic pain interventions promotes a healthier lifestyle has not been studied yet.

Evidence highlights that rehabilitation should focus on meaning in everyday life rather than on improving function alone [6], as meaning improves health and the ability to modify health behaviour for better well-being [7]. Thus, engaging in meaningful and purposeful activities promoting a healthier lifestyle could potentially enhance the effect of lifestyle interventions for people living with chronic pain by adding meaningful content.

The aim of this systematic review was to investigate whether chronic pain interventions including occupational engagement in everyday activities would be effective in

improving lifestyle compared to interventions not including occupational engagement or no intervention.

2. Methods

This systematic review was reported according to the PRISMA guidelines [8] (protocol registration CRD42020159279, PROSPERO).

2.1. Criteria for inclusion

According to the new classification of chronic pain proposed by the World Health Organisation (WHO) in the International Classification of Diseases for mortality and morbidity statistics (ICD-11) [9], randomised controlled trials (RCTs) including adults ≥18 years of age with primary pain conditions ≥3 months were eligible: widespread chronic pain, chronic primary musculoskeletal pain, chronic primary visceral pain, chronic primary headache or orofacial pain, including other and unspecified types of chronic primary pain (see Appendix 1 for diagnosis codes). Mixed chronic pain diagnoses were allowed for inclusion if the treatment programme was not diagnosis-specific. Peer-reviewed publications in English, German, Italian, Swedish, Norwegian or Danish were eligible.

The eligible interventions had to target at least one of the primary outcomes and their changes from baseline to any available follow-up in lifestyle-related parameters: body anthropometrics, e.g., body weight in kilograms (kg; continuous), Body Mass Index (BMI; interval) and waist circumference in centimetres (cm; continuous); physical activity level measured in hours and minutes (continuous) or number of walking steps (continuous); alcohol consumption in units per week (continuous); cigarettes smoked per week (continuous); self-perceived sleep quality level (ordinal); and self-perceived stress level (ordinal). The lifestyle-related outcomes had to be assessed by validated methods delivering objective measurements (weighing scales, measuring tapes, or pedometers) or self-reports, e.g., The Karolinska Sleep Questionnaire (KSQ), Depression Anxiety, or Stress Scales

(DASS). Trials that assessed only physical function, e.g., Six Minute Walk Test (6MWT) or Time Up to GO (TUG) test, were not eligible for inclusion. Although an improved physical function may help reduce sedentary time, we considered it not directly reflecting a change in health behaviour towards increased physical activity level.

Additionally, eligible interventions had to include an occupational engagement component, i.e., relevant assessment tools and explicit authors' reports on performing meaningful and purposeful daily activities as part of an intervention strategy. The relevant assessment tools could be those measuring occupational performance, occupational disability, or pain interference with daily activities, e.g., The Canadian Occupational Performance Measure (COPM), or occupational functioning/ disability related to self-care, productivity and/ or leisure, e.g., Brief Pain Inventory (BPI), Dallas Pain Questionnaire (DPQ), Fibromyalgia Impact Questionnaire (FIQ), Oswestry Disability Index (ODI), or Pain Disability Index (PDI). The eligible interventions could: a) be delivered by occupational therapists or multidisciplinary teams; b) have individual, group, or mixed approaches; and/or c) operate with non-pharmacological treatment methods, alone or in combination with pharmacological treatment. Eligible comparators were interventions not involving occupational engagement as an active component of the impact, i.e., with no planned practising of daily occupations during the intervention period, or no intervention.

2.2. Criteria for exclusion

The following pain conditions of nonprimary character according to the ICD-11 [9] were excluded: chronic cancer-related pain, i.e., pain caused by active malignancy or pos-cancer sequelae; chronic postsurgical and post-traumatic pain; chronic secondary musculoskeletal pain in joints, bones, tendons, muscles, soft tissues or vertebral column of inflammatory, infectious, autoimmune, or metabolic etiology; chronic secondary visceral pain; chronic central and peripheral neuropathic pain, e.g., that caused by stroke or diabetic neuropathy;

chronic secondary headache or orofacial pain; or other specified chronic pain. Please see the diagnosis codes excluded in Appendix 1. Pregnant or postpartum women and particular labor force or social groups that received treatment specifically related to their work (e.g., athletes, nurses, dentists, musicians, or students).

2.3. Search method and study selection

We searched the databases Ovid MEDLINE, Embase, PsycINFO, CINAHL, Cochrane, Scopus, Web of Science, OTseeker, ClinicalTrials.gov, OpenGrey and the web engine Google Scholar for relevant publications (first search on November 21-24, 2019). The alerts for the saved literature database searches were monitored regularly until the end of the study inclusion process to detect additional publications. Reference lists of relevant publications were manually searched for eligible articles. We performed the last search repeating the original database-specific search strategy (Appendix 2) on June 25, 2021. PICO format for the clinical question guided the block search process. A librarian specialist in health sciences assisted with adjusting the search terms and strategy.

The first (SSN) and the last author (JRC) independently screened the identified RCTs for titles and abstracts using a selection form developed for this study (Appendix 3). All RCTs deemed eligible by one of the two authors were checked independently in full text by the same authors. Any disagreement about including individual trials was subject to discussion until consensus. EndNote X8 software (Clarivate Analytics), released 8 November 2016, and Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) available at www.covidence.org were used for sourcing and sorting the search results.

2.4. Data extraction

Items recommended by the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network in the template for intervention description and replication (TIDieR)

guided the data extraction [10]. Using a data extraction form developed in Microsoft Excel-software, the first author extracted information on the author(s), year of publication, country of origin, study design, participant characteristics, sample size (total and in groups, at baseline and follow-ups), program title (if any), treatment concepts, comparators, providers of the experimental content, description of the occupational engagement component including the assessment tools used, lifestyle outcomes according to the inclusion and exclusion criteria and their reported assessments at baseline, post-intervention and long-term follow-up. The last author then validated the data extraction. Any disagreements, e.g., interpretation of the occupational engagement component, were solved by consensus.

2.5. Methodological quality assessment and the overall quality of evidence

The revised version of the Cochrane risk-of-bias tool for randomised trials (RoB 2 tool) informed the risk-of-bias assessment [11]. The authors SSN and AB answered the series of signalling questions grouped in five domains evaluating various aspects of trial design for the outcomes assessed: Risk of bias raised from the randomisation process; Risk of bias due to deviations from the intended interventions; Missing outcome data; Risk of bias in measurement of the outcome; and Risk of bias in selection of the reported result. The risk of bias judgements ('Low', 'Some concerns' or 'High') within each domain were guided by the proposed algorithms to answer the signalling questions. The overall risk of bias was determined for each RCT based on in-domain assessment. Disagreements between the two authors were solved by discussion until consensus was met. The Cochrane Robvis visualisation tool was used for a tabular summary.

2.6. Analysis and synthesis

We structured the evidence synthesis around the lifestyle outcomes and the effect measures reported in the included trials. We performed a meta-analysis using a random effects model and for outcome measures of continuous data, a standardised mean difference (SMD),

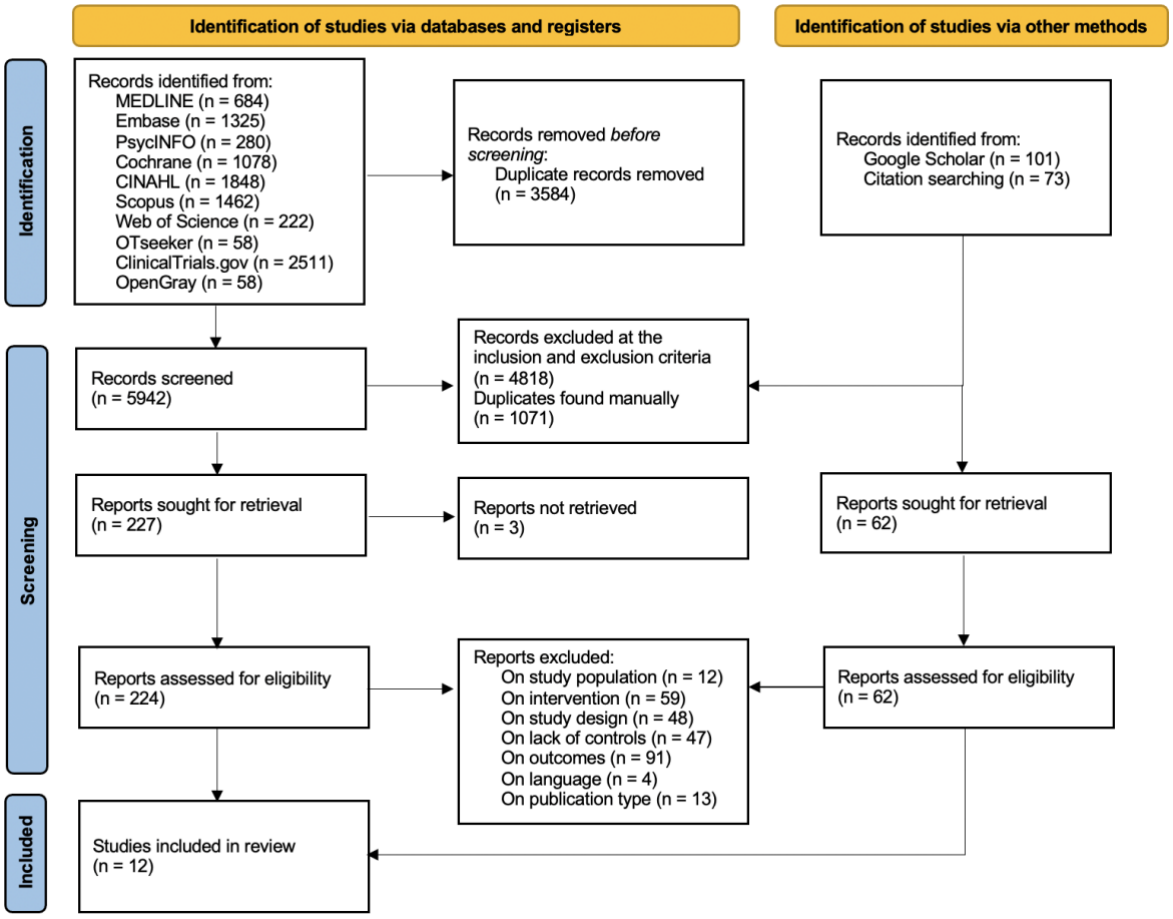
converted to Hedges' g to detect corrected (unbiased) effect sizes, [12] was calculated when at least two trials reported on the same outcome domain. Grouping of pooled results for each lifestyle-related outcome in the meta-analysis was based on the outcome assessments post-intervention and at the last available long-term follow-up after the completed intervention. To adjust for differences in the direction of the assessment scales, e.g., when decreasing scores meant not a decline but an improvement in an outcome, we multiplied the mean values of the relevant outcomes by –1 as recommended by Cochrane (para. 9.2.3.2.) [13]. The standard deviations remained herewith unmodified. In case of insufficient data reports, the effect estimates were calculated from the data available, e.g., frequencies and graphs. SMD (Hedges' g) estimates were used to interpret the pooled effect size of including occupational engagement in chronic pain interventions following the general rule of thumb for the interpretation, i.e., that Hedges' g ≥0.2 represents a small effect, ≥0.5 a moderate effect and ≥0.8 a large effect.

Measures of consistency (heterogeneity, I^2) were provided for each outcome. The heterogeneity evaluation was guided by the Cochrane group recommendations (para. 9.5.2.) [13], where the inconsistency values were considered on the continuum from 0% indicating no inconsistency between the results of individual trials and 100 % indicating maximal inconsistency. The method proposed by The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) working group guided the interpretation of the results from the meta-analysis [14]. Evidence from trials not eligible for inclusion in the meta-analysis was summarized narratively. Confidence intervals and the 5% significance level guided the results' interpretation [15]. We evaluated the overall certainty of the evidence using the GRADE approach by grouping the evaluation ratings according to each outcome domain.

3. Results

After excluding duplicates, we screened 6,262 titles and abstracts for eligibility and obtained 286 articles for an independent full-text assessment. Then, we excluded 274 articles, leaving 12 articles reporting on 11 trials for a synthesis (Figure 1).

Figure 1. Flowchart for the study



Reasons for exclusion of articles that initially appeared to meet the inclusion criteria could be assessment of physical function and not physical activity level [16], promoting occupational engagement in all groups involved [17, 18], or using lifestyle outcomes only to monitor baseline differences between groups [19]

Table 1

Characteristics of the included trials

Study reference[a]	Participants (diagnoses, n randomised/ completed, age, gender, pain duration/ intensity & settings)	Intervention and comparators (duration/ follow-up, n included in the analyses, treatment contents & providers)	Occupational engagement component explicated, mean (SD) & assessment tools	Lifestyle-related outcomes[b], mean (SD) & assessment tools
Soares & Grossi, 2002 (RCT), Sweden [22]	Fibromyalgia (100%) n=53/ 46; ≥18≤64 yr, mean 45(9) yo 100% females Pain duration (y) mean 3.6(3.3); Pain intensity (0-100 scale), mean 85.5(12.6) General practice	10 wk/ FU1(PI) 10 wk/ FU2 6 mo IG1, n=18/ 15 at FU2: Educational intervention (EI) aimed self-management incl. education, information, and discussions on health-related topics; treatment contract on individual occupational goals; and consultations with experts/ OT & PT IG2, n=18/ 14 at FU2: Behavioral intervention (BI) incl. CBT, relaxation, and biofeedback/ Psychologist & physician CG, n=17: WL (no treatment)	Engaging in active behaviors, CSQ[c] IG1: Intervention informed by individual treatment contract between the patients and the therapists incl. personal expectations, fears, goals, and needs IG2: Didactic information and practical training aimed acquisition and development of pain coping skills incl. homework and evaluation	**Sleep quality,** KSQ[d] BL, IG1: 3.94 (0.80); IG2: 3.69(0.83); CG: 3.62(0.81) FU1, IG1: 3.87(0.83); IG2: 3.64(0.91)*; CG: 3.74(0.80) FU2, IG1: 4.08(1.04); IG2: 3.21(1.19)*; CG: NR
Cedraschi et al, 2004 (RCT), Switzerland [23]	Fibromyalgia n=164/ 129; mean 48.9(9.7) yo 93% females Pain duration (y) mean 8.9(5.9); Pain intensity (0-105 scale), mean 65.4(16.9) University clinic	6 wk/ FU1(PI) 6 wk/ FU2 6 mo IG, n=84: Multidisciplinary self-management programme incl. swimming, relaxation, exercises, ADL impact, and didactic information and discussion/ PT, OT, physician, and psychologist CG, n=80: WL (usual care allowed)	Fibromyalgia impact on daily activities, FIQ[e] Self-management incl. OT sessions aimed difficulties and solutions in ADL monitored through weekly diaries, individual activity planning, and adjusted activity pacing, to minimise	**Sleep quality,** Pott & Silverman questionnaire BL, IG: 2.2(1.4); CG: 2.1(1.3) FU1: NR FU2, IG: 2.6(1.3); CG: 2.1(1.5)

			fatigue and pain, and increase the activity level	
Jousset et al., 2004 (RCT), France [27]	Low back pain (100%) n=86/ 83; mean 52.0 (16.7) yo 32.6% females Pain duration, (y) mean NS; Pain intensity (0-10 scale), mean 4.8(2.2) Regional rehabilitation centers	5 wk/ FU1(PI) 5 wk/ FU2 6 mo IG, n=42: Multidisciplinary functional restoration program (FRP)/ PT, OT, Psychologist & Dietician CG, n=41: Active individual therapy (AIT) incl. standard functional training and exercise prescription/ PT	Pain interference with ADL, DPQ[f] Pain interference with work/leisure activity, DPQ[g] OT training for flexibility, endurance and coordination, weightlifting, and work simulation	**PA-level** (participation in sports/ leisure activities), diary BL: NR FU1: NR FU2, IG: 76.2% increase*; CG: 51.2% increase
Fontaine & Haaz, 2007 (pilot RCT), USA [24]	Fibromyalgia (100%) n=48/ 34; ≥18 yr, mean 50.2(9.1) yo 95.8% females Pain duration (y) mean 7.1(4.3); Pain intensity (0-10 scale), mean 5.7(5.6) University clinic	12 wk/ FU(PI) 12 wk IG, n=22/ 14: Lifestyle physical activity program (LPA): A CBT-based physical activity promotion program based on Active Living Every Day[g] incl. self-monitoring, goal setting, and problem-solving aimed integration of moderately intense PA in daily life/ NS CG, n=26/ 20: Fibromyalgia education (FME) incl. information on exercise and physical activity but no tailored recommendations/ NS	Fibromyalgia impact on daily activities, FIQ[e] Practicing brisk walking, gardening, mowing the lawn, using the stairs instead of the elevator of 10 to 30 min. bouts to match PA recommendations	**PA-level,** Pedometer (walking steps) BL, IG: n=2337(±427); CG: NR FU, IG: n=3970(±598), 69.8% increase**, 71% improvers; CG: NR, 25% improvers
Fontaine et al. 2010 (RCT) [20] & Fontaine et al.	Fibromyalgia (100%) n=84/ 73; ≥18 yr, mean 47.7(10.7) yo	12 wk/ FU1(PI) 12 wk/ FU2 6 mo/ FU3 12 mo IG, n=46/ 30 at FU2 and FU3: Lifestyle physical activity program (LPA): A CBT-	Fibromyalgia impact on daily activities, FIQ[e] Practicing brisk walking, gardening, mowing the	**BMI**, weight (kg) divided by height (m^2)

2011 (RCT), USA [21]	95.7% females Pain duration (y) mean 7.6(6.2); Pain intensity (0-100 scale), mean 56.5(25.3) University clinic	based physical activity promotion program based on Active Living Every Day[g] incl. self-monitoring, goal setting, and problem-solving aimed integration of moderate-intensity PA in daily life/ NS researchers CG, n=38/ 23 at FU2 and FU3: Fibromyalgia education (FME) incl. information, question and answer, and social support, with no tailored recommendations (minimal intervention)/ NS	lawn, using the stairs instead of the elevator of 10 to 30 min. bouts to match PA recommendations	BL, IG: 31.4(8.4); CG: 29.8(6.2) FU1, IG: 31.0(9.0); CG: 29.9(6.2) FU2: NR FU3: NR **PA-level,** Pedometer (walking steps) BL, IG: n=4788(±2135); CG: NR FU1, IG: n=5837(±1770), 54.0% increased PA**; CG: NR/ NS FU2, IG: n=4496(±3228); CG: n=4142(±2286) FU3, IG: n=4589(±3190); CG: n=3897(±2460)
Ruehlman et al., 2012 (RCT), USA [31]	Migraine/headaches, 65.5%; Back injury/ disease, 60.5%; Tension headaches, 41%; OA, 31%; Facial/ jaw pain, 29%; Premenstrual pain, 28%; Cluster headache, 16%; Pelvic injury/ disease, 12%; RA, 7%; Cancer, 1% (≤ 3 pain diagnoses per participant)	7 wk/ FU1(PI) 7 wk/ FU2 14 wk IG, n=162: Online self-management program incl. CBT, interpersonal, and self-management approaches/ Psychologists CG, n=143: WL, NS usual care (treatment regimens may vary)	Pain interference with daily life, e.g., recreation activity, chores, work, and self-care, PCP-EA[h] Off-line activities aimed practicing new skills, e.g., exercise and relaxation, or/and implementation of	**Stress,** DASS[i] BL, IG: 8.84(5.53); CG: 7.87(5.44) FU1, IG: 7.30(5.01); CG: 7.67(6.46)

	n=305/ 280; ≥18 yr, mean 45 yo Pain duration (y) > 2 (89,5%); Pain intensity (0-5 scale), mean NS, min. 1.65(1.58) - max.3.94 (1.39) 64% females Online		personal goal-directed behavior	FU2, IG: 7.36(5.21)**; CG: 7.64(5.63)
Cederbom et al., 2014 (RCT, feasibility trial), Sweden [29]	Musculoskeletal pain (100%) n=23/ 16; ≥65 yr, mean 84 yo 100% females Pain duration (y) mean 27.5(21.5); Pain intensity (0-100 scale), mean 48.3(25.7) Municipal primary health care service	12 wk/ FU1(PI) 12 wk/ FU2 3 mo IG: n=12 BL/ 10 at FU1 and 9 at FU2: Behavioral medicine intervention added physical therapy principles incl. analysis of individual physical and psychological characteristics, and social and physical environmental factors; environmental impact on the ability to perform everyday activities and difficulties in occupational performance; goal setting; practicing of goal behavior/ PT CG: n=11 BL/ 7 at FU1 and 7 at FU2: Brief PA advice/ PT	Pain-related disability, CPGQ[j] Monitoring (activity diary) and modification of duration and intensity of the everyday PA to match PA recommendations	**PA-level,** The Frändin-Grimby scale BL, IG: 2.4(0.51); CG: 2.4(0.52) FU1, IG: 2.7(0.48)*; CG: 2.6(0.54) FU2, IG: 2.6(0.53); CG: 2.6(0.54)
Ismael Martins et al., 2014 (RCT), Brazil [25]	Fibromyalgia (100%) n=27/ 27; ≥28≤67 yr, mean 42.5(9.8) yo 64% females Pain duration (y) mean 4.2(NS); Pain intensity (0-10 scale), mean 6.6(2.7)	12 wk/ FU1(PI) 12 wk IG, n=12: Weekly Interdisciplinary Program (WIP) incl. educational activities, physical therapy, stretching, ergonomics and postural orientations combined with CBT-based strategies and approaches to psychosocial and occupational features/ Physician, OT, PT, psychologist, and social worker	Fibromyalgia impact on daily activities, FIQ[e] Integration of a home exercise program, ADL ergonomics, and postural guidance	**Sleep quality,** PSP[k] (Overnight sleep quality item) BL, IG: 72.2(8.6); CG: 91.2(6.4) FU, IG: 92.3(8.4); CG: 98.3(7.4)

	University clinic	CG, n=15: Consultation in pain clinic with walking advise/ NS		
Bourgault et al., 2015 (RCT), Canada [26]	Fibromyalgia (100%) n=56/ 56; ≥18 yr, mean 48 yo 92.9% females Pain duration (y) mean 13.8(9.9) Pain intensity (0-10 scale), mean 6.5(1.9) University clinic	12 wk/ FU1(PI) 12 wk/ FU2 3 mo (IG & CG)/ FU3 6 mo/ FU4 12 mo IG, n=28: Multidisciplinary self-management program PASSAGE[m], incl. tailored exercise therapy and educational/psychological tools for self-management of fibromyalgia/ NS CG, n=28: WL, NS usual care (non-pharmacological/ pharmacological regimens may vary)	Fibromyalgia impact on daily activities, FIQ[e] Pain interference with daily activities, BPI[n] Client-entered approach incl. a patient contract with three personal outcome goals to be met, minimally acceptable changes expected, and an agreement on adherence to the program	**Sleep quality,** CPSI[l] (the overall sleep quality score) BL, IG: 2.75(1.82); CG: 2.89 (2.59) FU1, IG: 4.09(2.04); CG: 3.72(2.30) FU2, IG: 4.33(2.18); CG: 3.57(2.37) FU3, IG:; CG: NR FU4, IG:; CG: NR
Cederbom et al., 2019 (RCT), Norway [30]	Chronic musculoskeletal pain – Orthopedic diseases (88%); Rheumatoid arthritis (21%); Neurological diseases (20%); Diabetes (14%); Cancer (10%), mean 3.7 reported diagnoses per participant) n=105/ 105; ≥75 yr, mean 85 yo 87.6% females Pain duration (y) mean 22.4(22.5)	12 wk/ FU1(PI) 12 wk/ FU2 3 mo IG, n=52: Behavioral medicine intervention (BMPI) based on integrated behavioral medicine and physical therapy principles incl. tailored goal setting, tailored exercise, and progress monitoring/ PT CG, n=53: PA recommendations and advice/ PT	Pain interference with daily activities, BPI[n] Individual exercise doses adjusted to personal goals, e.g., walking indoors/ outdoors, safe stairs climbing, or holding balance)	**PA-level,** The Frändin-Grimby scale BL, IG: 2.4(0.7); CG: 2.4(0.8) FU1, IG: 2.7(0.8); CG: 2.5(0.8) FU2, IG: 2.6(0.7); CG: 2.5(0.9)

	Pain intensity (0-10 scale), mean 4.5(1.9) Municipal primary health care service			
Ariza-Mateos et al., 2020 (RCT), Spain [28]	Chronic pelvic pain (100%) n=44/ 44; ≥18≤65 yr; mean 44(9) yo 100% females Pain duration (y) mean 6.6(4.9) Pain intensity (0-10 scale), mean 5.9(1.9) University clinic	6 wk/ FU(PI) 6 wk IG, n=22: Client-centered approach to workload-capacity balance incl. didactic information, clarification of time consumption, energy expenditure, attention focus, personal goals, goal work, and evaluation/ PT CG, n=22: An information leaflet about chronic pelvic pain, physical activity, fear of movement, false beliefs, active lifestyle, and behavioral advice/ PT	Occupational performance and satisfaction, COPM[o] Client-centered approach incl. determination of painful activities in self-care, productivity, and leisure, and personally adjusted activity exposure plan	**PA-level**, IPAQ[p] PA: BL, IG: 1563.65(918.15); CG: 1220.85(1040.32) FU*, IG: 2248.53(1145.21); CG: 1150.55(573.54)

Note. BL = baseline; BMI = Body Mass Index; CBT = cognitive behavioral therapy; CG = control group; diff. = difference; FU = follow-up; HRQoL = Health-Related Quality of Life; IG = intervention group; incl. = inclusive; min. = minimal; MET = Metabolic Equivalent of Task; mo = month(-s); n = number; OA = Osteoarthritis; NR = not reported; NS = not-specified; OT = occupational therapist; p = p-value; PA = physical activity; PI = postintervention; PT = physical therapist; RA = Rheumatoid arthritis; RCT = randomized controlled trial; wk = week(-s); WL = waiting list; y=year(-s); yo = years old

* $p<0.05$; ** $p<0.001$

[a] Author (-s), study design & country of origin; [b] Body composition, PA-level, alcohol consumption, smoking, sleep quality, and stress; [c] CSQ, Coping Strategy Questionnaire; [d] KSQ, Karolinska Sleep Questionnaire; [e] FIQ, Fibromyalgia Impact Questionnaire; [f] DPQ, Dallas Pain Questionnaire; [g] Described in: Blair SN. Active Living Every Day. Human Kinetics, Champaign, IL, 2001; [h] PCP-EA, Profile of Chronic Pain Extended Assessment; [i] DASS, Depression Anxiety and Stress Scales; [j] CPGQ, Chronic Pain Grade Questionnaire; [k] PSP, Post-Sleep Protocol; [l] CPSI, Chronic Pain Sleep Inventory; [m] Described in: Barcellos de Souza J, Charest J, Marchand S. École interactionnelle de fibromyalgie: description et évaluation. Douleur et analgésie. 2007; 20: 213–218.; [n] BPI, Brief Pain Inventory; [o] COPM, The Canadian Occupational Performance Measure; [p] IPAQ, The International Physical Activity Questionnaire (see Appendix

3.1. Characteristics of the included trials

The twelve articles of the eleven RCTs included a total of 995 adults aged ≥ 18 years (Table 1). One RCT was reported in two different papers [20, 21]. Chronic pain diagnoses represented in the trials were fibromyalgia (n=6) [20-26], low back pain (n=1) [27], pelvic pain (n=1) [28], unspecified musculoskeletal pain (n=2) [29, 30] and mixed pain (n=2) [30, 31]. The included trials reported on pain intensity and duration when describing their study samples, but none attempted any pain phenotyping [32].

We observed diversity in intervention approaches, contents, duration, and follow-up time. Although the experimental content of the trials can generally be characterised as client-centred and pain coping-oriented, they used different treatment strategies such as education [22], behavioural approach [20-22, 24, 26, 29, 30], functional rehabilitation [27] and comprehensive self-management training including didactic information/ education, behaviour change and exercise [23, 25, 28]. One RCT compared two treatment strategies and a control group [22]. The comparators were treatment regimens not including occupational engagement such as a brief physiotherapy consultation and advice or exercise prescription [25, 27-30], information/ education with no tailored approach [20, 21, 24], waiting list with usual care allowing for variable regimens [23, 26, 31], or a waiting list with no treatment [22]. No other treatments were reported for any of the intervention groups in the included trials. The intervention descriptions provided in the trials allowed for identification of the occupational engagement component and distinguishing it from any alternative. The assessment tools assisting the identification of the occupational engagement component in the included trials can be found in Appendix 4.

The median duration of the interventions in the sample was 12 weeks (min. 5; max. 12) and six months for long-term follow-up (min. 0; max. 12). Three trials had no other follow-up than that postintervention [24, 25, 28]. One RCT had two follow-up assessments, 6

and 12 months after the ended intervention [21]. Four interventions involved multidisciplinary teams of providers (n≥2), e.g., physicians, psychologists, physical therapists, occupational therapists, dieticians, or social workers [22, 23, 25, 27]. Four trials had intervention providers representing a single health profession such as psychologists [31] or physical therapists [28-30]. In three trials, the providers remained unspecified or described as researchers [20, 21, 24, 26]. One of the interventions was delivered online [31].

The following outcomes were assessed in the included trials: physical activity level [20, 21, 24, 27, 29, 30], sleep quality [22, 23, 25, 26], stress [31], and BMI [20, 21]. None of the RCTs assessed outcomes such as waist circumference, alcohol consumption, or smoking. One RCT assessed multiple (≥2) lifestyle factors of interest in this review [20, 21]. Six RCTs targeted lifestyle explicitly [20, 21, 24, 25, 28, 31].

3.2. Risk of bias

The overall risk of bias was evaluated as low in 9.1% of the trials (n=1), uncertain in 54.5% (n=6), and high in 36.4% (n=4). The results of the critical appraisal of the methodological quality assessment and the weighted summary plot of the methodological quality assessment with the RoB-2 tool are presented in Appendix 5 and 6, respectively.

Randomisation was explicated in all trials but insufficiently reported in four [22, 24, 25, 31]. The same happened with the reports on allocation concealment in six trials [20-22, 24, 25, 27, 31]. Neither of the included RCTs blinded the participants and intervention providers, which is also difficult when evaluating behavioural interventions. The participants assessed self-reported data in 90.9% of the included trials (n=10), not allowing for blinding the assessors. Two trials used pedometers for walking step assessment [20, 21, 24], while Fontaine & Haaz (2007) used both assessment pedometers and self-reported data.

Six RCTs (54.5%) calculated the sample sizes necessary for their studies [20, 21, 24, 26, 28-30] and one of those failed to reach the sufficient sample size [29]. Three RCTs

(27.3%) performed statistical analyses of the data as treated [23, 26, 29] and not the intention-to-treat (ITT) analysis considered the gold standard for randomised controlled design allowing for an analysis according to randomisation. One of the included trials had no clear report on the type of analysis performed [25]

Two trials analysed participants' adherence to interventions [20, 21, 30] and one analysed the providers' adherence to the treatment protocol [26]. Five trials reported dropout rates with reasons [24, 27-30].

3.3. Effectiveness of chronic pain interventions including occupational engagement

We conducted a meta-analysis on the available data from post-intervention and long-term follow-up assessments of physical activity levels assessed in six trials and sleep quality assessed in four trials (Table 2). Of the two long-term follow-up assessments (at 6 and 12 months) in one of the trials reporting on physical activity level, only the latter was included in the meta-analysis as the most sustainable result [21].

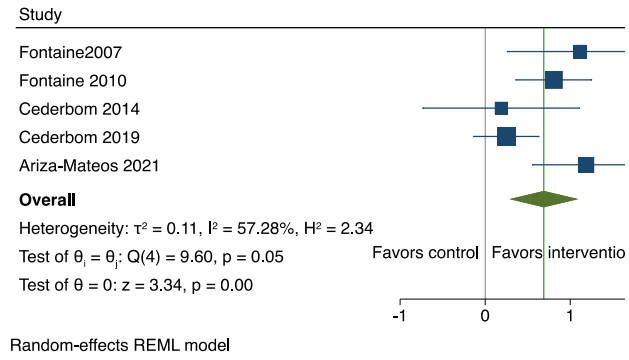
3.3.1. Physical activity level. In total, six trials reported on physical activity levels. Our meta-analysis was conducted on the effect estimates post intervention from five trials [20, 24, 28-30] and at the long-term follow-up from four trials [21, 27, 29, 30]. In all trials, the experimental treatment was compared to other treatments without the occupational engagement component. The effect estimates favoured intervention. The meta-analysis suggested that including occupational engagement may increase physical activity level compared to other treatments post-intervention 6-12-weeks from baseline (SMD = 0.69 [0.29; 1.09]), or at 3-12-months follow-up after completed intervention (SMD = 0.14 [-0.15; 0.44]). Although the substantial level of heterogeneity (I^2=57.28%) between the RCTs assessing physical activity postintervention could be further investigated in a meta-regression model, we decided against, since only a few trials were available for comparison, which limited the applicability of the method.

All single trials observed an increase in physical activity in the intervention group, while most detected its significant increase in the intervention group [20, 24, 27-29]. However, physical activity improvement reported postintervention in adults living with fibromyalgia [20] declined to nonsignificant levels at 6 and 12-months follow-up [21]. A similar decline was observed by Cederbom et al. [29].

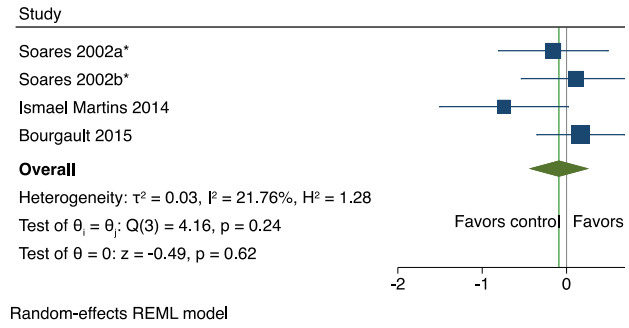
Table 2. Summary effect of interventions including occupational engagement compared to other or no intervention

Summary effect post-discharge

Physical activity level post-intervention, 6-12 weeks from baseline

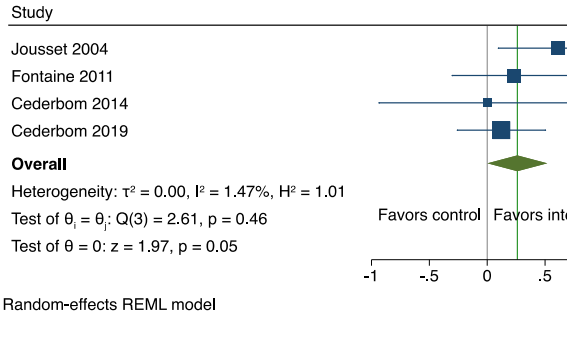


Sleep quality, 10-12 weeks from baseline

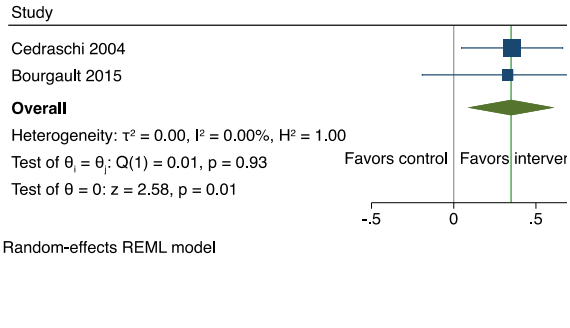


Summary effect at follow-up

Physical activity level at follow-up, 3-12 months after intervention



Sleep quality, 3-6 months after intervention



CI=confidence interval; I2=I-square heterogeneity statistic; IV=weighted mean difference; PA = physical activity; SD=standard deviation
* Refers the data from Table 1: Soares 2002a - intervention group 1; Soares 2002b - intervention group 2.

3.3.2. Sleep quality. In total, four trials investigated sleep quality in adults living with fibromyalgia using different treatment approaches [22, 23, 25, 26]. Deviating results from a significant or nonsignificant increase to a decrease in sleep quality were seen in three trials

after 10-12-weeks-long interventions including occupational engagement [22, 25, 26]. Moreover, Cedraschi et al. had no reports available for sleep quality postintervention [23]. The meta-analysis showed no difference in sleep quality at short term (SMD = -0.09 [-0.45; 0.27]; I^2=21.76%) between the treatment groups and controls.

Based on the data from two RCTs, the meta-analysis found a small effect (SMD = 0.35 [0.08; 0.61]) of multidisciplinary self-management including occupational engagement on sleep quality at 3-6 months follow-up compared to the waiting list receiving usual care with no occupational engagement component [23, 26]. However, the sleep evaluation in the RCT of Cedraschi et al. was rather an investigation of patient satisfaction with sleep after the treatment received and not on a sleep quality questionnaire like in other trials [23]. The study of Soares et al. was excluded from the meta-analysis due to no available long-term follow-up data on sleep quality in the control group. However, the authors reported on significant increase in the outcome in the behavioural intervention group [22].

3.3.3. Stress. The outcome was represented in only one RCT, thus not deemed eligible for meta-analysis [31]. This RCT compared an online self-management programme for mixed chronic pain diagnoses with a waiting list allowing for usual care and found a significant decrease in stress post-intervention and at 14-weeks follow-up.

3.3.4. BMI. BMI was only assessed in two articles reporting on one RCT and thus not eligible for meta-analysis [20, 21]. This RCT found no significant effect on BMI after a 12-weeks intervention implementing CBT-informed physical activity in daily life with fibromyalgia compared to fibromyalgia education. No long-term follow-up results (at 6 and 12 months) were reported.

3.4. Data synthesis

Examination of the overall evidence quality using the GRADE approach demonstrated its low to very low level (Table 3).

Most included trials had an uncertain or high overall risk of bias, with one trial that had an overall low risk [30]. Risk of bias was the main reason for downgrading the evidence level. Heterogeneity (inconsistency) was also present. Considering the few RCTs per outcome and the low overall evidence quality, we evaluated the total evidence certainty of the effectiveness of including occupational engagement in chronic pain interventions as low.

Table 3. Summary of Findings

Occupational engagement component included in chronic pain treatment of adults compared with other or no treatment				
Patient or population:	Adults with primary chronic pain			
Intervention:	Using occupational engagement			
Comparison:	No occupational engagement component			
Outcomes	**Comparator**	**Anticipated absolute effect (95% CI)**	**Number of participants (studies)**	**Quality of the evidence (GRADE) a**
(A) Physical activity level, SD units: two different instruments used - (a) 6-point ordinal scale; (b) pedometer-driven walking step count; and c) activity diary. Low scores mean lower physical activity level.	Other treatment (brief advise/ information leaflet/ standard physiotherapy/ fibromyalgia education).	At 6-12-weeks from baseline: SMD 0.69 higher (0.29 to 1.09 higher) g; (b) Observed significant increase in physical activity participation (walking steps) in the intervention group compared to controls.	298 (5)	⊕⊕○○ c d e f (Low)
		At 3-12-months after intervention: (a) SMD 0.26 higher (0.0 to 0.52 higher) g; (b) Observed significant increase in physical activity participation (n registered activities) in the intervention group compared to controls.	257 (4)	⊕⊕○○ c e f (Low)
(B) Sleep quality, SD units: four different instruments used - (a) 9-point ordinal scale*, high scores mean low quality of sleep; (b) 10-point ordinal scale, high scores mean high quality of sleep; (c) 0-5-item Likert scale, high scores mean high quality of sleep; and (d) 30-390-point interval scale, high scores mean high satisfaction with sleep quality/good quality of sleep.	Other treatment (consultation with walking advise) or no treatment (waiting list, usual care allowed).	At 10-12-weeks from baseline: SMD 0.09 lower(0.45 lower to 0.27 higher) h.	300 (4)	⊕⊕○○ c e f (Low)
		At 3-6-months after intervention: (a) SMD 0.35 higher (0.08 lower to 0.61 higher) h; (b) Observed significant increase in sleep quality after a behavioral intervention compared to an educational intervention and controls.	266 (3)	⊕⊕○○ c e f (Low)
(C) Stress level, 4-point ordinal scale used. Lower scores mean stress decrease.	Other treatment (waiting list with non-specified usual care, treatment regimens may vary).	At 14-weeks from baseline: mean 0.93 lower (standard error 0.30), p<0.00.	305 (1)	⊕○○○ c e (Very low)
(D) BMI, calculated from weight (kg) divided by height (m2).	Other treatment (Fibromyalgia education).	At 12-weeks after intervention: mean 1.1 higher (5.3 lower to 2.9 higher).	84 (1)	⊕○○○ b e (Very low)
Abbreviations: CI, confidence interval; d, day; MD, mean difference; n, number; SD, standard deviation; SMD, standardized mean difference				
** In Soares (2002), adjusted for direction*				
a Quality rated from 1 (very low quality) to 4 (high quality)				
GRADE Working Group grades of evidence				
High	We are very confident that the true effect lies close to that of the estimate of the effect.			
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different			
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.			
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect			
b Evidence limited by inconsistency				
c Evidence limited by imprecision				
d Evidence limited by heterogeneity				
e Evidence limited by small sample size				
f Evidence limited by risk of bias (suspicion of selective reporting bias)				
g Based on Hedges'g interpretation of effect sizes				

4. Discussion

We hypothesised that interventions including occupational engagement would improve lifestyle in people living with chronic pain and summarised the evidence on the effectiveness

of such interventions on the following lifestyle factors: physical activity, sleep, alcohol consumption, smoking, stress, and BMI. Although limited by a lack of eligible studies and low to very low-quality evidence, our study suggested that engagement in daily occupations included as a component in multidisciplinary chronic pain treatment may increase short-term physical activity and slightly increase long-term sleep quality.

4.1. Increase in physical activity level

The meta-analysis based on the six RCTs demonstrated an increase in physical activity after behavioural interventions for fibromyalgia and musculoskeletal pain (i.e., low back and pelvic pain) including occupational engagement compared to other treatments, e.g., fibromyalgia education and brief physiotherapy advise. While the beneficial effect mainly appeared post intervention, that declined at the long-term follow-up. Only a few trials were deemed eligible for inclusion in this review because of insufficient documentation of the occupational engagement component, inconsistent assessment of relevant lifestyle factors, or no control treatment as main reasons. Additionally, the exclusion of nonprimary pain diagnoses in this review let few trials be included in the meta-analysis. However, this review adds to the evidence on how occupational engagement in self-care, work, and leisure may help accumulate physical activity [33]. Facilitating physical activity through occupational engagement in activities such as gardening and household performed with moderate intensity did not increase pain levels [34] and were experienced as more pleasurable and motivating than formalised exercise [35]. Future investigations including more relevant studies may shed light on both the effect size and effect sustainability of interventions including occupational engagement for physical activity promotion.

The universal benefits of physical activity and its ability to give at least a modest effect with few adverse events are well-known [36]. Thus, future reviews with more high-quality trials might lead to a stronger effect estimate. Surprisingly, we found no eligible trials using

holistic mind-body techniques like yoga, Pilates, and tai chi, which anticipate value-based and self-determined participation [37] and are often used in physical activity trials [36]. Most of the occupational therapy treatment approaches [4, 5, 38, 39] could lead to more physical activity and inspire future interventions including occupational engagement. Occupational therapists may also learn from other fields of healthcare and adapt new relevant approaches in occupational therapy practice [40]. However, more physical activity through habitual daily activities implies careful planning and tailoring through, e.g., gradual exposure, energy conservation techniques, and assistive devices should be considered to reduce possible adverse effects [41, 42]. All in all, occupational therapy methods of facilitation physical activity may be useful for people living with chronic pain, but stronger evidence on this topic is needed.

4.2. Improvement in sleep quality

The small improvement found in long-term sleep quality up to 6 months after behavioural and educational interventions including occupational engagement should be interpreted carefully, because only two trials were included in the meta-analysis. The interventions in both trials represented the multidisciplinary self-management of fibromyalgia compared to the waiting list and applied a bio-psychosocial approach which seems relevant in managing the complexity of pain and sleep association [43]. The treatment benefits were small and appeared only in the longer term.

Sleep is linked to occupational engagement, because presleep cognitive arousal strongly predicts sleep quality and better sleep improves occupational performance the next day [44]. However, this review could not tell if this causality also worked vice versa, i.e., that improving occupational engagement during the day would help to improve sleep. Further trials investigating how occupational engagement influences sleep in people living with chronic pain are needed.

4.3. Decrease in stress

One RCT reported a significant stress reduction after a web-based intervention that targeted various chronic pain conditions through activity pacing, exercise, relaxation, goal setting, and implementation of goal-directed behaviour in a population with mixed pain diagnoses compared to the waiting list. However, the quality of the evidence was considered very low and did not provide sufficient evidence for a firm conclusion. Since stress and pain are linked together due to neural mechanisms in the limbic system [45], we anticipate that any intervention enhancing adaptation to daily life with chronic pain can reduce stress to a certain degree. This review urges further research on the topic.

4.4. Improvement in BMI

One trial reported no significant change in BMI after a 12-weeks-long CBT-based physical activity promotion programme for fibromyalgia compared with fibromyalgia education. The trial demonstrated very low-quality evidence, not allowing for firm conclusions.

Weight loss interventions are time-consuming and require ongoing monitoring and maintenance activities [46]. In a relatively brief intervention that does not have BMI as its primary target, achieving a significant weight loss in the participants is unlikely to happen.

We noticed during the literature search process that in trials on chronic pain, BMI was often used for baseline comparison between the groups, while it was not used as an outcome. However, previous research has observed higher frequencies of overweight and obesity in the chronic pain population compared to the general population [47], making the outcome relevant to evaluate in chronic pain trials. That could also help identify approaches that may prevent overweight and obesity in people living with chronic pain, which would promote their health.

4.5. Limitations

Despite the comprehensive literature search process, we cannot exclude that we missed relevant trials due to focusing only on primary chronic pain diagnoses. People living with diagnoses excluded from this review, e.g., osteoarthritis, constitute an essential part of the chronic pain population and share the need for lifestyle improvement [48, 49]. Inclusion of other chronic pain populations might have changed our results, e.g., the effect estimates regarding physical activity level. We anticipate achieving a larger effect size if our meta-analysis included no treatment as a comparator. Further investigation of occupational engagement included in interventions for a broader scope of chronic pain diagnoses would be relevant.

The studies identified in this review needed to have sufficiently explicated study characteristics to allow for their eligibility evaluation, which may also have limited the evidence available for the analysis. Most included RCTs had low methodological quality, and the overall evidence certainty was low to very low. Additionally, none of the included studies attempted chronic pain phenotyping as recommended by The mission of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), which would help the interpretation of the differentiated treatment effects and enhance the clinical relevance of the results [32]. The limitations call for a careful interpretation of the results of this review.

4.6. Implications for practice and research

(i) Future trials addressing modifiable lifestyle factors could consider including an occupational engagement component to impact health and well-being;

(ii) In-detail descriptions of the occupational engagement component in chronic pain interventions will improve research transparency;

(iii) Monitoring of lifestyle-related outcomes could be relevant in chronic pain trials, not only at baseline but also at long-term follow-up, to support a comprehensive evaluation of the impact on health in the chronic pain population;

(iv) Further research is needed to determine the effectiveness of including occupational engagement in interventions, e.g., targeting physical activity level, sleep quality, stress, and excessive body weight in people living with various chronic pain diagnoses and phenotypes.

5. Conclusions

This systematic review suggested that occupational engagement in daily activities included as a component in multidisciplinary interventions for chronic pain treatment may increase physical activity in the short term and sleep quality in the long term. However, the overall evidence on the effectiveness of chronic pain interventions including occupational engagement on physical activity level, sleep quality, stress, and BMI in adults with primary chronic pain was low, thereby not allowing for firm conclusions. The impact on smoking and alcohol consumption remained unrevealed. Evidence on the effectiveness of including occupational engagement in chronic pain treatment, alone or in combination with other approaches, is still scarce and demands further rigorously designed investigations.

Author's declaration of authorship contribution

All authors contributed to the manuscript according to the author roles and responsibilities defined by the International Committee of Medical Journal Editors (ICMJE) (http://www.icmje.org/).

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Conflict of interests

The authors have no conflict of interest to declare.

Data availability statement

The materials supporting the data extraction, analysis, synthesis, and conclusions in this review can be obtained by contacting the corresponding author.

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Appendix 11

Study II publication inclusive appendices

Observational Studies

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Associations of health-related quality of life with sociodemographic characteristics, health, pain, and lifestyle factors, and motivation for changing lifestyle in adults living with chronic pain: a cross-sectional exploratory study

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Abstract

Objectives: We investigated the associations between health-related quality of life (HRQoL) and health, pain and lifestyle factors, as well as motivation for lifestyle changes, in adults living with chronic pain referred to a Danish pain centre.

Methods: A total of 144 outpatients completed a questionnaire on HRQoL (EQ-5D-5L), health, pain, lifestyle factors (Body Mass Index [BMI], physical activity, smoking, alcohol, physical fitness, eating, sleep and stress) and motivation for lifestyle changes. We used multiple linear regression analyses to assess associations between HRQoL and the independent variables.

Results: The participants (age mean 50 years, 81% females) had ≥2 body pain sites (93%), BMI≥25 (64%), sedentary lifestyle (43%) and multiple (n≥2) elevated metabolic risk factors (58%). Most considered lifestyle important for HRQoL (72%) and expressed moderate to very high motivation for changing lifestyle (92%). Poorer HRQoL in the study population was significantly associated with higher pain intensity in the most painful body site (β=−0.316, p=0.001) and very poor sleep quality (β=−0.410, p=0.024). Serious-to-extreme problems in usual activities were associated with significantly poorer health (β=−0.328, p=0.030).

Conclusions: Adults living with chronic pain participating in this survey had significantly lower self-evaluated HRQoL than the general population. Lower HRQoL was significantly associated with greater pain intensity and poor sleep quality. Serious-to-extreme problems in usual activities, such as work, study, housework, family and leisure, were associated with poorer self-evaluated health. We observed high frequencies of overweight, obesity, sedentary lifestyle, pain in multiple body sites and multiple lifestyle-related risk factors in the study population. Most participants felt motivated for changing lifestyle. Further interventions addressing pain alleviation, sleep quality, prevention of problems in usual activities and promotion of healthy lifestyle, e.g. physical activity and healthy eating, are needed to estimate the effect of a lifestyle-oriented

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approach on health and quality of life in people living with chronic pain. The results of this study will inform the research project reg. SJ-703, the Danish the Research Ethics Committee for Region Zealand, Denmark.

Keywords: activities of daily living; health behaviour; health-related quality of life; healthy lifestyle; pain management.

Introduction

Chronic pain is a severe health challenge with multiple negative consequences for the individual, the health care system and society [1]. Over the past decades, it has become evident that non-pharmacological treatment options are effective and beneficial when treating chronic pain because of their mild or none side effects, compared to pain medication use [2, 3]. Recent evidence highlights the need for comprehensive non-pharmacological interventions aimed at multiple lifestyle factors to prevent chronicity in people living with chronic pain [4]. The lifestyle factors, such as physical activity, Body Mass Index (BMI), tobacco and alcohol consumption, physical fitness, healthy eating, sleep quality and stress, are considered modifiable and relevant for lifestyle management of chronic pain [5]. Interventions that target lifestyle through physical activity and exercise can lower the meta-inflammatory effects of chronic pain, reduce pain and improve function and quality of life [6–9]. However, healthcare interventions can also approach lifestyle through targeting everyday human activities and interpret lifestyle as the way of living based on habitual occupational choices and routines, e.g. regarding eating, sleeping, or being physically active [10]. Evidence suggests that occupational therapy interventions targeting participation in daily activities related to self-care, work and leisure while taking healthy lifestyle considerations into account can improve overall health and well-being among people living with chronic pain [11–13]. Considering lifestyle from an occupational therapy perspective may broaden the focus in lifestyle interventions from improving metabolic health to overall well-being and quality of life. Health-related quality of life (HRQoL) has been considered a relevant effect measure in chronic pain interventions because of its ability to capture the overall improvement in health and well-being [14], despite possible fluctuations in the self-perceived HRQoL in specific life areas. We hypothesised that occupational therapy lifestyle intervention as a treatment modality focussing on everyday occupations and lifestyle to improve HRQoL might be useful in multidisciplinary chronic pain treatment. However, it would be relevant to clarify the interrelations between HRQoL in various everyday life areas and health, pain and lifestyle factors and motivation for changing lifestyle to adapt such an intervention to a particular chronic pain cohort. Since gender differences also seem to influence participation and response to pharmacological and non-pharmacological chronic pain interventions such as lifestyle interventions [15, 16], identifying possible gender effects on motivation for participation in a lifestyle intervention could improve treatment adherence, responsiveness and tailoring. To inform the development of a lifestyle occupational therapy intervention for adults living with chronic pain referred to a Danish pain centre, we wanted to investigate how HRQoL in the population is associated with sociodemographic characteristics, health, pain and lifestyle factors, as well as how motivated the population is for changing lifestyle.

Methods

Study design

We conducted a cross-sectional exploratory study among adults with chronic pain reported according to the STROBE extension for cross-sectional studies [17, 18].

Setting

The Multidisciplinary Pain Center (MPC) at Naestved Hospital (Region Zealand, Denmark) is a specialised regional pain centre that consults around 1,000 outpatients with complex chronic pain conditions annually and provides multidisciplinary pain treatment delivered by physicians, nurses, psychologists, physiotherapists and a social worker.

Participants

A convenience sample of 144 outpatients referred to the MPC, who were either in-treatment or recently completed the treatment at the time of the investigation, was contacted by e-mail between December 2018 and March 2019. All participants were aged ≥18 years, had ≥3 months of pain experience before the investigation and had complex health challenges that no longer could be covered by general practice, demanding a specialised multidisciplinary intervention.

Data collection

An online questionnaire of 101 questions was developed for the study, using SurveyXact by Ramboell (Aarhus, Denmark) software. The questionnaire was pilot tested for possible inconsistencies and misinterpretations among a group of 11 outpatients and health professionals and adjusted in terms of the ease of completing the questionnaire. The questionnaire was primarily available for completion

online. Two rounds of online distributions were planned and conducted. The procedure was extended with the third round of reminders to increase the response rate. Three reminders were sent by e-mail at 10 days intervals to increase the response rate. Additionally, the outpatients having an appointment at the MPC were asked if they wished to participate. The participants could complete the questionnaire either on paper or iPad, depending on their preferences. Practical support was available from trained instructors (graduated occupational therapists), both in-person in the waiting room at the MPC, by phone or by e-mail.

Variables

Sociodemographics: We assessed the highest educational level reached (according to the Danish Educational Nomenclature [19]) and the employment status (classified according to the Danish Health Authority's National Health Survey 2017 [20]) of the participants. We calculated gender and age from the civil registration number containing the participants' birth date and gender identification.

HRQoL: The primary outcome of interest for this study was HRQoL in mobility, self-care, usual activities (in work, study, housework, family and leisure), pain/discomfort and anxiety/depression assessed by the EQ-5D-5L, EuroQol (hereafter, EQ-5D). HRQoL was measured on a five-point categorical scale: 1='no problems', 2='slight problems', 3='moderate problems', 4='severe problems' and 5='extreme problems' (EQ-5D values) [21, 22]. EQ-5D is a standardised instrument for the assessment of current self-rated HRQoL [23]. We obtained the EQ-5D survey form in Danish (EuroQol; Registration ID: 28126). For regression analyses, we calculated a cumulative utility score (EQ-5D Index) with the help of the Danish EQ-5D valuation set (Crosswalk DK Value set) applied to the EQ-5D values [24]. The EQ-5D Index ranges from – 0.594 to 1 and considers all states below zero being 'worse than death', while 'one' expresses 'perfect health' [25].

Health status: HRQoL-related health perceived on the assessment day and measured on a visual analogue scale (EQ-5D, EQ-VAS) from 0='the worst health you can imagine' to 100='the best health you can imagine' was the secondary outcome of interest for this study [21, 22].

Pain: Pain sensation was registered on a body chart (see Appendix A), representing 45 anatomic regions in anterior and posterior body positions to quantify pain spreading as an indicator for pain sensitivity [26]. The participants marked all painful body sites during the last week and then the most painful body site during the same period. If the participants marked more than one body site as the most painful, these results were not included in the analysis. We used the valid and reliable 11-point NRS-scale ranging from 0='no pain' to 10='worst pain imaginable' to evaluate pain intensity for the most painful body site [27]. Current medication use for pain relief (categorised as yes/no), including medication type specification for the consumption of both non-prescription analgesics (e.g. paracetamol) and opioids (e.g. morphine), were registered. Pain relief medication regimen was registered as yes/no.

Lifestyle factors: Variables physical activity, BMI, smoking, alcohol consumption, physical fitness, healthy eating, sleep quality and stress were included to capture the self-reported lifestyle status of the participants and identify the lifestyle factors that needed attention.

Physical activity: Average weekly amount of time in hours and minutes used at moderate and vigorous physical activity was reported according to the 2019 physical activity advice for adults to determine the risk of a sedentary lifestyle [20]. The participants were asked to report all physical activity related to leisure time and transport varying more than 10 min at a time. Increased heart rate and intensive breathing defined moderate physical activity, while vigorous physical activity demanded also sweating and meantime difficulty in leading a conversation.

BMI: BMI for each participant was calculated by dividing weight in kilograms by the square of the height in metres, with the threshold of BMI≥25 for overweight and BMI≥30 for obesity, to evaluate the overweight and obesity bound health risks [28]. To calculate BMI, we used self-reported body weight and height, considered valid measures in males and females across various social groups [29].

Smoking and alcohol: The participants reported smoking cigarettes and alcohol drinking status as yes/no, supported by reports on an average weekly number of cigarettes and alcohol consumption in standard units, e.g. 330 mL (beer), 120 mL (wine) and 40 mL (liquor) [30]. Other types of smoking other than cigarettes were not included.

Physical fitness, healthy eating, sleep quality and stress: The participants were asked to use a five-items categorical scale inspired by the Danish Health Authority's National Health Survey 2017 [5, 20] to evaluate each lifestyle factor last month. The categorical scale included items 'very good', 'good', 'neither good nor poor', 'poor' and 'very poor' for physical fitness and sleep quality. The same scaling principle guided the participants in evaluating their eating from 'very healthy' to 'very unhealthy' and stress from 'very low' to 'very high'. All the scales were provided with an additional category ('do not know') for indecisive responses. To keep the assessment load as low as possible, we decided not to ask for a further in-detail evaluation.

Motivation: The participants were asked how motivated they were for working with lifestyle changes during their chronic pain treatment using a five-items categorical scale developed for the study, choosing correct response among the following, either 'very high', 'high', 'moderate', 'low', 'very low' or 'do not know' (for indecisive responses).

Analysis

We conducted the descriptive statistical analysis, estimating means and standard deviations (SD) for continuous variables and frequency distributions for categorical variables. We described and compared the mean of the EQ-5D Index and the proportions of specific HRQoL-related problems in the participants with the Danish normative population means [31] using a two-sample t-test.

We applied the following rules to the tests of the association between HRQoL and health, pain and lifestyle factors, as well as motivation for changing lifestyle: a) For all categorical variables, categories with observations n<5 were collapsed with the next category, e.g. extreme and severe levels; b) 'Do not know'-answers were

recoded as indecisive answers to the middle position on the five-item scales ('neither good/nor poor') and included in the analysis.

We included all the independent variables in a multiple linear regression model because of their sufficient clinical relevance for HRQoL in people living with chronic pain and practical relevance for the research objectives of this study [32]. In the analysis, dichotomised EQ-VAS score (VAS 0–50/51–100) was used for 'poor' or 'good' health status (independent variable, binary). All the regression models contained covariates gender (male-female) and age (continuous). Finally, we explored possible significant associations between the specific EQ-5D domain scores, i.e. HRQoL-related problems in the particular life areas (categorical) and health (EQ-VAS as the dependent variable, continuous) using multiple linear regression analysis. We tested the assumptions underpinning multiple linear regression analysis visually by scatterplots that showed a linear relationship between HRQoL and the independent variables, and Q–Q plots, and numerically by Shapiro–Wilk W test that showed normal distribution of the residuals. Inspection of Variance Inflation Factor (VIF) values for the independent variables was conducted to check their multicollinearity. The residuals' variance homogeneity (homoscedasticity) was inspected by plotting the residuals vs. fitted (predicted) values. We reported the multiple linear regression analysis results as poorer or better health, based on the beta (β) coefficients.

We analysed the association of motivation (a binary variable 'very highly to highly motivated' or 'other', e.g. 'moderately motivated' to 'very low motivated' or 'no opinion') with gender and age (grouped) using a logistic regression model. We inspected the logistic regression model using post-estimation tools, such as calculating predicted residuals, estimating predicted margins and the Pearson $\chi 2$ test for goodness of fit. The logistic regression analysis results were reported in odds ratios as predicted difference in motivation level, accounted for gender and age.

We evaluated statistical significance at the 95%-confidence level (95% CI), $p<0.05$, for all the tests. We used Stata/IC 16.0 (StataCorp, College Station, TX, USA) for the data analysis.

Results

Descriptive analysis

Sociodemographic characteristics and pain experience

Of the 289 outpatients approached, 144 reports were obtained (response rate 50%). Some survey responses were incomplete (n=32, 22%), but we used the available data from those in the analyses. We experienced partial missingness as missing completely at random (MCAR), with no linkage to sociodemographics or other characteristics. The responder-nonresponder analysis revealed no differences in age (mean 50; SD 13) and a lower frequency of women (70%) among the nonresponders compared to the responders (81%), see Table 1. About 30% of the participants had primary or secondary school as their highest level of education. Although 86% were of the working-age (18–64 years), only 24% of the population

Table 1: Sociodemographic and pain-related characteristics of the participants.

Variable (sample size, n)[a]	Value (mean [SD]; frequency [range])
Females	
In responders (n=144)	117 (81%)
In nonresponders (n=145)	101 (70%)
Age, years	
In responders (n=144)	50 (13; 19–81)
In nonresponders (n=145)	50 (13; 26–94)
Age groups, years old (n=144)	
18–24	3 (2%)
25–34	20 (14%)
35–44	22 (15%)
45–54	50 (35%)
55–64	29 (20%)
65–74	17 (12%)
≥75	3 (2%)
Highest achieved education level (n=139)[b]	
Primary and lower secondary school	32 (23%)
Secondary school	10 (7%)
Vocational education	34 (24%)
Short-cycle higher education	28 (20%)
Medium-cycle higher education	30 (22%)
Long cycle higher education	5 (4%)
Employment status (n=139)	
Employed[c]	33 (24%)
Unemployed[d]	59 (43%)
On disability pension	20 (14%)
Retired	21 (15%)
Students/trainees	6 (4%)
Body pain sites (n=126)	
0	3 (2%)
1	6 (5%)
2	21 (17%)
3	3 (2%)
4	9 (7%)
5	7 (6%)
≥6	77 (61%)
Body pain spreading, % of the body (n=126)	
Up to 25	77 (61%)
25–50	28 (22%)
50–75	12 (10%)
Over 75	9 (7%)
Body pain location[e] (n=126)	
Low back	65 (52%)
Lower spine	44 (35%)
Thoracic spine	32 (25%)
Shoulders/upper arms (front/back)	28 (22%)
Head (front/back)	27 (21%)
Knees (front/back)	27 (21%)
Feet (dorsal/plantar)	27 (21%)
Abdomen	26 (21%)
Back	26 (21%)
Hands (dorsal/palmar)	25 (20%)
Neck	19 (15%)
Chest	13 (10%)
Elbows/forearms (front/back)	10 (8%)
Thighs/lower legs (front/back)	8 (6%)

Table 1: (continued)

Variable (sample size, n)[a]	Value (mean [SD]; frequency [range])
Major body pain sites (n=125)	
Low back	34 (27%)
Knees (front/back)	12 (10%)
Neck	11 (9%)
Feet (dorsal/plantar)	10 (8%)
Shoulders/upper arms (front/back)	9 (7%)
Thighs/lower legs (front/back)	8 (6%)
Head (front/back)	7 (6%)
Abdomen	7 (6%)
Thoracic spine	7 (6%)
Lower spine	7 (6%)
Hands (dorsal/palmar)	6 (5%)
Back	4 (3%)
Elbows/forearms (front/back)	2 (2%)
Chest	1 (1%)
Pain intensity in the most painful body site[f] (n=122)	8 (2; 3–10)
Taking opioids for pain relief[g] (n=138)	70 (51%)

[a]The total n of the reports in each question category is provided. [b]The categories refer to the Danish Educational Nomenclature [14]. [c]Employee or self-employed (full or part-time). [d]At-home staying and on sick leave. [e]The sum of the frequencies does not give 100%, one participant may have had more than one body pain site. [f]Pain intensity in most painful body site on 0–10 NRS-scale within the last month. [g]As a regimen or pro necessitate. SD, standard deviation.

were associated with the labour market and wholly or partly self-supported economically.

The vast majority (90%) of the participants had multiple body pain sites (≥2). More than half of the participants took opioids for pain relief, such as Morphine, Tramadol or similar, either as regimen or pro necessitate. The most common body pain sites were low back (52%), lower spine (35%) and thoracic spine (25%). The low back acted as the most painful body site in 27% of the participants.

Lifestyle factors and motivation for changing lifestyle

Sixty-four percent of the participants were overweight, obese or severely obese (Table 2). Forty-seven percent were current smokers, while none had a high-risk alcohol consumption and 73% reported no alcohol consumption at all. Forty-three percentof the participants did not reach the World Health Organisation's recommended minimum of 150 min of moderate physical activity per week for

Table 2: HRQoL, health and lifestyle in the participants.

Variable (sample size, n)[a]	Value (mean [SD]; frequency [range])
BMI (n=113)	
Underweight (BMI<18.5)	4 (4%)
Normal weight (BMI≥18.5 <25)	36 (32%)
Overweight (BMI≥25 <30)	25 (22%)
Obese (BMI≥30 <40)	42 (37%)
Severely obese (BMI≥40)	6 (5%)
Physical activity weekly, minutes (n=113)	
0	20 (18%)
<150	28 (25%)
≥150 <300 (min. recommended)[b]	21 (18%)
≥300 <600	26 (23%)
≥600	18 (16%)
Smoking (n=113)	47 (42%)
Alcohol consumption[c] (n=113)	
None	82 (73%)
Low risk[d]	30 (26%)
Moderate risk	1 (1%)
Physical fitness (n=113)	
Very good	1 (1%)
Good	9 (8%)
Neither good/nor poor	36 (32%)
Poor	36 (32%)
Very poor	30 (26%)
Don't know	1 (1%)
Eating habits (n=113)	
Very healthy	3 (3%)
Healthy	31 (27%)
Neither healthy nor unhealthy	63 (56%)
Unhealthy	11 (10%)
Very unhealthy	3 (3%)
Don't know	2 (1%)
Stress (n=113)	
Very low	10 (9%)
Low	20 (18%)
Neither low nor high	46 (40%)
High	20 (18%)
Very high	11 (10%)
Don't know	6 (5%)
Sleep (n=113)	
Very good	2 (2%)
Good	6 (5%)
Neither good/nor poor	37 (33%)
Poor	36 (32%)
Very poor	32 (28%)
Presense of multiple metabolic risks[e] (n=113)	66 (58%)
Importance of lifestyle for quality of life (n=112)	
Very important	37 (33%)
Important	44 (39%)
Neither/nor	22 (20%)
Slightly important	1 (1%)
Very slightly important	1 (1%)
Don't know	7 (6%)

Table 2: (continued)

Variable (sample size, n)[a]	Value (mean [SD]; frequency [range])
Motivation for changing lifestyle[f] (n=112)	
Very highly motivated	29 (26%)
Highly motivated	46 (41%)
Moderately motivated	28 (25%)
Low motivated	3 (3%)
No opinion	6 (5%)
HRQoL	
EQ-5D Index score[g] (n=122)	0.397 (0.254; −0.196–0.824)
EQ-5D Profile[h] (n=122)	
Only level 1 or 2 items	2(2%)
Several level 3 items, no level 4 or 5	25(20%)
Min. one level 4 or 5 item	95(78%)
Health (EQ-VAS score 0–100) (n=121)	45 (24; 1–95)
1–25	32 (26%)
26–50	44 (36%)
51–75	35 (29%)
76–95	10 (8%)

[a]The total n of the reports in each question category is provided. [b]Corresponding to the WHO recommendations on physical activity for adults [27]. [c]No reports in the category 'Don't know'. [d]Corresponding to the limits for low risk (≤7 units/week for women; ≤14 units/week for men) and moderate risk (above the low risk limits), The Danish Health Authority [24]. [e]Risky health behaviour in multiple (n≥2) lifestyle areas, such as BMI≥25; Physical activity weekly, minutes <150; Poor or very poor Fitness; High or very high stress; Smoking 'yes'. [f]No reports in the category 'very low motivated'. [g]Scores >0='worse than death'; '1'='perfect health'. [h]Index 11111=full health; 55555=worst health. SD, standard deviation, BMI, Body Mass Index.

adults. The observed frequencies of sedentary lifestyle (43%) and obesity (42%) were higher compared to the general adult Danish population, comparable with the study cohort at gender and age distribution (17% obese and 29% inactive in 2017) [20, 33, 34]. Many participants evaluated their physical fitness (66%) and sleep quality (68%) 'poor to very poor', while most placed their eating habits at 'neither good/nor poor' (58%) and stress at 'neither low/nor high'-level (41%). However, the majority of the participants (72%) considered lifestyle as an important or very important factor for good quality of life, independently of gender (p=0.12) or age group (F=0.20). Ninety-two percent expressed moderate to very high motivation for changing lifestyle. Multiple (n≥2) metabolic risks in various combinations such as BMI≥30, sedentary lifestyle, unhealthy eating, poor physical fitness, poor sleep quality, high stress level and cigarette smoking were found in 58% of the participants.

Health and HRQoL

Most participants (62%) experienced rather poor health (EQ-VAS score 0–50) and moderate-to-extreme levels of the problems (scores≥3) in pain/discomfort (94%), usual activities (81%) and mobility (61%), see Figure 1.

The two-sample t-test showed that the mean of EQ-5D Index in the study sample differed from the general Danish adult population norms calculated on the sample, comparable with the participants in this survey (n=15.700; age mean 47; SD 16; range 20–79). Thus, the sample had significantly lower HRQoL values than the general population (p=0.000; diff. −0.492 (95% CI −0.520; −0.464)). Maximal cumulative HRQoL-scores observed in the study cohort (EQ-5D Index score max.=0.824) were below the mean value for the general population (EQ-5D Index score mean=0.889; SD 0.154). As in this study sample, the most frequent problem reported by the general Danish population was pain/discomfort experienced at the moderate-to-extreme level by 19–52%, while amongst Danes in general, only 7–35% reported the moderate-to-extreme level of problems in usual activities, and 2–25% – in mobility [31].

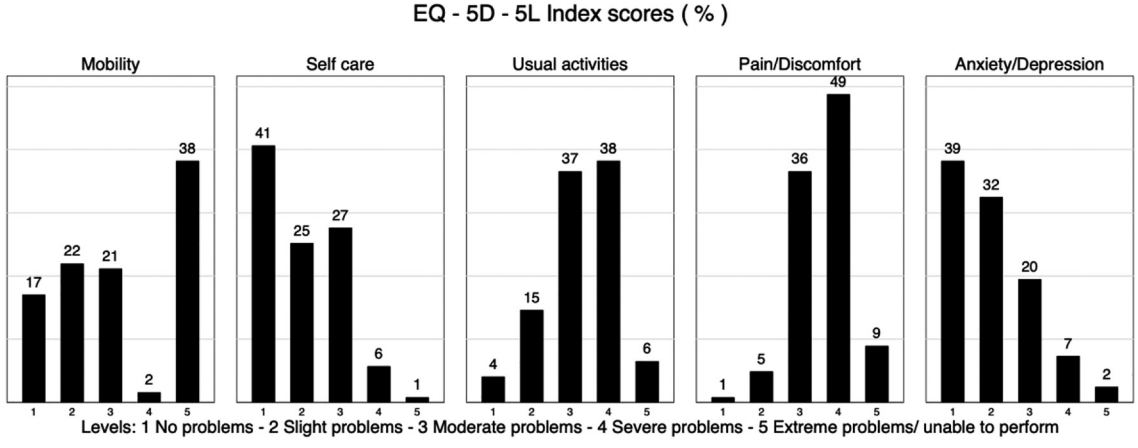

Figure 1: The proportions of HRQoL-related problems in mobility, self-care, usual activities, pain/discomfort and anxiety/depression in the study sample.

The observed associations

Associations of HRQoL with health, pain and lifestyle factors

The multiple linear regression model (p=0.001; 113 observations), including pain intensity in the most painful body site, health, BMI, physical activity level, physical fitness, eating habits, sleep quality and stress level adjusted for gender and age, explained 39% of the variances in HRQoL. HRQoL was significantly poorer in the participants with higher pain intensity in the most painful body site (β=−0.316, p=0.001), as well as at the presence of very poor sleep quality (β=−0.410, p=0.024), holding other variables constant (Table 3).

The residual plots showed linear relationships between the dependent and independent variables. Q–Q plot and the Shapiro–Wilk W test (p=0.084) delivered no reason to reject the assumption of normally distributed residuals. The residual-vs.-fitted plot illustrated the homogeneity of the variance. The tolerance values for the model variables >0.1 and VIF=2.65 for the independent variables raised no multicollinearity concern.

Table 3: Multiple linear regression results on the association HRQoL with health, pain and lifestyle.

Explanatory variable (ref.)	Coef.	SE	t	p-Value	Beta
Gender (Ref. 'male')	−0.041	0.056	−0.74	0.463	−0.065
Age	0.001	0.002	0.68	0.499	0.070
Health status, 'good health' (Ref. 'poor health', EQ-5D VAS 0–50)	0.027	0.048	0.56	0.577	0.051
Pain intensity[c], NRS (Ref. 0 = 'no pain')	−0.051	0.015	−3.35	0.001[b]	−0.316
BMI (Ref. 'underweight to normal weight')					
Overweight	0.059	0.063	0.94	0.351	0.096
Obese to severely obese	0.040	0.053	0.76	0.448	0.078
PA (Ref. '>150 min weekly')					
<150 min weekly	−0.036	0.055	−0.64	0.521	−0.061
None	0.007	0.069	0.10	0.923	0.010
Smoking tobacco	−0.062	0.048	−1.29	0.200	−0.120
Alcohol consumption	0.065	0.052	1.24	0.219	0.114
Physical fitness (Ref. 'good to very good')					
Neither good nor poor	0.061	0.089	0.68	0.496	0.113
Poor	0.022	0.092	0.24	0.807	0.041
Very poor	−0.032	0.103	−0.31	0.756	−0.056
Eating habits (Ref. 'good to very good')					
Neither good nor poor	0.016	0.060	0.26	0.794	0.031
Poor or very poor	0.031	0.095	0.126	0.744	0.040
Sleep quality (Ref. 'good to very good')					
Neither good nor poor	−0.123	0.097	−1.05	0.297	−0.187
Poor	−0.152	0.100	−1.53	0.130	−0.279
Very poor	−0.101	0.101	−2.29	0.024[a]	−0.410
Stress level (Ref. 'very low')					
Low	0.109	0.096	1.13	0.261	0.163
Neither low nor high	0.123	0.086	1.44	0.154	0.242
High	0.023	0.099	−0.23	0.815	−0.035
Very high	0.072	0.108	0.66	0.511	0.084

F=2.62; df (22; 90); p=0.001; R^2=0.3906; Adj. R^2=−0.2416. PA, physical activity; SE, standard error; Ref., reference category. [a]Significant at 0.05. [b]Significant at 0.01. [c]In the most painful body site.

Associations between specific HRQoL-related problems and health

The multiple linear regression model (p=0.002; 121 observations), including HRQoL-related problems in mobility, self-care, usual activities, pain/discomfort and anxiety/depression adjusted for gender and age, explained 24% of the variances in health. The health score was significantly poorer in those with serious-to-extreme HRQoL-related problems related to usual activities (β=−0.328, p=0.030), holding other variables constant (Table 4).

The residual plots revealed linear relationships between the dependent and independent variables. Q–Q plot and the Shapiro–Wilk W test (p=0.56) delivered no reason to reject the assumption of normally distributed residuals could. The residual-vs.-fitted plot illustrated the homogeneity of the variance. No concern of multicollinearity arose from the tolerance values for the model variables >0.1 and VIF=2.16.

Associations between motivation for changing lifestyle, gender and age

The logistic regression model (p>0.598, 112 participants) showed that high motivation for changing lifestyle was not statistically significantly associated with neither gender nor age of the participants (Table 5). The motivation was highest in the age group of 25–34 years old.

Post-estimation tests revealed 10 covariate patterns in the model. We could not reject the goodness of fit of the model, according to the results of the Pearson χ2 test (p>0.45).

Discussion

This survey investigated the associations between HRQoL in adults living with chronic pain and their sociodemographic characteristics, health, pain, lifestyle factors and motivation for changing lifestyle to inform the development of a lifestyle-oriented occupational therapy program. Reports from 144 adults living with chronic pain showed

Table 4: Multiple linear regression results on the association between HRQoL-related problems in mobility, self-care, usual activities, pain/discomfort and anxiety/depression, and health.

Explanatory variable	Coef.	SE	t	p-Value	Beta
Mobility					
Serious-to-extreme problems	−6.270	5.225	−1.20	0.233	−0.130
Moderate problems	−7.281	6.437	−1.13	0.261	−0.126
No to slight problems (Ref.)					
Self-care					
Serious-to-extreme problems	0.180	9.197	0.02	0.984	0.002
Moderate problems	3.916	5.130	0.76	0.447	0.074
No to slight problems (Ref.)					
Usual activities					
Serious-to-extreme problems	−15.622	6.934	−2.25	0.026[a]	−0.328
Moderate problems	4.180	6.491	0.64	0.521	0.085
No to slight problems (Ref.)					
Pain/discomfort					
Serious-to-extreme problems	−14.333	9.431	−1.52	0.131	−0.299
Moderate problems	−10.046	9.197	−1.09	0.277	−0.204
No to slight problems (Ref.)					
Anxiety/depression					
Serious-to-extreme problems	9.115	7.146	1.28	0.205	0.115
Moderate problems	−6.874	5.422	−1.27	0.208	−0.116
No to slight problems (Ref.)					
Pain intensity in major body pain site	0.913	1.505	0.61	0.545	0.061
Gender (male)	−4.519	5.225	−0.86	0.389	−0.075
Age	−0.159	0.159	−1.00	0.320	−0.089

F=2.89; df (12; 108); p=0.002; R^2=0.2429; Adj. R^2=0.1588.
[a]Significant at 0.05. SE, standard error; Ref., reference category.

Table 5: Logistic regression results on the association between gender and age, and the motivation for working with lifestyle changes.

Explanatory variable	Odds ratio	SE	z	p-Value	[95% CI]	
Gender						
Male	0.840	0.427	−0.34	0.732	0.310	2.277
Age groups, years old						
35–44	4.270	3.927	−1.58	0.114	0.704	25.895
45–54	1.660	1.007	0.84	0.403	0.506	5.449
55–64	1.157	0.751	0.22	0.823	0.324	4.131
65+	1.825	1.344	0.82	0.414	0.431	7.726

CI, confidence interval; SE, standard error.

that higher pain intensity in the most painful body site (β=−0.316, p=0.001) and a very poor sleep quality (β=−0.410, p=0.024) was associated with poorer HRQoL. The study sample's cumulative HRQoL-score was significantly lower than in the general Danish population (p<0.000; diff. −0.49 (95% CI −0.52; −0.46)). Serious-to-extreme problems in usual activities (β=−0.328, p=0.030) were significantly associated with lower self-evaluated health.

The significant association found between sleep quality and HRQoL in this study has previously also been demonstrated in the general chronic pain population [35]. Poor sleep quality is associated with a two to three times higher risk of greater pain intensity, increased inflammatory markers, and poorer physical health [36]. Previous evidence has linked sleep with HRQoL and found that chronic pain compromises them both [37]. Occupational therapy can promote better sleep quality by helping the participants establish occupational balance based on value-based occupational choices, appropriate occupational planning, knowledge of energy expenditure and use of assistive devices [38].

In occupational science, human health and well-being are considered dependent on a balanced interrelationship between daily occupations related to self-care, productivity and leisure, and the individual's personality and the environment [39]. From this perspective, our findings on the association between severe-to-extreme problems in usual activities and poorer self-evaluated health may underscore the importance of preventing a decline in occupational performance. Likewise, it would be recommendable to assess individual occupational performance deficiencies in work, study, housework, family and leisure at the intervention baseline and elaborate on their improvement.

Besides usual activities, the participants in this study also experienced pain/discomfort and mobility problems that severely affected their HRQoL. Similar HRQoL domains were also the most affected in the general Danish population [31], yet the problem prevalence in this study cohort was about twice as high. Previous research in chronic pain has found that pain, fear of movement, anxiety and depression were interconnected, negatively affecting each other and associated with poor health and HRQOL [40]. The burden of chronic pain observed in the study cohort seemed severe, primarily because of pain spreading, where 93% of the participants had pain in two or more body sites, and 61% had pain in six or more. That supports the evidence highlighting that pain alleviation remains one of the most attractive treatment outcomes for the chronic pain population [33]. However, since taking pain medications has been perceived to enhance the

burden of chronic pain and is associated with adverse events [34, 35], it would be reasonable to approach chronic pain non-pharmacologically, e.g. through a lifestyle-oriented intervention.

Physical activity was not associated with HRQoL in this study cohort. However, previous research has demonstrated that increased physical activity improves health and well-being in various chronic pain conditions [8, 9, 35]. Moreover, the relatively high frequency of sedentary lifestyle detected amongst the participants of this study urges all health professionals to initiate efforts that would reverse this tendency. Therefore, occupational therapists should assist people living with chronic pain to a more physically active life, e.g. while helping them set occupational goals and accomplish the goal work.

Given that 64% of the participants were overweight, obese or severely obese, besides the sedentary lifestyle, we expected the participants also to report unhealthy eating habits, as those are known to impact human metabolic health [41]. Unexpectedly, only 13% of the participants in this study reported unhealthy eating habits, which is 3% less than in the general adult Danish population [20, 34]. This finding could be an instance of misreporting sensitive health behaviour information, as seen previously in health surveys [42]. Even more surprising was that the participants' self-perceived HRQoL seemed to be higher in those with poor eating habits, which could find an explanation in the 'comfort food'-phenomenon where stress and chronic pain predisposes to a calorically dense food intake as a coping strategy [43]. At the same time, this survey revealed a high frequency of two or more lifestyle-related risks (58%), which was more than twice as high as in the general Danish population (24% in men, 19% in women in 2017) [20]. Motivational rates for changing lifestyle were also higher in our sample (92%) than the general Danish population ≥16 years in 2017. In the general population, 71% would like to be more physically active, 56% would like to eat healthier, 33% would like to reduce their alcohol consumption, and approximately 75% of the smokers would like to quit [20]. Thus, despite the low frequency of reported unhealthy eating habits but high anticipated high-risks of poor metabolic health and comorbidity observed in the sample, we argue for targeting eating habits in an occupational therapy lifestyle intervention.

Knowing that non-pharmacological treatment of chronic pain remains a more sustainable and safer alternative or addition to the often insufficient pharmacological treatment [4, 44–47], we believe that occupational therapy has the necessary tools and methods for targeting lifestyle factors from an occupational performance and participation perspective. However, more evidence is needed on the delivery and responsiveness to comprehensive lifestyle interventions in people living with chronic pain, i.e. appropriate subgrouping, treatment doses, gender differences, program adherence to determine the ways of reaching sustainable lifestyle changes and improved HRQoL.

Implications

- Pain intensity and sleep quality are important factors to consider when assessing the quality of life in adults living with chronic pain;
- Addressing problems in usual activities, such as work, study, housework, family and leisure, are essential for the improvement in the health status of the chronic pain population;
- Further research is needed to clarify if a comprehensive multidisciplinary lifestyle-oriented intervention program would improve health and quality of life in adults living with chronic pain.

Limitations

A larger study sample might have demonstrated further associations between HRQoL and other independent variables than pain intensity and sleep quality. Despite the assistance offered by the researchers, only a few participants took contact and received support. More supportive outreach research activities and fewer questions might potentially have helped to avoid missing data. Selection bias towards the participants capable of completing the survey regarding internet access, time and sufficient Danish language, might have been present. Furthermore, a greater number of men might also have affected the results of the analyses of differences between men and women. Therefore, these results need to be cautiously interpreted. The cross-sectional study design and self-reported retrospective data may also contain recall bias, misreporting and social desirability bias, particularly in lifestyle-related data. Anyhow, the support delivered by the research team during the survey distribution and conduct allowed us to reach out to the outpatients who may generally find participating in research activities difficult, which may have strengthened the generalisability of the current investigation.

Conclusion

Adults living with chronic pain participating in this study had significantly lower cumulative HRQoL-score than the

general Danish population. Lower HRQoL in the study cohort was significantly associated with greater pain intensity and poor sleep quality, while the serious-to-extreme degree of problems in usual activities was associated with poorer self-evaluated health. Many participants experienced pain spreading, were overweight and obese, and had a sedentary lifestyle. Most participants were motivated for changing their lifestyle, independent of gender and age. Further health interventions aiming at pain alleviation, better sleep quality, prevention of severe problems in usual activities and promotion of physical activity and healthy eating are needed to estimate the effectiveness of such approaches on health and quality of life in adults living with chronic pain.

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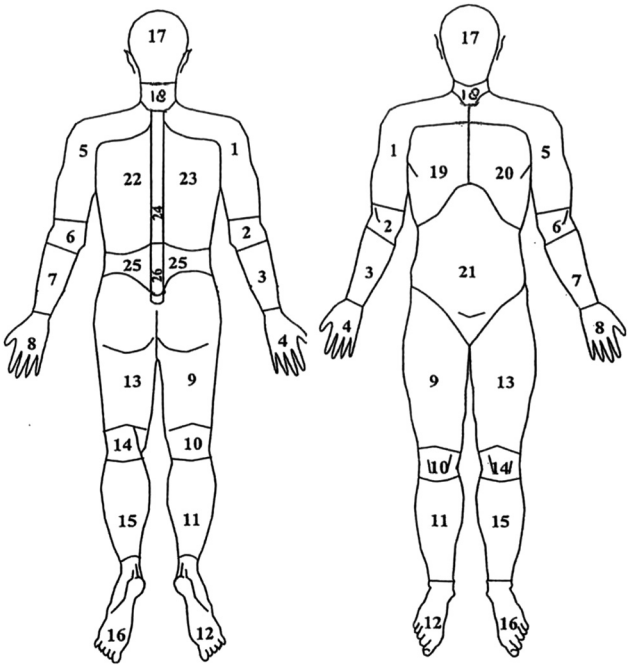
Competing interests: Authors state no conflict of interest.

Informed consent: Informed consent has been obtained from all participants in this study.

Ethical approval: The Data Protection Committee in Region Zealand, Denmark (REG-043-2018) approved the protocol. According to the Danish legislation (The Executive Order of the Law on the Ethical Treatment of Health Science Research Projects, § 14, para. 2), questionnaires and surveys that do not include human biological material should not be notified for the Research Ethics Committee approval. The results of this study will inform the research project registered SJ-703 by the Danish the Research Ethics Committee for Region Zealand, Denmark. This study followed the principles of the Helsinki Declaration (the 7th edition).

Data statement: The authors confirm that the data supporting the findings of this study are available within the article and its Appendix A. Additional data associated with this study are available on request from the corresponding author.

Appendix A: Body chart with 45 pain sites on the front and back of the human body



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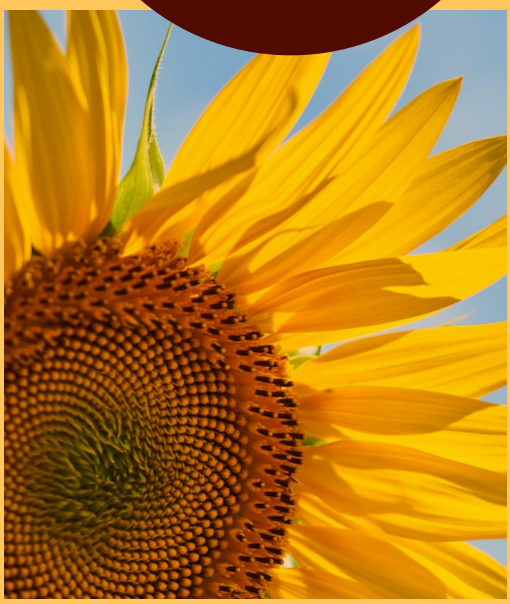
Appendix 12

Participant information letter, feasibility study

ERGOTERAPIEN PÅ NÆSTVED SYGEHUS HAR ET EKSTRA TILBUD TIL DIG SOM SMERTEPATIENT I TILLÆG TIL DEN ØVRIGE SMERTEBEHANDLING

Har du interesse eller behov for at forbedre daglige vaner og rutiner?

Lærer du bedst ved at prøve tingene?



KRONISKE SMERTER FORSTYRRER HVERDAGSLIVET OG SUND LIVSSTIL...

Den ergoterapeutiske forskning viser, at ved at gøre det der giver mening og livskvalitet i det daglige kan styrke helbredet

Du vil få ergoterapi 8 gange over 15 uger sideløbende med anden planlagt behandling (af dem 2 gange individuelt og 6 gange på et hold af max. 6 faste deltagere)

Tilbuddet har fokus på hverdagsgøremål, regelmæssig bevægelse og sundere spisevaner og sigter en højere livskvalitet for dig som smertepatient

Læs mere om forløbet på de næste sider

Deltagerinformation om deltagelse i et sundhedsvidenskabeligt forskningsprojekt

"Ergoterapeutisk livsstilsintervention til patienter med kroniske non-maligne smerter"

Protokol, version 1.5, revideret 05.08.2020

Vi vil spørge, om du vil deltage i et videnskabeligt forskningsprojekt, der udføres i samarbejdet mellem **Tværfagligt smertecenter og Ergoterapien på Næstved sygehus**. Denne skriftlige deltagerinformation vil give dig flere oplysninger om projektet. Hele forløbet vil omfatte en forberedende pilotundersøgelse og et efterfølgende lodtrækningsforsøg. Du inviteres hermed til deltagelse i **pilotundersøgelsen**.

Deltagelse i projektet vil give dig mulighed at **modtage ergoterapi som en del af smertebehandlingen**. Ved visitationssamtalen til smertecentret vil du blive spurgt, om du er interesseret i at deltage og giver din accept til at blive kontaktet telefonisk af en projektkoordinator med henblik på videre afklaring. Før du beslutter dig, skal du fuldt ud forstå, hvad det går ud på, og hvorfor vi gennemfører det. Vi vil derfor bede dig om at **læse denne deltagerinformation grundigt** og eventuelt bede en pårørende eller nær ven at gennemgå materialet sammen med dig.

Hvis du viser interesse til visitationssamtalen, vil en projektkoordinator fra ergoterapien ringe dig op og i samråd med dig **afklare, om du er i målgruppen for projektet**. Dernæst vil der blive aftalt et møde med henblik på **uddybende mundtlig information** om projektet og besvarelse af eventuelle spørgsmål. Du får mindst en uges betænkningstid, inden du giver dit samtykke om deltagelse. Ekstra betænkningstid kan aftales.

Skriftligt samtykke til deltagelsen i projektet vil blive indhentet inden opstart i forbindelse med dit fremmøde ifølge behandlingsplanen eller, hvis ønsket, med post i en frankeret svarkuvert. Du skal være opmærksom på, at dit samtykke giver forsøgsansvarlig og dennes repræsentant direkte adgang til oplysninger fra dine patientjournaler som er nødvendige for projektets gennemførelse og kontrol med data undervejs i forløbet, fx kontaktoplysninger og aftalekalender som er nødvendige for videre planlægning. Journaldata vil igen blive indhentet på undersøgelsesdage (se planen for forløbet på s. 3) for at sikre, at eventuelle ændringer i dine forudsætninger for deltagelse (så som medicinændringer, nyopstået sygdom eller frafald) registreres korrekt. Al data som bliver indhentet via patientjournalen vil blive videregivet til forsker og anvendt **udelukkende til forskningsformål.**

Alle dem som giver sit samtykke til at deltage i projektet vil blive indkaldt til en **forundersøgelse**. Du vil blive tilsendt information om undersøgelsesdagen til E-boks eller post. Forundersøgelsen vil finde sted i et roligt lokale. Til alle aftaler inden opstart i projektet er du **velkommen til at tage et familiemedlem, en ven eller en bekendt med.**

Det er frivilligt at deltage i forskningsprojektet. Du kan når som helst og uden at give en begrundelse trække dit samtykke tilbage, uden at det får konsekvenser for din nuværende eller fremtidige behandling.

Formål med projektet

Forskningen viser, at livsstil kan have indflydelse på kroniske smerter. Projektet går ud på, at den nuværende behandling til kroniske smertepatienter på det Tværfaglige smertecenter, Næstved sygehus, vil blive tilføjet et nyt tilbud om livsstilsorienteret ergoterapi.

Pilotundersøgelsen har til formål at teste, om det efterfølgende lodtrækningsforsøg kan gennemføres som planlagt. Til pilotundersøgelsen vil der blive rekrutteret 48 ambulante patienter på Tværfagligt Smertecenter, Næstved sygehus. Yderligere 228 patienter vil deltage i lodtrækningsforsøget. I alt, vil der blive rekrutteret 276 patienter som svarer til følgende udvælgelseskriterier:

- Er mellem 18 og 65 år
- Har oplevet vedvarende smerter i over 3 måneder
- Ikke lider af hovedpine/ migræne
- Ikke har aktuel depression
- Ikke har alvorlige psykiatriske diagnoser, alkohol- eller stofmisbrug
- Har evt. indtag af opioider liggende stabilt på under 30 mg om dagen
- Har danskkundskaber som tillader deltagelse i spørgeskemaundersøgelser og interview
- Ikke er tilknyttet andre behandlingstilbud for kroniske smertepatienter
- Kan gå selvstændigt en distance på min. 100 meter

I pilotundersøgelsen vil alle 48 patienter deltage i livsstilsorienteret ergoterapi og den nuværende behandling. Hermed er pilotprojektet ikke forbundet med reduktion i kvaliteten af behandlingen, tværtimod vil alle deltagere kunne forvente en bedre behandling, end hvis de ikke deltager i projektet.

Plan for pilotundersøgelsen

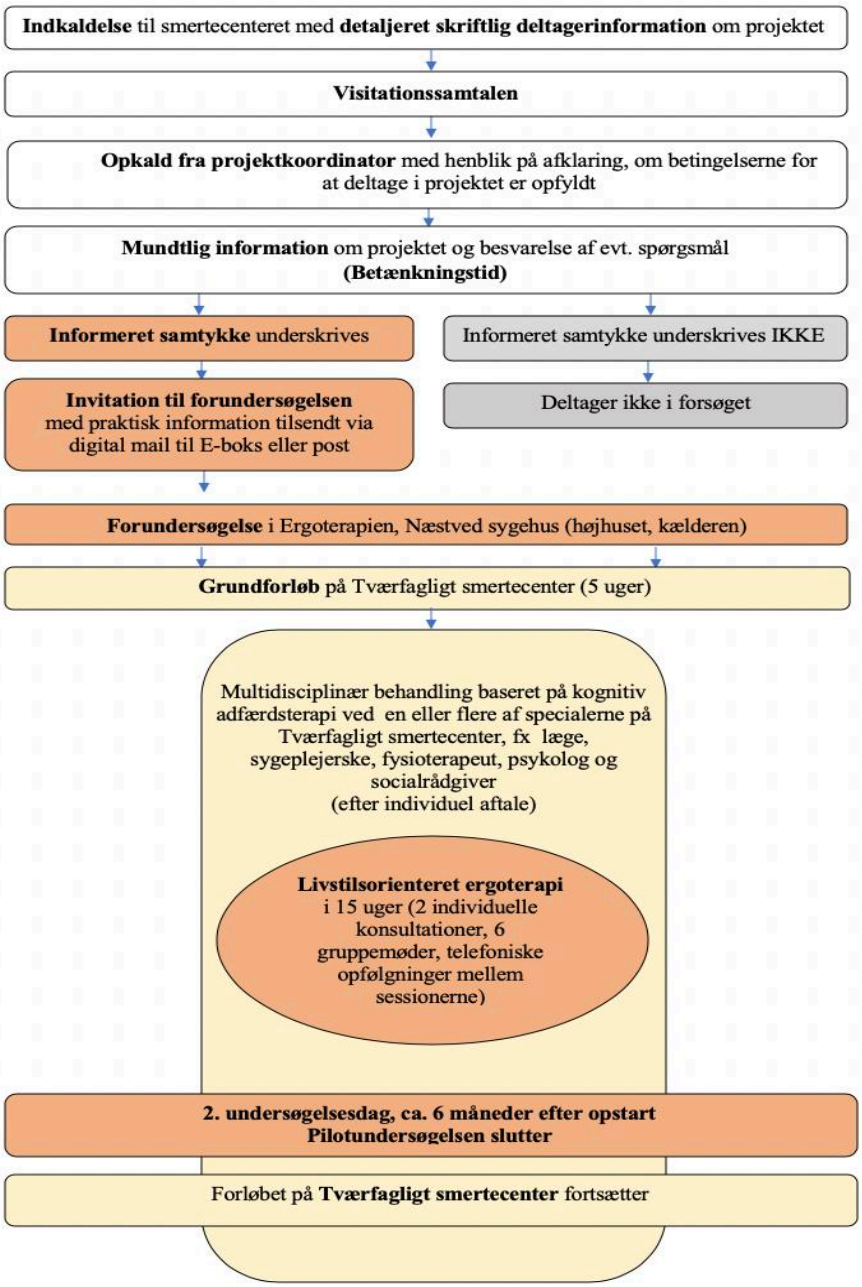
Efter du har givet samtykke til deltagelse i projektet, får du invitation til 1. undersøgelsesdag. I pilotundersøgelsen vil der i alt være 2 undersøgelsesdage á ca. 2,5 timers varighed (med pauser) i løbet af undersøgelsesperioden. Undersøgelsesdagene vil ligge: 1) Ca. en uge inden opstart på grundforløbet i smertecentret; 2) Efter afslutning på den ergoterapeutiske intervention (ca. 6 måneder efter opstart). Pilotundersøgelsen vil følge planen for interventionsgruppen i det efterfølgende lodtrækningsforsøg, men have kortere udstrækning (15 uger mod 1 år i lodtrækningsforsøget, se evt. skemaet på s. 3).

Inden du møder op til en undersøgelsesdag, vil vi bede dig om at udfylde et spørgeskema i PainData register for de danske kroniske smertepatienter (www.paindata.dk). Spørgeskemaerne skal give mere viden om fysiske, sociale og psykiske/ emotionelle forhold omkring din tilstand. På selve undersøgelsesdagen vil du få undersøgt dine hverdagsudfordringer via en interviewbaseret test

sammen med en ergoterapeut. Du vil få målt din højde, vægt, livomfang, blodtryk og smertesensibilitet.

På undersøgelsesdagene får du også udleveret en måleenhed for bevægelsesaktivitet til hjemmebrug i de efterfølgende 4 dage. Denne måleenhed skal du have på dig (på dit venstre lår) på alle døgnets tidspunkter, og din bevægelsesaktivitet registreres digitalt. Der vil kun blive registreret, om du befinder dig i bevægelse eller i ro, dvs. om du sidder stille eller går osv. Enheden er simpel i brug, og du bliver givet en grundig instruktion om dennes anvendelse. Måleenheden skal afleveres tilbage igen, f.eks. ved det næste fremmøde i behandlingsforløbet eller efter aftale. Undersøgelsdagene afsluttes ved en observationsundersøgelse, hvor du vil blive bedt om at udføre to mindre aktiviteter efter eget valg.

Dit behandlingsforløb vil se ud som på skemaet nedenfor:



Livsstilsorienteret ergoterapi

Det livsstilsorienterede ergoterapeutiske forløb tillægges den nuværende multidisciplinære behandling baseret på kognitiv adfærdsterapi og har fokus på:

- meningsfulde daglige aktiviteter i relation til egenomsorg, produktivitet, fritid og hvile;
- spisevaner og rutiner (fx vejen af mad fra supermarkedet til spisebordet og køleskabet);
- daglig bevægelse (fx gåture og andre måder til at øge bevægelse i dagligdagen på);
- energibesparende principper og teknikker de daglige gøremål.

Der er fremmøde i forløbet hver 14. dag i Ergoterapiens lokaler på Næstved sygehus. I modsatte uger er der planlagt telefonisk opfølgning på målarbejdet, således vil deltagerne i interventionen have ugentlige kontakter med en ergoterapeut.

Du får overblik over dine daglige aktiviteter; opnår indsigt i dine værdier og prioriteter; får inspiration til ønskede livsstilsændringer; får øvelsen i at sætte overskuelige mål; oplever små successer med målarbejdet; får mulighed for at dele erfaringer med ligestillede; samt få afprøvet relevante hjælpemidler.

En af de individuelle konsultationer kan gennemføres som et hjemmebesøg men henblik på indretning og ergonomi i hjemlige omgivelser, så de fremmer dit målarbejde mest effektivt. Der vil være mulighed for at inddrage andre fagpersoner og myndigheder i behandlingsperioden, hvis relevant og efter dit ønske.

Nytte ved projektet

Projektet vil bidrage med ny viden om effekten af arbejdet med livsstil ved kroniske smerter og forbedre behandlingstilbud til kroniske smertepatienter.

Bivirkninger, risici, komplikationer og ulemper

Projektet er ikke forbundet med bivirkninger, risici, komplikationer eller ulemper. Behovet for at faste op til blodsukkermåling, brug af bevægelsesmåleenheden og måling med algometer skønnes at være de eneste mulige årsager til eventuelle gener, dog ikke forbundet med risiko for helbred. Vi har vurderet disse målinger som nødvendige, for at kunne monitorere effekten af interventionen på flere livsstilsfaktorer der kan spille en rolle i udvikling og forværring af kronisk smerteproblematik, f.eks. et ustabilt eller for højt glukoseniveau i blodet. Hvis du oplever problemer med dit helbred, mens projektet står på, vil vi bede dig om at oplyse os om det. Projektet er omfattet af Patienterstatningsordningen med mulighed for at søge kompensation i tilfælde af sundhedsskade.

Udelukkelse fra og afbrydelse af forsøg

Deltagelse i projektet forudsætter, at du ikke samtidigt opstarter i andre tilbud rettet mod håndtering af kroniske smerter. Deltagelse i projektet kan afbrydes til enhver tid:

- Hvis du selv ønsker det
- Hvis du melder dig til andre tilbud til håndtering af kroniske smerter sideløbende med projektet
- Hvis der opstår helbredsmæssige komplikationer (forudsætter en lægelig vurdering)

Dem der afbryder sin deltagelse i projektet vil have mulighed for at fortsætte med den multidisciplinære smertebehandling.

Oplysninger om økonomiske forhold

Projektet foregår på Tværfagligt smertecenter, Næstved sygehus, i samarbejdet med Ergoterapien på Næstved sygehus. Initiativ til projektet er taget af Afdelingen for Fysioterapi og Ergoterapi Næstved-Slagelse-Ringsted sygehuse i samarbejde med Tværfagligt smertecenter, Næstved sygehus.

Hovedparten af midlerne til gennemførelse af projektet vil komme fra forskningsfonde i Region Sjælland. Den Lokale Forskningsfond har støttet Afdelingen for Fysioterapi og Ergoterapi Næstved-Slagelse-Ringsted sygehuse med midlerne til udarbejdelse af protokollen (75.000) og interventionsmanualen (75.000). Ergoterapeutforeningen har støttet projektet med 120.000 Dkk til dækning af studieafgiften til Syddansk Universitet, Ph.D.-skolen, for Svetlana Solgaard Nielsen, projektlederen. Andre fonde bliver inddraget i finansiering af projektet. Deltagerinformationen vil blive opdateret omkring den opnåede støtte til projektet, når endelig finansiering foreligger. Ved opdateringer i deltagerinformationen vil Den Videnskabsetiske Komité i Region Sjælland blive orienteret.

Projektetdeltagerne vil ikke modtage nogen form for honorar for deltagelsen. Nogle patienter vil være berettiget til dækning af transportudgifter i forbindelse med fremmøde på behandlingsstedet i overensstemmelse med reglerne der kan læses på regionens hjemmeside www.regionsjaelland.dk under Patientbefordring: http://www.regionsjaelland.dk/Sundhed/patient-i-region-sjaelland/patientbefordring/Sider/regler-om-patientbefordring-transport.aspx.

Opbevaring af data

Data vil blive opbevaret elektronisk og i papirform. Sikrede elektroniske lagringsmuligheder vil blive anvendt. Ikke- elektroniske data vil blive opbevaret aflåst i Ergoterapien, Næstved sygehus, Ringstedgade 61, 4700 Næstved.

Data vil blive anonymiseret efter den sidste patient bliver afsluttet i forsøget og opbevaret med henblik på videnskabelig formidling og undervisning indtil bortskaffelsen senest 10 år efter afslutningen, dvs. opbevaringstiden vil vare indtil udgangen af år 2031. Der vil ikke blive indsamlet eller opbevaret biologiske prøver i projektet. Projektet er også rapporteret til det offentlige datatilsyn i Region Sjælland. Der kan søges om videregivelse af data fra projektet som er nødvendige for udførelsen af andre statistiske og forskningsprojekter som er godkendt hos de interne (regionale) datatilsynsførende, eller hos Datatilsynet. Videregivelsen kan finde sted, efter en skriftlig tilladelse er indhentet hos den forsøgsansvarlige. Informationen om videregivelsen af data skal fremgå i protokolbeskrivelser for de respektive projekter. Forskningsprojekter der modtager data fra dette projekt skal håndtere oplysningerne, så enkeltpersoner ikke kan identificeres ved rapportering af resultater. Ved afsluttet undersøgelse, skal data tilintetgøres eller overføres til arkiv.

Adgang til projektresultater

Projektet forventes at blive afsluttet ved udgangen af 2020, når alle data er gjort op. Projektets resultater vil blive offentliggjort i videnskabelige tidsskrifter og på konferencer i Danmark og udlandet, fra år 2019 og frem. Både positive og negative resultater vil blive offentliggjort.

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i projektet, og at du føler dig forberedt til at tage beslutningen om din eventuelle deltagelse.

Vi beder dig også om at læse det vedlagte materiale "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt". Hvis du vil vide mere, er du meget velkommen til at kontakte undertegnede.

Med venlig hilsen, den forsøgsansvarlige:
Svetlana Solgaard Nielsen, ergoterapeut, kandidat i ergoterapi
Afdelingen for Fysioterapi og Ergoterapi, Næstved-Slagelse-Ringsted sygehuse
Fælledvej 11, 4200 Slagelse
E-mail: ergo.livsstil@gmail.com; Mob. 51252255

Projektidentifikation

- SJ-703 (Den Regionale Videnskabsetiske Komité for Region Sjælland)
- REG-052-2018 (Datatilsynet i Region Sjælland)

Appendix 13

Informed consent, feasibility study

Informeret samtykke til deltagelse i et sundhedsvidenskabeligt projekt

Forskningsprojektets titel

Ergoterapeutisk livsstilsintervention til patienter med kroniske non-maligne smerter

Protokol, version 1.5, revideret 05.08.2020

Erklæring fra patienten:

Jeg bekræfter hermed at have modtaget skriftlig og mundtlig information om projektet og har tilstrækkeligt kendskab til forskningsprojektets formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg er informeret om, at min deltagelse er frivillig, og at jeg når som helst og uden begrundelse kan trække mit tilsagn om deltagelse tilbage, uden at dette på nogen måde vil påvirke den nuværende eller fremtidige behandling.

Jeg er opmærksom på, at mit samtykke giver forsøgsansvarlig og dennes repræsentant adgang til mine journaloplysninger. Jeg er indforstået med, at de indhentede data vil kun blive anvendt til forskningsformål.

Jeg giver samtykke til at deltage i forskningsprojektet, og har fået en kopi af dette samtykkeark.

Navn:

Dato: Underskrift:

Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser for dig?

Ja_____(sæt x) Nej_____ (sæt x)

Erklæring fra den der afgiver information:

Jeg erklærer, at patienten har modtaget mundtlig og skriftlig information om forskningsprojektet. Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i projektet.

Navnet på den der afgiver information:

Dato: Underskrift:

Appendix 14

Personal intervention plan

Bekræftelse vedr. deltagelse i et sundhedsvidenskabeligt forskningsprojekt "Ergoterapeutisk livsstilsintervention til patienter med kroniske smerter"

Kære ,

Hermed vil vi bekræfte, at du er tildelt plads på forløbet med følgende møde- og konsultationstider:

Dato	**Kl.**	**Indhold**	**Sted**
21.10.20 Torsdag	9.30-11.30 OBS: ca. 2,5 t. varighed	Forundersøgelse/BASELINE Undersøgelsen består af: Ergoterapeutisk undersøgelse; Måling af højde, vægt, taljemål og smertesensibilitet; Påsætning af bevægelsesmåler til hjemmemåling; Praktisk test med to selvvalgte aktiviteter. OBS: Du må gerne have bukser på som er lidt løse og evt. nemt kan smøges op til brug ved smertesensibilitetstest og påsætning af bevægelsesmåleren på venstre lår. INDEN du møder op, vil vi gerne bede dig om **at besvare et spørgeskema på www.paindata.dk** (tager ca. 1 time, hvor du kan gå til og fra) **og et tillægsspørgeskema** til projektet via linket: https://paindata.dk/pain/s/99/ (tager ca. 15 min.). Du skal bruge dit cpr.nr. til at logge på.	Ergoterapien, Næstved sygehus Indgang via hovedindgangen og ned til kælderen
07.12.20 Mandag	10.00-12.00	Gruppe: **Introduktion til forløbet: fokusområderne Meningsfuld aktivitet, Sunde spisevaner og Daglig bevægelse**	Ergoterapien, Næstved sygehus
14.12.20 Mandag	09.30-10.30	Individuel telefonkonsultation Samtalen vil vare ca. 30 min. i det afsatte tidsrum	Telefonisk samtale
21.12.20 Mandag	10.00-11.00	Individuel konsultation: **Målsætning**	Ergoterapien, Næstved sygehus
28.12.20 Tirsdag	09.30-10.30	Individuel telefonkonsultation Samtalen vil vare ca. 30 min. i det afsatte tidsrum	Telefonisk samtale
04.01.20 Mandag	10.00-12.00	Gruppe: **Energibesparende principper og teknikker**	Ergoterapien, Næstved sygehus
11.01.20 Tirsdag	09.30-10.30	Individuel telefonkonsultation Samtalen vil vare ca. 30 min. i det afsatte tidsrum	Telefonisk samtale
18.01.20 Tirsdag	10.00-12.00	Gruppe: **Bevægelse og velvære**	Ergoterapien, Næstved sygehus

25.01.20 Mandag	9.30-10.30	Individuel telefonkonsultation Samtalen vil vare ca. 30 min. i det afsatte tidsrum	Telefonisk samtale
01.02.20 Mandag	10.00-12.00	Gruppe: **Måltider og spisevaner**	Ergoterapien, Næstved sygehus
08.02.20 Mandag	9.30-10.30	Individuel telefonkonsultation Samtalen vil vare ca. 30 min. i det afsatte tidsrum	Telefonisk samtale
Uge 7 - pause			
22.02.20 Mandag - eller 23.02.20 Tirsdag		Individuel konsultation, hjemmebesøg Aftales individuelt efter opstart og med hensyn til gældende anbefalinger	Eget hjem
01.03.20 Mandag	9.30-10.30	Individuel telefonkonsultation Samtalen vil vare ca. 30 min. i det afsatte tidsrum	Telefonisk samtale
08.03.20 Mandag	10.00-12.00	Gruppe: **Indkøb og køkkenindretning**	Ergoterapien, Næstved sygehus
15.03.20 Mandag	9.30-10.30	Individuel telefonkonsultation Samtalen vil vare ca. 30 min. i det afsatte tidsrum	Telefonisk samtale
22.03.20 Mandag	10.00-12.00	Gruppe: **Opsamling og afslutning**	Ergoterapien, Næstved sygehus
23.03.20 Mandag	10.30-12.30 OBS: ca. 2 t. varighed	Slutundersøgelse/ FOLLOW-UP Undersøgelsen består af: Ergoterapeutisk undersøgelse; Måling af højde, vægt, taljemål og smertesensibilitet; Påsætning af bevægelsesmåler til hjemmemåling; Praktisk test med to selvvalgte aktiviteter. OBS: Du må gerne have bukser på som er lidt løse og evt. nemt kan smøges op til brug ved smertesensibilitetstest og påsætning af bevægelsesmåleren på venstre lår. INDEN du møder op, vil vi gerne bede dig om at besvare **et slutspørgeskema til projektet via linket: https://paindata.dk/pain/s/100/** (tager ca. 30 min. at udfylde). Du skal bruge dit cpr.nr. til at logge på.	Ergoterapien, Næstved sygehus

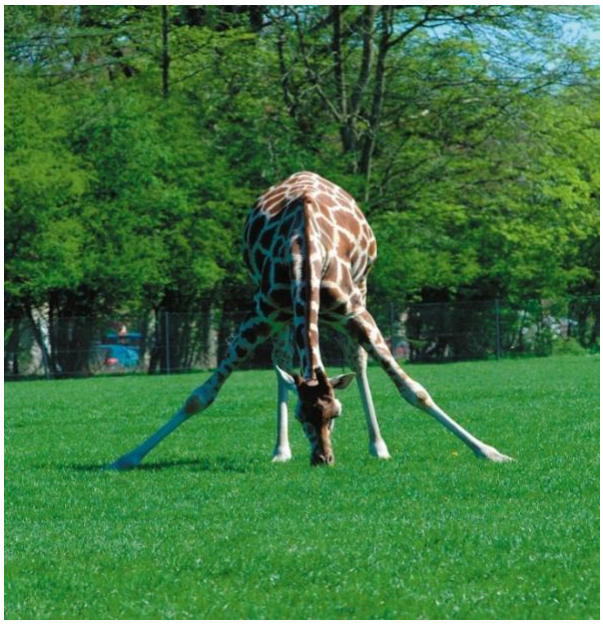
Med venlig hilsen,

Ergoterapien, Næstved sygehus (højhuset)
Ringstedgade, 61, kælderen
Tlf. 56 51 40 71; 56 51 44 45

Appendix 15

Patient handbook

REDESIGN DIN HVERDAG
MED ERGOTERAPI
til kroniske smertepatienter



Deltager: _____

Kontakt: Ergoterapien, Næstved sygehus
Sekretær: Tlf. **56 51 40 71** (kl. 8-15);
E-mail Ergoterapien: nae-ergoterapi@regionsjaelland.dk
Lise Mikkelsen, ergoterapeut:
Tlf. **56 51 44 45** (mandage kl. 8-9.30)
Projektansvarlig Svetlana Nielsen, ergoterapeut, phd-studerende
E-mail: ergo_livsstil@gmail.com

REGION SJÆLLAND – vi er til for dig

PROgrez

ERGOTERAPEUT FORENINGEN

SDU

Print: Grafisk center, SDU

Projektet "Ergoterapeutisk livsstilsintervention til patienter med kroniske smerter"

Projektet gennemføres i samarbejde mellem Afdelingen for fysioterapi og ergoterapi (Næstved, Slagelse og Ringsted sygehuse) og Tværfagligt smertecenter (Næstved sygehus)

Projektidentifikation:

- SJ-703 (Den Regionale Videnskabsetiske Komité, Region Sjælland)
- REG-052-2018 (Datatilsynet, Region Sjælland)

HJERTELIG VELKOMMEN I ERGOTERAPIEN PÅ NÆSTVED SYGEHUS!

Indholdsfortegnelse

Meningsfulde aktiviteter fremmer sundhed

- Mennesker er skabt til at være aktive
- Når vi er i gang med ting som giver os mening og værdi:
  - vi føler os aktive
  - vi udvikler os
  - vi oplever livskvalitet
- Vær bevidst om det der giver mening for DIG
- Sæt prioriteter ud fra dine værdier og start med det vigtigste - det giver størst tilfredshed
- Selvom meningsfulde aktiviteter stadig koster energi, får vi mere energi tilbage og bliver mere glade!

Hvad der giver mening og livskvalitet for dig?

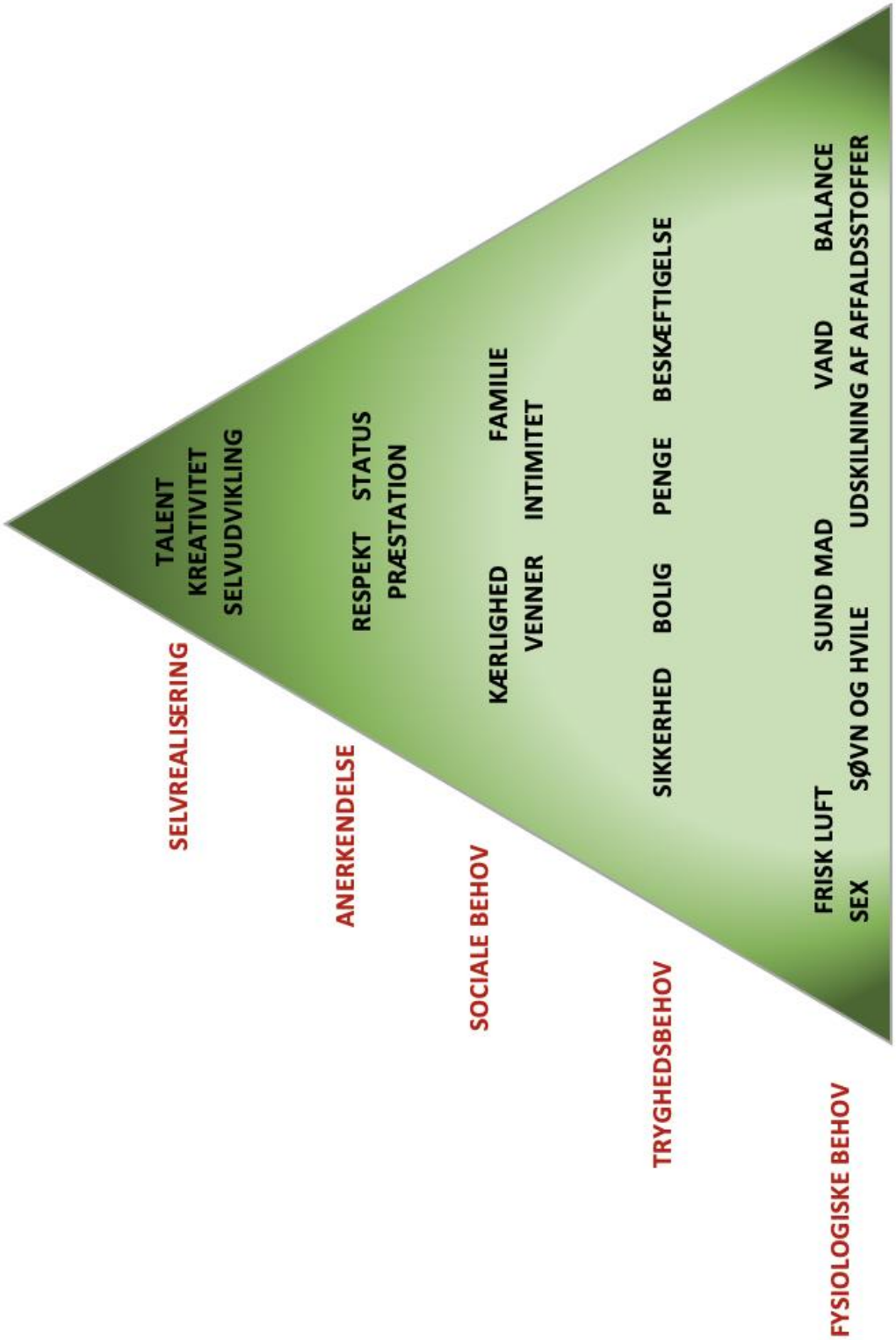
1. _____
2. _____
3. _____
4. _____
5. _____

- Følelsen af FLOW (en fordybelsestilstand, hvor tiden "forsvinder) undervejs i de daglige aktiviteter fremmer helende processer i kroppen og sindet, da den styrker vores selvtillid og hjælper at "glemme" bekymringer, så vi får lov til at slappe af og opleve god livskvalitet

Hvilke aktiviteter, du kender, har størst potentiale for en FLOW oplevelse?

_____
_____ .
_____

Maslow's Behovspyramide



(Huitt, W., 2007)

Fordele og ulemper ved at spise sundt

+	÷

De 10 kostråd (Fødevarestyrelsen)

Billede: www.altomkost.dk

På hvilket punkt kan du med stor sikkerhed forbedre dine spisevaner? Prioritér gerne ét kostråd.

_____

Du kan også prøve:

- At læse mere på www.altomkost.dk
- At følge kostrådene på Facebook – søg på ”kostraad”
- Se film om de 10 kostråd på - https://www.youtube.com/watch?v=ZpGtyq-d6Qo

Fordele og ulemper ved at være fysisk aktiv

+	÷

Hvilken form for bevægelse, synes du, er rigtig sjov?

_____

_____

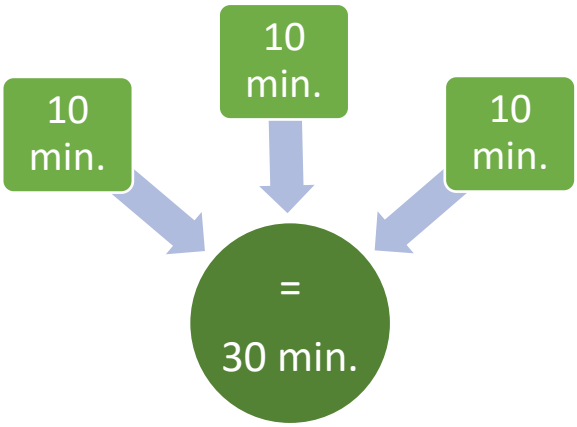
_____

_____

Anbefalinger til fysisk aktivitet for voksne

BEVÆGELSESAKTIVITET I MODERAT TEMPO

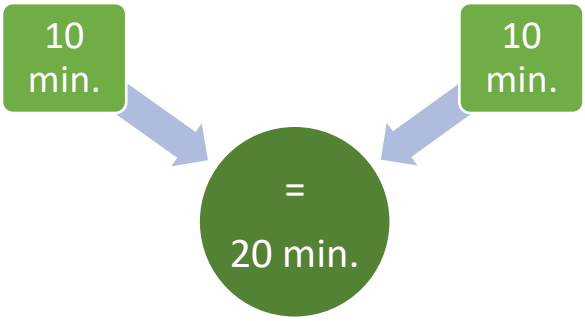
(forpustet, men kan stadig føre en samtale undervejs)



+

INTENSIV BEVÆGELSESAKTIVITET

(forpustet, sved på panden, kan ikke føre en samtale undervejs)



Du må gerne bevæge dig mere end det, men helst ikke mindre

Egne noter

Uge 2 Telefonisk opfølgning: vandindtag og daglige skridt

Til næste gang vil jeg afprøve:

I forhold til vandindtag

_____

_____

_____

_____

_____

I forhold til daglig bevægelse

_____

_____

_____

_____

_____

Uge 3 Målsætning, individuelt

Kortsigtet mål for en udvalgt meningsfuld aktivitet

_____

_____

_____

_____

_____

Kortsigtet mål for spisevaner

_____

_____

_____

_____

_____

Kortsigtet mål for daglig bevægelse

_____

_____

_____

_____

_____

HUSK:

- Vaneændringer kræver tid og energi
- Tag ikke fejl - et lille mål er stor nok
- Keep it simple – vælg nemme løsninger
- Små ændringer kan have stor effekt og holder længst
- Giv ikke op!

Egne noter

Uge 4 Telefonisk opfølgning: kortsigtede mål

Introduktion til hjemmeopgaven: ugeskema

Notér venligst dine aktiviteter med start fra dagen i morgen og 7 dage frem: Brug skemaet på næste side.

Du kan evt. samle aktiviteter i grupper, fx bad som en samlet betegnelse for flere beslægtede aktiviteter. Husk også hvileperioder og søvn.

Egne noter

UGESKEMA for daglige aktiviteter **Uge_____**

KL.	Ugedag:	Smerte 0-10*	Ugedag:	Smerte 0-10*	Ugedag:	Smerte 0-10*	Ugedag:	Smerte 0-10*	Ugedag:	Smerte 0-10*	Ugedag:	Smerte 0-10*	Ugedag:	Smerte 0-10*
06-12														
12-18														
18-24														
24-06														

*Smerte 0-10: 0 = ingen smerte; 10 = værst tænkelig smerte

Uge 5 Opsamling på hjemmeopgaven: ugeskema

Hvad har ugeskemaet fortalt?

Hvilke gøremål virker mest belastende på mig?

_____

_____

_____

_____

_____

Hvordan kan jeg gøre dem mindre belastende?

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Energibesparende teknikker - generelt

Hvad er energibesparende teknikker?
Energibesparende arbejdsmetoder handler om hvordan man bevidst anvender sin energi. Det betyder ikke at man skal gøre mindre i løbet af dagen men at man er bevidst om hvordan man bruger sine kræfter og hvordan man udfører forskellige aktiviteter.

1. **Prioritering**
- Bliv bevidst om, hvilke ting du bruger tid og kræfter på
- Hvor meget energi kræver de forskellige aktiviteter?
- Hvad skal du gøre?
- Hvad ønsker du at gøre?
- Hvad forventer du af dig selv?
- Hvad oplever du, at andre forventer af dig?

2. **Planlægning**
- Planlægning kan gøre dig mere bevidst om, hvad du bruger kræfter på
- Brug din dagsform hensigtsmæssigt
- Del de tungeste og mest tidskrævende opgaver op
- Planlægning kan være vanskelig, når dagformen varierer

3. **Tempo**
- Kroppen skal lige i gang – start langsomt
- Arbejd i et moderat tempo med små pauser undervejs
- Brug hvilestillingerne

4. **Arbejdsstillinger**
- Skift arbejdsstilling
- Ret overkroppen – brug de store muskelgrupper
- Gode hvilestillinger
- Stående eller siddende?

5. **Fysiske omgivelser**
- Tilpasning og placering af udstyr
- Placering af dig selv i forhold til det du arbejder med
- Fysiske ændringer i egen bolig

6. **Hjælpemidler**
- Middel til at opnå selvstændighed i forhold til aktivitetsudførelse
- Middel til at spare på energi, fx sparer du ca. 25% energi på at sidde ned fremfor at stå op
- Middel til at optimere arbejdsstilling
- Middel til at mindske smerter

Energibesparende teknikker - Specifikke råd

Planlægning af aktiviteten

Generelt:

- Brug din dagsrytme hensigtsmæssigt og planlæg aktiviteten til tidspunkter på døgnet, hvor du har det bedst.
- Hvis aktiviteten er fysisk anstrengende for dig, så tag din medicin inden du går i gang.
- Hvis der er flere i familien, kan man lave en fast arbejdsfordeling i forhold til, hvad der er tungt og ikke så tungt, samt hvad de forskellige aktiviteter kræver af tidsforbrug.
- Planlæg din hverdag og find en god balance mellem aktivitet og hvile. Sørg for at lægge pauser ind i løbet af dagen, i stedet for at fuldføre alle aktiviteter på en gang, så du bliver udkørt, og efterfølgende trænger til en lang pause.
- Planlæg aktiviteten, så du har tid og mulighed for at holde små pauser undervejs, hvis du får brug for det.
- Anvend afslapningsteknikker både når du skal hvile dig i løbet af dagen og før sengetid om aftenen.

Køkken: (indkøb + madlavning)

- Planlæg menuen på forhånd.
- Lav en indkøbsliste efter hvordan butikken er indrettet, i forhold til de varer du skal have.
- Tag alle ingredienser og redskaber frem inden du går i gang med madlavningen. Placer ingredienser og redskaber så tæt på som muligt.
- Hav altid hel - / halvfabrikerede madvarer i fryseren til de dage, hvor du ikke har kræfter til at lave mad.
- At servere maden i gryderne medfører færre tunge løft og efterfølgende mindre opvask.
- Når du skal strække dig ind over bordet, så kan du støtte med den ene hånd på bordet, samtidig med at du strækker det modsatte ben lidt bagud. På den

måde holder du ryggen ret, samtidig med at du holder armen i ro og det bliver lettere at trække vejret.

- Når du tømmer opvaskemaskinen, så behøver du ikke at stille de ting ind i skabet, som du ved du skal bruge senere på dagen. Når du tømmer opvaskemaskinen, - så tag det evt. i etaper. Sæt det først på opvaskelågen, bordet og derefter op i skabet.

Rengøring:

- Når du køber en ny støvsuger, så undersøg filter typen. HEPA-filter anbefales. Det kan også være en god idé at undersøge længden på skaftet til støvsugerslagen. Et langt regulerbart skaft kan give dig bedre arbejdsstilling.
- Saml på forhånd alt udstyret sammen du skal bruge til at vaske gulv.
- Flyt møblerne på forhånd, så kan du lettere komme til at vaske gulvet.
- Vurdér om du kan bruge en mikrofiber-moppe i stedet for en lang kost og klud.

Tøjvask:

- Tøj bliver ofte blødere af at tørre i en tørretumbler og behøver ikke at blive strøget.
- Anvend et letvægts-dampstrygejern.

Rede seng:

- Ved dynebetræk som er vendt med vrangen ud, kan du undgå de store energikrævende bevægelser.
- Et stræklagen holder sig bedre på plads end et almindeligt lagen.
- Vurdér om det er nødvendigt at skifte alt sengetøjet på samme dag eller om du kan fordele det over flere dage.
- Ved opredning af seng: Husk at husstøvmider trives bedst i en opredt seng. Så man kan med god samvittighed lade sengen stå uredt for en stund. Undgå brug af sengetæpper. De er ofte tunge og kræver en del energi at få lagt hen over sengen.

Personlig hygiejne:

- Tænk over hvilket tøj du vil have på og læg det frem dagen inden.
- Tag alt med dig, som du skal bruge og sørg for at det er let tilgængeligt.
- Tør dig med små håndklæder eller frottébadekåbe i stedet for store håndklæder.

Tempo

Generelt:

- Arbejd i et moderat tempo med rolige bevægelser.
- Hold små pauser undervejs i stedet for at skynde dig og blive udkørt, så du efterfølgende trænger til en lang pause.
- Husk på, at du skal have lyst og energi til at spise noget efterfølgende.
- Når du holder pause, - så find en god hvilestilling siddende eller stående. Sæt dig på en stol eller hvil dig ved at læne dig ind over et bord.

Vejrtrækningsteknik

Generelt:

- Husk at trække vejret helt ned i maven.
- Pust ud, anvend pustelyd / fløjtemund ved den mest anstrengende del af aktiviteten.
- Koordinér vejrtrækningen med dine bevægelser, så du får større kontrol over vejrtrækningen og tempoet bliver roligere.
- Husk at bruge vejrtrækningsteknik, når du bøjer dig ned og når du strækker armene.

Arbejdsstillinger og tilrettelæggelse af de fysiske omgivelser

Generelt:

- Arbejd med redskaberne tæt ind til kroppen. Det er mindre energikrævende end at arbejde langt væk fra kroppen.
- Anvend redskaber med langt skaft. Redskaberne bør være lette. Let - metal i stedet for træ-skaft og der bør være et godt greb. Placer f.eks. en støvklud i en gribetang.
- Pas på at du holder din brystkasse i en normal position – ligesom når du står oprejst. Prøv at bøje lidt i knæene eller brug redskaber med langt skaft.
- Monter eksempelvis glidesøm med filt, filt stykker eller hjul under møbler som ofte skal flyttes.

- Hvis du går med tanker om at lave om i køkkenet/bryggerset, kan det være hensigtsmæssigt at placere ovn, opvaskemaskine, vaskemaskine og tørretumbler oppe i god arbejdshøjde.
- Et alternativ til at stå op, er at anvende en arbejdsstol. På den måde sparer du på din energi og kræfter. Sid ned under dele af aktiviteten, når det er hensigtsmæssigt.
- Arbejd med ryggen ret, så lungerne får optimale arbejdsforhold.
- Hvis du skal op i højden, så stå på noget som er stabilt, i stedet for at strække dig og / eller arbejde med hænderne over hovedet.

Køkken: (indkøb, madlavning, opvask)

- Brug en indkøbsvogn. En indkøbsvogn er god at støtte sig til og du slipper for at bære så meget.
- Skal du bøje dig ned for at hente noget, der er placeret lavt, så bøj i knæene og ikke i ryggen. Støt dig evt. til indkøbsvognen, hvis du har brug for hjælp til at komme op igen.
- Gå rundt om disken i stedet for at række ind over disken. Skal du bøje dig ind over disken, så støt dig til kanten med den ene hånd, samtidig med at du strækker det modsatte ben lidt bagud. På den måde holder du ryggen mere ret, den ene arm i ro, og det bliver lettere at trække vejret.
- Når du skal bære varerne hjem:
    - Det er lettere at bære varerne i en rygsæk end at bære dem i armene.
    - At transportere varerne i en indkøbstaske på hjul er mindre energikrævende end at bære poser.
    - Hvis man bruger bæreposer, så fyld dem halvt op og hav lige meget i hver pose.
- Når du kommer hjem, så sorter varerne i en god arbejdshøjde f.eks. på køkkenbordet. Hvis det er nødvendigt at bære, så undgå at bruge tunge kurve. De vejer meget i sig selv.
- Placer ting i køkkenskabet, så det er lettest at nå det du oftest bruger.
- Anvend et rullebord, serveringsbord eller alternativt rollatoren når du skal transportere mad og service. Ønsker du at bære det, er det lettest at bære servicet i en kurv frem for på en bakke.
- Når du dækker bord, så tag en side ad gangen.
- Du kan også sidde på en stol ved opvaskemaskinen, når du tager ud eller sætter noget ind i den.
- Et alternativ til at stå op, når du vasker op, er at sidde på en stol. Husk at stolen skal være høj nok, så du sikrer en god arbejdsstilling. For at komme så tæt på bordet som muligt kan du åbne skabslågerne og sætte benene ind i skabet.
- Hvis du skal bøje dig ned for at sætte ting i eller for at tage noget ud af opvaskemaskinen, så kan du støtte med den ene hånd på bordkanten, samtidig

med at du strækker det modsatte ben lidt bagud. På den måde holder du ryggen ret og den ene arm i ro, og det bliver lettere at trække vejret.

Rengøring:

- Arbejd med ret ryg og med armene tæt ind til kroppen. En måde at gøre det på er, at lægge støvsugerslagen bag om ryggen. På denne måde vil du automatisk rette din ryg og armene vil komme tættere til kroppen.
- Flyt kroppen og brug benene i stedet for at strække dine arme ud, når du støvsuger.
- Når du skal støvsuge under bordet, sofaen eller lignende, så kan du sidde på en stol i stedet for at stå forover bøjet. Når du sidder ned, kan du komme længere ned, samtidig med, at du retter ryggen mere. Du kan evt. støtte dig til bordet / sofaen med den ene hånd mens du strækker det modsatte ben lidt bagud. Du holder ryggen ret samtidig med, at den ene arm er i ro og det bliver lettere at trække vejret.
- Ved at sætte hjul eller filt under enkelte møbler (f.eks. potteplanter som står på gulvet osv.), så kan du lettere flytte rundt på dem, samt lettere støvsuge med en god arbejdsstilling.
- Du kan sidde i sofaen, mens du støvsuger den, i stedet for at stå bøjet ind over sofaen.
- Undgå for mange pyntegenstande som står og samler støv. Vask genstande som tåler at komme i opvaskemaskinen.
- Placer bøger og pyntegenstande i bog – og vitrineskab for at undgå støv.
- Vælg møbler som ikke tiltrækker sig støv.
- Undgå at bære unødigt. Skub for eksempel spanden med gulvmoppen eller brug et rullebord.
- Hvis du bruger en spand; - så fyld den ikke mere end 1/3 op.
- Skal du bukke dig ned til spanden, kan du støtte dig til spisebordet eller en hylde med den ene hånd, samtidig med at du løfter/strækker det modsatte ben lidt bagud. På denne måde holder du ryggen ret, den ene arm i ro og det bliver lettere at trække vejret.
- Sæt spanden på en stol eller lignende for at få den op i en god arbejdshøjde.
- ”En 3 – hjulet spandevogn” er et hjælpemiddel, som hæver spanden op i højden, så den er lettere at tage med sig.
- Brug vinduesskraberen vandret på vinduet i stedet for lodret.

- Ved gulvvask: arbejd tæt ind til kroppen. Hvis du bruger en gulvmoppe bliver det lettere. Anvend vægtoverføring når du vasker, brug ikke kun armene.
- Rengøring af badekar: Sid på en stol/ på kanten af badekaret/badekarsbrættet/på knæ i stedet for at bøje dig, når badekaret skal rengøres. Brug rengøringsudstyr med langt skaft.
- Rengøring af bruseniche: Sid på en stol/på knæ, når gulvet skal vaskes. Alternativt rengøringsudstyr med langt skaft.
- Rengøring af håndvask: Sid på en stol ved håndvasken.
- Rengøring af toilet: Ved bøj og stræk hen over toilettet kan du støtte dig med den ene hånd på toilettet eller på vasken. Stræk det modsatte ben lidt bagud. På den måde holder du ryggen ret, den ene arm i ro og det bliver lettere at trække vejret. Sid på hug eller knæ, når du skal vaske den nederste del af toilettet.
- Brug rengøringsudstyr med langt skaft.

Tøjvask:

- Det kan være praktisk at anvende en vasketøjskurv på hjul eller et rullebord, så kan man lettere få vasketøjet til og fra vaskemaskinen og tørrepladsen.
- Stil vasketøjskurven på en stol, så højdeforskellen til vaskemaskinen / tørretumbleren ikke er så stor.
- Anvend lave tørrestativer frem for høje tørrestativer.
- Placér en vaskebalje eller tøjkurv under tørrestativet, når du hænger store tekstiler op, f.eks. lagen og lignende. Så slipper du for at anstrenge dig for, at det ikke berører underlaget.
- Tørretumbler kan lette arbejdet. Tøj bliver meget glattere og behøver ikke strygning efter tørretumbling.
- Det er lettere at sidde ned end at stå op, når du lægger vasketøjet sammen. Husk en god arbejdshøjde.

Stryge:

- Anvend vægtoverføring når du stryger. Brug benene mere end armene og lad varme og dampen gøre det meste af arbejdet, - og ikke din muskelkraft.
- Et andet alternativ er at sidde ned, når du stryger. Indstil strygebrættet efter din siddehøjde.

Rede seng:

- Det er lettere at rede en seng, der er placeret frit i rummet med hovedenden mod væggen. Her vil du lettere kunne nå hele sengen og slippe for at strække dig (du kan gå rundt om sengen).

Ind/ud af bil:

- Når du skal ind og ud af bilen, så kan det være en fordel at have sædet skubbet tilbage, da du vil få bedre plads til at komme ind og ud af bilen.
- Når du skal ind i bilen, så sæt dig på sædet og før derefter benene enkeltvis ind i bilen.
- Når du skal ud af bilen, så før benene ud enkeltvis før du rejser dig op.
- Ved at bruge en tynd siddepude, som har to dele, der drejer mod hinanden (”drejeskive”) kan ud – og indstigningen blive lettere.
- Sørg for at du sidder godt i bilen. Brug tid på at indstille sæde og lignende.

Personlig hygiejne:

- Anvend en badebænk, når du tager et bad.
- En badebænk kan også benyttes foran vasken, når du f.eks. skal vaske dig, børste tænder, barbere dig eller lignende.
- For at undgå at bruge for meget energi på at holde balancen; så læg skridsikre måtter på gulvet, opsæt håndtag på væggen både udenfor og inden for badekar/bruseniche.
- Ved hjælp af en børste med langt skaft undgår du at bruge store armbevægelser, når du skal vaske fødderne og ryggen.
- Hvis nedre af- og påklædning er anstrengende kan du bruge hjælpemidler med langt skaft (f.eks. skohorn og strømpepåtager) og/eller elastiske snørebånd.
- Omorganisér i hylder og skuffer, så det du bruger oftest er i den mest hensigtsmæssige højde. F.eks. strømper og undertøj i den skuffe der er mest tilgængelig.
- Du kan sidde ned ved nedre af- og påklædning.

Havearbejde:

- Når du skal flytte ting rundt i haven er det en god idé at tænke på hvilke alternativer, der er til at bære tingene.
    - Anvend f.eks. trillebør eller lign. med hjul til at køre redskaberne rundt i haven.
    - Sæt krukker og potter på plader med hjul, så de er lette at flytte.
    - Anvend en slangevogn, - en vogn med hjul, som haveslagen er viklet omkring.
    - Anvend selvvandingssystem i stedet for at vande hver dag.

Egne noter

Uge 6 Telefonisk opfølgning: kortsigtede mål

OBS på sko som sidder fast på foden til næste gang

Uge 7 Bevægelse og velvære

Idéer til at øge din ugentlige mængde af fysisk aktivitet

_____

_____

_____

_____

_____

Afspænding

- Søvn og hvile, lige som fysisk aktivitet, er med til at holde balancen i hverdagen
- Mangel på søvn og hvile opleves af mange kroniske patienter, derfor er alternative veje til at "geare ned" og aktivere kroppens afslapningssystem (det parasympatiske system) er vigtige
- Du kan praktisere afspændings- eller visualiseringsøvelser ubegrænset i løbet af dagen. Disse er indspillet i forskellige længder og kan findes på nettet, fx denne: https://www.youtube.com/watch?v=DXzk5i4Ofe8
- Brug gerne materialer fra autoriserede psykologer og uddannede instruktører i fx mindfulness.

Egne noter

Uge 8 Telefonisk opfølgning: kortsigtede mål

Uge 9 Måltider og spisevaner

Madlavning

- Skær frugt og grønt ud og stil dem klar

Fordi: Vi vælger det som er nemt tilgængeligt

- Lav kun den mængde mad, I kan spise

Fordi: Som forbrugsbevidste mennesker vil vi nødigt levne. Hellere supplere med et lille mellemmåltid senere, hvis sulten melder sig.

- Sørg for, at de fleste af de 5 smagssanser er præsenteret: sød, surt, salt, bitter og umami

Fordi: Jo flere sanser stimuleres, jo hurtigere indtræder mæthedsfornemmelse, og mæthedsfølelsen varer længere

Derudover kan du prøve:

- Lade måltidet være farverig

Fordi: vi bliver hurtigere mætte, når vi ”spiser med øjnene”, det vil sige, flere sanser kommer i spil

Servering af maden og spisning

- Spis siddende og tænd ikke for tv, pc, tablet og mobil, mens du spiser

Fordi: Ved at have det fulde opmærksomhed på maden, spiser vi mindre på de ca. 20 min., hvor mæthed begynder at kunne mærkes

- Vær opmærksom på, at vi spiser mere i selskab med andre

Fordi: Måske skal du beslutte dig på forhånd, at du kun tager én portion, når I er flere ved bordet

- Spis lidt hver 3.time

Fordi: det giver en god rytme i fordøjelsessystemet

- Hold dig fra småspisning mellem de planlagte måltider og under madlavning

Fordi: Vores hjerne regner småspisning ikke for et rigtigt måltid, så vi tror, at vi spiser mindre end virkeligheden er

- Spis af små tallerkener og skåle

Fordi: Det forebygger overspisning

- Skænk maden i køkkenet og lad salaten stå på bordet

Fordi: det bliver nemmere at spise flere grøntsager (brug evt. en stor ske til salaten)

- Drik kalorieholdige drikke som juice, sodavand, saft og øl af høje slanke glas

Fordi: Et bredt glas af samme højde vil rumme mere af produktet, dvs. flere kalorier

- Find et andet sted til at sidde og slappe af end i køkkenet

Fordi: Spisetrangen bliver ikke stimuleret unødigt

Y-tallerkenmodel (modellen til vedligeholdelse af vægt)

1/5 kød, fisk osv. (protein)

2/5 grøntsager

2/5 kartofler/ pasta/ brød (stivelse)

T-tallerkenmodel (eller Slanketallerkenmodel)

1/4 kød, fisk osv. (protein)

1/2 grøntsager

1/4 kartofler/ pasta/ brød (stivelse)

Derudover kan du prøve:

- Lade spisningen af 1 portion strække sig over mindst 20 min.

Fordi: mæthedsfornemmelsen indtræder først efter denne periode, så bliver det nemmere ikke at overspise

Egne noter

Uge 10 Telefonisk opfølgning: kortsigtede mål

Egne noter

Uge 11 Hjemmebesøg: tilpasning af egne omgivelser i forhold til målarbejdet

Egne noter

Uge 12 Telefonisk opfølgning: kortsigtede mål, opfølgning på ergonomi og indretning i eget hjem der fremmer/ hæmmer målarbejdet

Uge 13 Køkkenindretning, opbevaring af mad og indkøb

Køkkenindretning og opbevaring af mad

- Placér den sunde mad i øjenhøjde

Fordi: Der er 30% større chance for at ting placeret i øjenhøjde bliver valgt

- Byt om på køleskabsindholdet, fx sæt syltetøj ned i grøntsagsskuffen og grøntsager højere op

Fordi: Det bliver nemmere at vælge grønt

- Lad maden ikke stå fremme

Fordi: Vi bliver unødvendigt fristet ved synet af mad

- Pak sunde retter i husholdningsfilm frem for stanniol

Fordi: Det, vi hurtigt kan få øje på, bliver oftest vores første valg

- Det som ikke skal friste skal i uigennemsigtige beholdere og væk fra synsfeltet

Fordi: Det hjælper at undgåfristelser

- Ompak store poser til mindre portioner

Fordi:

  - Jo større emballage, jo mere forbruger vi
  - Tilfredshed er den samme, om vi får et lille bid eller en hel pose
  - Det er de første få mundfulde der gør forskel, ikke resten
- Stil kalorieholdige madvarer og drikke ud i skuret/ på de øverste hylder eller andet svært tilgængeligt sted

Fordi: svært tilgængelige ting tiltrækker mindre

Idéer til små forandringer i eget køleskab og køkken

Hvad i dit køleskab skal stå i øjenhøjde?

_____

_____

Hvad i dit køleskab skal væk fra synet?

_____

_____

Har du mad stående fremme? Hvilken type mad? Hvor kan den opbevares i stedet?

_____

_____

Hvad skal pakkes ind i husholdningsfilm? Hvad skal ind i helst ikke-gennemsigtig beholder?

_____

_____

Hvilke madvarer kan du ompakke i mindre portioner for at minimere forbrug?

_____

_____

Hvilke madvarer skal helt ud i skuret (andet længst placeret sted)?

_____

_____

Indkøb

- Tjek, hvad du har hjemme i forvejen, lav madplan og køb stort men sjældent

Fordi: Jo sjældnere du køber ind, jo mindre chance der er for fristelser

- Vælg en indkøbskurv i passende størrelse, alt efter, hvor meget du vil købe ind

Fordi: Jo større indkøbskurv, jo mere føler vi trang til at fylde den

- Klar dig uden indkøbskurv, hvis du kun er ude efter et par ting

Fordi: Det forebygger impulskøb

- Køb ikke ind på tom mave

Fordi: Det forebygger impulskøb

- Køb ind efter aftensmaden

Fordi: Det forebygger impulskøb

- Brug mint-tyggegummi for at dæmpe duften fra bage- og slikafdelingen

Fordi: Det neutraliserer duften af bagværk

- Start indkøbsturen i grøntsagsafdelingen

Fordi: Vi bruger mest tid i starten af indkøbsturen. Det give en større chance til, at frugt og grønt vil fylde mere i indkøbskurven

- Brug tiden ved kassen på fx en vejrtrækningsøvelse eller gennemgang af indkøbssedlen

Fordi: Ved kassen sker der ofte impulskøb, derfor kan afledning være godt for både sundhed og pengepungen

10 hurtige om Nøglehulsmærke:

Hvilke udsagn passer? (Sæt X)

1. ___ Nøglehulsmærket tildeles kun økologiske madvarer
2. ___ Nøglehulsmærket betyder bæredygtig produktion
3. ___ Kun Nøglehulsmærket hjælper at skelne de sunde madvarer fra de usunde
4. ___ I nøglehulsmærkede mad er der max mulig mængde fuldkorn
5. ___ Nøglehulsmærket betyder mindre fedt sukker og salt, samt flere fuldkorn
6. ___ Nøglehulsmærket betyder et sundere valg inden for en bestemt varegruppe
7. ___ Nøglehulsmærket er Miljø- og Fødevareministeriets officielle ernæringsmærke
8. ___ Nøglehulsmærkede mad er mest for dem der har diabetes
9. ___ Nøglehulsmærke er fælles nordisk ernæringsmærke
10. ___ Man skal gå efter den grønne Nøglehulsmærke, den sorte er knap så god

(Fødevarestyrelsen og Forbrugerrådet Tænk)

Fødevaremærker

Disse tre tegn er de statslige fødevaremærker med det højeste niveau af kvalitetskrav:

Nøglehulsmærket

Fuldkornsmærket

Ø-mærket

- Mærker fra forskellige organisationer som Dyrenes Beskyttelse, Astma-Allergi Forbundet, Fair Trade er ikke nødvendigvis mindre gode end de statslige mærker, men deres krav til produktet er knap så reglementerede
- Producenternes egne ernæringsmærker, fx Kellogs og Nestlé, har markedsføring som formål. Deres krav er endnu sværere at gennemskue

Når du håndterer ting:

Tjek gerne beskrivelsen af energibesparende principper og teknikker, både generelle og specifikke, for mere inspiration

Næringsdeklarationer

Næringsdeklaration er listen med ingredienser der er i maden. Den første ingrediens på listen er der mest af i den pågældende vare. Jo længere ned på listen er en ingrediens, jo mindre af den der er i denne vare.

Energi- og næringsindholdet står angivet for 100 g/ 100 ml eller 1 portion af produktet. OBS på, hvor mange gram en portion er målt til (det er ikke sikkert, at mængden passer med det, du plejer at spise!) Energibehovet for en gennemsnitsdansker er ca. 2000 kcal for kvinder og 2500 kcal for mænd.

Anbefalingerne for fordelingen og mængden af fedt, kulhydrat og protein i det daglige energiindtag er: Kulhydrat - 45-60 %; Protein -10-20 %; Fedt - 25-40 %. Vær opmærksom på, at 1 gram fedt giver dobbelt så meget energi som 1 gram protein eller 1 gram kulhydrat. Selvom fedtholdige produkter som olie, mayonnaise osv. har højt kalorieindhold, bliver der typisk brugt lidt af dem.

Kostfiberindholdet viser, hvor groft produktet er. Kostfibre gavner fordøjelsen og forlænger mæthedsfølelsen. Fuldkornsmærkede produkter er rige på kostfibre. Betegnelsen ”grov” giver derimod ikke automatisk garanti for, at der er højt indhold af kostfibre i produktet.

Når du er ude i supermarkedet, se især efter følgende:

- **Salt** bliver også angivet som Natrium (1g natrium = 2,5 gram salt). For stort indtag af salt påvirker blodtrykket. Jo mindre salt der tilsættes maden, jo bedre. Den maksimale daglige norm er 5-6 gram salt.

- **Sukker** giver en hurtig energitilførsel og kortvarig lykkefølelse, hvor effekten forsvinder igen efter kort tid. Svingninger i blodsukkeret på baggrund af sukkerindtag kan føre til træthed, humørsvingninger og livsstilssygdomme. Der anbefales at spise så lidt tilsat sikker som muligt og max 50 g tilsat sukker om dagen for kvinder og 60 g – for mænd.

- **Mættet fedt**, lige som salt og sukker, skal gerne holdes på et minimum. For højt indhold af disse i kosten kan føre til udvikling af kroniske tilstande. Det mættede fedt findes i kød, smør, mælk og ost m.m. Mættet fedt kan føre til forhøjet kolesterol og udvikling ag hjerte-karsygdomme.

- **Tilsætningsstoffer** (eller E-numre) tilfører maden mere farve, smag eller bedre konsistens. De kan både være naturlige og kemisk fremstillede. Hvis der ikke er E-numre i varedeklarationen, betyder det ikke, at der ikke er tilsætningsstoffer (fx kaldes E-300 citronsyre).

- **Allergener** fremhæves med fed skrift eller blokbogstaver. Allergenerne er fx mælk, nødder, æg, hvedemel.

Dem der gerne vil ned i vægt skal også se efter:

- **Kalorietal pr. 100 g af produktet** – må IKKE forveksles med kalorietal pr. portion som typisk er væsentlig mindre end de 100 g
- **Stivelse,** i fx light mælkeprodukter, bliver ofte tilsat for at bibeholde den gode konsistens, når sukker og fedt bliver fjernet (fx i yoghurt mm.) Stivelse og sukker har samme kaloriemængde, derfor er det ikke garanteret, at light-madvarer vil give et lavere kalorieindtag.

Holdbarhed og madspild

Holdbarhedsdato (”Mindst holdbar til”/ ”bedst før”) angiver datoen, hvor produktet bevarer den rapporterede kvalitet. Produktet skal ikke nødvendigvis smides ud efter denne dato, men man skal vær opmærksom på dens smag, duft og farve og smide for gammel mad ud. Sidste anvendelsesdato er derimod den frist, hvor maden kan gøre dig dårlig, hvis den bliver spist efter datoen.

Madspild kan koste en familie med børn omkring 7.000 om året og 11 milliarder kroner på landsplan (Landbrug og Fødevarer, 2014 – www.taenk.dk). God forberedelse hjælper til at undgå madspild, derfor prøv at gøre følgende, INDEN du køber ind:

1. Planlæg indkøb så sjældent, som det kan lade sig gøre
2. Lav en madplan for en hel uge
3. Lav en indkøbsliste for en hel uge
4. Tjek, hvad du har hjemme i forvejen
5. Køb ikke ind på tom mave (ha’ lidt nødder eller lign. ved hånden)
6. Tag’ en mindre kurv (eller ingen kurv!)
7. Køb den nødvendige mængde og pas på de ”gode tilbud”

Uge 14 Telefonisk opfølgning: evaluering af målarbejdet

Egne noter

Uge 15 Opsamling og afslutning

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TAK FORDI DU HAR VÆRET MED
OG ALT DET BEDSTE FREMOVER!

OPSKRIFTER TIL INSPIRATION

MORGENMAD

Havregrød – basisopskrift med lidt ekstra

INGREDIENSER TIL 1 PORTION

1 dl havregryn

1 dl mælk

1 dl vand

TOPPING
Revet æble
Banan i skiver
Knuste hørfrø

KAN OGSÅ TILSÆTTES

1 reven gulerød

1 tsk. chiafrø

0,5 tsk. gurkemeje

TILBEREDNING

Bland ingredienserne i en gryde

Lad koge få minutter

Eller overhæld bare blandingen med kogende vand (evt. varm mælk) i stedet for kogning

Lad da grøden stå og trække 3-5 minutter

MELLEMMÅLTIDER & SNACKS

GREENIE til 1-2 personer (eller 1 person 2 gange om dagen)

1 banan

1 håndfuld broccoli (frisk eller fra frost)

½-1 håndfuld spinat (frisk eller fra frost)

½ squash eller agurk

\+ Vand eller kokosmælk til den ønskede konsistens

KAN OGSÅ TILSÆTTES

Lidt æble eller appelsin

Ingefær

Mandler eller andre nødder

TILBEREDNING

Blend det hele

Blåbærsmoothie

150 gram (frosne) blåbær (evt. solbær, brombær eller andre bær)

1 banan

1 dl skyr

1 dl appelsinjuice

10 mandler

TILBEREDNING

Blend det hele

Hummus med grønt

Hummus (fædigkøbt) – skylles før brug

Gulerod, peberfrugt og agurk i stave

Kålbuketter af broccoli og/eller blomkål

Cherrytomater

Grøntsagsboullion eller vand tilsættes til den ønskede konsistens

HVIS DU VIL TILBEREDE KIKÆRTER SELV

- 200 g kikærter*
- ½ dl koldpresset rapsolie
- ½ dl ekstra jomfruolivenolie
- 3 spsk. tahin (sesampasta)
- Hvidløg
- Citron
- Havsalt
- Friskkværnet sort peber

Udblød kikærterne i min. 8 timer, kog dem møre, og dræn dem (gem kogevandet).

TILBEREDNING

Bland ærterne med de to slags olie, tahin og så store dele af kogevandet, så du opnår en passende konsistens.

Smag til med hvidløg, citron, salt og peber.

Anret med grønne stænger ved siden af (eller evt. salatblade)

FROKOST

Ærtemos

3 spsk. olivenolie

1 fed hvidløg

Lidt salt og peber

0,5 pakke frosne ærter

TILBEREDNING

Overhæld ærterne med kogende vand og lad stå 3-5 minutter

Blend ærter sammen med olivenolie og hvidløg

Smag til med salt og peber

TIL EN ENDNU MERE CREMET KONSISTENS

Blend kødet fra en avocado med

Kartoffelsalat med pesto og grønne og hvide bønner

1 dåse hvide bønner

Frosne grønne bønner

Kartofler

Grøn pesto

TILBEREDNING

Kog kartoflerne i letsaltet vand

Overhæld de frosne grønne bønner med kogende vand og lad stå ca. 5 min.

Hæld vandet fra kartoflerne og de grønne bønner

Evt. skær kartoflerne i mindre stykker

Bland kartofler og de to slags bønner

Vend pesto i

Æggekage med blomkål og bacon

½ blomkål

Raps- eller olivenolie

4 skiver bacon

6 æg

3 spsk. mælk

forårsløg

salt

peber

TILBEREDNING

Skær blomkålen i mindre buketter og kom det op i et ildfast fad

Dryp lidt olie ovenpå blomkålen

Læg baconskiver ovenpå

Sæt fadet i ovnen, og bag det i 10 minutter ved 200 grader (evt. sæt alarm på)

Pisk æg og mælk sammen

Tilsæt æggeblandingen lidt salt og peber og snittet forårsløg efter smag

Tag fadet med blomkålen ud af ovnen

Knæk/ skær bacon i mindre stykker og kom det tilbage i fadet

Hæld æggeblandingen over

Bag æggekagen til den er fast og færdigstegt (ca. 20 minutter)

IDÈ TIL NEM MADPAKKE

Grød to-go

- Et nemt mellemmåltid

Ingredienser til 1 portion

1 dl havregryn

1 tsk. chiafrø

1 drys stevia

1 drys vaniljepulver

1 spsk. hakkede nødder

2½ dl kogende vand

TILBEREDNING

Find beholder med låg der tåler kogende vand, fx et syltetøjsglas eller lignende

Kom ingredienserne **(undtagen kogende vand!)** i beholderen

Inden måltidet: tilsat kogende vand og rør rundt

Lad grøden trække i 5 min. under låg

SALATER

Spidskålsalat med broccoli

1 spidskål

1 broccoli i buketter

2 æbler

Lille håndfuld rosiner (eller tranebær)

0,5 dl sesamfrø

Olivenolie

Æblecidereddike

Salt

Peber

TILBEREDNING

Snit kålen fint

Skår broccoli i buketter (evt. hæld broccolibuketterne over med kogende vand og lad ligge i ca. 5 min., så bliver de knap så grove men stadig sprøde)

Skær æblerne i tern

Bland det hele sammen med sesamfrø og rosiner (eller tranebær)

Lav dressingen af 2 spsk. olivenolie, 3 spsk. æblecidereddike, salt og peber

Hæld dressingen over

Rødkålssalat

¼ rødkål

1 appelsin

Græskarkerner (eller evt. mandler eller andre nødder)

Dressing

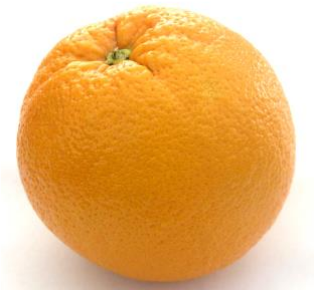
Koldpresset rapsolie

Æblecidereddike

Mild sennep

Salt

Peber



TILBEREDNING

Snit kålen fint

Skår appelsinen i både eller tern

Bland det hele og hæld dressingen over

AFTENSMAD

Hvidkålsuppe med eller uden kød

¼ af hvidkålshovedet (evt. ½ hvis en stor portion ønskes, andre ingredienser skal da dobles op)

4 kartofler

3 tomater (kan udelades)

2 gulerødder

1 løg

1-2 fed hvidløg

Salt og peber

Evt. andre krydderier, fx cayennepeber eller laurbærblade

TILBEREDNING

Hvidkål snittes

Kartofler og gulerødder skrælles og skæres i mindre tern

Tomater skæres i både

Kog vandet (eller boullionen) op og tilsæt kartofler og gulerødder

Skær op i løghovedet (skær et "kryds" så det hænger stadig sammen) – skal fiskes op ad gryden inden servering!

Lad det hele koge 10 min.

Tilsæt snittet hvidkål og tomater og lad koge 10 min. igen

HVIS ØNSKES KAN LAVES MED KYLLING ELLER OKSEKØD

Kylling eller oksekød koges

Boullion bruges i stedet for vand

Kødet skæres i småstykker og tilsættes suppen

Pasta med tomat-aubergine sauce

1 aubergine

1 dåse hakkede tomater

Koldpresset rapsolie til stegning

1-2 fed hvidløg

Pasta efter eget valg

Evt. andre krydderier, fx cayennepeber, chili eller basilikum (frisk eller tørret)

Evt. revet hård ost, fx af parmesan-type

TILBEREDNING

Aubergine skæres i tern og steges i rapsolie til en blødere konsistens

Tomater på dåse tilsættes

Retten varmes op

Snittet (eller presset) hvidløg og andre tørre krydderier tilsættes

Pasta (efter eget valg) koges 'al dente'

Tomat-aubergine sauce serveres særskilt eller blandes med den kogte pasta

Evt. toppes med ost og frisk basilikum

HVIS ØNSKES KAN SPISES SOM TILBEHØR TIL KØD, FISK ELLER KYLLING

Ovnbagte grøntsager – alene eller som tilbehør

Tag en ønsket mængde af:
Gulerødder
Kartofler
Pastinakker
Rødbeder
Rapsolie
Salt
Peber

Til dip

Ca. 2 dl græsk yoghurt eller creme fraiche
2 hvidløgsfed
Salt
Peber

TILBEREDNING

Skræl grøntsagerne
Skær på langs (i stænger), på tværs (i cirkler) eller i både
Put alle grøntsagerne i en pose
Bland ½-1 dl olie med presset hvidløg salt og peber efter eget smag
Hæld blandingen over grøntsagerne
Bind en knude på posen eller luk tæt på anden måde (evt. med en klemme)
Vend posen rundt, så olien er fordelt jævnt
Læg bagepapir i en bradepande
Hæld grøntsagerne ud på bradepanden
Bag 40-50 min. ved 200 grader (rør rundt ind imellem, hvis nødvendigt)

Til dip

Bland creme fraiche eller græsk yoghurt med presset hvidløg, salt og peber

DESSERT

Frugtsalat med topping

2 æbler

2 appelsiner

1 bakke vindruer

2 bananer

2 pærer (…eller andet frugt)

Evt. 2-3 stænger bladselleri for et højere fiberindhold

1 l skyr (evt. vaniljeskyr)

Honning

Vaniljesukker

Græskarkerner

TILBEREDNING

Skær frugt i tern og bland det hele sammen

Bland skyr med honning og vaniljesukker

Server frugt i mindre portioner toppet med skyr-blanding og græskarkerner

Appendix 16

Assessment protocol

TESTPROTOKOL

Registrering af forsøgspersoner (24 personer i alt)

- Registreringen starter inden første kontakt, ved godkendelse til projektet (Registreringsskema i Sharepoint/ teamsite)
- Når forsøgspersonen (FP) er godkendt til deltagelse af lægen, oprettes FP i registreringsskemaet i Excel og tildeles deltager ID
- Relevante informationer registreres derefter løbende i Registreringsskemaet, fx levering af mundtlig og skriftlig information, påmindelser om bekræftelse på deltagelsen osv.
- Ved første kontakt tilknyttes FP til forskningsprojektet i SP
- Kontakter til FP (personlige, skriftlige eller telefoniske) noteres i SP fortrinvis ved brug af de oprettede smartfrases (findes i Sharepoint/ teamsite)

Undersøgelser i projektet

- Alle deltagere testes to gange: 1. gang Ca. en uge før interventionens start; 2. gang Ca. en uge efter interventions afslutning (interventionen varer 12 uger)
- Undersøgelser foregår hovedsageligt i ergoterapiens testlokale som er indrettet til formålet. AMPS-testen kan evt. foregå i ergoterapiens køkken eller tilstødende arealer.
- Inden hver undersøgelsesdag:
    - Tidspunktet for undersøgelsen aftales direkte via tlf.
    - Samtidigt laves der aftaler for mødetidspunkter til de individuelle sessioner (1-3-7-11 session) og follow-up (Bed FP om at notere aftalerne og oplys om, at de aftalte tider også bliver send ud som en bekræftelse i FP's e-boks og i kopi i deltagermappen som udleveres på 1. session. Parkeringstilladelserne til alle gange udleveres også med mappen)
    - Oplys om, at hver undersøgelsesforløb varer ca. 3 timer inkl. en pause på 10 min. (evt. flere pauser kan gives ved behov)
    - FP må gerne have en madpakke med, lette snaks haves
    - Oplys vedr. tøjvalg til undersøgelsesdagen: tøjet som FP kan bevæge sig i, og hvor ærmene og buksebenene kan smøges nemt op
    - Aftal de to aktiviteter til AMPS-testen

  - Oplys om, at i bekræftelsesbrevet sendt til e-boks er der et link til et kort spørgeskema. Spørgeskemaet skal udfyldes inden undersøgelsen
- Efter telefonisk samtale:
  - Evt. køkkenlokalet bookes til AMPS-test
  - Deltagermappen klargøres, bl.a. med kopi af bekræftelsesbrevet
  - Evt. opdatér registreringsskemaet
- Inden undersøgelsen:
  - Snack og drikkevarer forberedes til undersøgelsesdagen
  - Testskemaer til registrering af resultater og skemaer til COPM og AMPS printes ud
  - Samtykke-ark printes ud til underskrift
  - Madvarer til AMPS-testen indkøbes
- Under tests i testlokalet er kun testleder og FP til stede (husk "optaget"-skiltet på døren!)
- Blinding af testledere: ikke relevant i pilotprojektet
- Samme testleder i hele forløbet: tilstræbes så vidt det er praktisk muligt

Testrækkefølge

Rækkefølgen må ikke brydes!

- Identitetstjek og indhentning af manglende kontaktoplysninger
- Informeret samtykke underskrives i påpirform inden undersøgelsen påbegyndes! (kun ved baseline)
- FP spørges, om han/hun har udfyldt spørgeskemaet i PainData (i pilotprojektet udfyldes fælles standard skema + Tillægsskema 1). Links tilsendes inden undersøgelsesdagen.

  OBS: Hvis FP ikke har udfyldt PainData-spørgeskemaet, når de møder op, tilbydes de muligheden for at udfylde spørgeskemaet umiddelbart efter undersøgelsen (oplys om evt. forlængede tid). En PC/ IPad med internetadgang stilles da til rådighed. Hvis afvises, opfordret FP at udfylde spørgeskemaet snarest muligt, fx efter hjemkomsten samme dag.
- Følgende tests gennemføres
  1. COPM (Bilag 1)
  2. Blodtryk (Bilag 2)
  3. Højde, vægt og BMI-udregning (Bilag 3)
  4. Taljemål (Bilag 4)

5. AMPS (Bilag 5)
6. Algometertest (Bilag 6)
7. Hjemmetest af bevægelsesaktivitet (actigraphy) i 4 døgn (Bilag 7)
   - Påsætning af måleren
   - Instruktion om brug
   - Notatark til hjemmebrug
8. Skemaer til udlevering (Bilag 8):

   8a. Standard registreringsskema til COPM-undersøgelse,

   8b. Skema til blodtryksapparatet Microlife BP A3L Comfort

   8c. Feedback skema til FP på resultater af vægt, højde, BMI, taljemål og blodtryk

   8d. Aktivitetsdagbog for 4-døgnsmåling

Beskrivelse af testprocedurer

Note: *"Skråskrift"* illustrerer direkte tale.

"Vær's'go og sæt dig ned. Først skal jeg oprette dig som deltager i projektet."

- FP bedes om at nævne sit fulde navn og cpr nr.
- Gyldig e-mailadresse og telefonnummer på FP indhentes

Udfyld testsskemaet.

"Inden vi går i gang, skal jeg bede dig om at underskrive samtykkeerklæringen. Jeg vil også høre dig, om du har nået at udfylde PainData-spørgeskemaet? Der har både været et langt spørgeskema og et kortere tillægsskema. Begge skal gerne være udfyldt."

<u>Hvis FP ikke har udfyldt spørgeskemaet:</u>

"Det er vigtigt, at spørgeskemaet bliver udfyldt tæt på undersøgelsesdagen. Hvornår vil det passe dig at udfylde det? (fx lige efter undersøgelsen på ergoterapiens pc/IPad eller hjemme, gerne samme dag)

"Du skal igennem nogle undersøgelser. Hele undersøgelsesforløbet kan tage op til 3 timer og har forskellige tests, hvor du både vil sidde ned og bevæge dig. Der er planlagt pauser undervejs. Sig endelig til, hvis du har brug for en ekstra pause. Der er juice, vand og snacks til rådighed."

"Det første, vi gør, er et ergoterapeutisk interview".

Bilag 1. COPM-interview

COPM-standard registreringsskema anvendes til notater

OBS at notere navn og deltager ID på skemaet!

Skriv resultaterne ned i feedback-skema til FP (hvis efterspørges)

COPM-interviewguide

ETP = ergoterapeut; FP = forsøgsperson

Trin i undersøgelsen	ETP	Kommentarer og ekstra spørgsmål
Indledning	*Vi skal snakke sammen en halv times tid. Det er en slags interview, hvor vi kommer igennem nogle trin. Jeg skal nok guide dig. Jeg skriver også lidt ned undervejs.* *Fokus i denne samtale vil være på dig og det, der betyder noget i dit hverdagsliv. Vi vil komme ind på, hvad du har brug for at gøre, er nødt til at gøre og har lyst til at gøre, men måske ikke gør aktuelt.*	
Trin1 **Problemafklaring**	*Nu skal jeg lige fortælle, at vi ergoterapeuter arbejder med aktiviteter. Og i denne undersøgelse er aktiviteter inddelt i tre grupper. De grupper skal vi ind på.*	
• **Egenomsorg**	*Den første gruppe er de aktiviteter, vi gør for at passe på os selv, og hvad vi har brug for, for at møde livet…* *Er noget af det vanskeligt for dig?*	Fx spise, tage tøj på, gå i bad, komme omkring… Ekstra: Hvordan går det med at tage tøj på? Kan du godt bøje dig ned og tage bukser/ sokker på? Er noget af det du laver, er vanskeligt for dig? Er der nogen ting, du måtte at opgive pga. smerter?
• **Produktivitet**	*Det andet område er det, som vi skal gøre, fordi vi føler os forpligtede til at gøre det, eller fordi det er nødvendigt at gøre.* *Er der nogle ting her, som du har udfordringer med?*	Fx arbejde, husarbejde, forskellige omsorgsopgaver i forhold til børn, forældre osv. Ekstra: Er noget af det du laver, er vanskeligt for dig? Kunne du tænke dig at gøre mere af det? Er der nogen ting, du måtte at opgive pga. smerter?

• **Fritid**	*Det sidste område er det, vi gør at lyst, for sjov eller af interesse.* *Hvad plejer du at lave, når du har "fri"?*	Ekstra: Er der noget, du været glad for at lave? Har du nogen hobby eller fritidsinteresse? Er noget af det du laver, er vanskeligt for dig? Er der nogen ting, du måtte at opgive pga. smerter?
Opsummering og verificering	*Du har nævnt…* *(opsummerer aktivitetsproblemer noteret i COPM-skemaet)* *Ligner det meget det, du har fortalt mig?*	
Overgang til vurdering af vigtighed og scoring	*Nu vil jeg gerne have dig til at score på de ting, du har nævnt. Der er i alt tre skalaer.*	
Trin 2 **Vurdering af VIGHIGHED** Aktivitetsproblem 1 Aktivitetsproblem 2…	*Først vil jeg gerne bede dig at vurdere, hvor vigtige de ting er.* *Skalaen går fra 1 til 10. 1 betyder, at det slet ikke er vigtigt for dig, og 10 betyder, at det er enormt vigtigt for dig.* *Vi tager én ting ad gangen…* *Hvor vigtigt der er for dig på en skala fra 1 til 10?* *Hvor vigtigt…? (Gentages)*	Skala for VIGTIGHED tages frem Vær sikker på, at PT har forstået princippet i scoringen (Guider scoringen igennem alle nævnte aktivitetsproblematikker)
Prioritering af aktivitetsproblematikker	*Ud af de ting, vi har talt om, kan du vælge fem ting, som du kunne tænke dig, at vi fokuserer behandling på. Du behøver ikke at vælge alle fem ting, men det er max fem der må vælges.*	Spørg ind til evt. uoverensstemmelser mellem scoring og prioritering
Trin 3 & 4 **Scoring for udførelse og tilfredshed** Aktivitetsproblem 1 – udførelse Aktivitetsproblem 1 - tilfredshed	*Vi går videre med de ting, du har valgt, og tale om, hvordan det så rent faktisk går i dag?* *Jeg har en anden 1-10 skala, hvor 1 betyder "kan slet ikke" og 10 – "kan enormt godt"* *Hvordan går det med at…?* *Og så den anden skala for, hvor tilfreds er du med den måde, du kan gøre det på i dag?* *Skalaen er igen fra 1 til 10, hvor 1 betyder, at du slet ikke er tilfreds, og 10 – at du er enormt tilfreds.* *Hvordan går det med…? (Gentages)*	(Guider scoringen for udførelse og tilfredshed for én aktivitetsproblematik ad gangen)

Aktivitetsproblem 2 – udførelse Aktivitetsproblem 2 - tilfredshed		
Aftale om revurdering	*De ting, du har valgt i dag, vil vi arbejde med igennem behandlingsforløbet.* *Når behandlingsforløbet er slut, og du kommer til næste undersøgelsesrunde, vil vi bede dig om at score for udførelse og tilfredshed igen. Det vil gå meget stærkere, da vi ikke vil skulle igennem interviewet. Det er kun de sidste to skalaer, vi vil bruge fremover.*	
Trin 5 **Revurdering** (se Trin 3 & 4) Aktivitetsproblem 1 – udførelse Aktivitetsproblem 1 - tilfredshed Aktivitetsproblem 2 – udførelse… Aktivitetsproblem 2 – tilfredshed…	*Vi skal kigge på, hvordan det går med de ting, du har sidst valgt at arbejde med i behandlingsforløbet.* *Jeg har en 1-10 skala, hvor 1 betyder "kan slet ikke" og 10 – "kan enormt godt"…* *Hvordan går det med at…?* *Og så den anden skala for, hvor tilfreds er du med den måde, du kan gøre det på i dag?* *Skalaen er igen fra 1 til 10, hvor 1 betyder, at du slet ikke er tilfreds, og 10 – at du er enormt tilfreds.* *Hvordan går det med…? (Gentages)*	(Guider scoringen for udførelse og tilfredshed for én aktivitetsproblematik ad gangen)

OBS udførelse

Note til den danske udgave: Hvis klienten ikke har prøvet at udføre aktiviteten i sin aktuelle tilstand, er det uhensigtsmæssigt at bede klienten forestille sig, hvordan han/ hun eventuelt ville kunne udføre aktiviteten. I stedet kan man enten bede klienten forsøge at udføre aktiviteten til næste møde og så score udførelse og tilfredshed der. Hvis dette ikke er muligt, så kan ergoterapeuten enten få klienten til at forholde sig til, hvilke aktiviteter, de har erfaret, aktuelt udgør et problem. Alternativt må man undlade at score, indtil klienten faktisk har prøvet at udføre aktiviteterne.

Referencer

Bac A, Chrabota U, Aleksander-Szymanowicz P. Occupational therapy based on Canadian Model of Occupational Performance and Engagement in rehabilitation process in patient with rheumatoid arthritis. Advances in Rehabilitation. 2015:41.

Carswell A, McColl MA, Baptiste S, Law M, Polatajko H, Pollock N. The canadian occupational performance measure: A research and clinical literature review. The Canadian Journal of Occupational Therapy. 2004;71(4):210-22.

Donnelly C, O'Neill C, Bauer M, Letts L. Canadian Occupational Performance Measure (COPM) in Primary Care: A Profile of Practice. The American journal of occupational therapy : official publication of the American Occupational Therapy Association. 2017;71(6):1-8.

Law M, Baptiste S, Carswell A, McColl MA, Polatajko HJ, Pollock N. Canadian Occupational Performance Measure (COPM) - Manual 5.0. Canada: The Canadian Association of Occupational Therapists (CAOT); 2014.

Bilag 2. Blodtryk

"Du har siddet ned et stykke tid, og det passer godt med, at du får målt dit blodtryk."

Udstyr

- Microlife BP A3L Comfort
  Obs: Apparatet kan gemme målingerne for to uafhængige personer. Stil den altid på Bruger 1 (se Bilag 8b: knap 10 skubbes op til ikonet "Bruger 1")

- Manchet: str. M-L (22-42 cm overarm omkreds)

Procedure ved måling af blodtryk

1. FP skal sidde behageligt **uden korslagte** ben i en stol med ryglæn ved et bord til sin venstre side
2. Skuldrene skal være afslappede og ve. arm let flekteret og understøttet af bordet
3. Venstre ærme smøges op, så den **ikke strammer** (manchetten **må ikke** anbringes uden på skjorter eller lign., da dette vil resultere i svagere pulssignal)
4. Manchetten påsættes med direkte kontakt til huden på FPs venstre overarm ca. 2 cm over albuebøjningen, så manchetten er i samme position som hjertet

   OBS: slangen skal vende nedad, og arterie-mærket (ca. 3 cm lang bar) som skal ligge over den arterie der løber på indersiden af armen

5. Manchetten sluttes til apparatet ved at manchetslangen (7) sættes ind i tilslutningsstedet (3), så langt den kan komme (se Bilag 8b)
6. Der vælges MAM-målemetoden (se Bilag 8b: skub MAM-kontakten (9) på siden af apparatet til position "3", "MAM" bliver synlig på displayet), hvor apparatet udfører automatisk tredobbelt måling

"Dette apparat foretager 3 målinger en efter hinanden med 15 sek. pause. Denne metode er mere pålidelig end ved enkeltmålinger. Maskinen udregner selv gennemsnittet, og dit blodtryk bliver først vist, når alle 3 målinger er udført. Hvis en af målingerne er tvivlsom, vil der automatisk blive lavet måling nr. 4. Du skal prøve at slappe af og ikke spænde under hele seancen. Træk vejret normalt og tal ikke. Når jeg trykker på knappen, fyldes manchetten med luft, og det vil stramme om armen. Dette er normalt og ubehaget er kortvarigt. Jeg starter målingen."

7. Måling foretages ved tænd på knap (1) (se Bilag 8b)

   OBS: Der tales ikke under målingen!

Målingen kan stoppes når som helst ved at trykke på tænd/sluk-knappen (1) (ser Bilag 8b).

8. Resultatet vil vises på displayet: det systoliske (16) og det diastoliske (17) blodtryk, og hjertefrekvensen (18) (se Bilag 8b)
9. Når målingerne er færdige, fjernes manchetten
10. Skriv resultaterne ned i feedback-skema til FP (hvis efterspørges) og på testskemaet
11. Efter registreringen: Slet data uden at gemme (tryk tænd/ sluk-knappen (1) indtil "M" (26) blinker; bekræft for at slette aflæsning ved at trykke på M-knappen (11), se Bilag 8b)
12. Sluk apparatet (displayet slukker af sig selv om ca. 1 min.)

OBS: internationale anbefalinger (ref. The European Society of Hypertension (ESH), The American Heart Association (AHA) and The Japanese Society of Hypertension (JSH))

For lavt blodtryk:	systolisk < 100	diastolisk < 60	Spørg egen læge/ evt. følg personen til læge
Optimalt blodtryk:	systolisk 100-130	diastolisk 60-80	Selvkontrol
Forhøjet blodtryk:	systolisk 130-135	diastolisk 80-85	Selvkontrol
For højt blodtryk:	systolisk 135-160	diastolisk 85-100	Søg lægehjælp
Faretruende højt blodtryk:	systolisk > 160	diastolisk > 100	Søg STRAKS lægehjælp!

Eks: blodtryk på 140/ 80 mmHg eller 130/ 90 mmHg angiver, at blodtrykket er for højt

Referencer

Okifuji A, Hare BD. The association between chronic pain and obesity. Journal of pain research. 2015;8:399-408.

Stergiou GS, Parati G, McManus RJ, Head GA, Myers MG, Whelton PK. Guidelines for blood pressure measurement: development over 30 years. The Journal of Clinical Hypertension. 2018;20(7):1089-91.

Yarows SA, Patel K, Brook R. Blood Pressure Monitoring. 2001, 6:145-147

Bilag 3. Højde, vægt og BMI*-udregning

*BMI bliver udregnet automatisk under vejning

”Du skal have målt din højde og vægt. Samtidig bliver der udregnet dit BMI.”

Procedure ved højdemåling

1. Bed FP om at:
   1) Stille sig på foden af højdemåleren UDEN SKO
   2) Kigge lige frem for sig (kontroller at hovedet ikke er sænket eller hævet)
   3) Slappe af i skuldrene
   4) Lade armene hænge afslappet langs siderne
   5) Stå med strakte ben og knæene samlet
   6) Have vægten fordelt på hele foden med hælene næsten samlet
   7) Lade baghovedet, skulderbladene, ballerne og hælene så vidt muligt røre tommestokken
   8) Tage en dyb vejrtrækning og stå ret

   OBS: Hvis det ikke er muligt at stå som anført overfor, så bed FP om at stå ret

2. Aflæs højden vandret ved hjælp af den indbyggede vinkelmåler til den nærmeste millimeter (i cm med decimaltal). Benyt evt. skammel.

   OBS: Hvis aflæsningen falder mellem to værdier bruges altid den laveste værdi

3. Notér resultatet på testskemaet

   OBS: FP behøver ikke tage sko på, da næste test udføres igen uden sko

Procedure ved vægtmåling og BMI-udregning

Indstillet på forhånd for ALLE FP:

- STANDARD kropstype (ikke ATHLETIC) = denne indstilling springes automatisk over ved målinger
- Analyse-funktion (ikke vægt alene), da ellers bliver BMI ikke udregnet automatisk

1. Tryk på TÆND-knap (O/O) for at tænde vægten = display viser PT 00
2. Tryk PT (Clothes Weight), vælg 1 for minus 1 kg for tøj (éns for ALLE FP) = PT 1.0
3. Følg blinklysene:

- Når pilen "STEP ON" på vægten blinker, skal FP stille sig på vægten UDEN SKO og overtøj
- Indtast alderen
- Indtast højde fra tidligere måling

OBS: i hele cm = rundet op eller ned til nærmeste hele cm-tal

4. Vægten indstiller sig selv et øjeblik = display viser STAY
5. Når "STABILIZED"-pil blinker, bliver vægten vist på skærmen (evt. bliver sedlen med målingerne udskrevet)
6. Notér resultatet for vægt og BMI på testskemaet

Referencer

Fisher E, Brzezinski RY, Ehrenwald M, Shapira I, Zeltser D, Berliner S, et al. Increase of body mass index and waist circumference predicts development of metabolic syndrome criteria in apparently healthy individuals with 2 and 5 years follow-up. LID - 10.1038/s41366-018-0312-x [doi]. (1476-5497 (Electronic)).

Okifuji A, Hare BD. The association between chronic pain and obesity. Journal of pain research. 2015;8:399-408.

WHO. Physical status: the use and interpretation of anthropometry. Report of a WHO Expert Committee. WHO Technical Report Series 854 [Internet]. 1995.

Bilag 4. Taljemål

OBS: Der skal ikke måles taljeomkreds hos gravide (spørg ind til evt. graviditet)

1. Bed FP om at stille sig med vægten fordelt ligeligt på begge ben (12-15 cm mellem fødderne) og armene ned langs siden
2. Bed FP om at løfte tøjet på overkroppen lidt op og væk fra taljeområdet
3. Placer målebåndet rundt om maven og midt imellem spidsen af hoftebenet og det nederste stykke af ribben

   OBS: målebåndet må ikke stramme, så huden folder under den
4. Når målet tages, skal FP instrueres i at ånde ud (maven skal være afslappet)
5. Taljemålet rundes op eller ned til nærmeste cm
6. Notér resultatet på testskemaet

Referencer

Fisher E, Brzezinski RY, Ehrenwald M, Shapira I, Zeltser D, Berliner S, et al. Increase of body mass index and waist circumference predicts development of metabolic syndrome criteria in apparently healthy individuals with 2 and 5 years follow-up. LID - 10.1038/s41366-018-0312-x [doi]. (1476-5497 (Electronic)).

Okifuji A, Hare BD. The association between chronic pain and obesity. Journal of pain research. 2015;8:399-408.

Bilag 5. AMPS

The Assesment of Motor and Process Skills (AMPS-testen) er et nyskabende observationsredskab, som anvendes til at vurdere kvaliteten af personers udførelse af huslige (instrumentelle) og personlige dagligdagsaktiviteter (ADL). Kvaliteten af personens aktivitetsudførelse vurderes ved at måle på graden af fysisk anstrengelse, effektivitet, sikkerhed og selvstændighed i forhold til 16 motoriske og 20 procesmæssige færdigheder. De motoriske og procesmæssige ADL-færdigheder er paralleller til de målrettede handlinger som er defineret under Activities og Participation i the International Classification of Functioning, Disability and Health (World Health Organization, WHO, 2001) og er således de små dele af aktivitetsudførelsen, som når de er udført en efter en, resulterer i, at den overordnede opgave udføres.

Forberedelse:

1. Telefonisk kontakt til patienten x dage før undersøgelsesdagen mhp. at udvælge 2 aktiviteter (med udgangspunkt i patientens dagligdag og ud fra AMPS opgavekatalog)
2. Terapeuten sørger for at relevante redskaber evt. ingredienser er tilstede (Evt. indkøb, brug indkøbskort)
3. Terapeuten læser opgaven grundigt igennem

Vurdering:

1. Patienten gøres bekendt med 1. opgave og regler omkring denne.
2. Patienten gøres bekendt med faciliteterne. Herunder afprøvning af skabe/skuffer olign.
3. Patienten sættes i gang med opgaven, mens terapeuten observerer og noterer.
4. Når patienten er færdig gentages ovenstående i forhold til 2. opgave

Kodning:

1. Begge vurderinger scores efter AMPS scoringsark (påføres deltager ID)
2. Begge scoringsark indtastes i AMPS computerprogram (OTAP)
3. Der udprintes rapport med grafer af de motoriske færdigheder og de procesmæssige færdigheder (påføres deltager ID)
4. På baggrund af ovenstående og observation udarbejdes journalnotat i SP
5. Scorene skrives som testresultater for AMPS for den pågældende undersøgelsesgang på testskemaet

Referencer

Kizony R, Katz N. Relationships between cognitive abilities and the process scale and skills of the assessment of motor and process skills (AMPS) in patients with stroke. OTJR. 2002;22(2): 82-92.

CIOTS. Assessment of Motor and Process Skills: Volume I – Development, Standardization, and Administration Manual. Center for Innovative Occupational Therapy Solutions (CIOTS). 7th Edition ed. USA: Three Star Press, Inc.; 2012.

Nielsen K, Wæhrens E. Occupational therapy evaluation: use of self-report and/or observation? Scandinavian journal of occupational therapy. 2015;22(1):13-23.

Bilag 6. Måling af smertesensitivitet med algometer (pain-pressure cuff)

Udstyr

- Pain-pressure cuff
- Seng eller briks (i testlokalet)
- Aflang lejringspude (pølle) under knæ
- Smertesensitiverings hardware - PC til smertesensitivering

OBS: markøren på VAS-fjernbetjeningen har tendens til at glide nedad, hvis den holdes vertikalt.
Sørg derfor for at FP holder VAS fjernbetjeningen horisontalt under testene.

Opsætning af hardware

- Still kompressoren frem ved siden af briksen (typisk står der i forvejen)
- Tag smertesensitiverings PC'en frem fra modulet på hjul, sæt den ovenpå modulet og tænd

OBS: Adgangskode til smertePC: T7

- Tjek, om den lange grå USB-kabel er tilsluttet bag på kompressoren samt til smertesensitiverings PC'en
- Tjek, om de 2 manchetter er tilsluttet hver sin slange foran på kompressoren
- Tænd kompressoren på hovedkontakten bagpå (evt. de 2 grønne kontakter foran, hvis slukket)

Installering af forsøgsperson

- Forsøgspersonen (FP) bedes at sætte sig op på briksen som er indstillet, så en behagelig og afslappet position er mulig
- Begge underben skal gøres fri for beklædning
- Placér en pølle ind under FP's knæhaser således at FP kan sidde afslappet med let bøjede ben
- Påfør manchetten som er tilsluttet den **blå** slange om højre ben (index-benet) og manchetten som er tilsluttet den **røde** slange om venstre ben
- Manchetterne påføres, så der stadig kan være en pegefinger mellem dem og skinnenbenene, uden at de glider ned

Smertesensitiverings software

- Åbn softwaren på skrivebordet (Cuff1)
- Når softwaren åbnes dukker der et pop-up vindue op, hvor man skal klikke ”ok”
- Indtast deltager ID nummer på FP, testerens initialer samt testnummer (indtast 1 for baseline-undersøgelsen og 2 for follow-up) i de 3 vinduer over start-knappen
- Ved klik på ”start” starter første test – når testen er afsluttet (FP har trykket gul stopknap) vil næste klik på ”start” starte test 2, osv.

OBS: Softwaren registrerer hvis VAS-markøren ikke er sat ned til 0, hvorved den ikke starter, før dette er gjort. Sørg derfor for at VAS-markøren altid står på 0 når en test startes.

Instruktion

Før test

”Ved hjælp af dette instrument undersøger vi din smertetolerance/ -tærskel. Vi er særligt interesserede i at vide, hvordan forløbet vil påvirke din smertetolerance/ -tærskel.”

Smertemonitorering 1 (NRS pre)

Der udføres NRS-smertescore (0-10), når FP har fået påført begge manchetter og sider afslappet og klar inden første test.

”Hvordan vil du vurdere din smerte lige nu fra 0=ingen smerte til 10=værst tænkelige smerte?”

Notér scoren på testskemaet under VAS pre-test

Test 1 (Ramp1)

”Der kommer et langsomt stigende tryk om dit højre ben (hvor den blå manchet er tilsluttet). Du skal via fjernbetjeningen rangere din smerteoplevelse i takt med det stigende tryk. Det betyder, at første gang du mærker smerte, skal du flytte markøren til der hvor du vurderer at du ligger smertemæssigt (forestil evt. VAS-skala 0 til 10: ingen smerte – værst tænkelig smerte). I takt med stigende smerte, flytter du markøren tilsvarende. Når du kommer til et punkt, hvor du ikke kan udholde mere smerte, så trykker du på den gule stop-knap og testen vil derved stoppe (trykket i manchetten fjernes)”.

Notér scorene for PDT, PTT og PTL på testskemaet under Ramp 1

Test 2 (Temp.Sum.1)

"Der kommer nu 10 impulser, hvor du skal rangere dine smerter ved hver impuls. Impulserne har hver ca. 2 sek. varighed og vil mærkes som et eksplosivt stigende tryk. Mellem hver impuls har du ca. 1 sek. pause. Rangér din smerteoplevelse løbende, indtil de 10 impulser er afviklet. Her skal du ikke selv stoppe testen – den stopper automatisk efter de 10 impulser".

Notér VAS-scorene 1-10 på testskemaet under Temp.Sum.1

Test 3 (Ramp2)

"Nu foretager vi præcis den samme type test som under første test – dog nu på modsat ben."
(Se test 1 for instruktion)

Notér scorene for PDT, PTT og PTL på testskemaet under Ramp 2.

Test 4 (CPM1)

"Der kommer nu tryk i begge manchetter. På dit venstre ben (rød slange) kommer der et eksplosivt stigende tryk som rammer et plateau og forbliver der under resten af testen. På dit højre ben (index-benet, blå slange) kommer det langsomt stigende tryk som du kender fra test 1 og test 3. Du skal sørge for KUN at fokusere på din smerteoplevelse fra trykpåvirkningen på dit højre ben (index-benet) og abstrahere fra evt. smerter fra tryk på det modsatte ben. Du gør ligesom i test 1 og 3, hvor du flytter markøren i takt med stigende smerter og slutteligt stopper testen ved tryk på gul knap, når du ikke kan udholde mere smerte".

Notér scorene for PDT, PTT og PTL på testskemaet under CPM1

Smertemonitorering 2 (NRS post)

Der udføres igen NRS-smertescore (0-10), efter FP har fået fjernet manchetterne omkring underbenet efter 4. og sidste test.

"Hvordan vil du vurdere din smerte lige nu fra 0=ingen smerte til 10=værst tænkelige smerte?"

Notér scoren på testskemaet under VAS post-test.

Indtastning:

- NRS pre (før test)
- Test 1 (Ramp1)
- Indtast PDT, PTT og PTL i testark. Test 2 (Temp.Sum.1)
- Indtast alle 10 VAS-værdier i testark. Test 3 (Ramp2)
- Indtast PDT, PTT og PTL i testark. Test 4 (CPM1)
- NRS post (efter test)

Referencer

Dinesh J, Patty F. Actigraph and actical physical activity monitors: A peek under the hood. Medicine and science in sports and exercise. 2012;44(1): 86-89.

Bilag 7. Bevægelsesmålere (Actigraphy, hjemmetest)

Introduktion

Testlederen introducerer FP til bevægelsesmåleren:

- Placering på kroppen: Midt på venstre lår
- Hvad der kan måles - kort: benets position i forhold til lodlinjen, genkendelse af bevægemønstre som gang og cykling

  OBS: Actigraphen kan ikke skelne hvorvidt personen sidder eller ligger ned, når den er placeret på låret. Derfor skal søvn og hvile i liggende stilling noteres i dagbogen

- Kontinuerlig måling i 4 døgn: actigraphen skal blive på kroppen i hele perioden
- Forbehold: det er muligt at tage brusebad, hvis der er en vandtæt film over (sættes på hos de fleste, undtagen allergikere overfor plastret

  OBS: FP skal afholde sig fra at tage karbad, gå i svømmehal og bade i havet

Påsætning af Actigraph

- Actigraphen initialiseres elektronisk via computerens software ”ActiLife”
    - Tænd for ActiLife-programmet
    - Fanen Devices åbner
    - Tilslut actigrafen til pc (den vil blive synlig på skærmen – tjek om serienummer passer, initialiseringsprocessen sletter data fra apparatet)
    - Sæt flueben ved den rigtige actigraf
    - Tryk Initialize – Regular initialization (øverst)
    - Et nyt vindue vil åbne: Starttidspunktet noteres (Sæt den 10 min. frem i forhold til den aktuelle tid), Sluttidspunktet skal ligge 4 døgn fremme i tiden
    - INGEN andre felter skal markeres ellers
    - Klik Subject Info nederst til højre (nyt vindue åbner, start-slut datoer vil fremgå øverst)
- I Subject Info:
    - Tast ”Deltager ID-bas” (for baseline) eller ”Deltager ID-fol” som Subject name for follow-up

- Gender: vælg køn
- Race: ved tvivl, spørg FP (se i scroll-down menu efter muligheder)
- Monteringssted: thigh
- Side: som udgangspunkt **altid venstre side**

OBS: hvis FP udtrykkeligt beder om at have actigraphen påsat det højre ben, er det helt ok. Vær da opmærksom på det når "dominans" vælges. Lav gerne en note om det på dagbogen.

- Dominans: Tjek testskemaet eller, hvis info mangler, spørg FP om han/hun er højre- eller venstredominant
  - Vælg "dominant" i dropdown-menuen hvis venstredominant
  - Vælg "nondominant" i drop downmenuen hvis højredominant
- vægt, højde tastes IKKE ind
- Tryk Initialize 1 device nederst til højre (initializeringen er afsluttet og vinduet lukkes)

- FP afklæder sig, så det venstre ben er blottet fra hofte til knæ

OBS: arbejdsstilling og brug evt. en lav skammel

- Actigraph placeres midt på låret mellem nederste trussekant og knæ ud fra et visuelt skøn
  - Nederst påsættes et stykke Fixomull for at beskytte huden (filt-agtigt plaster)
  - Actigraphen monteres ovenpå Fixomull med toupétape (dobbeltklæbende)
  - Det hele dækkes af vandtæt plaster af typerne "Mepore" eller "Opsite Flexifix, 10x10cm"

OBS: Det er vigtigt, at plasteret påsættes på en måde så det ikke skaber et træk på huden. Herved undgås langt de fleste hudgener!

- Op til 2 stk. "Flexifix 10x10" må udleveres med hjem, så huden får luft nogle timer mellem skift.

OBS: bruges de ekstra stykke plaster ikke, må FP meget gerne levere dem tilbage sammen med apparaterne!

Dagboginstruktion

- Testlederen noterer actigraphens stregkodenummer og tidspunktet for påsætning (dato og klokkeslæt) på dagbogen
- FP informeres om og får noteret datoen i dagbogen (Bilag 8B), hvornår han/hun skal fjerne apparaterne
- Testlederen instruerer FP i at udfylde dagbogen korrekt de fire døgn apparaterne bæres. Der skal noteres dagligt tidspunkter for, hvornår FP:
    - står op
    - fx går på arbejde, møder op på sygehus eller har anden beskæftigelse
    - holder hvilepauser (evt. en middagslur)
    - har fyraften, fx hjemkomst efter en aktivitet ude af huset
    - går i seng til natten
    - har perioder uden apparatet
- Dagbogen returneres sammen med actigrafen efter de 4 døgn

Afmontering og aflevering af apparater

- Actigraphen afmonteres af FP selvstændigt
- Tapen/plasteret pakkes omkring apparaterne så intet bliver væk, og de lægges sammen med dagbogen i en frysepose eller kuvert og AFLEVERES til testlederen SÅ HURTIGT SOM MULIGT og senest ved næste fremmøde på sygehuset
- Sammen med dagbogen og apparaterne kan evt. overskydende stykker ”Opsite Flexifix 10x10” også afleveres

OBS: VI SKAL HAVE ALLE APPARATER IGEN, OGSÅ SELVOM DE ER TAGET AF FØR TID, ELLER EN ANDEN UREGELMÆSSIGHED ER SKET!

Aflæsning af data fra actigraphen

- For at tømme Actigraphen:
    - Tænd for ActiLife-programmet
    - Fanen Devices åbner

- Tilslut actigrafen til pc (den vil blive synlig på skærmen – tjek om serienummer passer)
- Tjek Serial nr. skal passe
- Tjek Subject name (”Deltager ID-bas” (for baseline) eller ”Deltager ID-fol” (for follow-up) – som var indtastet ved initialisering)
- Tryk Download øverst
- Nyt vindue åbner

OBS: Data gemmes ifht. initialiseringsdato/startdato og IKKE download-dato

- Kryds af i boksen ”Subject name – Start dato”
- Kryds af i Add biometric and user information (skal være krydset af, står der automatisk)
- Agd-fil skal ikke genereres (feltet til højre, ingen kryds dér)
- Vælg Change location (øverst) til en mappe ”Actigraf_pilot_baseline” på pc’en
- Klik Download all devices til højre (hvis bliver spurgt: Overwrite file? – klik Ja)
- Download finished viser sig på skærmen med blåt
- Kobl actigrafen af pc’en
- Sæt actifrafen til opladning

Arkivering af dagbøger

Dagbøger fra testrundene arkiveres i deltagernes fysiske mapper i arkivet under deltager ID

Referencer

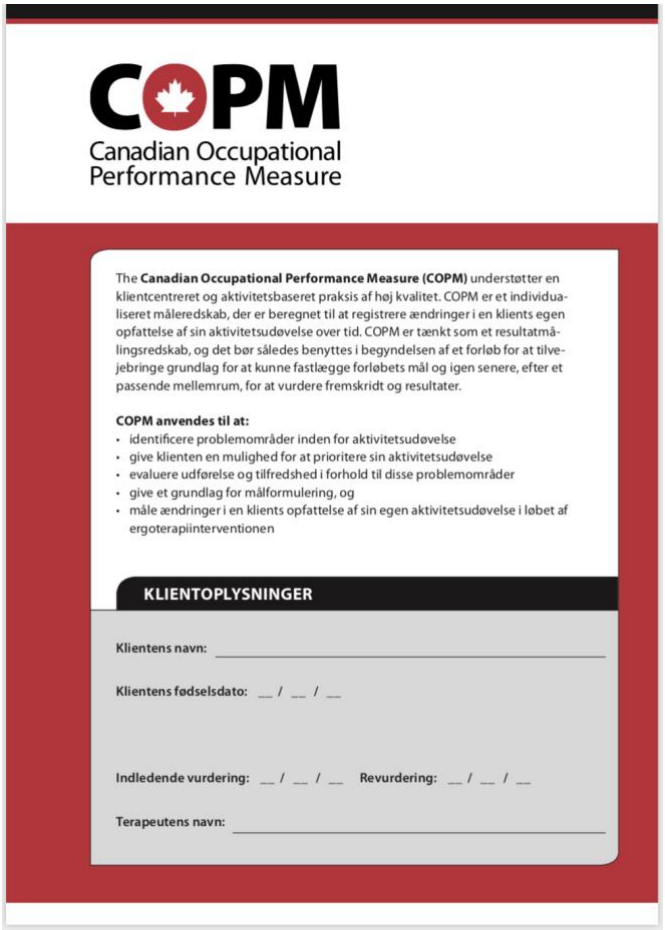
Baron R, Forster M, Binder A. Subgrouping of patients with neuropathic pain according to pain-related sensory abnormalities: a first step to a stratified treatment approach. The Lancet Neurology. 2012;11(11):999-1005.

Skou ST, Graven-Nielsen T, Rasmussen S, Simonsen OH, Laursen MB, Arendt-Nielsen L. Widespread sensitization in patients with chronic pain after revision total knee arthroplasty. Pain. 2013;154(9):1588-94.

Bilag 8. Skemaer

8a. Standard registreringsskema til COPM-undersøgelse

[Kopieres fra master-kopi eller downloades via www.etf.dk, anvend eget login]



COPM
Canadian Occupational Performance Measure

The **Canadian Occupational Performance Measure (COPM)** understøtter en klientcentreret og aktivitetsbaseret praksis af høj kvalitet. COPM er et individualiseret måleredskab, der er beregnet til at registrere ændringer i en klients egen opfattelse af sin aktivitetsudøvelse over tid. COPM er tænkt som et resultatmålingsredskab, og det bør således benyttes i begyndelsen af et forløb for at tilvejebringe grundlag for at kunne fastlægge forløbets mål og igen senere, efter et passende mellemrum, for at vurdere fremskridt og resultater.

COPM anvendes til at:
- identificere problemområder inden for aktivitetsudøvelse
- give klienten en mulighed for at prioritere sin aktivitetsudøvelse
- evaluere udførelse og tilfredshed i forhold til disse problemområder
- give et grundlag for målformulering, og
- måle ændringer i en klients opfattelse af sin egen aktivitetsudøvelse i løbet af ergoterapiinterventionen

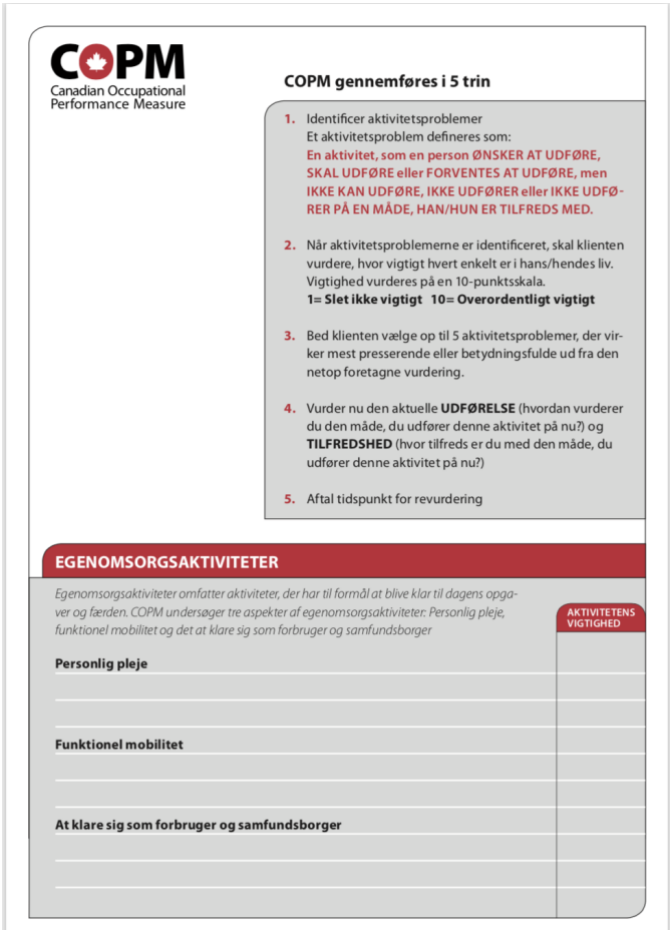
KLIENTOPLYSNINGER

Klientens navn: _____

Klientens fødselsdato: __ / __ / __

Indledende vurdering: __ / __ / __ Revurdering: __ / __ / __

Terapeutens navn: _____



COPM
Canadian Occupational Performance Measure

COPM gennemføres i 5 trin

1. Identificer aktivitetsproblemer
   Et aktivitetsproblem defineres som:
   En aktivitet, som en person ØNSKER AT UDFØRE, SKAL UDFØRE eller FORVENTES AT UDFØRE, men IKKE KAN UDFØRE, IKKE UDFØRER eller IKKE UDFØRER PÅ EN MÅDE, HAN/HUN ER TILFREDS MED.
2. Når aktivitetsproblemerne er identificeret, skal klienten vurdere, hvor vigtigt hvert enkelt er i hans/hendes liv.
   Vigtighed vurderes på en 10-punktsskala.
   1= Slet ikke vigtigt 10= Overordentligt vigtigt
3. Bed klienten vælge op til 5 aktivitetsproblemer, der virker mest presserende eller betydningsfulde ud fra den netop foretagne vurdering.
4. Vurder nu den aktuelle **UDFØRELSE** (hvordan vurderer du den måde, du udfører denne aktivitet på nu?) og **TILFREDSHED** (hvor tilfreds er du med den måde, du udfører denne aktivitet på nu?)
5. Aftal tidspunkt for revurdering

EGENOMSORGSAKTIVITETER

Egenomsorgsaktiviteter omfatter aktiviteter, der har til formål at blive klar til dagens opgaver og færden. COPM undersøger tre aspekter af egenomsorgsaktiviteter: Personlig pleje, funktionel mobilitet og det at klare sig som forbruger og samfundsborger

AKTIVITETENS VIGTIGHED

Personlig pleje

Funktionel mobilitet

At klare sig som forbruger og samfundsborger

PRODUKTIVE AKTIVITETER

Omfatter aktiviteter, der har til formål at tjene til livets opretholdelse, passe hjem og familie, yde hjælp til andre og/eller udvikle egne evner. COPM undersøger tre typer af produktive aktiviteter: Lønnet eller ulønnet arbejde, husligt arbejde, skole/uddannelse og leg.

AKTIVITETENS VIGTIGHED

Lønnet eller ulønnet arbejde

Husligt arbejde

Skole/uddannelse og leg

FRITIDSAKTIVITETER

Fritidsaktiviteter omfatter de aktiviteter, der udøves af en person, når denne er fri for produktive forpligtelser. COPM undersøger: Stillesiddende fritidsaktiviteter, fysisk aktive fritidsaktiviteter, sociale aktiviteter

AKTIVITETENS VIGTIGHED

Stillesiddende fritidsaktiviteter

Fysisk aktive fritidsaktiviteter

Sociale aktiviteter

SCORING

UDFØRELSE: (Hvordan vurderer du den måde, du aktuelt udfører denne aktivitet på?)
1= Slet ikke i stand til at udføre den ⟷ 10= Kan udføre den overordentligt godt

TILFREDSHED: (Hvor tilfreds er du med måden, du aktuelt udfører denne aktivitet på?)
1= Slet ikke tilfreds ⟷ 10= Overordentligt tilfreds

Tid 1: __ / __ / __ **Tid 2:** __ / __ / __

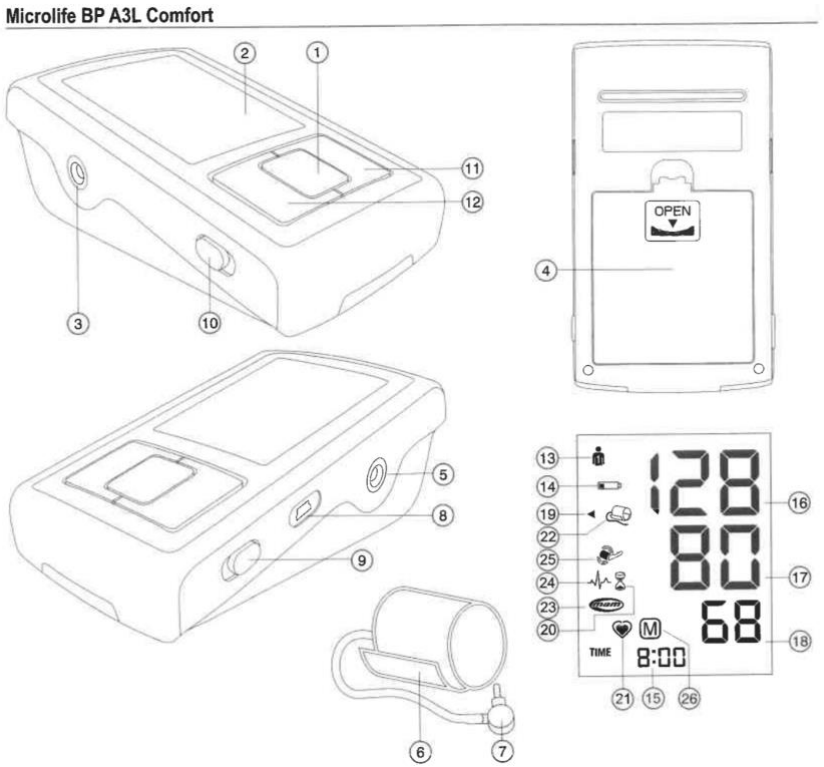
Aktivitetsproblemer	Aktivitetens vigtighed	Udførelse T_1	Tilfredshed T_1	Udførelse T_2	Tilfredshed T_2
		Udførelse i alt T_1	Tilfredshed i alt T_1	Udførelse i alt T_2	Tilfredshed i alt T_2
SCORE I ALT					
		Udførelse gennemsnit T_1	Tilfredshed gennemsnit T_1	Udførelse gennemsnit T_2	Tilfredshed gennemsnit T_2
GENNEMSNIT SCORE (Samlet score/antal problemer)					
				Ændring i udførelse	Ændring i tilfredshed
ÆNDRING I SCORE (T_2- T_1)					

NOTER OG IAGTTAGELSER

Indledende vurdering

Revurdering

8b. Vejledning til blodtryksapparatet Microlife BP A3L Comfort



Microlife BP A3L Comfort DA

① Tænd/sluk-knap
② Display
③ Tilslutningssted for manchet
④ Batterirum
⑤ Stik til strømadapter
⑥ Manchet
⑦ Manchet-slange
⑧ USB-port
⑨ MAM kontakt
⑩ Knap til valg af bruger
⑪ M-knap (Memory/hukommelse)
⑫ Tidsknap

Display
⑬ Brugerindikator
⑭ Batteri-display
⑮ Dato/tid
⑯ Systolisk værdi
⑰ Diastolisk værdi
⑱ Puls (hjertefrekvens)
⑲ Trafiklys-indikator, viser niveauet for det målte blodtryk
⑳ MAM Interval-tid
㉑ Pulsindikator
㉒ Indikator for kontrol af manchet
㉓ MAM metode
㉔ Indikator for uregelmæssig puls (arytmi) – PAD
㉕ Indikator for armbevægelse
㉖ Gemte værdier

Kære kunde,
Din nye Microlife blodtryksmåler er et pålideligt medicinsk instrument til at foretage målinger på overarmen. Det er simpelt at bruge, præcist og kan i høj grad anbefales til blodtryksmåling i hjemmet. Dette instrument blev udviklet i samarbejde med læger, og kliniske tests viser, at dets målenøjagtighed er meget høj.*
Læs venligst disse instruktioner omhyggeligt, så du forstår alle funktioner og sikkerhedsinformationen. Vi ønsker, at du er tilfreds med dit Microlife produkt. Kontakt din lokale Microlife-kundeservice, hvis du har spørgsmål, problemer eller ønsker at bestille reservedele. Din forhandler eller apotek kan give dig adressen på Microlife importøren i dit land. Ellers kan du se på Internettet på www.microlife.com, hvor du kan finde masser af information om vore produkter.
Hold dig sund – Microlife AG!

** Dette apparat er testet i henhold til ESH protokol og ISO81060-2:2013.*

Læs instruktionerne omhyggeligt før brug af apparatet.
Type BF godkendt
Tåler ikke fugt

8c. Feedback skema til deltagere med testresultater (vægt, højde, BMI, taljemål og blodtryk)

Navn: **CPR nr.**

Undersøgelsesgang 1	**Dato:**	**Undersøgelsesgang 2**	**Dato:**
	Kl.:		**Kl.:**

COPM-undersøgelse

De 5 vigtigste aktivitetsproblematikker i prioritetsrækkefølge

Blodtryk (BT)

Undersøgelsesgang 1				**Undersøgelsesgang 2**			
	Systolisk (mmHg)	Diastolisk (mmHg)	Hvilepuls Slag/min (BT)		Systolisk (mmHg)	Diastolisk (mmHg)	Hvilepuls Slag/min (BT)
1. BT måling				**1. BT måling**			
2. BT måling				**2. BT måling**			
3. BT måling				**3. BT måling**			
4. BT måling				**4. BT måling**			

Højde, vægt og taljemål

Højde (cm) (u. sko)	

Undersøgelsesgang 1				**Undersøgelsesgang 2**			
Vægt (kg) (uden sko/tøj fratrukket)				**Vægt (kg)** (uden sko/tøj fratrukket)			
BMI (kg/m2)				**BMI** (kg/m2)			
Taljemål (uden tøj)	1.mål	2. mål	Gennemsnit	**Taljemål** (uden tøj)	1.mål	2. mål	Gennemsnit

8d. Aktivitetsdagbog for 4-døgnsmåling

Actigraf nr._____

Navn:_____

Deltager ID_____

Startdato (1. døgn): _____ (dg/ md/ år)

Kl._____:_____ (time og min)

Slutdato (4.døgn): _____ (dg/ md/ år)

Kl._____:_____ (time og min)

Døgn	**Klokken for start af en aktivitet (time og min.)**	**Aktiviteter er der noteres**
Undersøgelses -dagen		Fri fra arbejde, sygehus (fri/ ”fyraften”)
		Hvilepause 1 (hvis relevant)
		Hvilepause 2 (hvis relevant)
		Sengetid
		Uden apparatet (hvis apparatet tages af/ falder af)
1. Døgn		Stod op
		Beskæftigelse 1 (gik på arbejde, mødte op på sygehus og lign.)
		Beskæftigelse 2 (ved flere aftaler den pågældende dag)
		Fri fra arbejde, sygehus (fri/ ”fyraften”)
		Hvilepause 1 (hvis relevant)
		Hvilepause 2 (hvis relevant)
		Sengetid
		Uden apparatet (hvis apparatet tages af/ falder af)

2. Døgn		Stod op
		Beskæftigelse 1 (gik på arbejde, mødte op på sygehus og lign.)
		Beskæftigelse 2 (ved flere aftaler den pågældende dag)
		Fri fra arbejde, sygehus (fri/ ”fyraften”)
		Hvilepause 1 (hvis relevant)
		Hvilepause 2 (hvis relevant)
		Sengetid
		Uden apparatet (hvis apparatet tages af/ falder af)
3. Døgn		Stod op
		Beskæftigelse 1 (gik på arbejde, mødte op på sygehus og lign.)
		Beskæftigelse 2 (ved flere aftaler den pågældende dag)
		Fri fra arbejde, sygehus (fri/ ”fyraften”)
		Hvilepause 1 (hvis relevant)
		Hvilepause 2 (hvis relevant)
		Sengetid
		Uden apparatet (hvis apparatet tages af/ falder af)
4. Døgn		Stod op
		Beskæftigelse 1 (gik på arbejde, mødte op på sygehus og lign.)
		Beskæftigelse 2 (ved flere aftaler den pågældende dag)
		Fri fra arbejde, sygehus (fri/ ”fyraften”)
		Hvilepause 1 (hvis relevant)
		Hvilepause 2 (hvis relevant)
		Sengetid
		Uden apparatet (hvis apparatet tages af/ falder af)

Appendix 17

Participant assessment file

TESTRESULTATER

DELTAGER ID_____

Navn: **CPR nr.**

E-mail: **Tlf.:**

Adresse:

Evt. bemærkninger:

Undersøgelsesgang 1	**Dato:**	**Undersøgelsesgang 2**	**Dato:**
	Kl.:		**Kl.:**

Dominans (HØ eller VE)	**Actigraph nr. baseline**	**Actigraph nr. follow-up**

Vedlægges kopi af:
COPM-undersøgelsen, version 5.0
AMPS-testark
(Begge påføres deltagerens ID)

OBS: registrering fra actigrapherne downloades i ActiLife-programmet, ikke nedskrives her

Blodtryk (BT)

Undersøgelsesgang 1	Systolisk (mmHg)	Diastolisk (mmHg)	Hvilepuls Slag/min (BT)	**Undersøgelsesgang 2**	Systolisk (mmHg)	Diastolisk (mmHg)	Hvilepuls Slag/min (BT)
BT (MEM) måling				**BT (MEM) måling**			

Højde, vægt, BMI og taljemål

Højde (cm) (u. sko)

Undersøgelsesgang 1				**Undersøgelsesgang 2**			
Vægt (kg) (uden sko/tøj fratrukket)				**Vægt (kg)** (uden sko/tøj fratrukket)			
BMI (kg/m2)				**BMI** (kg/m2)			
Taljemål (uden tøj)	1.mål	2. mål	Gennemsnit	**Taljemål** (uden tøj)	1.mål	2. mål	Gennemsnit

CUFF-algometri

Undersøgelsesgang 1	**Undersøgelsesgang 2**
VAS **Pre test: _____**	**VAS** **Pre test: _____**
Ramp1 PDT_____ PTT_____ PTL_____	**Ramp1** PDT_____ PTT_____ PTL_____
Temp.sum.1 1 _____ 6 _____ 2 _____ 7 _____ 3 _____ 8 _____ 4 _____ 9 _____ 5 _____ 10 _____	**Temp.sum.1** 1 _____ 6 _____ 2 _____ 7 _____ 3 _____ 8 _____ 4 _____ 9 _____ 5 _____ 10 _____
Ramp2 PDT_____ PTT_____ PTL_____	**Ramp2** PDT_____ PTT_____ PTL_____
CPM1 PDT1_____ PTT1_____ PTL_____ PDT2_____ PTT2_____	**CPM1** PDT1_____ PTT1_____ PTL_____ PDT2_____ PTT2_____
VAS **Post test: _____**	**VAS** **Post test: _____**

Appendix 18

Life Management Series certificates for continued education

The USC Mrs. T.H. Chan Division of Occupational Science and Occupational Therapy

presents this

Certificate of Completion

to

Svetlana Solgaard Nielsen

for completion of the professional learning course entitled

Life Management Series: Introduction to Lifestyle Redesign®

Instructor: Chantelle Rice Collins, OTD, OTR/L, CDE

and is awarded .6 CEUs (6 contact hours; 7.5 PDUs for NBCOT) on January 25, 2019.

Grace Baranek

Grace Baranek, PhD, OTR/L, FAOTA
Associate Dean, Chair, and Mrs. T.H. Chan Professor of Occupational Science and Occupational Therapy

APPROVED PROVIDER of CONTINUING EDUCATION by The American Occupational Therapy Association, Inc.

The USC Mrs. T.H. Chan Division of
Occupational Science and Occupational Therapy

presents this

Certificate of Completion

to

Svetlana Solgaard Nielsen

for completion of the professional learning course entitled

Life Management Series: Lifestyle Redesign® for Chronic Pain and Headache Management

Instructors: Ashley Uyeshiro Simon, OTD, OTR/L, MSCS and
Lindsey Reeves, OTD, OTR/L

and is awarded .6 CEUs (6 contact hours; 7.5 PDUs for NBCOT) on
February 9, 2019.

Grace Baranek

Grace Baranek, PhD, OTR/L, FAOTA
Associate Dean, Chair, and Mrs. T.H. Chan
Professor of Occupational Science and
Occupational Therapy

APPROVED PROVIDER of CONTINUING EDUCATION
by The American Occupational Therapy Association, Inc.

Appendix 19

Evaluation forms for patients' self-perceived relevance, timing, and mode of delivery

Hold_____ UGE nr._____ DATO:_____

Evalueringsskema
(sæt ´et X i hver række)

	MEGET RIGTIGT	RIGTIGT	HVERKEN ELLER	IKKE RIGTIGT	SLET IKKE RIGTIGT	VED IKKE
Tidsmæssig placering på dagen var passende	☐	☐	☐	☐	☐	☐
Tidsforbrug var passende	☐	☐	☐	☐	☐	☐
Materialet var relevant	☐	☐	☐	☐	☐	☐
Materialet var nemt at forstå	☐	☐	☐	☐	☐	☐
Undervisningsformen (individuel eller i gruppe) var passende	☐	☐	☐	☐	☐	☐
Jeg er tilfreds med dagen	☐	☐	☐	☐	☐	☐
KOMMENTARER:						

Appendix 20

Process evaluations checklists for evaluation of the fidelity of delivery

Procesevaluering

Levering af mundtlig information om pilotprojektet

HUSK: kopi af samtykke

__Alle deltagere skal have fået mundtlig information
__Betænkningstid gives
__Deltagelsen er frivillig og kan afbrydes når som helst og uden begrundelse
__Ingen konsekvenser for det nuværende eller fremtidige behandlingsforløb

__Projektet laves i samarbejde mellem Tværfagligt smertecenter og Ergoterapien på Næstved sygehus
__To dele: pilotprojekt og kontrolleret lodtrækningsforsøg
__Det ergoterapeutiske forløb starter efter grundforløbet
__Forløbet har tre fokusområder: meningsfulde aktiviteter (individuelle), sunde spisevaner (ud fra de 10 kostråd) og daglig bevægelse (ud fra Sundhedsstyrelsens anbefalinger for voksne)
__Faste hold af 6 deltagere pr. hold
__Forløbet varer 15 uger med fremmøde hver 14.dag (5 gruppemøder og 2 individuelle møder, hvor den ene tilbydes som et hjemmebesøg)
__I modsatte uger vil der være telefoniske opfølgninger på et aftalt tidspunkt
__Gruppemøder vil altid være kl. 10-12 og forløbe som en kombination af korte oplæg, fælles diskussion, hjemmeopgaver og praktisk afprøvning
__Ingen risici for helbredet eller omkostninger, udover transport (kørselsgodtgørelse kan evt. søges)

__Samtykke skal underskrives ved forsat ønske om deltagelse

__Alle deltagere skal have lavet en forundersøgelse inden start på grundforløbet eller snarest muligt efter
__Efter afsluttet forløb skal der ligeledes laves en slutundersøgelse
__Undersøgelsen varer ca. 2,5 time og består af:
- __Afklaring af aktivitetsproblematikker i hverdagen, måling af blodtryk, højde, BMI-udregning, vægt, taljemål og smertesensitivitet
- __Bevægelsesmålere udleveres til hjemmetest og skal bæres på kroppen i 4 dage (instruktion gives på undersøgelsesdagen)
- __Undersøgelsen afsluttes med udførelsen af to praktiske opgaver efter dit eget valg (en ergoterapeut kontakter dig telefonisk med henblik på det)

__Når du har besluttet dig for deltagelse, sender vi et forløbsplan med datoer og emner til din e-boks
__Forløbsplanen oplysninger om forberedelsen til undersøgelsesdagen, blandt andet besvarelse af spørgeskema og praktiske råd om påklædning
__Du er altid velkommen til at kontakte den projektansvarlige med spørgsmål på det nummer der står i deltageinformationen

Dato d.d._____ **Hold nr._____** **Deltager ID:_____**

Procesevaluering – Baseline

___ Forhåndssamtykke underskrevet og kopi taget

___ Samtykke underskrevet og kopi taget

___ PainData standard skema udfyldt

___ PainData tillægsskema udfyldt

___Tests udfyldt i rækkefølge:

1. COPM

___Initial COPM-score beregnet

2. Blodtryk
3. Højde
4. Vægt, BMI
5. Taljemål

___Kort feedback givet på:

- blodtryk - forhøjet eller ej
- aktuelt BMI-niveau og fedtprocent
- taljemål - normen, gråzonen eller risikozonen

___Nævnt, at testene vil der blive kigget på igen senere ved individuel samtale efter opstart på det ergoterapeutiske forløb

6. Algometertest

___Evt. forklaret, at testen måler nervesystemets smerteølsomhed

7. Actigraf (sensoren påsat og dagbog udleveret)

___Informeret, at alle tests vil blive gentaget ved slutundersøgelsen

8. AMPS

Procesevaluering – 4. session (telefonisk konsultation)

___ Spørg ind til målarbejdet med det valgte kortsigtede mål for meningsfulde aktiviteter

- ___ Vurdér behovet for tilpasninger af målformuleringen?
- ___ Vurdér behovet for hjælpemidler?
- ___ Vurdér behovet for involvering af egne omgivelser og netværk?
- ___ Vurdér behovet for involvering af andre fagpersoner?

___ Spørg ind til målarbejdet med det valgte kortsigtede mål for spisevaner

- ___ Vurdér behovet for tilpasninger af målformuleringen?
- ___ Vurdér behovet for hjælpemidler?
- ___ Vurdér behovet for involvering af egne omgivelser og netværk?
- ___ Vurdér behovet for involvering af andre fagpersoner?

___ Spørg ind til målarbejdet med det valgte kortsigtede mål for daglig bevægelse

- ___ Vurdér behovet for tilpasninger af målformuleringen?
- ___ Vurdér behovet for hjælpemidler?
- ___ Vurdér behovet for involvering af egne omgivelser og netværk?
- ___ Vurdér behovet for involvering af andre fagpersoner?

___ Spørg kort ind til notatføring i dagbogen

___ Orientér deltageren om hjemmeopgaven til næste gang: ugeskema

___ Evaluér sessionen ved at krydse af for deltageren på evalueringsskemaet

Procesevaluering – 5. session, gruppe (på sygehuset)

___ Præsentér dagens emne : Energibesparende principper og teknikker

___ Lav en opsamling på hjemmeopgaven

- ___ Lad gruppen reflektere over mest belastende aktiviteter
- ___ Lad deltagerne notere de mest belastende gøremål til dato på s. 12 i kompendiet

___ Fortæl om energibesparende principper

___ Analysér sammen med deltagerne, hvordan deres mest belastende gøremål kan gøres mindre belastende

___ Spørg ind til, hvad deltagerne vil evt. prøve af derhjemme af at det lærte på dagen

___ Evalueringsskema udfyldes af deltagerne

Appendix 21

EuroQol project registration

Fra: **EuroQol Research Foundation** userinformationservice@euroqol.org
Emne: Your request to use EQ-5D has been received (Registration ID: 28126)
Dato: 4. december 2018 kl. 10.28
Til: ssolgaard@health.sdu.dk

Your request to use EQ-5D has been received

Registration ID: 28126

Dear Svetlana Solgaard Nielsen,

Thank you for registering your study/trial/project or other at the EuroQol website. **We aim at sending you a reply within 5 working days.**

Meanwhile, here are some links to information on EQ-5D you may find interesting:

- EQ-5D User Guides on how to use EQ-5D and how to analyse and report EQ-5D data
- Information on choosing a value set
- Frequently Asked Questions
- Key references on EQ-5D

You are kindly invited to visit our website to find more information on EQ-5D and EuroQol.

You sent us the following information:

Your details

Title / Salutation	Mrs.
First name	Svetlana Solgaard
Last Name / Family Name	Nielsen
Work environment	University: staff
Other work environment	
Organization	Department of Public Health, The University of Southern Denmark
Postal Address	J.B. Winsløws Vej 9A
Postal / Zip code	5000
City	Odense C
Country	DK
Email	ssolgaard@health.sdu.dk
Phone	+4551252255

Intended use of EQ-5D

Title / Description / Study Code	LIfestyle and quality of life among chronic pain outpatients at multidisciplinary pain center - Mixed methods study
Objective	The mixed methods study is aimed to inform the development of occupational therapy intervention to be added to the current treatment of chronic pain outpatients admitted to the Multidisciplinary Pain Center at Naestved Hospital, Zealand Region, Denmark.
Source of funding / Sponsor	The Local and Regional Research Funds, Zealand Region, Denmark
Please list CROs / Vendors if applicable	
EQ-5D use	Research (intend to publish the results)
Other EQ-5D use	
	Observational study (including case-control, cohort and cross-

Study design / Primary use	Observational study (including case-control, cohort and cross-sectional studies)
Other design / Primary use	
Clinical area	Pain
Other clinical area	
Number of patients / respondents for this registration	18
Start date (year only)	2.018
End date (year only)	2.019

Requested EQ-5D versions

Requested available versions	Danish (Denmark) / EQ-5D-5L Self-Complete - Paper Danish (Denmark) / EQ-5D-5L Self-Complete - REDCap - Laptop/Desktop Danish (Denmark) / EQ-5D-5L Telephone - Paper
Requested unavailable versions	
Desired date of availability	

Permissions

Are you planning to modify EQ-5D?	No
Planned EQ-5D modification	
Are you prepared to have this information published in any EuroQol reports/surveys regarding usage of EQ-5D? (Note that only anonymised information will be published)	Yes
Can we contact you by email in case of important product notifications? (Note that you can always opt-out / ask to be removed from the mailing list)	Yes
I agree with the terms of use and privacy statement	Yes

Kind regards,

EuroQol Research Foundation

Appendix 22

Study III publication inclusive appendices

International Journal of Qualitative Studies on Health and Well-being

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/zqhw20

Feasibility assessment of an occupational therapy lifestyle intervention added to multidisciplinary chronic pain treatment at a Danish pain centre: a qualitative evaluation from the perspectives of patients and clinicians

Svetlana Solgaard Nielsen, Jeanette Reffstrup Christensen, Jens Søndergaard, Vicki Oldenschläger Mogensen, Anette Enemark Larsen, Søren T. Skou & Charlotte Simonÿ

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Feasibility assessment of an occupational therapy lifestyle intervention added to multidisciplinary chronic pain treatment at a Danish pain centre: a qualitative evaluation from the perspectives of patients and clinicians

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ABSTRACT

Purpose: As part of intervention feasibility evaluation before conducting a clinical trial, this study aimed to investigate perspectives of patients and clinicians involved in the occupational therapy lifestyle-oriented programme REVEAL(OT) [Redesign your EVEveryday Activities and Lifestyle with Occupational Therapy] which was added to multidisciplinary chronic pain treatment.

Methods: We conducted three focus group interviews, two with eight voluntarily selected patients and one with four clinicians. Data were analysed using Braun & Clarke's semantic data-driven analysis.

Results: Patients reported satisfaction with the intervention and a greater acceptance of living with chronic pain through increased understanding of pain mechanisms, more effective daily planning and improved social interaction. Patients felt empowered to change lifestyle habits by restarting habitual interests, prioritizing joyful occupations for improved occupational balance, and lifestyle modifications. Contact to occupational therapists and peer support were important empowering factors for working with lifestyle goals. Patients and clinicians expressed their views on further improvement of the REVEAL(OT).

Conclusions: Patients and clinicians found the lifestyle-oriented occupational therapy programme relevant as an add-on to the multidisciplinary chronic pain treatment. A need was expressed for a reduced information and treatment load and a higher degree of communication and cooperation among the clinicians involved in the intervention.

ARTICLE HISTORY

Accepted 27 June 2021

KEYWORDS

Program evaluation; pain management; pain clinics; rehabilitation; health behaviour

Introduction

The worldwide weighted prevalence of chronic pain in the adult population is estimated to be about 20% (Andrew et al., 2014). Chronic pain has large negative personal and socio-economic consequences such as severe disturbances in work, domestic chores, child caring and studying, and high health care costs (Kronborg et al., 2009). Multidisciplinary biopsychosocial treatment meets chronic pain patients' needs and is cost efficient (Kronborg et al., 2009; Scascighini et al., 2008). As a stand-alone solution, none of the available non-pharmacologic treatment modalities is superior which urges different treatment options to be included in comprehensive chronic pain rehabilitation (Turk, 2002). Non-pharmacologic treatment options and team-based approaches with a follow-up were top-ranked by patients as effective facilitators promoting their chronic pain rehabilitation (Becker et al., 2017).

Lately, the need for comprehensive programmes focusing on lifestyle in chronic pain patients has been highlighted (Nijs et al., 2020). A vicious circle of chronic pain often leads to improper lifestyle choices such as inactivity, improper nutrition and isolation, and impairs the everyday life in work, leisure and self-care. This in turn can lead to poorer mental and metabolic health and elevate risks of comorbidity with other severe health states such as heart disease, diabetes and stroke. However, many health-related lifestyle factors such as physical activity, eating habits, smoking, alcohol consumption, and stress are modifiable and eligible for inclusion in healthcare interventions (van Hecke et al., 2013). Another interpretation of lifestyle is the individual's way of living formed

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through occupational engagement and performance of daily activities determined by personal needs, wishes, and resources (Velde & Fidler, 2002, p. 10). Several examples provide evidence of how professional occupational therapy assistance can promote a healthier lifestyle in people living with chronic pain by helping them perform everyday occupations that are value-based, healthy, and balanced (Clark et al., 2015; Lagueux et al., 2018, 2021; Simon & Collins, 2017).

Building on the MRC framework and supporting literature (O'Cathain et al., 2019), we developed an occupational therapy intervention REVEAL(OT) [Redesign your EVEveryday Activities and Lifestyle with Occupational Therapy] combining the following elements: a) occupational therapy evidence on lifestyle management of chronic pain; b) population-centred information on health-related quality of life, health, lifestyle, and motivation for changing lifestyle; and c) attention to how the intervention can potentially be implemented in the existing multidisciplinary treatment (usual care) for chronic pain at a Danish pain centre. The knowledge acquired throughout the intervention development process will be published in a scientific report after the final feasibility round and contain all the relevant references to collect the evidence from the research activities conducted.

According to the Medical Research Council (MRC) guidelines, complex interventions should be developed and pilot-tested before being evaluated in a clinical trial (Abraham et al., 2015). A qualitative evaluation offers insight into stakeholders' perspectives in a healthcare intervention and may reveal facilitators and barriers for implementation to serve clinical reasoning and support treatment choices (Moore et al., 2015; Rycroft-Malone & Burton, 2015). This study aimed to evaluate user perspectives from participation in the initial feasibility study of the lifestyle-oriented occupational therapy intervention conducted as an add-on treatment to usual care to identify its benefits and challenges for participating patients and clinicians and inform the design and conduct of a future clinical trial.

Materials and methods

Design

Following the nature of applied research, this qualitative evaluation adopted the realist paradigm explaining reality through individual experiences of the stakeholders involved in a healthcare intervention either as recipients or deliverers. Two focus group interviews with patients and one with clinicians were conducted using semi-structured interview guides inspired by Halkier (Halkier, 2016, pp. 23–50). Data analysis was guided by the data-driven qualitative semantic approach proposed by Braun & Clarke, with systematic inductive coding and the development of patterns throughout the data (Braun & Clarke, 2006).

Setting

This study was conducted from April to October 2019 in cooperation between Naestved, Slagelse and Ringsted Hospitals (Region Zealand, Denmark) represented by the department for physiotherapy and occupational therapy and its occupational therapy unit (OTU, Naestved Hospital), the department of anaesthesiology and its multidisciplinary pain centre (MPC, Naestved Hospital), and the University of Southern Denmark. The MPC has been using the biopsychosocial model for chronic pain treatment since 2014 and delivered chronic pain management based on cognitive-behavioural therapy (CBT) led by a multidisciplinary team of physicians, nurses, physical therapists, psychologists and a social worker. The cooperation between the OTU and the MPC aimed to include the REVEAL(OT) into the multidisciplinary treatment practice.

Intervention

The lifestyle-oriented REVEAL(OT) intervention (Clinicaltrials.gov reg. NCT03903900; Region Zealand, Journal Number: SJ-703) underwent a feasibility evaluation. Usual care at the MPC started with a compulsory 5-week preparatory psycho-education course where all the healthcare disciplines represented their field of impact for the patients followed by an individually tailored treatment course. The REVEAL(OT) ran in parallel with usual care. Two versions of the REVEAL(OT) (1.0 and 2.0) (Figure 1). were subject to the feasibility evaluation. REVEAL(OT) 2.0 was an improved intervention based on the experiences from REVEAL(OT) 1.0, with reduced treatment intensity, adjusted according to the patients and clinicians' feedback, which should secure more proper compatibility with usual care. The REVEAL(OT) 1.0 lasted 12 weeks and contained eight group sessions of two hours and four individual one-hour sessions, providing weekly contact with occupational therapists. The REVEAL(OT) 2.0 lasted 14 weeks and contained four two-hour group sessions and three individual one-hour sessions every second week, where contact with occupational therapists also was provided.

Max. six patients were admitted pr. group. At baseline, the patients identified their occupational problems related to productivity, self-care and leisure activities that inspired further goal setting. Group sessions included information and discussion on meaningful occupations, healthy eating and daily physical activity concerning chronic pain. The patients learned about

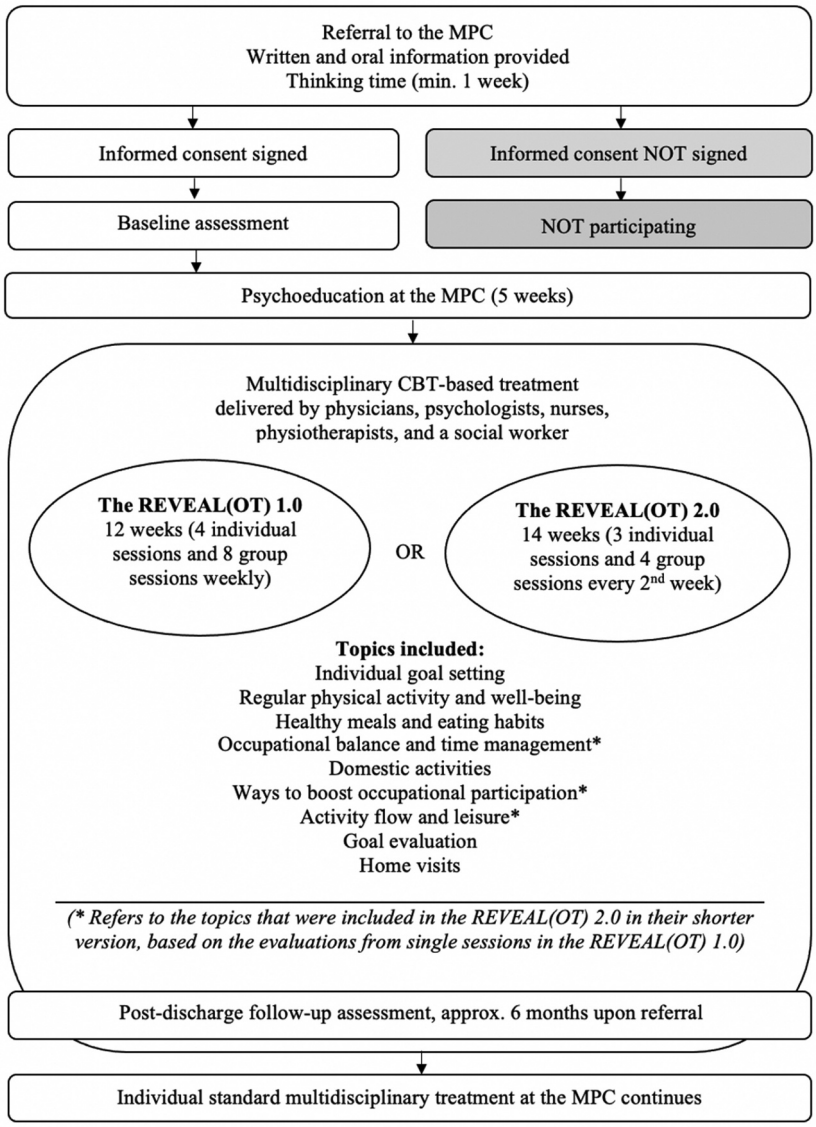

Figure 1. The structure of the REVEAL(OT) (versions 1.0 and 2.0).

obstacles in performing human occupations and low-grade inflammation mechanisms related to improper nutritional choices and sedentary lifestyle and how human habits emerge and can be modified. The patients reflected on the importance of meaningful occupational performance for health and well-being, implementing anti-inflammatory eating principles, and tailoring regular physical activity to their everyday life. The occupational therapist leading the course provided individually tailored motivational support to promote transfer of the new knowledge and experiences to the patients' everyday life. Skill training in performing challenging activities of daily living and lifestyle diaries for monitoring personal lifestyle goals related to occupational performance, healthy eating, and physical activity were implemented to help the patients smoothly transform the new knowledge to their everyday life and home environment. Individual sessions, including one or two home visits, were included to support the occupational therapy treatment tailored to the individual's needs. Also, the patients could borrow and try a variety of assistive devices such as ergonomic chairs, seats and lumbar cushions, swivel pads, kitchen utensils, bath benches, bath brushes with ergonomic handles, sliding layers, etc. The REVEAL(OT) was protocolized and manualised to enhance fidelity among the interventionists. Cooperation between the OTU and MPC should secure coordinated planning to cover the patients' treatment needs. Upon intervention discharge, the patients continued with their planned regular treatment at the MPC.

Participants

In the following, we use "patients" or "clinicians" for group specification purposes and "participants" when we refer to both groups.

The patients: An entire study cohort of 20 patients included in the feasibility studies was invited to participate. The inclusion and exclusion criteria for the patients followed the main study protocol (Registration number NCT03903900, Clinicaltrials.gov). Four patients took part in each of the two patient focus group interviews (FG1) and (FG2), i.e., eight patients in total. The patients were between 18 and 65 years old and had chronic pain diagnosed for at least three months. The patients harboured no acute pain or current comorbidities such as headache/migraine, cancer, depression, substance misuse, or severe psychiatric diagnoses such as psychoses. All the patients had sufficient Danish speaking skills. In focus groups 1 and 2, there were some patients who participated in version 1.0 of the REVEAL(OT), and some in version 2.0. Due to patients' timing preferences, we could not dedicate one focus group interview to an intervention version each. We observed no markable differences in patient experience from one intervention version to the other.

Initially, 15 patients consented to participation. Later, one patient withdrew because she entered another inpatient treatment programme and was full-time occupied. Three patients were sick on the day of the interviews, and another three did not show up for unknown reasons.

The clinicians: The clinician focus group (FG3) included one occupational therapist from the OTU who delivered the REVEAL(OT)-intervention, and three representatives from the MPC involved in usual care, e.g., one physician, one psychologist, and one physiotherapist. The rest of the employees at the MPC could not participate due to the current workload at the clinical units involved in usual care and the add-on intervention. Presentation of the participants —see Table I.

Data generation

An extern researcher, who neither planned nor delivered the intervention, conducted all the focus group interviews as a moderator (VOM) to reduce conflict of interests. The researcher who planned the intervention (SSN) performed observations during all the focus group interviews.

VOM and SSN led the three focus group interviews. We strived to establish an open and trustful atmosphere to encourage participants to share their opinion of how they perceived the REVEAL(OT) programme. Two semi-structured interview guides supported the conduct of the focus group interviews with patients and clinicians (Halkier, 2016, pp. 51–70). To facilitate free discussion, both semi-structured guides included few questions with a broad focus on the subject of our interest which should invite the participants to reflect without feeling restricted to a certain kind of response. The moderator supported a balanced degree of participation using additional questions of relevance pre-determined in the interview guides. We welcomed the participants to share any relevant information, including criticism and negative or missing experiences. Moreover, we prompted the clinicians who consented to participation to collect any relevant comments regarding the REVEAL(OT) among their colleagues who were occupied with work and could not participate. We provided the participants with ergonomic sitting chairs, food and beverages during the focus group interviews. We added 15 minutes to the estimated time consumption to avoid a time rush.

First, we conducted two focus group interviews with the patients. We asked the patient groups: 1. How did you work on changing your everyday habits during the REVEAL(OT) intervention?; 2. How did you implement experiences from the REVEAL(OT) intervention to everyday life?; 3. Please elaborate on the benefits and challenges of the programme; 4. How would you describe the most prominent effects of the REVEAL(OT) intervention on your daily life?

Second, we interviewed the clinicians, starting with a visual presentation of selected statements from the focus group interviews with the patients (Figure 2). We considered all the clinicians as one multidisciplinary clinical unit involved in the feasibility testing process regardless of their formal affiliation with either OTU or MPC. We asked the clinicians: 1. How would you describe your role and work concerning the REVEAL(OT) intervention as a novel treatment option added to usual care?; 2. Please reflect on the selected patients' statements and propose a further improvement of the REVEAL(OT) as an add-on treatment option incorporated into usual care; 3. Please evaluate the REVEAL(OT) regarding its strengths and limitations. 4. Please identify which outcomes the multidisciplinary chronic pain treatment should target to be effective.

The focus group interviews lasted 90 to 120 minutes. The interviews were recorded and transcribed verbatim by an extern assistant not affiliated with the current research.

Data analysis and interpretation

Seventy-six pages of transcribed single-line raw text were collected. The semantic analysis followed the six phases proposed by Braun & Clarke (Braun & Clarke, 2006). In Phase 1, SSN and VOM became familiarized with the data, comprehending the entire transcribed text, and obtained an overall understanding of the data. In Phase 2, the two authors generated initial codes independently using NVivo 12 software, version 12.6.0, and discussed discrepancies. The discrepancies emerged from a variety of possible interpretations

Table I. Presentation of the participants characteristics.

	Focus group interview 1 (FG1)				Focus group interview 2 (FG2)			
Patients	1 (FG1P1)	2 (FG1P2)	3 (FG1P3)	4 (FG1P4)	5 (FG2P5)	6 (FG2P6)	7 (FG2P7)	8 (FG2P8)
Gender	Female	Female	Female	Male	Male	Female	Female	Female
Age in years	60	52	24	51	60	60	58	62
Working status	Sick leave	Home-staying	Sick leave	Disability pension	Sick leave	Working 20 hours/ week	Disability pension	Sick leave
Pain origin	Lumbar disc herniation	Fibromyalga; Primary knee osteoarthri-tis; Occupa-tional injury (back)	Lumbar disc herniation; Abdominal pain; Head-ache	Occupational injury (back)	Cervical disc herniation; Osteochond-rosis; Spinal stenosis	Primary osteoarthri-tis; Sequelae after knee surgery	Spondylolis-thesis; Poly-neuropathy; Sequelae after spinal cord herniation surgery	Hip arthritis
Social status	Living with a partner, grown-up children	Living alone, grown-up children	Living with a partner, no children	Family with children (teens)	Living alone, grown-up children	Living with a partner, grown-up children	Living with a partner, grown-up children	Living alone, grown-up children
Occupational problems[a]	Participating in social events; Domestic chores; Having a job; Gardening	Initiating and completing activities; Eating regularly; Cleaning; Cooking; Baking	Memorizing new information; Moving around (without a wheel chair)	Stacking firewood, Consuming less sweetened beverages; Increasing physical activity;	Getting ind and out of the car; Having hobby (stuffing animals); Hunting; Doing woodwork;	Cycling (on a lady bicycle); Riding; Having guests; Carrying laundry	Putting clothes on; Gardening; Washing floors; Participating in bingo games	Standing up while cooking; Performing sitting activities (pc, knitting, etc.);
(Occupational problems[a])				Performing fine motor work; Keeping balance when shifting position	Sitting in the car			Performing dog training (as tutor); Sitting in the car; Walking by the beach (on uneven surface)
REVEAL(OT) version	1.0	2.0	1.0	1.0	2.0	2.0	2.0	2.0

	Focus group interview 3 (FG3)			
Clinicians	1 (FG3C1)	2 (FG3C2)	3 (FG3C3)	4 (FG3C4)
Profession	Physician	Psychologist	Physiotherapist	Occupational therapist
Gender	Female	Male	Female	Female

[a]*Problems in occupational performance and participation (max. 5) identified and prioritized according to their self-perceived meaningfulness by the patients using the Canadian Occupational Performance Measure as an assessment tool (Ref. Law, M., Baptiste, S., Carswell, A., McColl, M.A., Polatajko, H., & Pollock, N. (2019). Canadian Occupational Performance Measure (5th ed.-revised). Altona, Canada: COPM Inc.)*

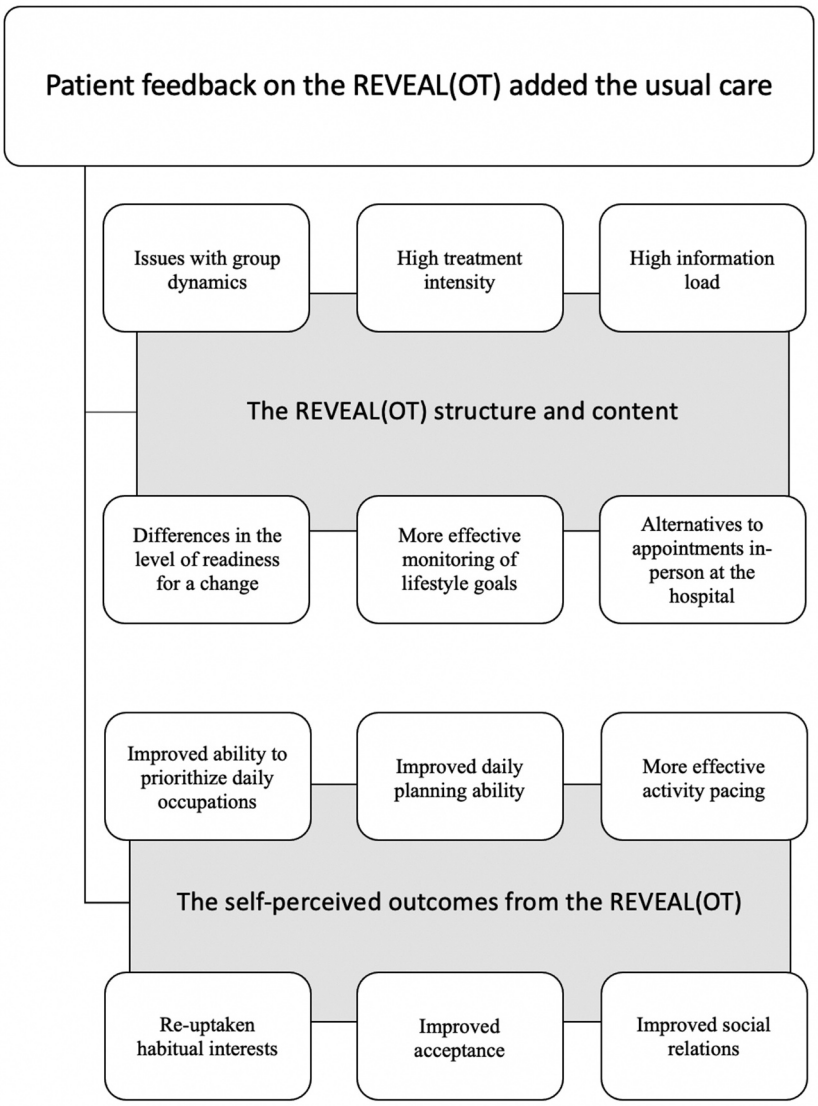

Figure 2. Selected patient statements as a moderation tool for interviewing the clinicians.

when coding the text. Interactions with spouses could be coded as "Spousal involvement", "Partner support", or "Family involvement" if children were included. We decided to allow a more general description for social relations because formal details were less important. For example, "Partner" was preferred over "Husband" or "Spouse". At the same time, we decided to focus on the contribution of an interaction type to an individual living with chronic pain because the output of the chronic pain treatment was in both patients and clinicians' concerns. Thus, words "Support" or "Accept" was preferred over those of more neutral character such as "Involvement". In Phase 3–5, searching, reviewing, defining and naming the themes that emerged from the initial codes were performed by SSN and CS. We needed a similar approach when reviewing and defining codes both from the patients and clinicians' perspectives. Thus, we decided to focus on the contributive role of each code in chronic pain treatment to guide us in further code grouping. As in the case of social interactions, we used distinguished codes defining phenomena that emerged within an individual living with chronic pain such as "Feeling accepted by others", from those of an external character such as "Supportive environments". In Phase 6, all authors contributed to the understanding and discussing the findings before elaborating on a cumulative report in the results and discussion sections. We included selected citations from the interviews to add transparency to the results. Relevant research supporting the discussion was applied to place the findings in a broader context and reveal commonalities and discrepancies.

Ethical considerations

The Ethical Committee in Region Zealand (SJ-703) and the Danish Data Protection Committee in Region Zealand (REG-052-2018) approved the study. We distributed an invitation with detailed information on the investigation to the potential participants at least one month before asking them to sign informed consent. All the participants were informed about the

focus group method, who the researchers were and how they would perform the investigation. We underscored that the focus group interviews would be subject to the confidentiality of personal data. The information provided before the investigation was repeated orally before starting each focus group interview. The first author provided oral and written information about the study and obtained consent at least one month before the first focus group interview. The participants received information on voluntary participation (i.e., both participation in the investigation itself or its parts, inclusive the right not to answer a question if not feeling comfortable), unrestricted withdrawal, confidentiality, anonymizing, and archiving the data. For data recording, storage and sharing, we used voice recorders, encrypted USBs, and software, approved for research activities following the General Data Protection Regulation (Regulation (EU) 2016/679). No adverse events caused by participation in the study were expected to occur.

Results

The eight patients and four clinicians who participated in the three focus group interviews (FG1-3) are presented in Table I.

The iterative reading of the transcribed text of FG1 and FG2 revealed that after participation in REVEAL(OT), the patients felt well-supported in managing and living with chronic pain in new and valuable ways. In addition, the patients provided recommendations for further enhancement of the intervention. Data from FG3 with the clinicians supported that the REVEAL(OT) was beneficial as an add-on to usual care and pointed out the necessity to adjust the information load, treatment intensity and multidisciplinary cooperation. Furthermore, the clinicians added suggestions for organizational amendments to improve the REVEAL(OT) implementation along with the existing pain management concept. The cumulative analysis included two themes: "Increased patient acceptance of living with chronic pain" and "Empowering patients to make lifestyle changes".

Increased patient acceptance of living with chronic pain

The patients expressed that their primary expectation from the chronic pain treatment at the MPC and OTU was pain reduction. When they realized that this was not realistic, the aim became to improve coping with pain in everyday life. As the most prominent output from the REVEAL(OT), the patients highlighted an increased acceptance of living with pain. They described that their acceptance grew because of greater awareness of their own needs and wishes and the acquired new ways of managing daily living with chronic pain. They could now skip the role of always sacrificing themself for others. They became more skilled in structuring their everyday activities, as described by one of the patients:

> Well, all those small domestic chores, they are running up all the time. I say "small" because I was doing those all the time. (…) [Now] I learned to give the others small tasks, acting smoothly instead of being tough and just doing it myself. One day they [children] were cooking, filling in the dishwasher and washing clothes. This way, I can concentrate on what I have to. I can now do the things I enjoy (FG1P4).

The patients experienced that their energy level and personal demands had changed after chronic pain onset. Guided by occupational therapists, they learned how to incorporate those changes in their everyday life. Accordingly, they found it easier to ask for help:

> "A change happened about cooking. I'm better now to ask if he [the patients' husband] would peel potatoes. So we are sharing workload" (FG2P8); "I'm aware now that there are other ways to handle things. I appreciate it deeply" (FG2P5); "I look at myself with new eyes, so I think that is the most important output of being here" (FG2P5).

The increased acceptance of living with chronic pain became particularly visible when the patients faced their social environment while they gradually became able to cease suppressing their own needs and fear of making others disappointed. The patients emphasized that awareness of their standpoint helped remove barriers between themselves and their social environment. One of the patients summarized it, while the others mutually consented by nodding their heads:

> The most important thing for me was to find space for myself … and say 'no' to what I can't or don't want or have the capacity for (…) That it is okay not to be able to cope with all that I was used to before. It has helped me, indeed (FG2P8).

The thoughts echoed in the patients' focus group that brought examples on how to stop being "a pleaser" and become more selective when inviting guests. A new understanding of how to set limits was valued as a personal strength and no longer seen as unpoliteness. Comprehending the patients' thoughts, one of the clinicians perceived that the patients became more self-assertive and explicit: *"When they begin to communicate in a new way and express their needs in terms of pain, then they show more respect for their pain condition and get more skilled in setting clear limits. One's social environment can handle that much more easily!"* (FG3C4).

The patients outlined that they also became better at being included in social groups while following the REVEAL(OT):

> Meeting other people that understand one's situation can also enhance the quality of life. I felt myself being all alone. That is why it is an incredible feeling to come here and be taken seriously, with that solution-oriented approach to things, pursuing the best possible result for you as a patient (FG2P5).

The feelings of acceptance and being accepted are complex mechanism because, as one of the clinicians put it: *"We cannot force anyone to accept one's condition. This is a process, and we do not know how long it would take. It is definitely a challenge for every clinician"* (FG3C4). From the clinicians' view, acceptance was linked to greater understanding and coping with pain.

The clinicians noted that close social network—especially spouses—may find it extremely difficult being caregivers for a person with chronic pain. Some of the patients expressed that they wished the REVEAL(OT) had informed their spouses about the intervention and how to support them:

> People expect one to get better after coming here. It was difficult to explain what we were doing here. You meet two hours a week, then eat more vegetables, drink water, and get more physically active … But what else was it for? It would be fine for the nearest ones to get some more information, just briefly (FG1P3).

Empowering patients to make lifestyle changes

The enhanced understanding of processes behind chronic pain highlighted by the clinicians in the previous theme was confirmed by the patients to be a starting point for them in changing habits. A patient said: *"It has been fantastic to understand that it is okay to peel some potatoes and then relax and sit and knit, and then to return and make some meatballs or whatever. (…) Because you manage those pain flares better"* (FG2P8).

The patients valued empathic professional communication as an empowering factor. It meant a lot for them that the occupational therapists were "*accommodating and friendly, and wished you*[patients] *the best"* (FG1P1). They described that active listening and involvement in one's personal life situation boosted their self-esteem and encouraged them to try out new things. The patients preferred face-to-face contact with clinicians. Alternatively, a communication platform allowing visual decoding (video instead of phone calls), because it worked empowering: *"I need to … to be able to 'read' people when I talk to them"* (FG1P1). However, phone calls were still considered applicable, but rather in the later sessions, in cases where contact already had been established.

Another empowering factor for patients in making healthier lifestyle choices was peer support during the REVEAL(OT). Peers inspired the patients to work with personal goals, maintain a healthy lifestyle and broaden perspectives: *"It helps to talk with others in the same situation because one tends to feel being the only one in the whole world who has it like this"* (FG1P3); *"It helps to support each other in getting new experiences"* (FG2P6).

The patients found peer support in the REVEAL(OT) beneficial for their treatment but also challenging. Most patients considered a well-functioning peer collaboration to be associated with readiness to share useful personal experiences and being ready to try new things: *"I think participating in such an intervention, one must have to keep the mind open and be receptive"* (FG1P3). At the same time, some patients were sensitive to (self-perceived) lack of engagement in peers, as it made them feel demotivated and could provoke conflicts within a group, demanding early conflict management.

In some patients, changing lifestyle began with restarting habitual interests, previously paused due to chronic pain: *"I started to knit again, both on a knitting machine and manually. But then I thought, I could also make some patchwork and dog collars as I used to but didn't have surplus to during the past two years"* (FG2P8). Though the activities did not ease the pain but could cause more pain afterwards, the patients did not regret their choice because of earning extra energy and joy from doing the value-based occupations: *"I know*, [participating in a choir concert] *will be pretty tough. I will be feeling in chatters the whole next week. But this is what I want"* (FG1P2); *"I have been hunting again! For the first time in the past four years, I had a surplus for that, despite the pain"* (FG2P5).

During the REVEAL(OT) programme, several strategies helped the patients revise and rearrange their daily structure to create space for pleasurable events, which implied a more balanced everyday life. Making value-based choices and activity pacing were the methods widely used for saving and gaining energy:

> "I split the tasks because I can't do that much cleaning. (…) I have also learned to structure my day so that I both get some rest, do exercises, and walk for half an hour every day" (FG1P1); "During the past month, I left some arrangements earlier because I also had plans for the next day and I also want to be able to do things tomorrow" (FG1P2); "I never make plans two days in a row. Always one day with plans, then a break for one day or maybe two" (FG1P3).

Besides doing more meaningful occupations, the REVEAL(OT) empowered the patients to live a healthier lifestyle. Using lifestyle diaries and regular follow-ups prompted sustainable habit changes. Satisfaction with the intervention appeared high in those who successfully achieved their lifestyle goals: *"I feel like I just can't live without that water. It makes*

a difference!" (FG1P2); *"I have eaten more fruit and vegetables. I haven't been good at it before"* (FG1P1).

Lifestyle diaries were considered an empowering tool for adaptation and maintaining lifestyle changes because knowledge and the initial motivation did not automatically lead to changing lifestyle habits. The element of practising in real life had a crucial influence on achieving personal lifestyle goals.

Using assistive devices during the REVEAL(OT) made everyday chores "doable" and was another factor considered empowering for changing lifestyle. The patients valued the opportunity highly *"to loan and try different things"* (FG1P1) while searching for a solution that matched their requirements: *"Instead of buying things* [to test them], *you knew when you bought* [an assistive device] *that you have tested it, and it worked"* (FG1P2). The latter patient have tried several lumbar cushion models and found one that enabled her to travel by car and participate in family gatherings and eating together without collapsing because of back pain.

The patients described as essential the connection between the treatment delivered in the hospital facilities and their home environment. Several patients expressed that their families would benefit from some brief information on the intervention contents. Even so, home visits met a degree of resistance in some patients who expressed that the output of the home visit was low, or the aim was not clear enough to be considered empowering for changing habits.

The parallel delivery of usual care and the REVEAL(OT) implied another barrier for empowering the patients as it reduced their overall surplus. Despite improvements made in the REVEAL(OT) 2.0 such as reduction of the information scope (fewer topics on the agenda) and the treatment intensity (from meetings every week to every second week), the patients still experienced the information and treatment load in the combined intervention to be too high. The clinicians agreed that the information and treatment load was sometimes difficult for the patients to handle. Both the patients and the clinicians proposed that the REVEAL(OT) should be carried out after the compulsory 5-week preparatory psychoeducation course, running parallel with the individually tailored treatment at the MPC that possessed higher flexibility and, thus, was more compatible with the add-on intervention.

The interview with the clinicians revealed a complication in the cooperation between the MPC and OTU, as there was a physical distance between the two hospital units. Not being able to get involved in everyday clinical practice on a daily basis was considered a barrier to interdisciplinary cooperation. When patient-related questions had to wait before getting clarified, this sometimes caused confusion among both the clinicians and the patients. The clinicians at the MPC expressed a need for greater insight into the treatment elements revealed within the REVEAL(OT) and more intensive communication between the OTU and the MPC.

Discussion

Patients' and clinicians' focus group-based evaluation of the REVEAL(OT) reflected patients' increased acceptance of living with chronic pain along with patient empowerment for changing lifestyle. The participation in the REVEAL(OT) was deemed satisfactory by the patients. However, specific improvements in the intervention were needed before conducting a clinical trial.

During this investigation, we gained an insight into the patient perspective of living with chronic pain and the compromising effect of chronic pain on multiple life areas and the identity in an individual (Vlaeyen et al., 2016). We were excited to observe how even a modest tailored adjustment in occupational performance can make the mechanism of change work and became a turning point towards improved quality of life. That suggests that occupational therapy could benefit health and well-being in chronic pain (Lagueux et al., 2018), also applied to this particular clinical setting.

Occupational science, i.e., a discipline systematically studying human occupations, participation and their relations to human health, supporting occupational therapy practice, links occupational engagement with our identity and the roles we perform throughout our lives, and their crucial importance for human health (Christiansen, 2004; Hocking, 2013). Benefits of improved occupational performance for health and well-being in people living with chronic pain have been seen in other occupational therapy research (Lagueux et al., 2021; Simon & Collins, 2017). The REVEAL(OT), like other nonpharmacological treatments of chronic pain, aims to enhance human coping ability through greater awareness of their own needs and wishes and less social avoidance (Turk & McCarberg, 2005). The unique role of the REVEAL(OT) as an add-on to usual care at the MPC could be attributed to its impact on the occupational dimensions of doing, being, becoming and belonging, essential for health and well-being (Wilcock, 1998; Yazdani & Bonsaksen, 2017). In the dimension of doing, patients participating in the REVEAL(OT) discovered new ways to perform meaningful or purposeful activities, experimented with new healthy recipes, and reduce sedentary time. In the dimension of being, patients established new healthy routines determined by their value-based choices. In the dimension of becoming, the focus shift from chronic pain diagnosis and disability to joyful or purposeful everyday content

and experienced themselves as actively making a meaningful difference in their lives. Meeting others and sharing experiences made patients feel belonging to an active group of people capable of coping with everyday obstacles and breaking out of the vicious circle of chronic pain.

Moreover, the REVEAL(OT) would bring a lifestyle-oriented focus into the existing chronic pain management, which international studies have previously proposed (Lagueux et al., 2018; van Hecke et al., 2013). Particularly, interventions targeting multiple (≥ 2) lifestyle factors within the same intervention has been urged (Nijs et al., 2020). The REVEAL(OT) explored how several relevant lifestyle factors can be tackled within chronic pain treatment at a Danish outpatient clinic, assisted by occupational therapists.

Specific clinical practice-bound differences between usual care and the lifestyle-oriented occupational therapy intervention were apparent. However, we have not found the two treatments to be conceptually opposed. The effect of CBT, on which the MPC has based its treatment, is evident (Skelly et al., 2020). While CBT focuses on cognitive processes such as thoughts, emotions, bodily sensations and behaviour, the REVEAL(OT) primarily worked with the behavioural dimension linked to performing meaningful everyday activities. The REVEAL(OT) targeted occupational behaviour concerning occupational problems identified at the intervention entry. Occupational therapy assessments applied in the REVEAL(OT) could deliver information helpful to the other healthcare disciplines at the MPC such as weekly activity schedules or clinical reports on working with occupational goals. If occupational therapy became an integrated part of usual care, occupational therapists could assist in measuring and evaluating the treatment effect on occupational performance and satisfaction, which some evidence links to self-efficacy (Thomas et al., 2020). Self-efficacy is, in turn, associated with chronic pain prognosis (Martinez-Calderon et al., 2018). The Danish private residential rehabilitation clinics use occupational therapy and a lifestyle-oriented approach in multidisciplinary chronic pain treatment (Schmidt et al., 2018). However, it is unknown how to apply their experiences to a public outpatient chronic pain clinic context, indicating the need for further investigation.

Further improvements in the REVEAL(OT) were needed, of which the reduction of the information and treatment load was the most crucial for the patients. Several solutions for reducing treatment and information load in the REVEAL(OT) could be considered. Firstly, the handouts for group sessions could be printed as a patient handbook to free the patients from systematizing and archiving the handouts by own hand. That would also facilitate patients' overview of the intervention contents and prevent possible loss of relevant materials. Secondly, conducting the REVEAL(OT) after the compulsory psychoeducation course, i.e., in parallel with the individual consultations at the MPC, could also release more surplus in the patients. Decreasing cognitive demands during the intervention would add energy surplus to the patients which is necessary to accommodate lifestyle changes (Nijs et al., 2020). Lower cognitive load also positively influences the group dynamics by releasing working memory, which is beneficial for communication skills such as the ability to take others' perspectives (Cane et al., 2017). At last, some programme elements such as home visits could be made optional when found relevant in cooperation with a patient. Though some patients would wish their close network received a brief information letter on the REVEAL(OT) contents and its impact, healthcare personnel entering home environments was seemingly perceived intimidating to some degree. Involving patients in decision making about their treatment and reflecting patient's actual needs are essential qualities of adequate pain rehabilitation (Oosterhof et al., 2014).

To improve the multidisciplinary cooperation, the clinicians proposed more frequent meetings between the clinical units involved and making the occupational therapy contribution to usual care more explicit and valuable. The benefits of having clinical units placed close to each other underpinned by the clinicians as an essential factor that would have improved multidisciplinary cooperation was eye-opening for us and inspired us for seeking new solutions. The Danish Health Authority has recently highlighted the role of occupational therapy in chronic pain rehabilitation and urged the inclusion of the occupational therapy competencies in multidisciplinary chronic pain management as its necessary treatment option, yet poorly represented in this area of healthcare in today Denmark (The Danish Health Authority, 2020). The REVEAL(OT) represents the first Danish experience of how occupational therapists can promote occupational performance and participation in chronic pain patients referred to a public Danish pain management centre. Findings from this study will inform the next feasibility phase in developing the REVEAL(OT) programme and inform the design and conduct of a future clinical trial. We hope that the REVEAL(OT) if found effective, will inspire stakeholders for including occupational therapy in the multidisciplinary treatment of chronic pain.

Limitations

This study's findings must be interpreted with the premises of qualitative focus group interview studies in mind. Though the small study sample has only provided an insight into opinions and experiences of this

particular group of chronic pain patients and clinicians, the participants represented forty per cent of the potential cohort of patients and clinicians who may have an opinion about, or experience with, the add-on intervention, which could be considered representative for this specific patient cohort (Vasileiou et al., 2018). A higher participation rate of both patients and clinicians might have revealed different themes and other interpretations relevant to the intervention evaluation. However, reflecting the two themes that emerged from the data analysis in this study, we believe that our findings may speak into similar experiences in a broader range of people living with chronic pain and multidisciplinary healthcare workers.

The patients who took part in the focus group interviews were probably more resourceful and motivated than those who refused to participate. Additional relevant data on the participants could have prompted further analysis, which remained unexplored in this study because of the few data categories included. Additionally, an apparent limitation was the non-participating nurses in the sample, though the representation of this group of healthcare professionals was the largest in the clinical setting studied. Both factors mentioned above elevated the risks of sampling bias in this study (Cheung et al., 2017). Involvement of all the healthcare disciplines represented within the multidisciplinary chronic pain treatment and its add-on treatment option, as well as a broad representation of patients with lower capacity for participation, would have provided us with perspectives from a broader scope of impactful stakeholders in the intervention development process (Concannon et al., 2014).

The semantic data-driven analysis claims that there is not only one way to identify themes in a dataset (Braun & Clarke, 2006). However, all the co-authors made efforts to secure that the analysis and interpretation of the results in this study would adequately reflect the opinions and experiences of patients and clinicians.

Conclusions

The patients were satisfied with the lifestyle-oriented occupational therapy programme REVEAL(OT) that promoted increased patient acceptance of living with chronic pain and empowered them for changing lifestyle. The patients and clinicians considered the REVEAL(OT) a relevant add-on to usual care and proposed further improvements such as reducing the information and treatment load and a higher degree of professional communication and cooperation.

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Data availability statement

Data supporting the results of this study can be accessed by contacting the corresponding author. https://portal.findresearcher.sdu.dk/en/persons/ssolgaard.

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Table I. Presentation of the participants characteristics

	Focus group interview 1 (FG1)				Focus group interview 2 (FG2)			
Patients	1 (FG1P1)	2 (FG1P2)	3 (FG1P3)	4 (FG1P4)	5 (FG2P5)	6 (FG2P6)	7 (FG2P7)	8 (FG2P8)
Gender	Female	Female	Female	Male	Male	Female	Female	Female
Age in years	60	52	24	51	60	60	58	62
Working status	Sick leave	Home-staying	Sick leave	Disability pension	Sick leave	Working 20 hours/ week	Disability pension	Sick leave
Pain origin	Lumbar disc herniation	Fibromyalga; Primary knee osteoarthri-tis; Occupa-tional injury (back)	Lumbar disc herniation; Abdominal pain; Head-ache	Occupational injury (back)	Cervical disc herniation; Osteochond-rosis; Spinal stenosis	Primary osteoarthri-tis; Sequelae after knee surgery	Spondylolis-thesis; Poly-neuropathy; Sequelae after spinal cord herniation surgery	Hip arthritis
Social status	Living with a partner, grown-up children	Living alone, grown-up children	Living with a partner, no children	Family with children (teens)	Living alone, grown-up children	Living with a partner, grown-up children	Living with a partner, grown-up children	Living alone, grown-up children
Occupational problems[a]	Participating in social events; Domestic chores; Having a job; Gardening	Initiating and completing activities; Eating regularly; Cleaning; Cooking; Baking	Memorizing new information; Moving around (without a wheel chair)	Stacking firewood, Consuming less sweetened beverages; Increasing physical activity;	Getting ind and out of the car; Having hobby (stuffing animals); Hunting; Doing woodwork;	Cycling (on a lady bicycle); Riding; Having guests; Carrying laundry	Putting clothes on; Gardening; Washing floors; Participating in bingo games	Standing up while cooking; Performing sitting activities (pc, knitting, etc.);
(Occupational problems[a])				Performing fine motor work; Keeping balance when shifting position	Sitting in the car			Performing dog training (as tutor); Sitting in the car; Walking by the beach (on uneven surface)
REVEAL(OT) version	1.0	2.0	1.0	1.0	2.0	2.0	2.0	2.0
					Focus group interview 3 (FG3)			
Clinicians	1 (FG3C1)		2 (FG3C2)		3 (FG3C3)		4 (FG3C4)	
Profession	Physician		Psychologist		Physiotherapist		Occupational therapist	
Gender	Female		Male		Female		Female	

[a]*Problems in occupational performance and participation (max. 5) identified and prioritized according to their self-perceived meaningfulness by the patients using the Canadian Occupational Performance Measure as an assessment tool (Ref. Law, M., Baptiste, S., Carswell, A., McColl, M.A., Polatajko, H., & Pollock, N. (2019). Canadian Occupational Performance Measure (5th ed.-revised). Altona, Canada: COPM Inc.)*

Appendix 23

Patient information letter, focus groups

Vedr. fokusgruppeinterview med deltagerne i ergoterapeutisk forskningsprojektet

”Ergoterapeutisk livsstilsintervention til patienter med kroniske non-maligne smerter”

Protokol, version 1.4, revideret 31.10.19

Vi er meget glade for, at du har vist interesse for at være med til evaluering af den ergoterapeutiske intervention til kroniske smertepatienter tilknyttet Tværfagligt smertecenter på Næstved sygehus. Evalueringen er en meget vigtig del i udvikling af behandlingsindsatser, derfor sætter vi stor pris på din tid og hjælp!

Hermed vil vi invitere dig til et fokusgruppeinterview

torsdag d. 28. november 2019 kl. 9.00 -11.00 (eller kl. 13.00 – 15.00)

Fokusgruppeinterview vil finde sted i undervisningslokalet i Ergoterapien på Næstved sygehus (hovedbygning, kælderen), på adressen: Ringstedgade 61, 4700 Næstved.

Til stede

Der inviteres ca. 10 deltagere til et enkelt interviewhold.

Interviewet vil være ledet af Vicki Mogensen, ergoterapeut, studerende på Kandidatuddannelsen i ergoterapi (Syddansk Universitet, Odense). Information indsamlet i fokusgruppeinterviewet vil være anonymiseret, analyseret og beskrevet i Vicki Mogensens kandidatspeciale. Analysen vil blive anvendt til justeringer i videre behandlingsforløb i forskningsprojektet.

Svetlana Nielsen, projektlederen i forskningsprojektet ”Ergoterapeutisk livsstilsintervention til patienter med kroniske non-maligne smerter” og medvejlederen på Vicki’ kandidatspeciale, vil være til stede som observatør.

Anonymitet og datasikkerhed

For at lette databearbejdningen, vil gruppesamtalen optaget på diktafon. Ved transskribering af data vil alle navne blive anonymiseret, så konkrete personer ikke kan identificeres. Alle optagelserne vil blive slettet, når undersøgelsen er færdigbeskrevet senest 01.07.2020. Opbevaring af data vil ske på en krypteret USB-enhed.

Praktiske oplysninger

Fokusgruppeinterview-undersøgelsen er ikke forbundet med bivirkninger, risici, komplikationer eller ulemper. Deltagelsen i undersøgelsen er frivillig og kan afbrydes til enhver tid uden konsekvenser for dig og dine fremtidige behandlingsmuligheder.

Projektdeltagerne vil ikke modtage nogen form for honorar for deltagelsen. Nogle patienter vil være berettiget til dækning af transportudgifter i forbindelse med fremmøde på behandlingsstedet i overensstemmelse med reglerne der kan læses på regionens hjemmeside www.regionsjaelland.dk under Patientbefordring: http://www.regionsjaelland.dk/Sundhed/patient-i-region-sjaelland/patientbefordring/Sider/regler-om-patientbefordring-transport.aspx.

Der vil blive serveret sandwich, kaffe, te og vand til mødet.

Adgang til projektresultater

Undersøgelsens resultater vil være tilgængelige via kontakt til biblioteket på Syddansk universitet (Odense) eller efter aftale med Svetlana Nielsen, projektlederen i forskningsprojektet "Ergoterapeutisk livsstilsintervention til patienter med kroniske non-maligne smerter".

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i fokusgruppeinterviewet, og at du føler dig forberedt. Hvis du har spørgsmål eller vil vide mere, er du meget velkommen til at kontakte undertegnede.

Med venlig hilsen,

Svetlana Solgaard Nielsen, ergoterapeut, kandidat i ergoterapi

Afdelingen for Fysioterapi og Ergoterapi, Næstved-Slagelse-Ringsted sygehuse

Fælledvej 11, 4200 Slagelse

E-mail: ergo.livsstil@gmail.com; Mob. 51252255

Projektidentifikation

- SJ-703 (Den Regionale Videnskabsetiske Komité for Region Sjælland)
- REG-052-2018 (Datatilsynet i Region Sjælland)

Appendix 24

Clinicians' information letter, focus groups

Vedr. fokusgruppeinterview med repræsentanter fra det tværfaglige team involveret i ergoterapeutisk forskningsprojektet

"Ergoterapeutisk livsstilsintervention til patienter med kroniske non-maligne smerter"

Protokol, version 1.4, revideret 31.10.19

Vi er meget glade for, at du har vist interesse for at være med til den tværfaglige evaluering af den ergoterapeutiske intervention til kroniske smertepatienter tilknyttet Tværfagligt smertecenter på Næstved sygehus. Evalueringen er en meget vigtig del i udvikling af behandlingsindsatser, derfor sætter vi stor pris på din tid og hjælp!

Hermed vil vi invitere dig til et fokusgruppeinterview

torsdag d. 30. januar 2020 kl. 12.00 -13.30

Fokusgruppeinterview vil finde sted i undervisningslokalet i Ergoterapien på Næstved sygehus (hovedbygning, kælderen), på adressen: Ringstedgade 61, 4700 Næstved.

Undersøgelsens formål

Fokusgruppeinterviewet har til formål at give større indsigt i, hvordan det tværfaglige samarbejde kan organiseres for bedst at støtte om patienternes udbytte fra det samlede behandlingstilbud, og skabe bedst flow og trivsel i arbejdsgange på tværs af de to afdelinger.

Til stede

Interviewet vil være ledet af Vicki Mogensen, ergoterapeut, studerende på Kandidatuddannelsen i ergoterapi (Syddansk Universitet, Odense). Information indsamlet i fokusgruppeinterviewet vil være anonymiseret, analyseret og beskrevet i Vicki Mogensens kandidatspeciale. Analysen vil blive anvendt til justeringer i videre behandlingsforløb i forskningsprojektet.

Svetlana Nielsen, projektlederen i forskningsprojektet "Ergoterapeutisk livsstilsintervention til patienter med kroniske non-maligne smerter" og medvejlederen på Vicki' kandidatspeciale, vil være til stede som observatør.

Anonymitet og datasikkerhed

For at lette databearbejdningen, vil gruppesamtalen optaget på diktafon. Ved transskribering af data vil alle navne blive anonymiseret, så konkrete personer ikke kan identificeres. Alle optagelserne vil blive slettet, når undersøgelsen er færdigbeskrevet senest 01.07.2020. Opbevaring af data vil ske på en krypteret USB-enhed.

Praktiske oplysninger

Deltagelsen i undersøgelsen er frivillig og kan afbrydes til enhver tid. Projektdeltagerne vil ikke modtage nogen form for honorar for deltagelsen.

Deltagerne bliver tilbudt sandwich, vand, te og kaffe ved mødets start.

Adgang til projektresultater

Undersøgelsens resultater vil være tilgængelige via kontakt til biblioteket på Syddansk universitet (Odense) eller efter aftale med Svetlana Nielsen.

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i fokusgruppeinterviewet, og at du føler dig forberedt. Hvis du har spørgsmål eller vil vide mere, er du meget velkommen til at kontakte undertegnede.

Med venlig hilsen,

Svetlana Solgaard Nielsen, ergoterapeut, kandidat i ergoterapi

Afdelingen for Fysioterapi og Ergoterapi, Næstved-Slagelse-Ringsted sygehuse

Fælledvej 11, 4200 Slagelse

E-mail: sveni@regionsjaelland.dk; Mob. 51252255

Projektidentifikation

- SJ-703 (Den Regionale Videnskabsetiske Komité for Region Sjælland)
- REG-052-2018 (Datatilsynet i Region Sjælland)

Appendix 25

Patient informed consent, focus groups

Informeret samtykke til deltagelse i et sundhedsvidenskabeligt projekt

Forskningsprojektets titel

Ergoterapeutisk livsstilsintervention til patienter med kroniske non-maligne smerter

Protokol, version 1.5, revideret 05.08.2020

Erklæring fra patienten:

Jeg bekræfter hermed at have modtaget skriftlig og mundtlig information om projektet og har tilstrækkeligt kendskab til forskningsprojektets formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg er informeret om, at min deltagelse er frivillig, og at jeg når som helst og uden begrundelse kan trække mit tilsagn om deltagelse tilbage, uden at dette på nogen måde vil påvirke den nuværende eller fremtidige behandling.

Jeg er opmærksom på, at mit samtykke giver forsøgsansvarlig og dennes repræsentant adgang til mine journaloplysninger. Jeg er indforstået med, at de indhentede data vil kun blive anvendt til forskningsformål.

Jeg giver samtykke til at deltage i forskningsprojektet, og har fået en kopi af dette samtykkeark.

Navn:

Dato: Underskrift:

Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser for dig?

Ja_____(sæt x) Nej_____ (sæt x)

Erklæring fra den der afgiver information:

Jeg erklærer, at patienten har modtaget mundtlig og skriftlig information om forskningsprojektet. Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i projektet.

Navnet på den der afgiver information:

Dato: Underskrift:

Appendix 26

Clinicians informed consent, focus groups

Informeret samtykke til deltagelse i fokusgruppeinterview for repræsentanter af det tværfaglige team involveret i ergoterapeutisk intervention til patienter med kroniske non-maligne smerter

Protokol, version 1.4, revideret 31.10.2019

Erklæring fra deltageren:

Jeg bekræfter hermed at have modtaget skriftlig og mundtlig information om undersøgelsen og har tilstrækkeligt kendskab til forskningsprojektets formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg er informeret om, at min deltagelse er frivillig, og at jeg når som helst og uden begrundelse kan trække mit tilsagn om deltagelse tilbage.

Jeg er indforstået med, at de indhentede data vil kun blive anvendt til forskningsformål. Jeg er orienteret om, at mine udtalelser i slutbeskrivelsen af resultaterne fra fokusgruppeinterviewet blive anonymiseret.

Jeg giver samtykke til at deltage i fokusgruppeinterviewet, og har fået en kopi af dette samtykkeark.

Navn:

Dato: Underskrift:

Erklæring fra den der afgiver information:

Jeg erklærer, at patienten har modtaget mundtlig og skriftlig information om forskningsprojektet. Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i projektet.

Navnet på den der afgiver information: Svetlana Solgaard Nielsen

Dato: 30.01.2020 Underskrift:

Projektidentifikation: SJ-703 (Den Regionale Videnskabsetiske Komité for Region Sjælland); REG-052-2018 (Datatilsynet i Region Sjælland)

Appendix 27

Semi-structured interview guide, focus group interviews with patients

Interviewguide

Fokusgruppeinterview med patienter

1-2 grupper
Af 20 patienter i alt: max. 10 pt. pr. gruppe indkaldes via e-boks (deltagerinformation sendes ud)

Inden mødet:

I god tid:	sandwich (forudbestilt); diktafon tjekkes/ oplades (evt. en pc med afkoblet sky- forbindelse i reserve);
På dagen:	forberede vand, kaffe, the, servietter, mælk, sukker, teskeer, papirblok, blyant, whiteboard pen, stempel til evt. befordringsblanketter

<u>Velkommen!</u>

(Presentation af intervieweren og observatøren)

I har alle sammen deltaget i det ergoterapeutiske smerteprojekt. Gruppen i dag er sammensat på tværs af de hold der har været igennem projektet fra april til oktober i år.
Som det første, vil jeg introducere dagens program. Derefter starter vi selve gruppeinterviewet. De to timer som er afsat til snakken er inklusive en spisepause. Derfor forventer vi at blive færdige med selve samtalen ca. 30-40 min. tidligere, så der bliver tid til sandwich, inden vi siger tak for i dag.

<u>Tavshedspligt</u>

Interviewet bliver optaget på diktafon for at lette bearbejdelsen af data. Ingen andre end mig vil høre optagelsen. Denne bliver destrueret, så snart alt er skrevet ned. Ingen navne vil blive nævnt i analyserne. Jeg skal også nævne, at det der bliver sagt i rummet må ikke videregives til uvedkommende.

<u>Undersøgelsens formål</u>

Forskningsprojektet handler på længere sigt om at afdække effekten af den ergoterapeutiske intervention som en del af behandlingstilbuddet til kroniske smertepatienter. Lige nu er vi i gang med at evaluere de første erfaringer med interventionen for at rette til de efterfølgende forløb.

Formålet med undersøgelsen i dag er at få dybdegående viden om hvad der er betydningsfuldt for patienterne når de skal samarbejde målrettet med personalet om at opnå ændringer i deres vaner.

Information om metoden

Denne form for interview adskiller sig fra den velkendte måde at gøre det på, hvor intervieweren stiller spørgsmål, og deltageren svarer. Nu er det jer der skal snakke og diskutere med hinanden. Jeg har nogle spørgsmål som jeg giver jer en ad gangen, og ellers griber jeg ind og hjælper jer på sporet, hvis der bliver behov for det. Jeg er interesseret i ALLE jeres oplevelser og erfaringer. Der er ingen rigtige eller forkerte svar. Både gode og dårlige oplevelser er velkomne.

Vi har alle sammen forskelligt temperament, men skal selvfølgelig udvise respekt for hinanden og holde en ordentlig tone.

Nogle gange kan der blive stille i lokalet, fordi folk skal tænke. Det er helt ok, så lad jer ikke blive presset af det. Hellere tage en tænkepause end forhaste sig med et svar!

Det er mening, at vi få skabt en dialog. Så jeg vil foreslå, at der er kun én der taler ad gangen.

Guide til spørgsmål under interviewet

Introduktionsrunde		
Nogle af jer har mødt hinanden før. Vi vil alligevel starte med en præsentationsrunde, hvor alle præsenterer sig kort (navn og alder)	Assistenten – evt. skriver navnene op på tavlen i en cirkel	
Åbningsspørgsmålet		Afrunde den indledende snak (hvis der er behov for uddybning):
I har under forløbet arbejdet med at ændre jeres vaner. Kan I fortælle noget om hvordan det er foregået?	Hvad har I konkret arbejdet med? Hvorfor har I arbejdet med det? Hvordan har det været? Hvad har det betydet for jer?	Nu har vi snakket om… Jeg vil vende tilbage til…/ Er der nogle der vil sige noget mere? Igen: Der er ikke rigtige eller forkerte svar.
Fokuserede spørgsmål		
Hvordan bruger I viden og erfaringerne fra forløbet i hverdagen?	Hvilke erfaringer har I gjort jer i forløbet? Hvordan har jeres prioritering af hverdagsaktiviteter ændret sig? Hvilke nye ting har I prøvet i forhold til spisevaner?	Har jeres indkøbsvaner ændret sig? Tilbereder I mad på an anden måde nu? Har prøvet nye retter? Har jeres rutiner omkring måltider ændret sig? Spiser I mere regelmæssigt?
	Hvor meget fokus har I på daglig bevægelse?	Oplever I sig selv nu som mere aktive i hverdagen?
Hvad har der været mest brugbart?	Hvad af de nye input har der været nemmest at tage til sig?	
Hvad kunne have været anderledes som kunne bedre understøtte jeres vaneændringer til et sundere livsstil?	Hvad har der været svært for jer at få til at fungere? Hvordan har det fungeret med længen på forløbet, antal mødegange, gruppestørrelsen, gruppesamarbejdet, hjemmebesøg?	

	Hvordan ville det have været med flere digitale løsninger, fx online møder individuelt eller i gruppe? Mails med information? Elektroniske påmindelser om aftaler?	
Projektet har livskvalitet som hovedmål på effekten af behandlingen. Hvis I tænker på jeres samlede behandlingsforløb (både smertecentret og ergoterapien), hvad synes I, det har betydet for jeres hverdagsliv? Og for livskvalitet?	Hvad kan vi ellers måle effekten på? Hvor træder effekten mest tydeligt frem i jeres hverdag? Har der været nogen forandringer ved jer, andre i jeres omgivelser har lagt mærke til? Har I fået nogle kommentarer fra andre?	
<u>Afsluttende spørgsmål</u>		
Vil I prøve at sige noget om, hvordan I har set på det med at ændre vaner før, I har været på forløbet, og nu?	Ved behov for yderligere uddybning: Nu har jeg spurgt om en masse ting… Det har været så spændende at høre…Tak for det! Men her til slut vil jeg lige høre jer om der er noget som i synes I mangler at fortælle, som vi ikke har fået snakket om?	
		Tak for jeres input! Det har været spændende og lærerigt! Hvis der opstår spørgsmål efterhånden, er I altid velkommen til at kontakte os på det telefonnummer der står i indkaldelsen til denne undersøgelse. Tak for nu!

Appendix 28

Semi-structured interview guide, focus group interview with clinicians

Interviewguide
Fokusgruppeinterview med sundhedsprofessionelle

1 tværfaglig gruppe af sundhedsprofessionelle involveret i behandlingen af kroniske smerter á max 8-10, fx (ønsket):

Læger	1-2
Sygeplejersker	2-3
Fysioterapeut	1
Socialrådgiver	1
Psykolog	1
Ergoterapeuter	2

Inden mødet:

I god tid:	sandwich (forudbestilt); diktafon tjekkes/ oplades (evt. en pc med afkoblet sky- forbindelse i reserve);
På dagen:	forberede vand, kaffe, the, servietter, mælk, sukker, teskeer, papirblok, blyant

<u>Velkommen!</u>

(Presentation af intervieweren og observatøren)

I har haft kendskab til og været direkte eller indirekte involveret i det ergoterapeutiske smerteprojekt. Vi vil sige tak for, at I har taget tid til at deltage i denne undersøgelse.
Som det første, vil vi gerne byde jer på en sandwich, inden undersøgelsen går i gang. Der er afsat ca. 1 time til selve gruppesamtalen.
(Sandwich tilbydes)

<u>Tavshedspligt</u>

Interviewet bliver optaget på diktafon for at lette bearbejdningen af data. Optagelserne bliver opbevaret fortroligt indtil de er transskriberet og herefter destrueret. Denne bliver destrueret, så snart alt er skrevet ned. Ingen navne vil blive nævnt i analyserne.

<u>Undersøgelsens formål</u>

Forskningsprojektet handler på længere sigt om at afdække effekten af den ergoterapeutiske intervention som har fokus på meningsfulde hverdagsaktiviteter, spisevaner og daglig bevægelse og er tillagt det nuværende behandlingstilbud til kroniske smertepatienter. Patienterne har deltaget i et forudgående fokusgruppeinterview. Formålet med undersøgelsen i dag er at få jeres input på hvad der bør prioriteres i det tværfaglige samarbejdet og i interventionen med smertepatienterne.

Information om metoden

Denne form for interview adskiller sig fra den velkendte måde at gøre det på, hvor intervieweren stiller spørgsmål, og deltageren svarer. Nu er det jer der skal snakke og diskutere med hinanden. Jeg har nogle spørgsmål som jeg giver jer en ad gangen, og ellers griber jeg ind og hjælper jer på sporet, hvis der bliver behov for det. Jeg er interesseret i ALLE jeres oplevelser og erfaringer. Der er ingen rigtige eller forkerte svar.

Nogle gange kan der blive stille i lokalet, fordi folk skal tænke. Det er helt ok, så lad jer ikke blive presset af det. Hellere tage en tænkepause end forhaste sig med et svar!

Det er mening, at vi få skabt en dialog. Så jeg vil foreslå, at der er kun én der taler ad gangen.

Introduktionsrunde		
I har mødt hinanden før. Vi vil alligevel starte med en præsentationsrunde, hvor alle præsenterer sig kort med navn og evt. rolle i forhold til patienterne og involvering i projektet.	Moderator sikrer at deltagerne kender hinanden.	Assistenten – evt. skriver navnene op på tavlen i en cirkel og supplerer præsententionen
Åbningsspørgsmålet		
Patienterne har nævnt følgende punkter som betydningsfulde i deres behandlingsforløb.		Lægger kort med patienternes udsagn på bordet
Hvis vi tager et kig på kortene, så er der nogle udtalelser fra interviewet med patienterne, hvad tænker i om disse? Præsenterer patienternes udsagn	*Kan I se hvad de mener?* *Har I oplevet noget andet?*	
Er der noget som har overrasket jer?	Hvad er dine tanker om dette?	
Er der andet I vil pointere, som kan give eftertanke til jer som professionelle?	Nu har vi snakket om… Jeg vil vende tilbage til…/ Er der nogle der vil sige noget mere? Igen: Der er ikke rigtige eller forkerte svar.	
Fokuserede spørgsmål		
Hvordan kan det som patienter siger, give mening ind i en faglig planlægning af interventionen?		
Hvis I skulle give et bud på, hvad er essentielt for et vellykket behandlingsforløb?	Hvorfor mener du det? Kan du/i uddybe det?	

Hvad er afgørende for samarbejdet mellem smerteklinikken og ergoterapien i behandlingen af kroniske smertepatienter?	Vælg gerne max. 2 mest vigtige for dig kvaliteter i samarbejdet.	
Hvordan skal vi kommunikere på tværs af faggrupperne?	Hvorfor tænker du det?	Møder om patienterne, hvor er der plads til dem?
Hvad vil I hver især mene, effekten af det samlede behandlingstilbud kan bedst ses på hos patienterne?	Hvad vil I mene er vigtigt at måle på, hvad tænker I vi kan måle på? Hvorfor tænker du det?	
<u>Afsluttende spørgsmål</u>		
Har i noget i mangler at sige, i synes vi skal have med os?		
Tak for jeres input! Det har været spændende og lærerigt! Hvis der opstår spørgsmål efterhånden, er I altid velkommen til at kontakte os på det telefonnummer der står i indkaldelsen til denne undersøgelse. Tak for nu!		

Kort til bordet:
(det med RØD er ikke til kort, men det vores egen beskrivelse)

Vi vil gerne fortælle jer om, hvad patienterne var kommet ind på i deres fokusgruppeinterviews.

Det har været givende at høre deltagerne om, hvad de især har mærket før-efter forskellen på. Alle sammen nævner en bedre evne til at prioritere og stå fast ved det, hvilket kommer til udtryk bl.a. ved det, at sige fra, bede om hjælp og tænke på egen behov.

Det nye i nogle af deltagernes liv var, at nogle var begyndt at genoptage gamle fritidsinteresser eller opstarte nye, fx fitness sammen med ægtefællen og børnene. Nogle andre er begyndt at mærke effekten af fx tilstrækkeligt vandindtag, dvs. det kan de ikke undvære mere.

En enkelt har ikke oplevet nogen forandring overhovedet, hvilket er forventeligt ud fra hendes forløb.

Vi blev overrasket af, at begge grupper har haft relativt høj enighed i deres udtalelser.

Alle syntes, vores intervention skal starte efter det grundforløb, som smertecenteret tilbyder, ikke samtidigt.

Der foreslås at ekskludere deltagere som ikke laver deres "hjemmearbejde" eller ikke vil prøve nyt. (Vurdering af paratheden for forandring?)

Patienterne har sagt resolut fra sms-påmindelser som mulighed pga. stressende effekt. Telefoniske konsultationer var accepteret som mulighed evt. længere inde i forløbet, når kontakten er etableret, og MEGET gerne via facetime/ skype eller andet, hvor man kan se hinanden.

Digital dagbog kom på tale i stedet for et papir-blyant løsningen.
De udleverede materialer bliver gemt "til senere læsning". Der blev foreslået at lave dem i form at reminders som er nemme at hænge op, fx på køleskabet.

En af patienterne har bemærket, at vores bevægelsesmålere over 4 dage kan måske ikke vise det reelle billede, hvis man nu rammer ferie eller andet, hvor aktivitetsniveauet afviger meget fra gennemsnittet. Dette har vi allerede selv tænkt på og arbejdet på at udskifte vores målere med nogle med større hukommelses volume.

Nogle vil gerne have opfølgningssessioner efter afsluttet forløb.

I forhold til effekten blev der nævnt, at forskellen især kan mærkes på: følelsen af at være accepteret af omgivelserne, selvbilledet/ væren sig-selv igen, sociale relationer, og planlægnings- og prioriteringsevnen.

Appendix 29

Codebook, thematic analysis

Codebook, Study III

File: REVEAL_User_perspectives.nvpx

Converted to NVivo R1 (License renewed 2021)

Codes

Name	Description	Files	References
Accept of chronic pain diagnosis		2	3
Appropriate multidisciplinary cooperation		2	45
Empathic OTs		2	4
Reading body language		1	1
Information load		2	8
Containing comprehensiveness in treatment		2	27
Homework		1	3
Visual materials		1	1
Treatment effect		2	8
Better mood		1	1
More frequent assessments		1	1
Rapport on personal occupational performance		1	1
Treatment load		3	17
Activity shift in-program		1	1

Name	Description	Files	References
App		2	4
Enough time in-program		1	2
Home visit		1	2
Individual consultations		1	1
Phone calls		2	7
Reminders		1	1
Shifting focus from pain		3	5
Being sick as a part of identity		3	5
Adverse events		1	1
Anger		2	3
Existential issues		1	5
Divorce		1	1
Having relationship		1	1
Finding advantages in chronic pain diagnosis		1	1
Low stress threshold		1	1
Pain		1	9
Pushing oneself hard		2	2
Difficult to be positive		1	1
Not being able to say no		2	3
Pretending being well		1	3
Serving others		2	2
Social sensitivity		2	3

Name	Description	Files	References
Difficult to contain others		1	1
Confronting the normality		1	1
Isolating oneself		1	1
Negativity in others		2	4
Not-supportive environments		2	4
Stigmatising chronic pain		2	2
Lack of accept		2	2
Lack of understanding		2	7
Variety of individual pain pictures		1	1
Expectations & hopes		1	41
Motivated participants		2	8
Seeking new knowledge		1	1
To differ good pain from bad pain		1	2
Space for pushing own limits		1	1
Stop negativity		1	1
Prioritizing own interests		3	10
Ability to let go		1	2
Ability to set limits		3	15
Asking for help		2	4
Look at oneself with new eyes		2	2
Readiness to change		2	3
Being open-minded		1	1

Name	Description	Files	References
Focus on quality of life		2	2
New ways of coping with pain		2	2
Supportive environments		3	6
Caretaker involvement		3	4
Partner involvement		1	1
Peer-support		1	10
Belonging to a group		3	18
Exchanging experiences		3	6
Gender balance in-group		1	1
Help each other		2	2
Talking to each other in-group		2	5
Good to be confronted with different points of view		1	1
Knowing others with the same problems		1	1
Meet in local groups		2	2
Self-help groups		1	1
Understanding society		2	8
Being socially accepted		2	5
Being paid attention to		2	2
Being understood by the social environments		2	3
Decision maker involvement		1	1
Municipal involvement		1	1
Empower healthy lifestyle		2	3

Name	Description	Files	References
Everyday activities & functioning		2	7
Activity pacing		2	11
Activity load		2	7
Effective planning		2	4
Energy economizing		2	4
Exaggerated cleaning at-home		1	1
New relaxation routines		1	6
Cleaning routine once a week instead of every day		1	1
Ergonomic guidance		2	2
Better knowledge before applying for assistive devices		1	1
Try different assistive devices		2	4
Low energy		2	5
New leisure activities		2	4
Restart of prior interests		1	3
Saving money		2	2
Healthy eating		2	6
Drinking enough water		2	4
Difficult to drink enough water		1	2
Eating more fruits and vegetables		1	1
Eating more regularly		1	2
Skipping meals		2	2
Purchasing healthier food		1	1

Name	Description	Files	References
Trying new recipes		1	1
Weight loss		2	3
More physical activity		1	3
Long-tine sitting		1	1
New habits		1	48
Having courage to try new things		2	5
Maintenance of new habits & routines		3	11
Long-term therapist contact		1	3
Resistant old habits		1	10

Appendix 30

Study IV, submitted manuscript inclusive appendices

Occupational therapy lifestyle intervention added to multidisciplinary treatment for adults living with chronic pain: A feasibility study

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Abstract

Objectives: To evaluate feasibility and outcomes of an occupational therapy lifestyle intervention to inform a future RCT.

Material and methods: Adult outpatients participated in a feasibility study of intervention REVEAL(OT) targeting meaningful activities and lifestyle added to standard multidisciplinary treatment at a pain centre (NCT03903900, Clinicaltrials.gov). Predefined research progression criteria were evaluated using a red-amber-green method. Pre-post changes in health-related quality of life, and occupational performance and satisfaction were measured.

Results: In 40 participants (85% females, 46.6±10.9 years old), satisfactory programme adherence (77,5%), patients' self-perceived relevance (97%), timing and mode of delivery (97%) and assessment procedure acceptance (95%) were demonstrated, and no adverse events causing discontinuation occured. Recruitment rate (n=5.7 monthly), retention (77.5%) and the fidelity of delivery (83.3%) needed improvement. We observed no significant improvement in HRQoL (0.04 95% CI -0.03; 0.12) but significant change in occupational performance (1.80 95% CI 1.25; 2.35; $p<0.001$), MCID≥3 in 13.8% and satisfaction (1.95 95% CI 1.06; 2.84; $p<0.001$), MCID ≥3.2 in 24% of the participants.

Conclusions: While meeting many research progression criteria suggesting that the REVEAL(OT) intervention is feasible, its recruitment, retention and delivery strategies need optimisation. Significant change in the COPM scores was observed. An RCT would evaluate the intervention effectiveness.

Keywords: activities of daily living, evaluation study, health behaviour, healthy lifestyle, health-related quality of life, pain management

Introduction

Multidisciplinary and multimodal treatment is the most beneficial approach to improve the quality of life in people living with chronic pain [1]. Previous research has urged new non-pharmacological treatment modalities such as lifestyle management in chronic pain treatment [2-4]. A recent survey revealed multiple elevated lifestyle risks in Danes living with chronic pain and moderate to high motivation for improving lifestyle as part of their chronic pain treatment course, supporting the relevance of focusing on lifestyle in chronic pain [5]. Occupational therapy has a decade-long history of targeting lifestyle through everyday occupations, improving human health and well-being [6-9]. A recent pilot study using the occupational therapy Lifestyle Redesign®-programme in a Canadian setting showed significant improvements in occupational engagement, life balance, mental health and pain self-efficacy in fibromyalgia patients [10]. However, more research on occupational therapy lifestyle management for chronic pain is still needed to evaluate whether it is a useful addition to multidisciplinary chronic pain treatment in clinical practice.

We developed an occupational therapy lifestyle management programme REVEAL(OT) (Redesign your EVEryday Activities and Lifestyle with Occupational Therapy) for adults living with chronic pain and adopted it to the standard multidisciplinary treatment of chronic pain offered at a Danish hospital. According to the MRC framework for developing and evaluating complex interventions, novel treatment programmes need comprehensive feasibility evaluation before initiating a full-scale randomised controlled trial (RCT) [11]. The objectives of the present study were to evaluate the feasibility and outcomes of the REVEAL(OT) intervention and determine further research steps before initiating an RCT.

Methods

Study design

This feasibility study (Clinicaltrials.gov reg. NCT03903900) followed the same protocol as expected for the RCT, excluding randomisation. Guided by the MRC framework [11], the iterative feasibility testing process should help improve the intervention and prepare it for the future RCT. The research complied with the principles of The World Medical Association's (WMA) Declaration of Helsinki, the European Union's (EU) General Data Protection Regulation (GDPR) and the Danish Data Protection Act [12, 13]. Regional Committee on Health Research Ethics in Region Zealand (Reg. SJ-703) and the Data Protection Authority for Region Zealand, Denmark (REG-052-2018) approved the study.

This report followed the CONSORT guidelines for reporting non-randomised pilot and feasibility studies (Appendix 1) [14]. The study comprised three feasibility rounds of the REVEAL(OT) 1.0-3.0 that took place between April 2019 to July 2021.

Settings

Two clinical units at Naestved Hospital in Region Zealand, Denmark, were involved in the chronic pain treatment delivery. The Multidisciplinary Pain Centre (MPC) delivered standard treatment based on cognitive-behavioural therapy (CBT) provided by physicians, nurses, psychologists, physiotherapists, and a social worker. The Occupational Therapy Unit (OTU) delivered the REVEAL(OT) treatment.

Participants

Adults ≥18<65 years old referred to the MPC with chronic non-malignant pain present ≥3 months at the inclusion were invited to participate. Exclusion criteria were acute/ sub-acute pain; cancer-related pain; unstable medicine intake over the past four weeks; daily opioid intake >30 mg; headache/migraine; currently diagnosed depression; current substance misuse; severe psychiatric diagnosis; poor Danish speaking skills and participation in other chronic

pain treatment programs. Severe psychiatric diagnoses were defined as a mental illness involving distortion in thinking and perception and leading to significant social and occupational dysfunction, e.g. schizophrenia and schizotypal, delusional, schizoaffective or psychotic disorders, or psychosis. Additional exclusion criteria for inability to walk a distance of min. 100 meters independently was added to secure group homogeneity. Well-treated headache, antidepressants against depression relapse, or similar conditions in past medical history were allowed if not the primary cause for the MPC referral. Habitual (not newly entered) physical training was neither an indicator for exclusion.

Recruitment

The MPC team screened the outpatients for age and the interest for participation, referring the relevant candidates to the OTU. The principal investigator provided detailed written and oral information on participation and performed eligibility screening. At least one week of consideration was provided, including additional phone or email contacts when relevant.

Intervention

The intervention description complied with the TIDieR recommendations (Appendix 2) [15]. The REVEAL(OT) focused on meaningful activities, value-based occupational choices, healthy eating and daily physical activity. By focusing on meaningful activities and value-based occupational choices, the REVEAL(OT) pursued to activate the transformative capacities of human occupation as an interaction between the occupational dimensions Doing, Being, Becoming, and Belonging [16, 17]. Physical activity guidelines for adults from the World Health Organisation [18] and healthy nutrition advice from the Danish population from the Ministry of Food, Agriculture and Fisheries in Denmark [19] in their versions available in 2019-2020, supported healthy lifestyle choices. Furthermore, the REVEAL(OT) construct was inspired by the Lifestyle Redesign®-programme, adapting its approach to meaningful activities and healthy lifestyle, combining individual and group sessions and using the

methods of didactic presentation, peer exchange, personal reflection, and direct experience [20]. Max. six patients could be admitted per group.

Two OTs who provided the intervention had 14 years of professional experience each. The OTs and the principal investigator attended the online continuing education course 'Life Management Series: Lifestyle Redesign® for Chronic Pain and Headache Management' approved by the American Occupational Therapy Association (AOTA). The therapists were provided with supervision by the principal researcher at least once a week or on-demand. The programme featured contacts with occupational therapists (OTs) at least every second week. The intervention contents covered: introduction to the course, occupation for health and well-being, benefits of daily physical activity, meals and eating habits, occupational balance and time management, productivity/ domestic activities (in-home), productivity/ activities out-of-home, ergonomics, flow experience, hobbies and leisure, goal setting, goal evaluation, home visits, and ending the group. Lifestyle diaries and pedometer for step counting supported the maintenance of the initiated lifestyle changes at home. Home visits for home ergonomics advice could be provided. Assistive devices for home use to support working with personal occupational goals were available for borrowing. The REVEAL(OT) was manualised and protocolled. The MPC team was contacted to solve additional patient-related issues when relevant. Upon the intervention discharge, the patients continued with their planned standard treatment at the MPC.

We illustrated the REVEAL(OT) treatment doses in time quotes (i.e., hours dedicated to each taxonomy element) (Appendix 3) by applying the occupational therapy intervention taxonomy based on the Person-Environment-Occupation model [21] and proposed by the latest review on occupational therapy for chronic pain [22] to the manualised intervention contents. The structural adjustments in the intervention were made to meet actual needs in the study cohort and clinical practice while the three-fold focus and topics included remained.

Regardless of the adjustments, all the participants followed the same procedures.

Data collection

Gender, age, years with pain and general health status at baseline were collected through PainData, the national registry for chronic pain patients referred to pain centres in Denmark [23].

Primary outcomes

Primary outcomes were predefined research progression criteria based on the 'traffic light' (red-amber-green) method (Table 1) [24].

Table 1. Research progression criteria for feasibility outcomes

Feasibility outcomes	**Evaluation source**	**Decision/ action to be taken**		
		Continue	**Solve**	**Stop**
Recruitment rate	n recruited per month (n/ group)	n ≥ 3 (5)	n = 2 (2)	n = 1 (1)
Participant retention	Completion rates	≥ 80%	< 80 ≥ 75%	< 75 %
Program adherence to >75% of sessions	Adherence rates	≥ 75%	<75 ≥ 50%	< 50%
Patients' self-perceived relevance, timing and mode of delivery	Patient evaluations (positive)	≥ 75%	< 75 ≥ 50%	< 50 %
Assessment procedure[1] acceptance	Patient evaluations	≥ 75%	< 75 ≥ 50%	< 50%
Adverse events, % discontinued	Patient journals and PainData	0%	≥ 1%	≥ 10%
Fidelity of delivery	Process evaluations	≥ 90%	< 90 ≥ 50%	< 50%

Note. [1] Assessment procedure planned for the RCT included: a) completion of PainData standard questionnaire with an attachment (developed for the project purposes) assessing sociodemographics, quality of life, pain self-efficacy, pain intensity, pain catastrophising, pain localisation and sleep quality; b) interview-based assessment of occupational performance and participation; c) measuring blood pressure, waist circumference and bioimpedance; c) cuff-algometry; and d) actigraphy for physical wake-time activity (see Appendix 4 for the assessment tools used)

Recruitment was registered by personal project id and date for eligibility screening, inclusive notes on allocation, withdrawal reasons or eligibility. Participant retention and programme adherence were recorded in each group's attendance forms, with back-up in the electronic patient journals and appointment schedule for the OTU. For patients' self-perceived relevance, timing, and mode of delivery, the participants independently filled out the patient evaluation forms developed for the intervention. The patient evaluation forms asked the participants: a) Was the scheduling of the session appropriate?; b) Was the timeframe for the session reasonable?; c) Were the session content relevant?; d) Were the intervention content easy to comprehend?; e) Was the mode of delivery (individual or in-group) appropriate?; f) Were you satisfied with your participation in the session? The patient evaluation forms in the REVEAL(OT) 1.0-2.0 were based on a 3-item Likert scale ('Agree', 'Disagree' or 'Don't know'), while a 6-items Likert scale ('Fully agree', 'Agree', 'Neither/ nor', 'Disagree', 'Definitely disagree' or 'Don't know') was used in the REVEAL(OT) 3.0. Both forms were provided with a comment box.

Fidelity of delivery and assessment procedure acceptance were evaluated using process evaluation forms completed by the OTs after each session. The process evaluation forms bullet-listed the session contents described in the intervention manual and allowed a rapid check of actions performed. Notes and comments were discussed during supervision with the principal researcher, and the challenges were solved by additional demonstration and instruction, e.g., in performing relevant assessments.

Adverse events were defined as unpleasant experiences such as discomfort, morbidity and mortality causing discontinuation from the REVEAL(OT) [25]. Adverse events were registered by the intervention providers and monitored in the electronic patient journals, assessing the date of occurrence, duration and potential consequences. Additionally, self-

reported adverse events were derived from the PainData registry. Causes for discontinuation from participation were clarified by phone.

Secondary outcomes

The secondary outcomes were assessed within two weeks before and after intervention participation. This paper reports on self-reported health-related quality of life (HRQoL) that will be the primary outcome for the RCT and occupational performance and participation as the outcome that guided the goal work during the intervention. All the secondary outcomes evaluated in the feasibility study (Appendix 4) will be described in detail and reported separately with reference to this paper.

HRQoL: EQ-5D-5L questionnaire (EuroQol reg. ID 28126, further EQ-5D) assessed problems in mobility, self-care, usual activities, pain/ discomfort, and anxiety/ depression ranged on a 5-point categorical scale from 1='no problems' to 5='extreme problems' (EQ-5D values) and self-perceived health on a 0-100 point visual analogue scale where 100 was the best imaginable health (EQ-5D VAS) [26-28]. From the EQ-5D data derived from the PainData registry [23], we calculated the cumulative HRQoL score (EQ-5D Index) using the Danish EQ-5D Crosswalk value set [29]. The EQ-5D Index ranging from -0.594 to 1 considers all states below zero being 'worse than death', while '1'='perfect health' [30].

COPM: The Canadian Occupational Performance Measure (COPM) helped identify and prioritize personal occupational problems related to self-care, productivity, and leisure on a 10-point scale according to their self-perceived importance, performance, and satisfaction with the performance (higher scores mean higher importance, performance and satisfaction) [31]. The COPM assessment as an outcome is valid, reliable and sensitive to change, i.e., in chronic pain studies [32].

Sample size

No sample size calculation was performed [33]. According to the rationale about feasibility,

we considered a minimum of 12 participants sufficient for this feasibility study, inclusive number or per cent required to reach the boundaries in predefined research criteria [34]. Acceptable dropout of max. 20% corresponded to the limits determined for the RCT.

Analysis

Primary outcomes were analysed descriptively for frequencies of the research criteria fulfilled, using Microsoft® Excel software, version 16.53, and compared with the predefined satisfactory estimates in the 'traffic light' method (Table 1).

The 6-items evaluation forms for participants' self-perceived relevance, timing and mode of delivery were collapsed to 3-items for better comparability. Hence, the answers 'Fully agree' and 'Agree' were categorized as 'Agree', and 'Neither/nor', 'Not agree' and 'Definitely not agree' as 'Not agree'. The category for indefinite answers ('Don't know') remained unchanged. The participant comments supported the interpretation of the results. Only adverse events causing discontinuation from the intervention were eligible for evaluation using the predefined research criteria. All adverse events were considered in terms of further intervention improvements. Evaluating the fidelity of delivery, we considered any session with ≥1 action deviating from the intervention protocol or manual for a delivery failure. The delivery failures were analysed for frequency and described using additional comments and observations on possible reasons.

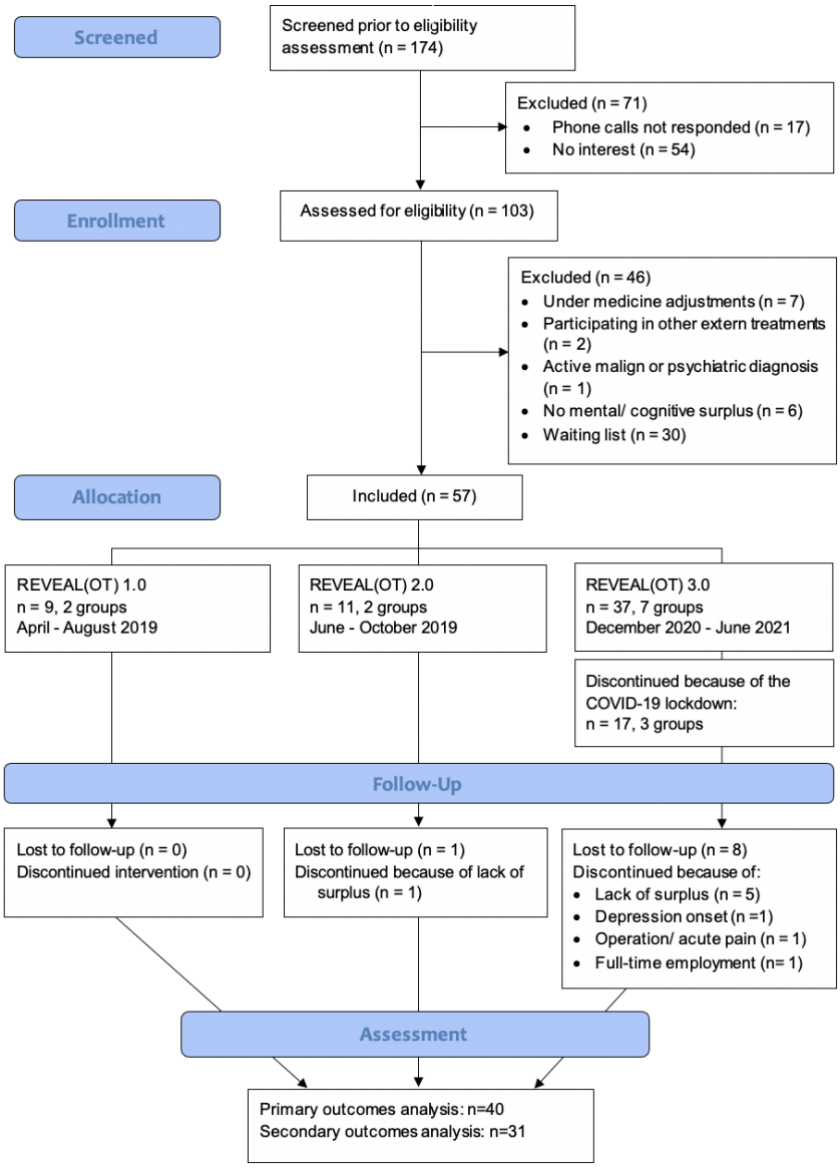
All the participants who had baseline and follow-up assessments were included in the secondary outcome analysis. Differences in change pre-post intervention in HRQoL and COPM in the intervention completers were assessed using paired t-tests. The percentage of participants who achieved the MCID for the COPM performance and satisfaction (min. 3 or 3.2-points difference in any direction, respectively) [35, 36] were reported. The statistical analyses of secondary outcomes were performed using Stata© 17.0 (Stata Statistical Software: Release 21. College Station, TX: StataCorp LLC). The 5% significance level

guided the interpretation of the outcomes observed.

Results

From January 2019 to October 2020, 174 outpatients were referred to the OTU regarding participation (Figure 1). Several outpatients were either not interested in participation (n=54) or not reachable by phone (n=17) despite min. 5 attempts per outpatient. Thus, of the 103 outpatients assessed for eligibility, 57 were included. Of those participating from January to March 2020, 17 participants (3 groups) discontinued involuntarily because of the COVID-19 lockdown and were excluded from the primary analysis.

Figure 1. Study flow diagram



Participant characteristics

The 40 participants (85.0% females) were aged 46.6±10.9 (23-64) years and had average pain duration of 10 years (median: 9.3; range 0.7-39) (Table 2). There was no significant difference between the completers and those who discontinued due to the lockdown (age, p-value=0.80; gender, p-value=0.75) or those who could not participate (age, p-value=0.72; gender, p-value=0.05).

Table 2. Sociodemographic and health-related characteristics of the study cohort

Variable	**Count (%) or mean (median; range)**
Females	
Study sample (n=40)	34 (85.0%)
Discontinued groups (n=17)	15 (88.2%)
Not included (n=117)	81 (69.2%)
Age, years	
Study sample (n=40)	46.6 (10.9; 23-64)
Discontinued groups (n=17)	47.4 (10.3; 22-63)
Not included (n=117)	45.8 (10.7; 22-63)
Age groups, years old (n=40)	
18-24	1 (2.5%)
25-34	6 (15.0 %)
35-44	9 (22.5%)
45-54	12 (30.0 %)
55-64	12 (30.0%)
Years with pain (n=35)	9.7 (8.7; 0.7-29.9)
<5	13 (37.1%)
5-9	8 (22.9%)
10-14	3 (8.6%)
15-19	6 (17.1%)
≥20	5 (14.3%)
Self-evaluated health, EQ-5D VAS 0-100 (n=36)	48.6 (20.2; 6-90)
0-24	5 (13.9%)
25-49	17 (47.2%)
50-74	11 (30.6%)
75-100	3 (8.3%)
Self-evaluated HRQoL, EQ-5D Index (n=35)	0.464 (-.109; .704)

Feasibility evaluation

The primary outcomes for the study were summarised (Table 3) and explained below.

Recruitment rate

Although the recruitment rate was 4.3-6.7 participants per month (n=5 per group) and seemed satisfactory according to the research criteria in the eight groups that received the programme, some groups ranged lower (two groups with 4 participants). Thus the recruitment criteria n≥3 per month did not guarantee a min. 5 participants in all groups. Recruitment reached the green level in REVEAL(OT) 2.0 and 3.0. However, we downgraded our overall evaluation of the research progression criteria for recruitment rate to the amber level.

With the mean of 5 participants per group and one year from baseline to the primary endpoint, one OT could deliver the REVEAL(OT) in its version 3.0 to mean 20 outpatients (4 groups) annually or 40 (8 groups) in 1.5 years. Thus, we would need to engage from 6 to 11 research sites in the future RCT estimated to include 228 participants. Of the total n outpatients referred to the intervention, 30 (17.1%) remained on the waiting list because no vacant place or appropriate group was available. Thus, running two or more groups at a time could be considered if clinical capacities allow.

Participant retention

Excluding the 17 participants that discontinued involuntarily due to COVID-19, the main reasons for dropout (n=9 of 40; 22.5% dropout rate) were mental or cognitive surplus deficit (n=6). Raised emotional pressure under the pandemic because of additional load, e.g., caretaker duties and homeschooling for children, or isolation and fear of the disease used to cause lack of surplus. In total, 31 (77.5%) participants completed the feasibility study, corresponding to the amber level for research progression. In the non-pandemics-exposed

Table 3. Research progression criteria summary

Research progression criteria	Total	Feasibility rounds			Evaluation	Considerations and comments
		1.0	2.0	3.0		
Recruitment rate (mean n recruited (referred) per month; n per group)	5.7 (17.5) 5 (4-6)	6.7 (28.0) 5 (4-5)	4.3 (13.3) 5 (5)	6.7 (27.3) 5 (5[1]-6)	Amber/ Solve	Recruitment n≥3 per month did not guarantee min. 5 in all groups, despite mean 5 per group; With the curent recruitment intensity, the recruitment must begin at least ≥2 months before baseline assessment
Participant retention[2] (n (total), %)	31 (40) 77.5%	9 (9) 100%	10 (11) 90.9%	12 (20) 60.0%	Green/ Continue	The lockdown affected the participant retention negatively, solutions allowing the intervention continues during force majore situations shal be considered; follow-up assessment completion needs to be secured
Program adherence to >75% of sessions, % mean (range)	77.5% (38.5-100)	77.8% (57.1-92.9)	81.8% (44.4-100)	75.0% (38.5-100)	Green/ Continue	Adherence ≤50% of the sessions can occure in few participants and needs attention; self-assessments demand more effective procedure
Patients' self-perceived relevance, timing and mode of delivery (% mean)	97.0% (91.9-100)	94.5% (87.3-100)	96.3% (89.6-100)	98.4% (92.5-100)	Green/ Continue	Continuous monitoring is useful; personal preferences may appear; sufficient time for peer-discussions shall be provided; afternoon groups may be relevant for some participants
Assessment procedure acceptance (n, %)	38 (40) 95.0%	9 (9) 100%	9 (11) 81.8%	20 (20) 100%	Green/ Continue	The assessment procedure may need the assessment load reduction; further evaluation of the outcomes may support the improvements; assessment performance needs closer monitoring for timely completion
Adverse events (% caused discontinuation)	0%	0%	0%	0%	Green/ Continue	Several participants experienced discomfort from cuff-algometry, though none was at health risk or discontinued
Fidelity of delivery (n, % evaluations collected; % contents delivered as planned)	80.1% 194 (233) 83.3%	60.7% 28 (37) 75.0%	100% 14 (23) 60.9%	100% 152 (173) 87.9%	Amber/ Solve	Peer-support component may barrier the fidelity of delivery, exceeding the protocolized time of delivery; the intervention providers need flexibility, e.g., extra calendar space for new appointments/ other problem solving

Note. [1] One participant stopped after baseline assessment; [2] Exclusive 17 participants who discontinued involuntarily due to the COVID-19 lockdown

groups in the REVEAL(OT) 1.0-2.0, the retention reached 90.9 and 100% regarding in-clinic assessments. Please see the graph representing retention in the REVEAL(OT) 1.0-3.0 in Appendix 5.

Issues with timely completing the online questionnaires were observed. Of the 31 pre-post questionnaire sets expected to be completed, 23 (74.2%) were returned. Efforts were made to secure the questionnaire completion, with a mean of 5 attempts per participant, including phone calls, digital post and messages. However, 8 (25.8%) participants had missing questionnaire data either at baseline or follow-up, or both, reportedly because of forgetfullness. In general, very few participants initiated a contact themselves to solve challenges with completing the online questionnaires at home. At the same time, no significant challenges were observed in adherence to the assessment in-clinic. The participants were offered time and electronic devices to complete the questionnaire in-clinic, but few had surplus to stay longer than the regular assessment session that varied 2-2.5 hours. In the REVEAL(OT) 3.0, the completion rate improved since the principal researcher received administrator access to the online questionnaire and made further efforts to promote the completion.

Programme adherence

We calculated the intervention sessions per participant before regular discharge (n=31) or declared discontinuation (n=9). The 40 participants attended 412 (83.9%) sessions of 492 available in total, mean 83.5% (38.5-100) sessions attended per participant. Thirty-one (77.5%) participants adhered to ≥75% of the programme delivered, placing the research progression criteria for programme adherence on the green level.

Patients' self-perceived relevance, timing, and mode of delivery

Of the total of 343 evaluation forms completed, 97.0% (91.9-100) of the participants responded positively to the questions (Appendix 6), placing the research evaluation criteria on

the green level. Some participants proposed schedule revision (5.8%), e.g., establishing afternoon groups, or providing more time for peer discussions and contact with OTs (4.1%).

Assessment procedure acceptance

Of the 40 participants, 2 (5%) participants refused to participate in the assessments such as cuff-algometry test at follow-up because of discomfort at baseline (n=1) or wearing an actigraph-unit because of prior occurrence of allergy (n=1) despite non-allergic medical tape provided. Thus, the research criteria for assessment procedure acceptance was 95.0%, corresponding to the green level. However, we observed various degrees of exhaustion in most participants after both assessment rounds.

Adverse events

Adverse events was registered in 8 (20%) participants, e.g. depression (n=2), short hospitalization for observation of heart (n=1) and gut (=1), hospitalization (anticipated, no date at baseline) for knee operation (n=1), emergency room visit (n=1), leg pain after cuff-algometry (n=1), and consulting a psychiatrist (n=1). None of the events was associated with the intervention. The depression diagnoses were obtained after intervention discharge and therefore not caused discontinuation. Discontinuation because of knee operation was expected but yet not scheduled at baseline. No serious adverse events led to discontinuation from the intervention, placing the research criteria on the green level for adverse events.

Fidelity of delivery

Of the 233 (80.1%) process evaluations completed by the OTs after a session delivered (1 per group or participant for group or individual sessions, respectively), 39 (16.7%) contained 45 amendments to the protocolled contents. Of those, 22 (48.9%) were not timely completed online PainData registry questionnaires; 9 (20.0%) indicated extra session time needed; 9 (20.0%) reported changes in testing order of planning convenience reasons; 3 (6.7%) registered difficulties in following the programme due to concentration deficit (all in the

participants from the COVID-19 pandemic-exposed groups); and 2 (4.4%) showed declined participation (in cuff-algometry and actigraphy testing as described above). All the amendments were related to single actions and not the full session content. However, if counting a session with any modification for a delivery failure, the fidelity of delivery with 194 entirely correctly performed sessions was 83.3%, placing the research criteria on the amber level. During supervision, the therapists' feedback revealed high flexibility demands in patient contact, e.g., extra calendar space available for alternative appointment time because of many acute amendments to the schedule or other urgent solutions.

Accept of randomisation

Additionally, we asked the participants who entered the REVEAL(OT) 3.0 programme (n=37) whether they would have participated if the study was an RCT, where controls would not receive the occupational therapy intervention. We received 36 (97.3%) positive responses, while one participant declined because of randomisation chance to no intervention.

Patient-reported outcomes

Of the 24 participants with complete pre-post online questionnaires, one was excluded because of deviations from the treatment plan (receiving higher doses of the standard treatment before starting in the REVEAL(OT)). We observed no significant pre-post difference in HRQoL (Figure 2 and Table 4).

The pre-post difference in COPM (Table 4) scores showed a significant effect for improved occupational performance 1.80 (95% CI 1.25; 2.35), $p<0.001$, and satisfaction with occupational performance by 1.95 (95% CI 1.06; 2.84), $p<0.001$, indicating overall successful and satisfactory resolution of self-reported occupational problems. However, only 13.8% of the participants reached the recommended clinical important difference (MCID) cut-off of ≥3 for COPM occupational performance while 24.1% reached that (MCID≥3.2 pct) for satisfaction. In the REVEAL(OT) 3.0 those levels were 27.3% and 45.5%, respectively.

Table 4. Differences in secondary outcomes pre-postintervention

Outcomes	n	Baseline	Follow-up	Mean diff.	SD	95% CI		Median (range)	p-value	MCID[1]
HRQoL	23	.429	.472	.04	.18	-.03	.12	.051 (-.210; .432)	.2494	-
COPM, Performance	29	3.36	5.10	1.80	1.44	1.25	2.35	1.5 (-1.2; 5.4)	<0.001**	13.8%
COPM, Satisfaction	29	2.55	4.40	1.95	2.34	1.06	2.84	1.9 (-1.4; 8.8)	<0.001**	24.1%

Note. Abbreviations: CI, confidence interval; COPM, The Canadian Occupational Performance Measure; MCID, Minimal Clinically Important Difference; n, number; SD, standard deviation

[1] ≥3 pct. for performance; ≥3.2 pct. for satisfaction

* p-value <.05, **, p-value <.001

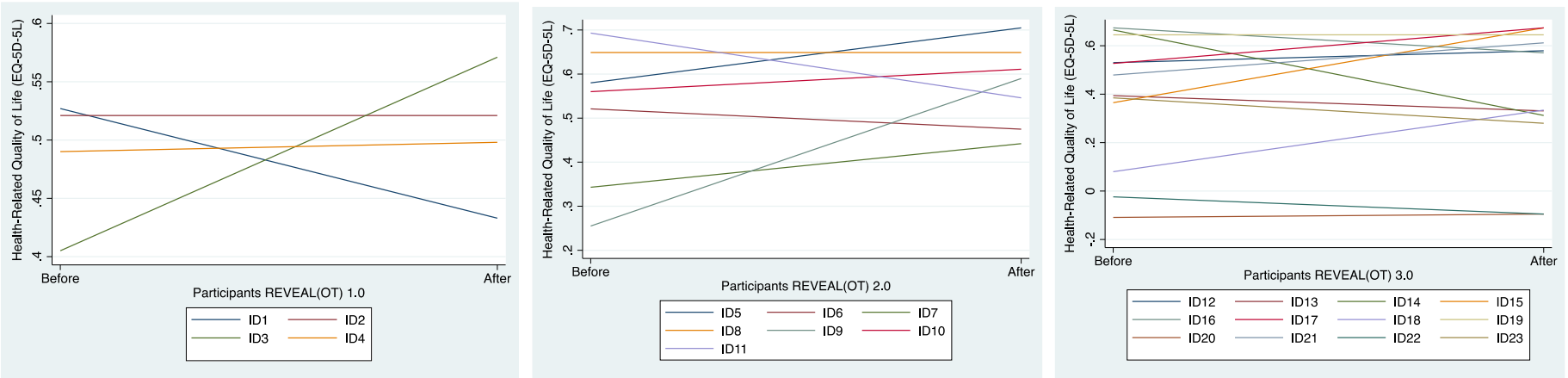


Figure 2. Participants' pre-post trajectories in Health-Related Quality of Life (EQ-5D-5L)

Discussion

This study evaluated the feasibility of a lifestyle-oriented occupational therapy intervention REVEAL(OT) added to the standard multidisciplinary treatment of adults living with chronic pain. The predefined research progression criteria regarding programme adherence; patients' self-perceived relevance, timing, and mode of delivery; assessment procedure acceptance; and adverse events were met, indicating that the REVEAL(OT) intervention is feasible. Several challenges regarding recruitment, participant retention and the fidelity of delivery were identified. Although outcomes need to be interpreted with caution, as the study was not powered to detect differences, we observed no improvement in HRQoL, but significant changes in the COPM scores while frequency of the proportion meeting MCID reached increased in the last feasibility round. This study nuanced the patient-reported beneficial effect of the REVEAL(OT) that was investigated previously by qualitative methodology, e.g., increased acceptance of living with chronic pain and empowerment for changing lifestyle [37]. The iterative feasibility testing process progressively improved quality of the REVEAL(OT), particularly regarding patients' self-perceived relevance, timing, and mode of delivery, and fidelity of delivery. This feasibility study informed further research steps to prepare the evaluation of intervention effectiveness [38].

Recruitment and retention are critical in trials and can often be challenging [39]. The current clinical capacity at the OTU was limited by few OTs, not allowing additional intervention therapists involved. Thus, almost every fifth outpatient referred to the REVEAL(OT) remained on the waiting list. Even having those included, we would not reach the sample size estimated for the future RCT. This highlights the need to add more recruitment centers in order to complete the RCT in time [39].

For participants retention, further reduction of the assessment load and easier control of self-assessments would be beneficial and prevent missing data, which is crucial for an RCT [40,

41]. Possibility of conducting the entire assessment session in-clinic, where project assistance can provide on-site support, can be considered. However, while revising the test battery, other relevant assessment tools could be considered for inclusion, e.g., measuring readiness for change [42, 43]. According to our earlier qualitative mid-term evaluation, readiness for participation among the REVEAL(OT) patient groups would increase motivation and peer interaction [37]. Such information obtained at baseline could also help identify the needs for further support of the participants to increase rentention.

Long-lasting pain itself imposes a higher risk of vulnerability [44, 45]. We experienced that the COVID-19 pandemic aggravated the vulnerability in the study cohort, supporting other evidence on the elevated levels of anxiety, isolation and inactivity in people living with chronic pain during this period [46, 47]. Multiple mental and cognitive issues observed in the last feasibility round may have had a negative impact on participant retention. Additional efforts shall be made to support retention despite the pandemic restrictions, e.g., more extensive use of online treatment delivery solutions, also to decrease the treatment load including transportation and time consumption.

When evaluating the fidelity of delivery, we considered any session with one or more amendments on the list of actions planned for the session as a delivery failure. If calculating the number of actions that failed, the progression criteria would probably be on the green level, because only single amendments were observed. However, the evaluation of fidelity of delivery on the amber level seems congruent with the need for more education in health behaviour coaching among the OTs which would provide more confidence in study procedures. Intervention providers' competence and behaviour are essential determinants of an appropriate intervention delivery [48-50]. In general, since occupational therapy is still poorly represented in public multidisciplinary chronic pain treatment in Denmark, more opportunities for continued education in the biopsychosocial approach to chronic pain

treatment, e.g., based on the International Association for Studies of Pain (IASP) curriculum for OTs [51], would encourage the Danish OTs with an interest in the field to get involved. However, we believe that the rigorous professional experience of the intervention OTs was essential. The programme delivery demanded a high degree of coordination, flexibility, and reflexivity to meet the participants' needs, which made it a comprehensive task [52]. We propose continuous monitoring of the fidelity of delivery at the later research steps to clarify its impact on the outcomes [38].

Feasibility studies do not allow for measuring long-term treatment effects [39]. Together with the lack of control group and high dropout rates in this study this precluded conclusions on the effects of the intervention on HRQoL and occupational performance and satisfaction. However, the improved COPM-scores in the entire study cohort supported the previously demonstrated beneficial impact of occupational therapy in chronic pain treatment [22, 53-55]. High rates of self-perceived relevance among participants confirmed the necessity of targeting lifestyle and self-determined meaningful activities in chronic pain treatment [56-58]. Though, the benefits for the everyday life observed seemed not to influence the self-reported HRQoL. Being aware that many participants did not reach MCID for the COPM, and that health behaviour changes are time consuming , further investigation of the outcomes in the short and long term is needed.

Limitations

Internal, non-blinded assessors and no separate registration files for the baseline and follow-up assessment, e.g., of the COPM scores, might have increased the risk of detection bias [59]. Qualitative interviews with the participants as a supplemental research activity will shed light on the in-depth opinions of the intervention's impact.

Using other methods for feasibility evaluation than the red-amber-green method, e.g., investigating in clinical utility aspects of the intervention such as possible disturbances, it

induce in current clinical care, or its social acceptance in different stakeholder groups [60], could possibly help generate new relevant knowledge. Furthermore, this would be relevant, because the current feasibility study did not include an assessment of the contextual feasibility, which has been highlighted as important in the 2021 edition of the MRC framework [11]. Whether REVEAL(OT) will improve the existing treatment of chronic pain remains unclear. However, by the inclusion of the REVEAL(OT) intervention, we need to be sure that the interdisciplinary treatment delivery context considered golden standard in tertiary chronic pain rehabilitation is secured. One of the basic prerequisites for the interdisciplinary cooperation – providing the treatment in same clinical facilities [1] – could not become real in the feasibility phase. We suggest that the interdisciplinary context of the REVEAL(OT) delivery is secured before launching an RCT.

Conclusion

An occupational therapy lifestyle intervention added to the standard multidisciplinary chronic pain treatment was feasible in terms of the research progression criteria, programme adherence, patients' self-perceived relevance, timing, and mode of delivery, assessment procedure acceptance, and adverse events. However, recruitment, participant retention and the fidelity of delivery need further optimisation including additional research sites, a revised assessment battery and more flexible delivery solutions, before initiating an RCT. While we observed no improvement in HRQoL, significant change in the COPM scores were observed. A future RCT is needed to evaluate the intervention effectiveness.

Author's declaration of authorship contribution

All authors contributed to the manuscript according to the International Committee of Medical Journal Editors (ICMJE) rules (http://www.icmje.org/).

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Conflict of interests

The authors have no conflict of interest to declare.

Data availability statement

The materials supporting the analysis and conclusions in this study can be obtained by contacting the corresponding author.

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Appendix 1. CONSORT 2010 checklist for feasibility study of the REVEAL(OT) intervention

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Feasibility, not randomised
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	Abstract
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	p. 3
	2b	Specific objectives or research questions for pilot trial	p. 3
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	p. 4 Appendix 2-3
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	pp. 4-5
	4b	Settings and locations where the data were collected	p. 4
	4c	How participants were identified and consented	p. 5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	pp. 5-7, one-arm
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	pp. 7-9 Appendix 4
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	p. 9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	NA

concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	p. 9-10 Table 1
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	pp. 10-11
	13b	For each group, losses and exclusions after randomisation, together with reasons	pp. 11-12 Figure 1 Appendix 5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	p.10 Figure 1
	14b	Why the pilot trial ended or was stopped	p.10
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	pp. 10-11 Table 2
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 1, one group
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	pp. 11-15 Table 3-4 Figure 2 Appendix 5-6
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	p. 13
	19a	If relevant, other important unintended consequences	pp. 12-13
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	pp.17-18
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	p.17
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and	

		considering other relevant evidence	pp. 15-18
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	p. 17
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	4 & abstract
Protocol	24	Where the pilot trial protocol can be accessed, if available	4 & abstract
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	p. 19
	26	Ethical approval or approval by research review committee, confirmed with reference number	p. 4

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix 2. The TIDieR Checklist for the REVEAL(OT) intervention description

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	p. 3	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	p. 5	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	p. 7-9	Appendix 4 Appendix 6
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	p. 6 p. 8	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	p. 6	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	p. 5-7	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	p. 4	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	pp. 10-11	Figure 1 Appendix 3
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	p. 5	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	p. 6	Appendix 3
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	pp. 11-15	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	pp. 12-14	Table 3

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Appendix 3. The REVEAL(OT) intervention impact on Person, Occupation and Environment

Main focus	**Type of impact***	**n (%) hours delivered per feasibility round**			
		Hours, total	1.0	2.0	3.0
Person	Training[1]	28.7	13.6 (47.4)	7.4 (25.8)	7.7 (26.8)
	Education[2]	53.0	13.2 (24.9)	25.6 (48.3)	14.2 (26.8)
	Skill development[3]	27.9	7.3 (26.2)	12.4 (44.4)	8.2 (29.4)
		109,6			
Occupation	Task adaptation[4]	19.8	6.4 (32.3)	7.4 (37.4)	6.0 (30.3)
	Occupational development[5]	105.8	37.3 (35.2)	28.1 (26.6)	40.4 (38.2)
		125,6			
Environment	Environmental modification[6]	17.8	7.7 (43.3)	4.1 (23.0)	6.0 (33.7)
	Support provision[7]	46.9	14.5 (30.9)	15.0 (32.0)	17.4 (37.1)
	Support enhancement[8]	0	0	0	0
		64,7			

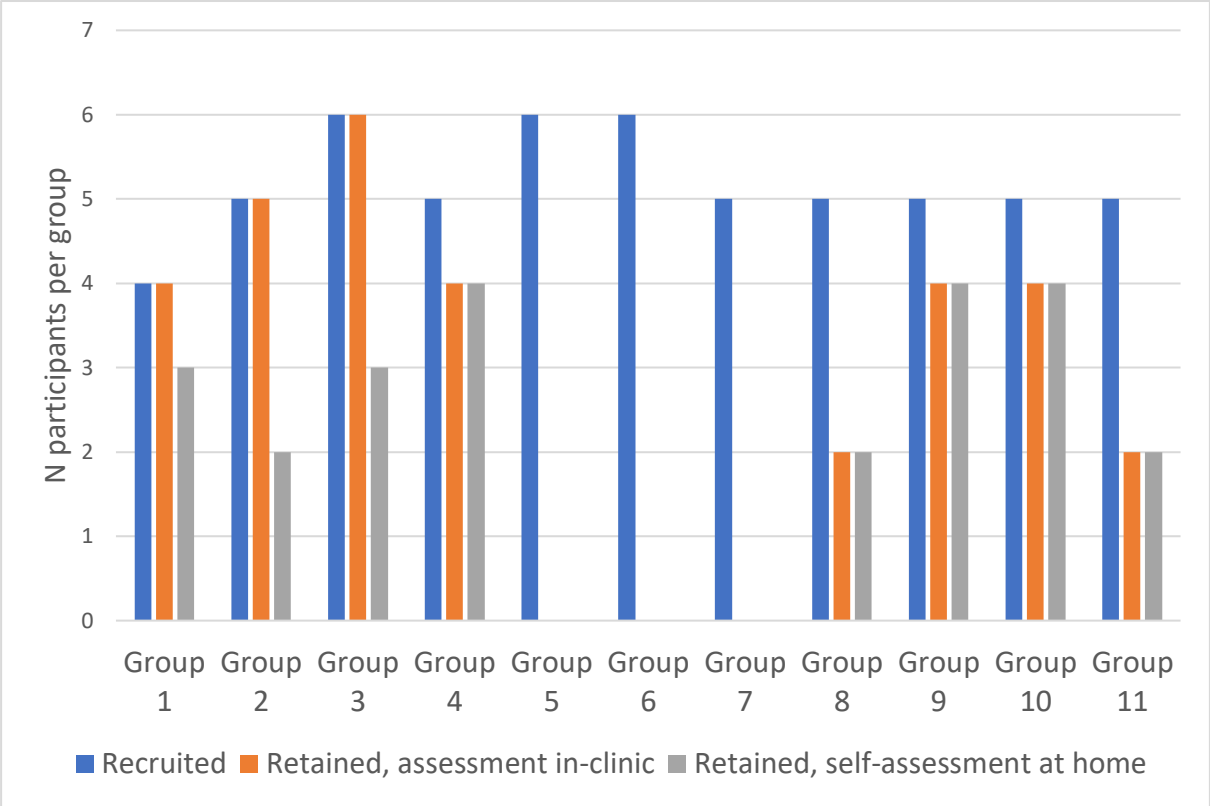
[*] *According to the occupational intervention taxonomy as described in McColl & Law (2013) [21]: [1] Enhancing performance of physical, psychological, cognitive, and social components, i.e., exercise and practice with no explicit occupational outcome; [2] Learning more about chronic pain, options for improvement, ways of preventing difficulties or improving occupational performance and function; [3] Improving performance of specific purposeful tasks/ the building blocks of occupation; [4] Modifying a task to permit it to be accomplished in a different manner given personal limitations; includes proximal adaptations and adaptive media; [5] Optimising participation in integrated occupations, such as vocational training, leisure programs, activities of daily living; [6] Modifying the non-human environment to enhance function. May include distal adaptive equipment, cueing, accessibility; [7] Provision of physical or psychological support by the therapist to enhance occupational performance; [8] Enhancing the ability of the family/caregivers and support system to provide support for occupational performance.*

Appendix 4. Outcomes of the REVEAL(OT) intervention

Parameter	Assessment tools	Self-assessment at home	Assessment in-clinic
Socio-demographic variables:	Generic questionnaire		
• Age, gender, civil status, education		X	-
• Employment		X	-
• Adverse events		X	-
QoL	EuroQOL (EQ-5D-5L Index)	X[1]	-
QoL	EuroQOL (EQ-5D-5L, EQ-VAS)	X[1]	-
Occupational performance and satisfaction	The Canadian Occupational Performance Measure (COPM)	-	X
Occupational performance, Motor & Process Skills	The Assessment of Motor and Process Skills (AMPS)	-	X
Occupational balance	The Occupational Balance Questionnaire (OBQ)	X[1]	-
Pain Self-efficacy	Pain Self Efficacy Questionnaire (PSEQ)	X[1]	-
Pain intensity	NRS (Numeric Range Scale) 0-10	X	-
Pain catastrophizing	Pain Catastrophizing Scale (PCS)	X	-
Pain localization	Body drawing	X	-
Sleep quality	Karolinska Sleep Questionnaire (KSQ)	X	-
Physical wake-time activity	Actigraphy units (4 days, monitored at-home)	-	X
BMI	Weight and height scale	X	X
Waist circumference	Measuring tape	-	X
Blood pressure	Sphygmomanometer	-	X
Pain sensitisation	CCPA (Controlled Cuff Pressure Algometry)	-	X

[1] Added to the original version of the Danish pain registry PainData

Appendix 5. Retention in feasibility study of the REVEAL(OT) 1.0-3.0



Note. Group 5-7 discontinued due to COVID-19 lockdown

Appendix 6. Participant evaluation reports

Item	Reports of the total n=343 and in feasibility rounds, n (%)		
	Agree	Disagree	Don't know
a) Was the scheduling of the session appropriate?			
Total	315 (91.9)	20 (5.8)	8 (2.3)
1.0	73 (92.4)	2 (2.5)	4 (5.1)
2.0	70 (89.6)	4 (5.7)	4 (5.7)
3.0	172 (92.5)	14 (7.5)	0 (0)
b) Was the timeframe for the session appropriate?			
Total	328 (95.6)	14 (4.1)	1 (0.3)
1.0	76 (96.2)	2 (2.5)	1 (1.3)
2.0	70 (89.7)	8 (10.3)	0 (0)
3.0	182 (97.8)	4 (2.2)	0 (0)
c) Were the session contents relevant?			
Total	336 (98.0)	0 (0)	7 (2.0)
1.0	73 (92.4)	0 (0)	6 (7.6)
2.0	77 (98.7)	0 (0)	1 (1.3)
3.0	186 (100)	0 (0)	0 (0)
d) Were the intervention contents easy to comprehend?			
Total	342 (99.7)	0 (0)	1 (0.3)
1.0	78 (98.7)	0 (0)	1 (1.3)
2.0	78 (100)	0 (0)	0 (0)
3.0	186 (100)	0 (0)	0 (0)
e) Was the form for delivery (individual or in-group) appropriate?			
Total	333 (97.1)	0 (0)	10 (2.9)
1.0	69 (87.3)	0 (0)	10 (12.7)
2.0	78 (100)	0 (0)	0 (0)
3.0	186 (100)	0 (0)	0 (0)
f) Were you satisfied with participation in the session?			
Total	397 (100)	0 (0)	0 (0)
1.0	79 (100)	0 (0)	0 (0)
2.0	47 (100)	0 (0)	0 (0)
3.0	186 (100)	0 (0)	0 (0)
Total mean %	97.0	1.7	1.3

Appendix 31

Personal goal work template

Arbejdsnotater fra individuelle samtaler

Patient: **ID nr.:** **Hold:**

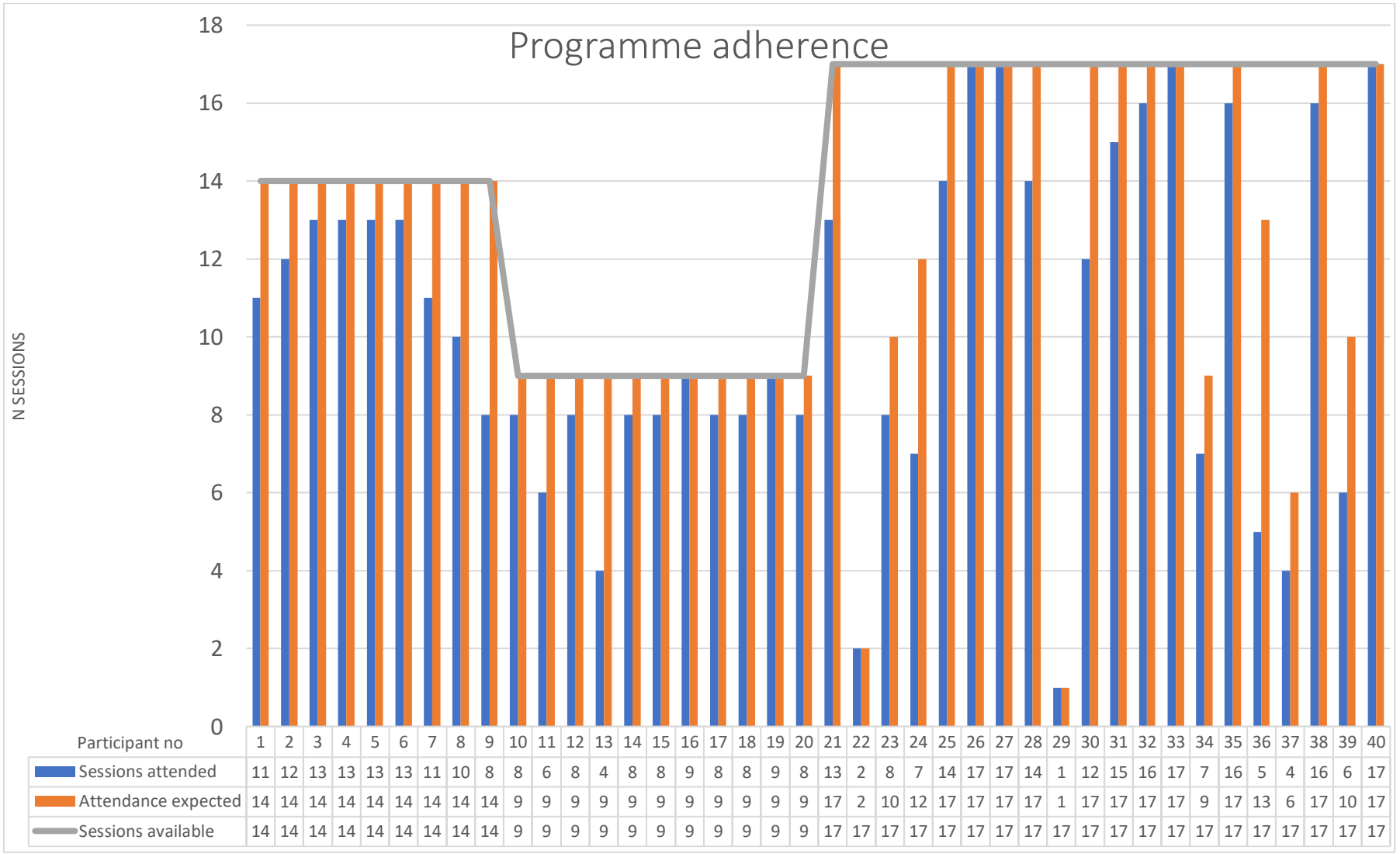
Meningsfulde aktiviteter	**Spisevaner**	**Regelmæssig bevægelse**
Langsigtet mål:	Langsigtet mål:	Langsigtet mål:
Kortsigtede mål:	Kortsigtede mål:	Kortsigtede mål:

Arbejdsnotater fra individuelle samtaler

Meningsfulde aktiviteter	**Spisevaner**	**Regelmæssig bevægelse**
Kortsigtede mål:	Kortsigtede mål:	Kortsigtede mål:

Appendix 32

Programme adherence diagramme

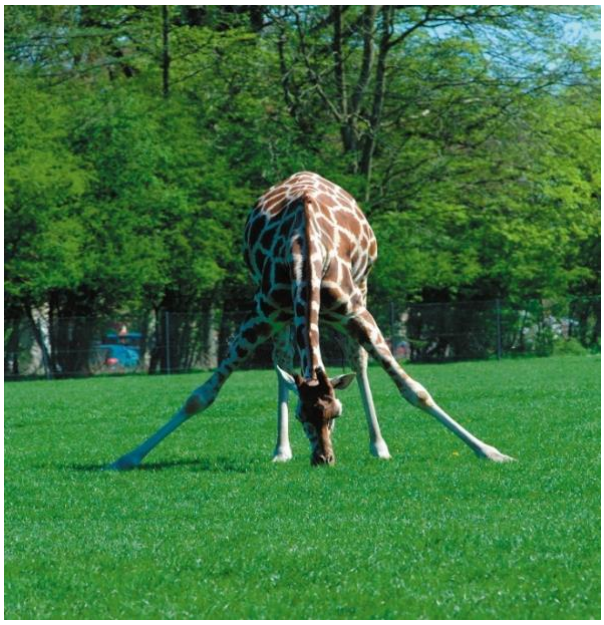


Participant no	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
Sessions attended	11	12	13	13	13	13	11	10	8	8	6	8	4	8	8	9	8	8	9	8	13	2	8	7	14	17	17	14	1	12	15	16	17	7	16	5	4	16	6	17
Attendance expected	14	14	14	14	14	14	14	14	14	9	9	9	9	9	9	9	9	9	9	9	17	2	10	12	17	17	17	17	1	17	17	17	17	9	17	13	6	17	10	17
Sessions available	14	14	14	14	14	14	14	14	14	9	9	9	9	9	9	9	9	9	9	9	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17

Supplementary file 1

Manual for the intervention providers

REDESIGN DIN HVERDAG
MED ERGOTERAPI
til kroniske smertepatienter



Deltager: _____

Kontakt: Ergoterapien, Næstved sygehus
Sekretær: Tlf. **56 51 40 71** (kl. 8-15);
E-mail: nae-ergoterapi@regionsjaelland.dk
Lise Mikkelsen, ergoterapeut:
Tlf. **56 51 44 45** (mandage kl. 8-9.30)
Svetlana Nielsen, ergoterapeut, projektansvarlig:
Tlf. **93 56 62 00**; E-mail: ergo_livsstil@gmail.com

REGION SJÆLLAND – vi er til for dig

PROgrez

ERGOTERAPEUT FORENINGEN

SDU

Interventionsmanual

Teoretisk baggrund

Kroniske smerter rammer hver 5. dansker og udgør et væsentligt problem for individet og samfundet (1). Non-farmakologiske tilbud bliver i dag fremhævet som det første valg i behandlingen af kroniske non-maligne smerter, da de ikke skaber afhængighed (2). Evidensen finder arbejdet med livsstilsfaktorer relevant ved kronisk smerteproblematik (3-6). Helhedstilgangen og livsstilsjusteringer ved kronisk smerte aktiverer hjernens plastiske egenskaber, og gør hermed op med tanken om smerte som et blivende fænomen (7). Det er især ændringerne i relation til de modificerbare livstilsfaktorer, som f. eks. smerte, mental helbred, co-morbide tilstande, rygning, alkohol, overvægt, fysisk aktivitet og træning, søvn, ernæring samt produktivitet og tilknytning til arbejdsmarkedet, der kan især have betydning for kroniske smertepatienter (3).

Ergoterapeuter og forskere fra University of Southern California (USA) har udviklet og i mange år haft succes med anvendelsen af livsstilsorienteret tilgang til patienter. Det ergoterapeutiske Lifestyle Redesign®-program viste sig at være effektiv og cost-effektiv (8, 9). Også specifikt i forhold til målgruppen af kroniske smertepatienter har programmet viste forbedringer i oplevelsen af livskvalitet, fysisk og social funktion, samt selv-kompetence (self-efficacy) (10).

Den ergoterapeutiske livsstilsorienterede intervention er planlagt på baggrund af den indsamlede evidens om Lifestyle Redesign®-programmet, brugerundersøgelsen (spørgeskema og interview) blandt ambulante smertepatienter tilknyttet Tværfagligt smertecenter i Næstved samt udtalelser om patienternes behov og klinisk relevans fra de sundhedsprofessionelle som arbejder med kroniske smertepatienter. Interventionen vil indgå i et klinisk randomiseret forsøg om effekten af en ergoterapeutisk livsstilsorienteret intervention på livskvalitet blandt voksne med kroniske non-maligne smerter.

Den ergoterapeutiske livsstilsorienterede intervention baserer sig hermed på aktivitetsvidenskabelig viden samt har fokus på sundhedsfremme og forebyggelse af kroniske tilstande gennem udvikling af sunde vaner or dagligdags rutiner (11). Aktivitetsvidenskab er en akademisk disciplin der ser menneskets engagement i en aktivitet som afgørende for et sundt og meningsfuldt liv (12). Via aktivitetsvidenskab bliver der skabt en tættere forbindelse mellem den akademiske viden og den ergoterapeutiske praksis, hvorved de kliniske valg bliver understøttet og sat i en større videnskabelige sammenhæng (13).

Interventionen, i tråd med WHO's brede sundhedsbegreb, bygger på den salutogenetiske forståelse af sundhed som oplevelse af fysisk, psykisk og socialt velvære og velbefindende, og ikke kun fravær af sygdom (14, 15). Den valgte tilgang skal bidrage til større forståelse for, at interventionen ikke er rettet mod "at finde fejl" i den nuværende sundhedsadfærd men mod at skabe en større bevidsthed om aktivitetsvalg og empowerment til sundhedsfremmende vaneændringer (16). I planlægningen af interventionen i praksis har der ligeledes været fokus på oplevelsen af sammenhæng (Antonovsky's Sense of Coherence (SOC)), og hermed meningsfuldhed, begribelighed of håndterbarhed af indholdet (17).

Formål

At tilbyde kroniske smertepatienter mulighed for at tilegne sig viden om aktiviteter og færdigheder til selv-ledelse af dagligdags aktiviteter. Styrket evne til at analysere egne aktiviteter i overensstemmelse med egne værdier forventes at føre til mere bevist aktivitetsvalg i det daglige, med bedre sundhed of højere livskvalitet til følge.

Deltagerne forventes at opnå større tilfredshed med deres daglige aktiviteter på baggrund af:

- større forståelse af aktiviteternes betydning for sundheden
- øget daglig bevægeaktivitet
- sundere spisevaner med flere grøntsager
- bedre søvn- og hvilerutiner
- tilegnede kompenserende strategier til at klare daglige gøremål

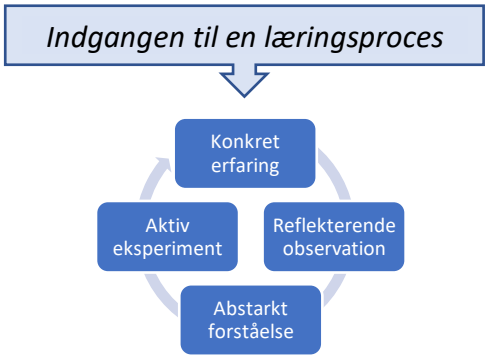
Metode

I lighed med det oprindelige Lifestyle Redesign®-program anvender interventionen metoder som didaktiske oplæg, erfaringsudveksling, erfaringsdannelse og refleksionsarbejde, samt elementer som patient uddannelse, selvstændig aktivitetsanalyse, problemløsning, motivationsarbejde og implementering af ny sundhedsadfærd i hverdagen.

Forandringer hos den enkelte deltager bliver fremmet via dannelsen af egne erfaringer ("learning by doing") i et socialt samspil, både med ergoterapeuten, og holdet. Den personlige erfaringsdannelse er tænkt som bærende fundament for analyse, refleksion, vidensdeling, motivation, og progression i forløbet. Dewey's erfaringspædagogik anvendt til aktivitetsvidenskab, og hermed forståelsen for aktivitetens transformative egenskaber som

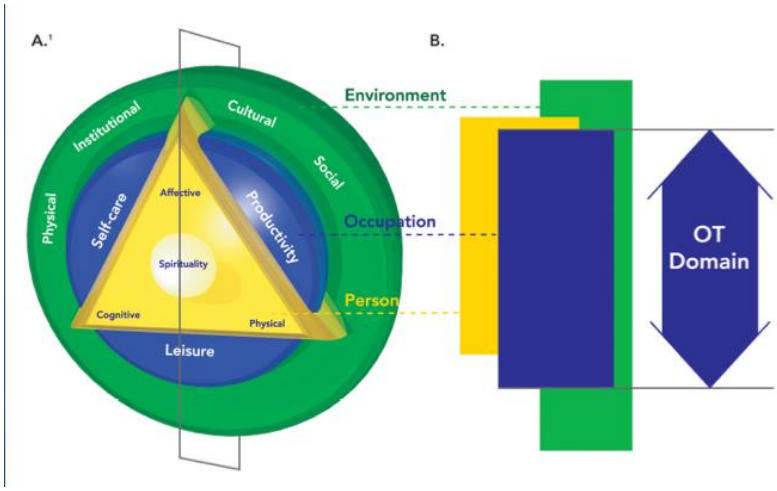
kommer til udtryk i interaktionen mellem individet og omgivelserne, er en af interventionens pædagogiske grundsten (18). I den transformative proces vil deltagerne fortløbende gennemgå stadierne fra a) en konkret oplevelse og dannelse af personlig erfaring, til b) reflekterende observation og eftertænksomhed, c) abstrakt forståelse og søgen efter svar, før det sidste stadie - c) aktivt eksperiment og afprøvning i praksis (Fig.1).

Fig. 1. Kolbs læringscirkel (19)



Interventionsudviklingsprocessen er styret af CMOP-E (Canadian Model of Occupational Performance and Engagement, Fig. 2) og CPPF (Canadian Practice Process Framework, Fig. 3) (20, 21).

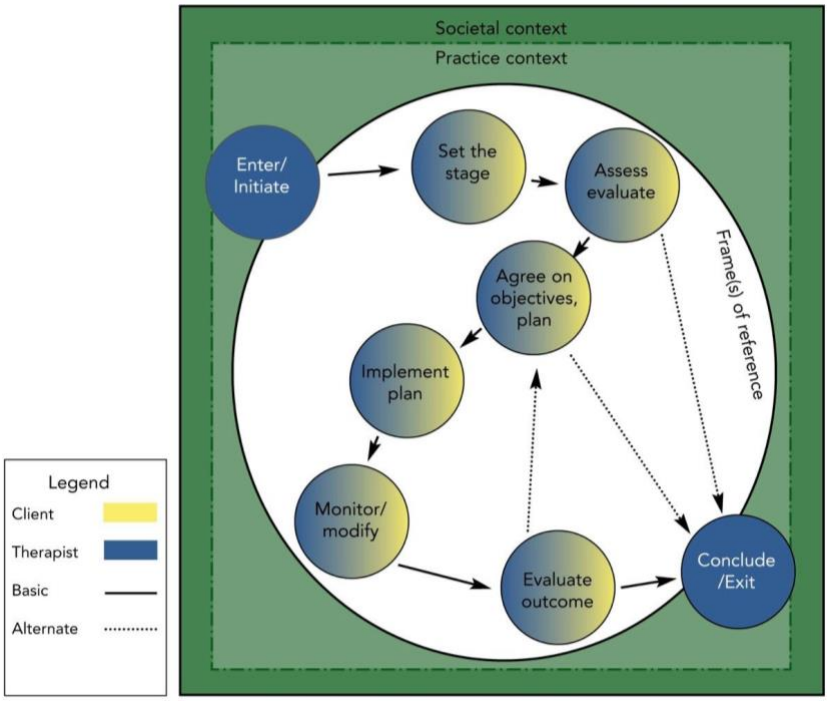
Fig. 2. CMOP-E og modellens domæner (20) (From: Townsend EA, Polatajko HJ. Enabling Occupation II: Advancing an Occupational Therapy Vision for Health, Well-being & Justice through Occupation. Ottawa, ON: CAOT ACE2007.)



[1] A. Refererer til den tidligere CMOP-model og CMOP-E

B. Tværsektorielt billede af domænerne og det ergoterapeutiske arbejdsområde

Fig. 3. Canadian Practice Process Framework (21) (From: Polatajko HJ, Townsend EA, Craik J. Canadian Model of Occupational Performance and Engagement (CMOP-E). In: Townsend EA, Polatajko HJ, editors. Enabling Occupation II: Advancing an Occupational Therapy Vision of Health, Well-being, & Justice through Occupation. Ottawa, ON: CAOT Publications ACE; 2007. p. 22-36.)



Der er svag evidens om effekten af struktureret målsætning i rehabiliteringen af voksne med erhvervede dysfunktioner på livskvalitet, deltagelse, self-efficacy og fysisk formåen (22). Alligevel finder vi uhensigtsmæssigt at undvære målsætningen, når interventionen sigter mod, at deltagerne opøver færdigheden i aktivitetsanalytisk arbejde. Evnen til analysere, hvad der fremmer eller hæmmer meningsfulde aktiviteter og sundere livsstil, skal danne grundlag for længerevarende og holdbare vaneændringer både i løbet af og efter interventionen (23). Målsætningen i interventionen bliver rammesat som kort- eller langsigtede mål, for at understøtte deltagernes motivation og gradueringsbehov i målarbejdet (24). Målene revideres og justeres løbende samt slutevalueres ved interventionens afslutning.

Interventionsergoterapeut

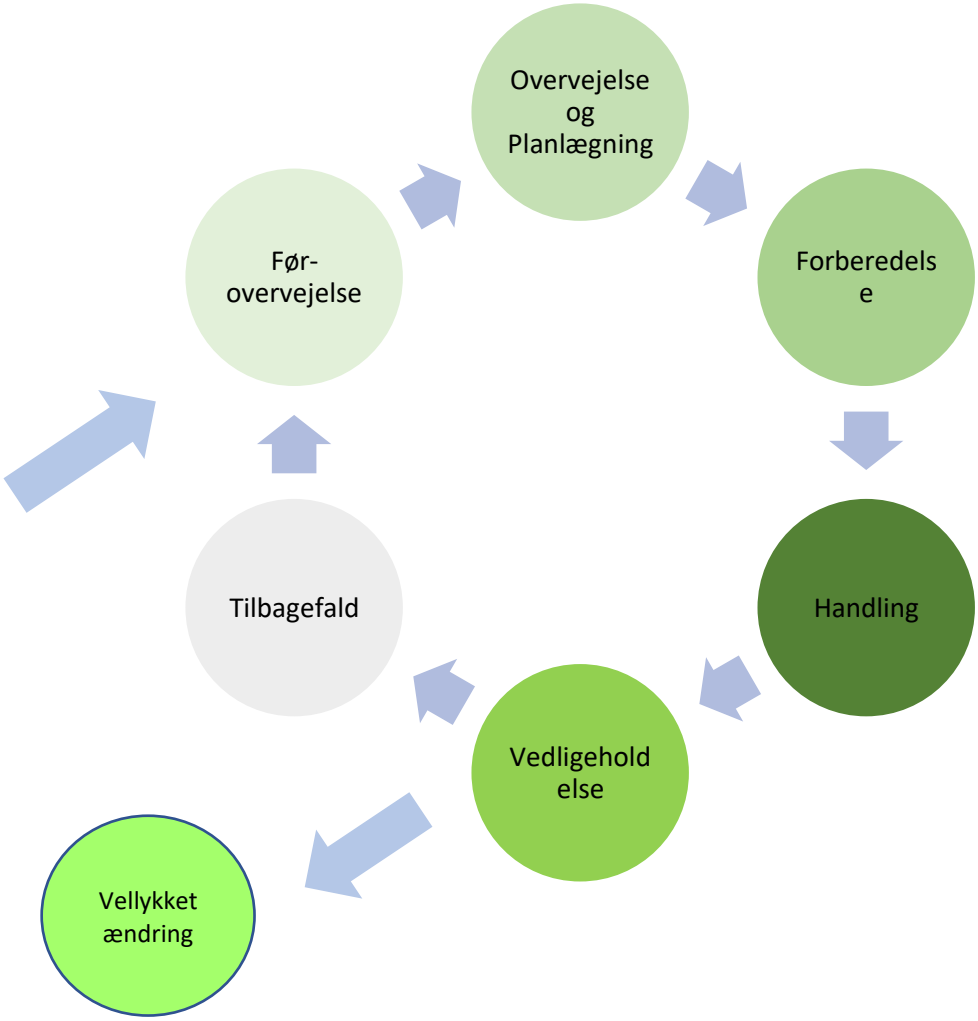
Interventionen er ledet af ergoterapeuter hvis rolle er:

- Præsentere udvalgte emner for deltagerne

- Facilitere individuel udvikling
- Facilitere gruppediskussion
- Vejlede omkring interventionsforløb og dets elementer
- Formidle kontakten til relevante samarbejdspartnere
- Evaluere indsatsen

Livstilsændringer er en tidskrævende proces, og vi forventer, at deltagerne går ind i forløbet med forskellige grader af motivation og parathed til forandring, hvilket vil skabe forskelligartede forløb og stiller øgede krav om klientcentrering. Prochaska og DiClemente' forandringscirkel (The Transtheoretical or Stages of Change model) med faserne Før-overvejelse, Overvejelse og Planlægning, Forberedelse, Handling, Vedligeholdelse og Tilbagefald illustrerer forandringsprocessens trin, som deltagerne vil gennemgå i løbet af interventionen, Fig. 4 (25). Ergoterapeutens opgave er derfor at møde og rumme hver enkelte deltager på deres præmisser, motivere til effektivt målarbejde og fremme den individuelle udvikling.

Fig. 4. Forandringscirklen (25)

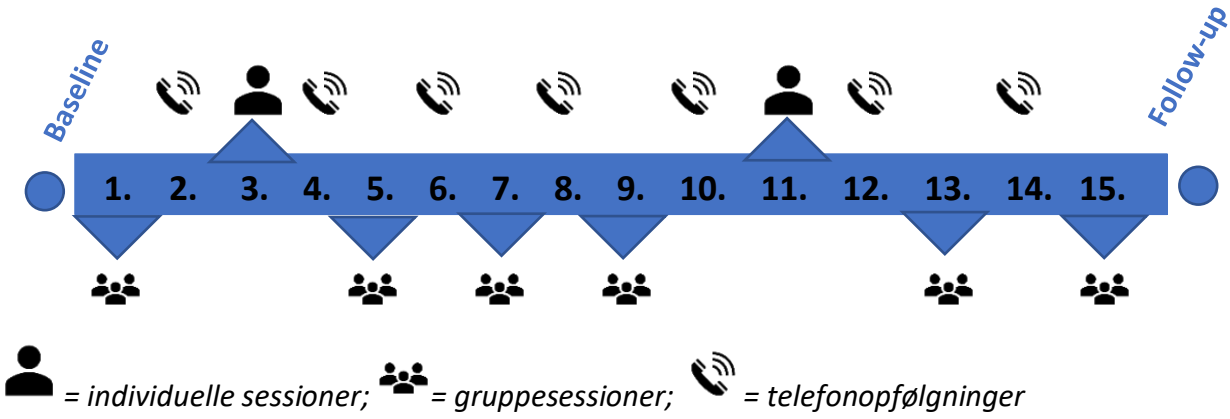


Deltagere

Deltagernes rolle er:

- Deltage aktivt i individuelle og gruppesessioner
- Identificere egne værdier
- Tilegne sig kompetencen i at gennemøre analysen af egen hverdag med identifikation af sundhedsfremmende og -hæmmende faktorer
- Sætte individuelle sundhedsfremmende mål i overensstemmelse med resultaterne af selv-analyse af hverdagsaktiviteter og identificerede egne værdier
- Planlægge aktiviteter til opnåelse af personlige mål
- Afprøve de planlagte sundhedsfremmende aktiviteter
- Dele personlige erfaringer
- Give og modtage feedback
- Bidrage til positiv atmosfære ved gruppesessioner
- Melde afbud ved sygdom

Skema over interventionsforløb



Interventionsstrukturen er tænkt at skulle give mulighed for at skabe en tryg atmosfære for deltagelsen igennem grundig introduktion og dialogbaseret drøftelse af indholdsmæssige og praktiske aspekter for deltagelsen. Interventionsstrukturen tilgodeser behov for gruppe- og individuelle møder samt hyppige telefoniske opfølgninger med henblik på individuel patient-terapeut kontakt uden transportbyrde. Hermed, af pragmatiske grunde, er der blevet valgt ikke at følge anbefalingen fra Lifestyle Redesign®-programmet om min. 5 individuelle sessioner per forløb (11). Interventionen i den nuværende form og længde er vurderet til at

matche bedst den kliniske praksis og patienternes forventninger. Pilotafprøvningen af interventionen inden lodtrækningsforsøg vil vise, hvorvidt disse antagelser har været korrekte.

Introduktion til intervention

Indholdet kan tilpasses løbende i forhold til gruppedynamikken, særlige begivenheder, samfundsmæssige tendenser eller kulturelle traditioner for at skabe større patientnær kontekst.

Interventionens hovedelementer omhandler meningsfulde hverdagsaktiviteter og deltagelse, aktiv livsstil (bevægelsesaktivitet) og sunde spisevaner. Vægtning af hovedelementerne i interventionen er fordelt således (udregnet på baggrund af deltagernes forventede aktive deltagelse i interventionen (= sessionernes varighed minus pausetid[1]):

- Meningsfulde hverdagsaktiviteter og deltagelse – ca. 50 % af den samlede aktive deltagelsestid;
- Bevægelsesaktivitet – ca. 25 % af den samlede aktive deltagelsestid;
- Sunde spisevaner – ca. 25 % af den samlede aktive deltagelsestid.

Interventionens fokus på meningsfulde aktiviteter vil danne grundlag for, at deltagerne under supervision af en ergoterapeut lærer at analysere egen hverdag og værdibaseret aktivitetsvalg, for at kunne praktisere dette i fremtiden, og hermed sikre meningsfuld aktivitetsudøvelse som fremmer sundhed og livskvalitet. Meningsfulde aktiviteter er dem, som mennesker er nødt til, har lyst til eller er forpligtet til at udføre (21). Retten til at praktisere meningsfulde aktiviteter opfattes i ergoterapien som en af grundlæggende menneskerettigheder som sikrer, at både enkelte individer og hele samfundet trives (26). Med en klientcentreret holistisk tilgang der hjælper patienterne til en dagligdag der fungerer, dvs. ved tilføjelse af den spirituelle og eksistentielle dimension til den biopsykosociale forståelse af kronisk smerte, kan den nuværende behandlingstilbud til kroniske smertepatienter blive endnu mere effektivt (27).

Bevægelsesaktivitet er inkluderet som det element i interventionen der vil støtte op om den meningsfulde aktivitetsudøvelse. Bevægelsesaktivitet forstås som fysisk aktivitet som er ønskelig, håndterbar og tilpas udfordrende for hver enkelte deltager. Regelmæssig fysisk

[1] Sessionernes varighed: for gruppesessioner - 120 min. i alt, med 100 minutters aktive deltagelse og 20 min. pause; for individuelle sessioner - 60 min. med aktiv deltagelse.

aktivitet er en vigtig faktor i sundhedsfremme og forebyggelse af livsstilssygdomme (28, 29). Fysisk aktivitet for kroniske smertepatienter tjener til forebyggelse af tilstødende kroniske tilstande som overvægt, diabetes, hjerte-karsygdomme osv. (30). Selvom der ikke er formuleret doserede anvisninger i forhold til fysisk aktivitet til kroniske smertepatienter, er der ingen tvivl om, at bevægelse bedre end inaktivitet (30, 31). Også her er det vigtigt med klientcentreret tilgang der medregner individuelle behov, ressourcer og begrænsninger og sikrer langsom progression (30). Hermed søges interventionen af give deltagerne nye positive erfaringer med tilpasset bevægelsesaktivitet ud fra eksisterende anbefalinger (28-30).
Interventionen vil inspirere deltagerne til sundere spisevaner ud fra evidensen om hensigtsmæssig kost generelt og specifikt ved kroniske ikke-cancerrelaterede smerter (32-34). Ergoterapeutisk indsats vil fokusere på processerne i et sundt måltid som en aktivitet – fra planlægning til indkøb, tilberedning, servering og selve spiseprocessen, inklusive madens individuelle og sociale betydning.

Interventionens opbygning

I alt 15 sessioner (2 individuelle, 6 gruppebaserede og 7 telefoniske) med følgende emner:

<u>Uge 1</u>

Introduktion til forløbet: Interventionens fokusområder (gruppe)

- Meningsfulde aktiviteter og deres sundhedsfremmende egenskaber – 10 min. oplæg og 15 min. værdibaseret aktivitetsvalg (øvelse)
- Sunde spisevaner: De officielle kostråd – 10 min. oplæg og 15 min. værdibaseret aktivitetsvalg (øvelse)
- Regelmæssig bevægelse: Sundhedsstyrelsens anbefalinger – 10 min. oplæg og 15 min. værdibaseret aktivitetsvalg (øvelse)
- Hjemmeopgave: registreringsskema for vandindtag og daglige skridt (til udlevering) - 15 min.
- Siden sidst/ afrunding – 15 min.

<u>Uge 2</u>

Telefonisk opfølgning: vandindtag og daglige skridt – 15 min. målgennemgang, 5 min. fysiske omgivelser og 10 min. opfølgning/ afrunding

<u>Uge 3</u>

Målsætning, individuelt: Kortsigtede mål for meningsfulde aktiviteter, spisevaner og daglig bevægelse – 40 min. og 10 min. opfølgning/ afrunding

Uge 4

Telefonisk opfølgning: kortsigtede mål – 15 min. målgennemgang, 5 min. fysiske omgivelser og 10 min. opfølgning/ afrunding

Introduktion til hjemmeopgaven: ugeskema

Uge 5

Energibesparende principper og teknikker (gruppe)

- Opsamling på hjemmeopgaven: ugeskema – 30 min.
- Gennemgang af energibesparende principper og teknikker – 20 min.
- Præsentation af hjælpemidler især med henblik på de tungere huslige opgaver – 30 min.
- Orientering om hjælpemiddelansøgning – 15 min.
- Siden sidst/ afrunding – 10 min.

Uge 6

Telefonisk opfølgning: kortsigtede mål – 15 min. målgennemgang, 5 min. fysiske omgivelser og 10 min. opfølgning/ afrunding

OBS på sko som sidder fast på foden til næste gang

Uge 7

Bevægelse og velvære (gruppe)

- Sundhedsstyrelsens anbefalinger til fysisk aktivitet for voksne – 20 min.
- Moderat daglig bevægelse – hvad betyder det i praksis? – 20 min.
- Den daglige energifordeling: afspænding – 40 min.
- Siden sidst/ afrunding – 10 min.

Uge 8

Telefonisk opfølgning: kortsigtede mål – 15 min. målgennemgang, 5 min. fysiske omgivelser og 10 min. opfølgning/ afrunding

Uge 9

Måltider og spisevaner (gruppe)

- Tilberedning af et måltid, inkl. Introduktion til små hjælpemidler – 50 min.
- Servering af måltider og spisning – 50 min.

- Siden sidst/ afrunding – 10 min.

Uge 10

Telefonisk opfølgning: kortsigtede mål – 15 min. målgennemgang, 5 min. fysiske omgivelser og 10 min. opfølgning/ afrunding

Uge 11

Hjemmebesøg: tilpasning af egne omgivelser i forhold til målarbejdet (tilvalg, mulighed for andre personlige ønsker) - 50 min. og 10 min. opfølgning/ afrunding

Uge 12

Telefonisk opfølgning: kortsigtede mål, opfølgning på ergonomi og indretning i eget hjem der fremmer/ hæmmer målarbejdet – 15 min. målgennemgang, 5 min. fysiske omgivelser og 10 min. opfølgning/ afrunding

Uge 13

Køkkenindretning, opbevaring af mad og indkøb (gruppe)

- Køkkenindretning og opbevaring af mad – 30 min.
- Indkøb, fødevaremærker og næringsdeklarationer – 30 min.
- Fælles spisning – 35 min.
- Siden sidst/ afrunding – 10 min.

Uge 14

Telefonisk opfølgning: evaluering af målarbejdet – 15 min. målgennemgang, 5 min. fysiske omgivelser og 10 min. opfølgning/ afrunding

Uge 15

Opsamling og afslutning (gruppe)

- Personlige mål/ ”storytelling” – 85 min.
- Siden sidst/ afrunding – 20 min.

NB alle sessioner indeholder:

- *Pacing*
- *Råd om hjælpemidler*

Individuelle sessioner

Individuelle sessioner 2 g. á 1 t. (mødegang 3 og 11, hvor nr. 3 foregår på klinikken og 11 - i deltagerens eget hjem). De individuelle møder bruges til individuelt tilpasset arbejde med afdækning af aktivitetsproblematikker, personlige mål, og ergonomisk vurdering af egne omgivelser.

Gruppesessioner

Gruppesessionerne finder sted i interventionsperioden 6 g. á 2 t. (mødegang 1, 5, 7, 9, 13 og 15). Grupperne sammensættes af max. 6 deltagere pga. patienternes skånebehov i forhold til sociale og kognitive krav i gruppesammenhæng, samt kapacitetsmæssige muligheder på det kliniske sted. Denne gruppestørrelse har vist sig at være tilstrækkelig til evt. at kunne finde ligesindede, fremme refleksionsarbejde og gennemføre praktiske øvelser, og samtidigt skabe diversiteten i erfaringsudvekslingen.

Materialer til uddeling

- Mødekalender (A4-side med overblik over mødedagene og emner i forløbet tilsendt via digital mail)
- Trykt kompendie med materialer fra forløbet
- Dagbog til afkrydsning i forhold til målarbejdetEvalueringsskema, 1 stk. pr. deltager ved afslutning på alle sessioner
- Procesevalueringsskema til interventionsterapeuterne for hver session

Praktisk huskeliste

- Dagsorden skrevet op på en flipover/ tavle
- Blankt papir
- Blyanter/ kuglepen
- Navneskilte
- Vand, krus og servietter
- White-board
- Post-its
- Evt.: kaffe/the, kamera, musikanlæg, blomster/ planter, led-fyrfadslys

Interventionsmanual

Note: *"Skråskrift"* illustrerer direkte tale.

Session 1. Introduktion

Gruppemøde i ergoterapien på Næstved sygehus

Formål med sessionen:

Etablering af patient-terapeutkontakten, præsentation af forløbet og introduktion til hjemmeopgaven (Skema til registrering af målarbejde i forhold til meningsfulde aktiviteter, bevægelse og spisevaner/ væskeindtag i det samlede forløb).

Huskeliste:

- Procesevalueringsskema for sessionen
- Whiteboard markere (min. 1 stk. pr. deltager)
- Dagbog til afkrydsning i forhold til målarbejdet
- Kompendier
- Vand på flaske 0,5 l x 4 pr. deltager
- Evalueringsskemaer
- Book returkørsel med Flextrafik
- Evt. modtage Actigraph-udstyr retur efter hjemmemålinger
- Indkøb til 'greenie'-smagsprøver til deltagerne
- Fremstilling af 'greenie'-smagsprøver

Sessionens forløb:

1.1 Præsentation og orientering om tavshedspligt – 5 min.

"Velkommen i ergoterapien! Jeg hedder… og er projektergoterapeut i et livsstilsorienteret forløb, hvor deltagerne vil arbejde med deres daglige aktiviteter, spisevaner og bevægelse. Det er mig, du kommer til at møde i hele forløbets periode, det vil sige, de næste 15 uger.

Jeg vil orientere jer om, at alle deltagere er underlagt tavshedspligt. Navne på deltagerne og anden information der kan gøre, at personen bliver genkendt af uvedkommende, må ikke bringes videre til andre.
Nu er det tid til at I præsenterer jer for hinanden ganske kort, så alle kender navnene på hinanden…"

- Deltagerne præsenterer sig selv kort
- Ergoterapeuten skriver navnene på tavlen eller flipchart i cirkel i rækkefølgen efter placeringen af deltagerne ved bordet
- Kompendier udleveres til deltagerne

1.2 Introduktion af forløbets fokusemner

1.3.1 Meningsfuld aktivitet og 'flow'

"Dette forløb vil dreje sig om de ting som vi gør hver dag og som giver mening i vores liv, enten fordi vi er nødt til at gøre, har lyst til at gøre, eller forventet til at gøre dem. Vi ergoterapeuter kalder disse ting for ***meningsfulde aktiviteter****.*
Meningsfulde aktiviteter er hovedelementet i forløbet, fordi evnen til at gøre de ting der giver vores liv mening er med til at skabe følelsen af god livskvalitet. Kroniske smerter har ofte den indflydelse på éns liv, at de ting der gør os stærkere, sundere og gladere bliver droppet eller udsat. Forløbet vil bringe det gode liv frem – frem for blot overlevelse! Du vil blive klogere på, hvad du gør i løbet af dagen, hvordan du gør, og hvorfor du gør det. Alt det med det resultat, at din følelse af mening og sammenhæng i hverdagen bliver større, og fornemmelsen af, at det er smerten der styrer bliver til gengæld mindre."

<u>Kompendiet s.3: Hvad der giver mening og livskvalitet for dig?</u>
"På s. 3 finder I en grøn boks med spørgsmålet ' Hvad der giver mening og livskvalitet for dig?'. Prøv at skrive et par svar på dette spørgsmål, gerne i prioritets rækkefølge."

- *Deltagerne noterer*

"Hvad har I skrevet? Er er nogen ting der går igen? Hvorfor er de så vigtige for jer?"

- *Deltagerne reflekterer*

"I dagligdagen bliver vi konfronteret med mange små valgsituationer. Når overskuddet ikke er ret stort, er det nemt at fravælge især de ting der er sjove og netop genopfylder os med energi. Det er svært at lægge alt-eller-inter-princippet væk og øve sig i at dosere mængden og intensiteten i det, vi laver. Det, at kende sine værdier, hjælper os at foretage det mest hensigtsmæssige valg.
*Derudover har meningsfulde aktiviteter helende og sundhedsfremmende virkning ved hjælp af en psykologisk mekanisme som hedder '**flow**'. 'flow' går ud på en følelse af at blive opslugt af en aktivitet, så tid og sted forsvinder.*
Evidensen siger, at tilstanden af 'flow' er stærkt stressreducerende, styrker selvtillid og genopbygger fysiske og mentale ressourcer, fordi vores krop og sind får lov til at slappe af. Vi kan slappe af, fordi vi føler for et øjeblik, at der er overensstemmelse i, hvad den enkelte kan, og hvad omgivelserne kræver. Det betyder, at i 'flow'-tilstanden kommer aktivitetens helende egenskaber frem, og vi glemmer at mærke efter og bekymre os for en stund. Kender i denne følelse? Hvilke aktiviteter giver jer fornemmelsen af 'flow'?"

Øvelsen: Hvilke aktiviteter, du kender, har størst potentiale for en 'flow'- oplevelse?
"Igen på s. 3 er der plads til et par stikord til aktiviteter, I synes er sjove og energigivende. Stikordene vil vi bruge senere, når I skal vælge, hvad er der relevant for jer at arbejde med i forløbet. Prøv at skrive ned 2-3 forslag."

- Deltagerne kommer med input

"Tilstanden af 'flow' varer ikke ret længe, den kommer et øjeblik og går, og så kommer den igen. For at 'flow' skulle finde sted, er det vigtigt at minimere forstyrrelser. Evnen til at holde forstyrrelserne ude kan trænes op, fx gennem meditation og afspænding som begge kan bringe os i ro. I forløbet vil vi vise jer nogle simple afspændingsøvelser som kan bruges i hverdagen."

Pause - 10 min.

('Greenie'-smagsprøver serveres)

1.3.2 Sunde spisevaner og regelmæssig bevægelse

*"De to andre emner i forløbet - **sunde spisevaner og regelmæssig bevægelse** – skal understøtte meningsfuld aktivitetsvalg i hverdagen, fordi forskning peger på, at det gode liv er i høj grad afhængigt af, hvordan vi spiser og bevæger os. På disse to områder vil vi gå ud fra de generelle sundhedsråd til danskerne.*

Forløbets vil strække sig over 15 uger. Evidensen siger, at denne periode burde være nok til at ændre en vane, hvis man prøver konsekvent. Derfor er vores forventning, at alle deltagere begynder at prøve nyt – på det passende niveau og i individuelt tempo. Det er kun igennem egne erfaringer, forandringen kan ske. Vi er her for at støtte jer i at finde frem til realistiske mål og arbejdet med dem.

Vi motiveres til at handle, når vi oplever behov. En amerikansk psykolog Abraham Maslow har opstillet en behovspyramide, hvor behovene er inddelt i kategorier."

Kompendiet s. 4: Maslow's Behovspyramide

" Tænk på denne pyramide som en bygning. Fundamentet skal være i orden, før vi begynder at bygge op i højden. Sund mad og regelmæssig bevægelse de mest grundlæggende betingelser for vores velbefindende. De repræsenterer vores krops basale behov, som vi ofte overhører. Ved at se koblingen mellem det basale og livkvalitet på den lange bane får mennesker en naturlig motivation til at foretage det sundere valg. Nogle kalder det at leve bevidst. Og det er ikke ensbetydende med at leve kedeligt! Forløbet vil give jer praktiske tips og færdigheder, som jeg håber, vil være en spændende og sjov læring. Af hensyn til omfanget af det, vi skal igennem sammen: de generelle anbefalinger fortæller os om det minimum, vi alle bør gøre for os selv af hensyn til mad og bevægelse. Vi kan nok ikke få hele 'minimumprogrammet' på plads i dette forløb, men I vil nærme jer målet og lære princippet bag vaneændringer. Vi skal tage fat i simple dagligdags ting, som er nemmere at overkomme end avancerede træningsprogrammer og kostplaner som sætter høje krav til ens mentale, fysiske og økonomiske ressourcer. Når krav er komplicerede, bliver det vanskeligt at følge dem. Det er hele pointen med at ændre livsstil og blive ved – at finde den rette balance mellem krav og det, man selv forstå som livskvalitet. Små ændringer holder simpelt hen længere. I vil lære at vælge simpelt og tænke fundamentet! Hvis der er nogle der får behov for eller mod på decideret trænings- eller kostplan, er der andre professioner der skal tage over. Det må vi snakke nærmere om ved de individuelle samtaler."

1.3.2.1 Sunde spisevaner

Kompendiet s. 5: Fordele og ulemper ved at spise sundt

"Jeg vil gerne bede jer om at tage en whiteboard-marker og skrive på tavlen fordele ved at spise sundt til højre og ulemper til venstre. Alt som I hver især ser det.

(Alternativt kan deltagerne udfylde skemaet i kompendiet).

- Ergoterapeuten læser op

"Hvilke ulemper kan være sværest at stå imod? Hvad kan man vælge at prøve som en løsning?"

- Deltagerne reflekterer

Kompendiet s. 6: De 10 kostråd

"Fødevarestyrelsen anbefaler danskerne:

1. *At spise varieret, ikke for meget og være fysisk aktive*
2. *At spise frugt og mange grøntsager*
3. *At spise mere fisk*
4. *At vælge fuldkorn*
5. *At vælge maget kød og kødpålæg*
6. *At vælge magre mejeriprodukter*
7. *At spise mindre mættet fedt*
8. *At spise mindre salt*
9. *At spise mindre sukker*
10. *At drikke mere vand*

På hvilket punkt kan du med sikkerhed forbedre dine spisevaner? Skriv gerne ned."

- *Deltagerne noterer*

"Vi kigger på det igen ved vores individuelle samtale i uge 3. I kompendiet er der også et par links, I kan gå ind på og læse mere om emnet."

1.3.2.2 Regelmæssig bevægelse

Kompendiet s. 7: Fordele og ulemper ved at være fysisk aktiv

"Jeg vil gerne bede jer om at tage en whiteboard-marker og skrive på tavlen fordele ved at være fysisk aktiv til højre og ulemper til venstre, igen efter jeges eget synspunkt.
(Alternativt kan deltagerne udfylde skemaet i kompendiet).

- Ergoterapeuten læser op

"Hvilke ulemper kan være sværest at stå imod? Hvad kan man vælge at prøve som en løsning?"

- Deltagerne reflekterer

Kompendiet s. 8: Anbefalinger til fysisk aktivitet for voksne

"Figurerne illustrerer Sundhedsstyrelsens anbefaling om, at voksne mellem 18 og 64 år er fysisk aktive med moderat til høj intensitet i min. 30 min. om dagen. Almindelige daglige gøremål (fx en tur i Bilka eller en runde med støvsugeren) tæller ikke med her! Derudover skal der gerne suppleres med øvelser der styrker muskler og knogler et par gange om ugen. Anbefalingerne er, som sagt, skal betragtes som en retningslinje. Hvilke mål bliver der sat og i hvilket tempo udviklingen skal ske, bestemmer I selv."

1.3.3 Hjemmeopgaver

"Ud fra vores tidligere erfaringer ved vi, at tidligt i forløbet er det vigtigt at gøre status på, hvordan tingene fungerer i dag for at kende udgangspunktet. Derfor får I en slags dagbog med hjem - eller nærmere et afkrydsningsskema."

- *Ergoterapeuten udleverer skemaet*

"Fra i morgen af vil jeg bede jer om at notere status i forhold til daglig bevægelse og et kostråd (at drikke mere vand). I skal skrive ned det antal skridt og den mængde vand i ca. milliliter, som I når op til fra dag til dag. Læg skemaet et synligt sted, så det ikke bliver glemt. Vi kommer til at bruge skemaet ved vores telefoniske opfølgninger og gruppemøder. Så må gerne tage både kompendiet og skemaet med hver gang.

I får hver 4 flasker vand á ½ l. Mellem 3 og 4 flasker af denne størrelse er ca. mængden, som et menneske skal drikke dagligt. Vi har valgt at starte med vand, fordi væskeindtag er en af grundstenene for vores velbefindende. Væskemangel alene kan føre til øget smerteoplevelse, give hovedpine, svimmelhed og træthed. Derfor er det vigtigt at øge væskeindtag til et tilstrækkeligt niveau. Prøv at øve dig i at fylde flaskene op med friskt vand hver dag og drikke lidt ad gangen i løbet af dagen. Husk at tage en flaske med dér, hvor du er, så vandet altid er ved hånden. Giv ikke op, selvom du kan komme til at glemme det en enkelt gang! Det er stadig en øvelse – en lille men vigtig øvelse."

- *Ergoterapeuten udleverer vandflaskene*

"Husk, at I ikke skal prøve at nå til et bestemt niveau, dvs. I kan på ingen måde ikke lave fejl. Lige nu har vi fokus på jeres almindelig daglige niveau i forhold til vandindtag og bevægelse. Har I spørgsmål til hjemmeopgaven?"

1.3.4 Evalueringer

"I vil opleve, at vi vil bede jer om at udfylde evalueringsskemaer løbende. Dette er for at indsamle information der vil hjælpe os at forbedre behandlingen. Vil I være søde at krydse af på skemaet i forhold til evalueringspunkterne?"

- Deltageren evaluerer

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Evt. Actigraph-udstyr tømmes for data

Session 2. Telefonisk konsultation

Formål med sessionen:

Opfølgning på første gruppesession og habituelt niveau for vandindtag og daglig bevægelse.

Huskeliste:

Procesevaluering for sessionen

Arbejdsark til notater om målarbejde

Kompendie (kopi)

Evalueringsskemaer

Sessionens forløb:

2.1 Hvordan er det gået siden sidst?

Ergoterapeuten spørger ind til hjemmeopgaven – at undersøge det habituelle niveau for vandindtag og daglige skridt og skriver resultaterne ned på arbejdsarket.

2.1.1 Vandindtag

”*Hvor meget vand plejer du at drikke til dagligt?”*

”Har du prøvet at ændre dit vandindtag siden sidste gang? Hvad har der været nemt at ændre? Hvad har der været svært at ændre?”

2.1.2 Daglig bevægelse

”Hvilken form for fysisk aktivitet plejer du at dyrke i løbet af ugen? Hvor ofte? Med hvor høj intensitet?”

”Har du prøvet at ændre dit aktivitetsmønster i forhold til bevægelse siden sidste gang? Hvad har der været nemt at ændre? Hvad har der været svært at ændre?”

2.1.3 Dagbog

"Hvordan fungerer det med notater i dagbogen?"

- Ergoterapeuten vejleder i forhold til det afprøvede og føring af dagbog
  - Placering af vand fremme i synsfeltet
  - Dosering af vand, fx i mindre/ større flasker, glas, karaffel
  - Smagsgivere i vandet
  - Andet?
- Ergoterapeuten anerkender foreløbige resultater og informerer om, at egentlige mål bliver sat ved individuel samtale næste gang

2.2 Evaluering

Læs op for deltageren fra evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes status på målarbejdet noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 3. Målarbejde

Individuel konsultation (på sygehuset)

Formål med sessionen:

Formulering af kortsigtede mål i forhold til meningsfulde aktiviteter, spisevaner og daglig bevægelse

Huskeliste:

Procesevaluering for sessionen

Arbejdsark til notater om målarbejde

Kompendie (kopi)

Evalueringsskemaer

Book returkørsel med Flextrafik

Sessionens forløb:

3.1 Meningsfulde aktiviteter

3.1.1 Opfølgning på COPM-undersøgelse, identificerede livsværdier og erfaringer med 'flow'

"Til startundersøgelsen har du nævnt nogle aktivitetsproblematikker, du oplever i dag."

- Ergoterapeuten læser aktivitetsproblematikkerne op fra COPM-undersøgelsen

"Hvilke livsværdier har du skrevet ned sidst?"

"Hvilke aktiviteter har du tidligere oplevet 'flow' ved?

3.1.2 Langsigtet mål for meningsfulde aktiviteter

"*Hvilken af dine aktivitetsproblematikker skal først blive forbedret, så du oplever større livskvalitet/ god overensstemmelse med dine livsværdier / 'flow'-oplevelse?" (se deltagerens egne noter på s. 2 i kompendiet)*

"Hvordan skal det se ud med den (aktivitetsproblematik), når du har opnået den forbedring, du ønsker? Med andre ord, hvad er slutresultatet?"

”Lad os sige, det kalder vi målet på langt sigt.”

- *Ergoterapeuten skriver det langsigtede mål ned på arbejdsarket med deltagerens mål*

3.1.3 Kortsigtet mål for meningsfulde aktiviteter

Ergoterapeuten vejleder om specifik, målbar og realistisk målsætning og støtter formuleringen af kortsigtede mål.

”Hvad vil være dit første skridt på vej til slutresultatet, som kan du prøve af indtil næste gang, vi snakker sammen, i forhold til dette mål? *Lad os kalde det målet på kort sigt.”*

- Ergoterapeuten skriver det kortsigtede mål ned

  ”Hvordan vil du afprøve det? Hvor vil du starte henne? Hvor ofte vil du prøve? Hvornår vil det være - dag og tidspunkt?”
- Ergoterapeuten skriver deltagerens udsagn ned og opfordrer at notere aftalen i kompendiet

3.2 Spisevaner

”Hvilken af de 10 kostråd er det mest relevant for dig at arbejde med?” (se deltagerens egne noter på s. 5 i kompendiet)

”Hvad vil du afprøve indtil næste gang, vi taler sammen? Hvor vil du starte henne? Hvor ofte vil du prøve? Hvornår vil det være - dag og tidspunkt?”

- Ergoterapeuten skriver deltagerens udsagn ned og opfordrer at notere aftalen i kompendiet

3.3 Daglig bevægelse

”Hvilken form for bevægelse, synes du, er sjov?” (se deltagerens egne noter på s. 6 i kompendiet)

”Hvad vil du afprøve indtil næste gang, vi taler sammen? Hvor vil du starte henne? Hvor ofte vil du prøve? Hvornår vil det være - dag og tidspunkt?”

- Ergoterapeuten skriver deltagerens udsagn ned og opfordrer at notere aftalen i kompendiet

3.4 Evaluering

Deltageren udfylder evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes mål noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 4. Telefonisk konsultation

Formål med sessionen:

Opfølgning på målarbejdet med meningsfulde aktiviteter, spisevaner og daglig bevægelse.

Huskeliste:

Procesevaluering for sessionen

Arbejdsark til notater om målarbejde

Kompendie (kopi)

Evalueringsskemaer

Sessionens forløb:

4.1 Hvordan er det gået siden sidst?

4.1.1 Meningsfulde aktiviteter

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?”

4.1.2 Spisevaner

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?”

4.1.3 Daglig bevægelse

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?"

4.2 Dagbog

"Hvordan fungerer det med notater i dagbogen?"

- Ergoterapeuten vejleder i forhold til det afprøvede og føring af dagbog

4.3 Hjemmeopgave: ugeskema

"På s. 11 i kompendiet finder du et ugeskema, som vi skal bruge næste gang. Jeg vil bede dig at notere dine aktiviteter med start fra dagen i morgen. Du må gerne gruppere aktiviteter, når det giver mening, fx "bad" eller "morgenhygiejne" for tandbørstning, barbering og toiletbesøg om morgenen. Brug gerne stikord eller korte noter."

4.4 Evaluering

Læs op for deltageren fra evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes status på målarbejdet noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 5. Energibesparende principper og teknikker. Husførelse.

Gruppemøde i ergoterapien på Næstved sygehus

Formål med sessionen:

At øge deltagernes forståelse for vigtigheden af en effektiv energifordeling og brug af hensigtsmæssige energibesparende løsninger ved praktiske gøremål i løbet af dagen og ugen

Huskeliste:

Procesevaluering for sessionen

Kompendie (kopi)

Evalueringsskema

Evt. farveblyanter/ markeringstusser

Book returkørsel med Flextrafik

Sessionens forløb:

5.1 Opsamling på hjemmeopgaven: ugeskema

"Vi skal se på, hvad de energibesparende principper betyder i jeres egen hverdag. I har udfyldt et ugeskema med fordeling af aktiviteter over uge. Hvilke gøremål virker mest belastende på jer? Prioritér 1-2 konkrete opgaver. På hvilken måde belaster de jer?"

- Deltagerne deler erfaringer

"Skriv de mest belastende gøremål til dato ned på s. 12 i jeres kompendie. Vi tager lidt teori først, og derefter ser på, hvad kan der gøres for at minimere belastningerne".

5.2 Generelle energibesparende principper

"Hvad er energibesparende principper? Det er baggrundstankene ved udførelsen af de praktiske gøremål som har betydning for, hvordan man bevidst anvender sin energi. Det betyder ikke at man skal gøre mindre i løbet af dagen men at man er bevidst om hvordan man bruger sine kræfter og hvordan man udfører forskellige aktiviteter."

1. **Prioritering**

- Bliv bevidst om, hvilke ting du bruger tid og kræfter på
- Hvor meget energi kræver de forskellige aktiviteter?
- Hvad skal du gøre?
- Hvad ønsker du at gøre?
- Hvad forventer du af dig selv?
- Hvad oplever du, at andre forventer af dig?

2. Planlægning

- Planlægning kan gøre dig mere bevidst om, hvad du bruger kræfter på
- Brug din dagsform hensigtsmæssigt
- Del de tungeste og mest tidskrævende opgaver op
- Planlægning kan være vanskelig, når dagformen varierer

3. Tempo

- Kroppen skal lige i gang – start langsomt
- Arbejd i et moderat tempo med små pauser undervejs
- Brug hvilestillingerne

4. Arbejdsstillinger

- Skift arbejdsstilling
- Ret overkroppen – brug de store muskelgrupper
- Gode hvilestillinger
- Stående eller siddende?

5. Fysiske omgivelser

- Tilpasning og placering af udstyr
- Placering af dig selv i forhold til det du arbejder med
- Fysiske ændringer i egen bolig

6. Hjælpemidler

- Middel til at opnå selvstændighed i forhold til aktivitetsudførelse

- Middel til at spare på energi, fx sparer du ca. 25% energi på at sidde ned fremfor at stå op
- Middel til at optimere arbejdsstilling
- Middel til at mindske smerter

Pause - 10 min.

5.3 Videre arbejde med ugeskema

”Hvordan kan jeres mest belastende opgaver blive mindre belastende?”

- Deltagere reflekterer
- Ergoterapeuten supplerer med inddragelse af de specifikke energibesparende teknikker målrettet deltagernes aktivitetsproblematikker

”Notér ideerne til forbedringer på s. 12 i jeres kompendie. På forløbet får I mulighed for at afprøve relevante hjælpemidler. Hvis en hjælpemiddel vil vise sig at være nyttigt, hjælper vi gerne med at lave en ansøgning til hjemmekommunen om det. I må gerne allerede nu begynde at undersøge, hvordan er proceduren for hjælpemiddelansøgninger i jeres kommune (hvem kan kontaktes, skal der udskrives en blanket eller foregår det hele digitalt). Vi vil komme nærmere ind på det ved afslutningen på forløbet”.

5.4 Aftaler til næste session

”På baggrund af det i har lært om energibesparende principper og teknikker i dag og jeres ideer til forbedringer på s. 12 i kompendiet, hvilken lille ændring vil I hver især prøve af, inden vi taler sammen igen næste gang?”

- Deltagerne kommer med input

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes status på målarbejdet noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 6. Telefonisk konsultation

Formål med sessionen:

Opfølgning på arbejdet med energibesparende principper og målarbejdet med meningsfulde aktiviteter, spisevaner og daglig bevægelse.

Huskeliste:

Procesevaluering for sessionen

Arbejdsark til notater om målarbejde

Kompendie (kopi)

Evalueringsskemaer

Sessionens forløb:

2.1 Hvordan er det gået siden sidst?

Hvordan gik det med indførelsen af energibesparende principper og teknikker? (se deltagerens arbejdsark for konkret tiltag)

Hvilke tilpasninger skal der til for, at det fungerer? (ved behov)

Kunne du tænke dig at prøve mere/ andet i forhold til energibesparende principper og teknikker og de mål, du tidligere har sat?

6.1.1 Meningsfulde aktiviteter

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?”

6.1.2 Spisevaner

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?”

6.1.3 Daglig bevægelse

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?”

6.2 Dagbog

”Hvordan fungerer det med notater i dagbogen?”

- Ergoterapeuten vejleder i forhold til det afprøvede og føring af dagbog

6.3 Aftale om hjemmebesøg

”Hvad har du behov for, at vi kigger nærmere på nu?”

- Ergoterapeuten vurderer, på hvilken måde tilpasninger af egne omgivelser vil fremme deltagerens målarbejde.
- Tidspunktet for hjemmebesøg aftales

I undtagelsestilfælde: En individuel konsultation på sygehuset komme på tale som erstatning for hjemmebesøg.

6Aftale til næste gang

Deltageren mindes om, at til næste gang skal han/ hun have fastsiddende sko på med henblik på intensitetstesten ved gang

6.5 Evaluering

Læs op for deltageren fra evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes status på målarbejdet noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 7. Bevægelse og velvære

Gruppemøde i ergoterapien på Næstved sygehus

Formål med sessionen:

Formål med sessionen at få indblik i, hvad der menes med moderat intensitet ved fysik aktivitet, og lære simple afspændingsøvelser som kan udføres på egen hånd i hverdagen

Huskeliste:

Procesevaluering for sessionen

Kompendie (kopi)

Evalueringsskema

Minutur

Whiteboard marker

Adgang til visualiseringsvideo og skærm, hvor denne kan vises

Fitness måtter

Lændepuder

Tæpper

Book returkørsel med Flextrafik

Sessionens forløb:

7.1 Gåture

"Sundhedsstyrelsen anbefaler alle voksne at dyrke moderat fysisk aktivitet i 30 minutter de fleste ugedage. På vores forløb har vi valgt gåture som den bevægelsesaktivitet der bør prøves af først. Der er flere grunde til, hvorfor gåture er så fantastisk fællesnævner for flere:

- *Nemt at praktisere*
- *Kan dyrkes alene eller med andre*
- *Kan varieres på flere måder – længden, terrænet, intensiteten og tid på dagen*
- *Kræver minimum af udstyr - kun et par sko som sidder fast på foden*
- *Giver en masse sanseinput fra kontakten til naturen*
- *Kan give afgrænset social kontakt - mulighed for at hilse på andre uden behov for længere samtaler*

- *Fylder lungerne med frisk luft*
- *Fremmer produktionen af D-vitamin*

7.1.1 Moderat gangtempo - intensitetstest

Vi skal gå udenfor (eller ud på gangen) og lave en test for, hvad det betyder i praksis at gå med moderat hastighed? Jeg sætter jer i gang og holder øje med uret."

- Holdet går udenfor på et sted som er fri for forhindringer og udfører testen (1-2 deltagere ad gangen)

"Vi samler op, når vi er tilbage i vores lokale. (Tilbage i undervisningslokalet) Hastigheden ved gang har betydning for, om pulsen kommer op. Det moderate gangtempo som ligger ca. på 100 skridt i minuttet gør, at vi bliver lettere forpustet og får sved på panden. Dette er tegn på, at kondition bliver trænet, og vi får forebygget hjertekarsygdomme.

7.1.2 Øget mængde af bevægelse i dagligdagen

Alle har gavn af at øge mængden af fysisk aktivitet en smule op. Selvom ændringer ikke vil virke stor, vil den have store positive effekter som vil bedre humøret, hjælpe at forbrænde kalorier og forebygge sygdom. Princippet i målarbejdet her må være den samme – at lave én lille forandring som bringer den enkelte tættere på målet.
Nogle gange er det klogt at starte ikke med selve bevægelsesaktivitet men med det praktiske. Tempoet kan sagtens blive højere hvis der er skabt gode betingelser for stabilitet ved gang, fx:

- *Fodtøj sidder fast*
- *Ruten er fri for forhindringer (ikke skiftende terræn)*
- *Der anvendes hjælpemidler til at give stabilitet undervejs*

Andre vigtige opmærksomhedspunkter som bliver tit overset og bremser de gode intentioner:

- *Har I tøj og fodtøj klar, så I kan komme af sted ved forskellige vejrforhold?*
- *Har I udfordringer ved påklædning, så der er måske brug for hjælpemidler?*
- *Mangler der en skohorn som er lang nok for ikke at skulle bukke ned?*
- *Skal der stå en skammel at sidde på?*

- *Vil elastiske snørebånd gør det nemmere at snøre sko?*

"Hvilken lille forandring vil hjælpe jer at øge mængden af jeres bevægelsesaktivitet?"

- *Deltagerne reflekterer*
- *Ergoterapeuten noterer på deltagernes arbejdsark, hvilke tiltag de har valgt*

"Skriv gerne jeres idé ned på s. 23 i kompendiet og prøv den af frem til næste gang. Vi vender tilbage til snakken ved det næste telefonmøde."

Pause - 10 min.

7.2 Afspændingsøvelser som inspiration til pauser og hvile i hverdagen

"Et menneske har behov for en harmonisk fordeling over daglige aktiviteter, så der er plads både til at bruge energi, og genopfylde den. I denne del at vores gruppegang skal vi se nærmere på hvile og det der hjælper os at restituere.
For at hvile, er det nødvendigt at 'geare ned', det vil sige, det parasympatiske system (dem som er ansvarlig for afslapning) skal aktiveres. Kroniske smerter medfører ofte, at det er det modsatte system (sympatiske system som er vores alamberedskab der står for blandt andet 'kamp og flugt' reaktionerne) der dominerer. Ved at forstå, hvilke aktiviteter der fremmer og hæmmer parasympatiske mekanismer i kroppen som er ansvarlige for, at vi får slappet af og genopbygget energi, kan vi selv få indflydelse på kvaliteten af vores søvn og hvile, og livskvaliteten i den sidste ende."

7.2.1 Den firkantede vejrtrækning

"Jeg vil introducere jer til en kort øvelse der ofte har stor effekt og hjælper at opnå afslapning og velvære, men også at øge koncentration og samle energi til daglige gøremål. Øvelsen hedder 'Den firkantede vejrtrækning' og går selvsagt ud på kontrol over vejrtrækningen. Den hjælper at tilføre gode portioner ilt til indre organer og hjernen, og forebygger hyperventilation. Vi laver en lille praktisk test, inden vi går i gang."

- Ergoterapeuten deler små sedler (fx post-its) ud til deltagerne

"Til at starte med, tæl jeres deres puls i et minut og skriv tallet ned på sedlen."

- Ergoterapeuten tager tid
- Ergoterapeuten sikrer, at alle har skrevet deres tal ned
- Ergoterapeuten tegner en firkant på tavlen

"I skal følge linjen på følgende måde:

- *Trække vejret ind, mens I følger linjen fra den venstre nederste hjørne op langs siden på 4 (tæller 1-2-3-4);*
- *Holde pause, mens I fortsætter horisontalt på 2 (1-2);*
- *Puster ud, mens I kører ned igen på 4 (1-2-3-4);*
- *Holder pause, indtil vi er tilbage til start på 2 (1-2)*

Nogle vil synes, det er nemmest at sidde med lukkede øjne. Det må I også gerne, bare i holder rytmen med vejrtrækningen. Vi skal lave øvelsen i to minutter. Vi starter nu (holder øje med tiden)."

- Øvelsen fortsætter i 2 min.

"Tæl jeres puls en gang til. Har I fået forskellige tal?"

- Kort opsamling på øvelsen

"*Denne simple øvelse kan give jer velvære på meget kort tid. Selv ét minut kan give effekt. Øvelsen kan praktiseres i forskellige situationer – hjemme, på arbejde, i køen i supermarkedet. Hvis det virker godt med noget visuelt, som vi lige har prøvet, kan I bruge alle de ting i jeres omgivelser der passer i formen. Siddende stilling kan anbefales, da nogle gange kan man blive lidt svimmel. Dette er ikke farligt, men blot en reaktion på ilttilførslen. Svimmelhed vil hurtigt aftage igen. Den daglige situation, hvor I skal helst holde jer fra at praktisere øvelsen, er bilkørsel."*

7.2.2 Visualiseringsøvelse

"Vi slutter af med en form for afspænding der hedder visualisering – en forestillingsøvelse, en slags drøm om noget behageligt. Den type øvelser må gerne bruges inden sovetid til

aktivering af det parasympatiske system (afslapningssystemet). I må gerne selv bestemme, om I sidder eller ligger ned. I må gerne holde øjnene lukket, både for bedre koncentration, og af hensyn til de andre."

- Ergoterapeuten starter video med en visualiseringsøvelse med naturlyde (fx "En tur på stranden")

7.3 Evaluering

Deltageren udfylder evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes mål noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 8. Telefonisk konsultation

Formål med sessionen:

Opfølgning på inddragelse af afspændingsøvelser i dagligdagen og målarbejdet med meningsfulde aktiviteter, spisevaner og daglig bevægelse.

Huskeliste:

Procesevaluering for sessionen

Arbejdsark til notater om målarbejde

Kompendie (kopi)

Evalueringsskemaer

Sessionens forløb:

8.1 Hvordan er det gået siden sidst?

Hvordan gik det med indførelsen af afspændingsøvelser i hverdagen?

Hvilke tilpasninger skal der til for, at det fungerer? (ved behov)

Kunne du tænke dig at prøve mere/ andet i forhold til afspænding og de mål, du tidligere har sat?

8.1.1 Meningsfulde aktiviteter

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?”

8.1.2 Spisevaner

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?"

8.1.3 Daglig bevægelse

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?"

8.2 Dagbog

"Hvordan fungerer det med notater i dagbogen?"

- Ergoterapeuten vejleder i forhold til det afprøvede og føring af dagbog

8.3 Evaluering

Læs op for deltageren fra evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes status på målarbejdet noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 9. Måltider og spisevaner

Gruppemøde i ergoterapien på Næstved sygehus

Formål med sessionen:

Formål med sessionen er at reflektere over egen måde at forberede og gennemføre måltider, samt øge forståelsen for spisevanernes betydning for livskvalitet og evnen til at håndtere smerter. Sessionens praktiske indhold har formål at understøtte deltagerne i deres målarbejde i forhold til ændringen til sundere spisevaner.

Huskeliste:

Procesevaluering for sessionen

Kompendie (kopi)

Evalueringsskema

Hjælpemidler til køkkenarbejde

Book returkørsel med Flextrafik

Indkøb til fælles madlavning

Sessionens forløb:

9.1 Tilberedning, servering og spisning af et måltid, inkl. introduktion til små hjælpemidler

"I dag skal vi prøve at tilberede et sundt frokostmåltid, og vi afslutter med fælles spisning kl. ca. 11.20. I få mulighed for at afprøve forskellige hjælpemidler og arbejdsteknikker der vil støtte jer i tilberedningen af sunde måltider med mere grønt og fiberrigt indhold.
Når vi kommer ud i køkkenet, vil jeg præsentere arbejdsopgaverne, og I får I mulighed for at melde jer på."

9.1.1 Køkkenaktivitet i træningskøkkenet med ergoterapeut: tilberedning af et sundt frokostmåltid og oprydning. Afprøvning af små hjælpemidler.

Ergoterapeuten præsenterer og fordeler arbejdsopgaverne mellem deltagerne.

1. Grøn salat – 1-2 deltagere
2. Alternativer til brød med pålæg – 1-2 deltagere
3. Frugtsalat med 2 slags topping – 2 deltagere

Pause – 10 min.

9.1.2 Køkkenaktivitet i træningskøkkenet med ergoterapeut: borddækning, fælles spisning, oprydning og opsamling på dagen - 45 min.

9.1.2.1 Tallerkenmodeller

Ergoterapeuten præsenterer Y og T-tallerkenmodel for deltagerne.

Y-tallerkenmodel (modellen til vedligeholdelse af vægt)

1/5 kød, fisk osv. (protein)
2/5 grøntsager
2/5 kartofler/ pasta/ brød (stivelse)

T-tallerkenmodel (eller Slanketallerkenmodel)

1/4 kød, fisk osv. (protein)
1/2 grøntsager
1/4 kartofler/ pasta/ brød (stivelse)

9.1.2.2 Andre gode råd om servering af mad og spisning

”Lad mig vise jer, hvad tallerkens størrelse betyder for vores spisevaner. Med den simple trick kan man forebygge overspisning. Tricket består i at vælge en mindre tallerken.”

- Ergoterapeuten demonstrerer ved at servere samme mængde salat eller anden ret (afmålt med målebæger eller køkkenvægt) på to tallerkener af forskellig størrelse

” I vil finde flere tips om spisning og servering af mad i jeres kompendie på s. 25-27.”

9.1.3 Opsamling på dagen

”Hvilke positive ændringer har I kunnet mærke siden der blev sat fokus på sundere spisevaner?”

- Deltagerne reflekterer

"Er der en mindre ændring i forhold til spisevaner I hver især vil prøve af, indtil vi ses igen næste gang?"

- Deltagerne fortæller, ergoterapeuten noterer på arbejdsark

9.1.4 Evaluering

Deltageren udfylder evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes mål noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 10. Telefonisk konsultation

Formål med sessionen:

Opfølgning på målarbejdet med meningsfulde aktiviteter, spisevaner og daglig bevægelse og inddragelse af små hjælpemidler, samt råd om madlavning og spisning i dagligdagen.

Huskeliste:

Procesevaluering for sessionen

Arbejdsark til notater om målarbejde

Kompendie (kopi)

Evalueringsskemaer

Sessionens forløb:

10.1 Hvordan er det gået siden sidst?

Hvordan gik det med indførelsen af den nye viden om madlavning og spisevaner i hverdagen?

Hvilke tilpasninger skal der til for, at det fungerer? (ved behov)

Kunne du tænke dig at prøve mere/ andet i forhold til madlavning og spisevaner og de mål, du tidligere har sat?

10.1.1 Meningsfulde aktiviteter

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?”

10.1.2 Spisevaner

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?"

10.1.3 Daglig bevægelse

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?"

10.2 Dagbog

"Hvordan fungerer det med notater i dagbogen?"

- Ergoterapeuten vejleder i forhold til det afprøvede og føring af dagbog

10.3 Evaluering

Læs op for deltageren fra evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes status på målarbejdet noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 11. Hjemmebesøg, individuelt

Individuelt møde i deltagerens eget hjem (hvis hjemmebesøg ikke er muligt, planlægges mødet som konsultation på sygehuset)

Formål med sessionen:

Formål med sessionen er at motivere til videre målarbejde og foretage nødvendige justeringer i egne omgivelser i forhold til de personlige mål.

Huskeliste:

Procesevaluering for sessionen

Kompendie (kopi)

Arbejdsark for deltagerens mål

Evalueringsskema

Evt. hjælpemidler relevante for den konkrete deltager

Sessionens forløb:

11.1 Vurdering af egne omgivelser ud fra deres understøttende egenskaber for deltagerens mål

"På forløbet har du arbejdet med meningsfulde aktiviteter, spisevaner og regelmæssig bevægelse (konkrete aktuelle mål for deltageren nævnes).

11.1.1 Hvordan kan dine fysiske og sociale omgivelser i hjemmet, efter din mening, understøtte dit arbejde med meningsfulde aktiviteter?

- Er der behov for at finde mere ergonomiske løsninger ved egenomsorgsaktiviteter (fx på badeværelset), produktivitet (fx husholdningsopgaver og køkkenarbejde) eller fritid (fx seng og den vante hvileplads).
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgangskreds som støtte til målarbejdet?

11.1.2 Hvordan kan dine fysiske og sociale omgivelser i hjemmet, efter din mening, understøtte dit arbejde med spisevaner?

- Er der behov for at finde mere ergonomiske løsninger ved i forhold til indkøb, madlavning og spisning?
- Er der behov for hjælpemidler?
- Er der behov for nudging til bedre vedholdenhed i forhold til sunde spisevaner?
- Er der behov for involvering af omgangskreds som støtte til målarbejdet?

11.1.1 Hvordan kan dine fysiske og sociale omgivelser i hjemmet, efter din mening, understøtte dit arbejde med regelmæssig bevægelse?

- Er der behov for at finde mere ergonomiske løsninger i forhold til påklædning før gåture, valg af egnet plads til hjemmeøvelser hjælp til at finde andre motionstilbud i lokalområdet?
- Er der behov for hjælpemidler?
- Er der behov for nudging til bedre vedholdenhed i forhold til fysisk aktivitet?
- Er der behov for involvering af omgangskreds som støtte til målarbejdet?

11.2 Evaluering

Deltageren udfylder evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes status på målarbejdet noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 12. Telefonisk konsultation

Formål med sessionen:

Opfølgning på målarbejdet med meningsfulde aktiviteter, spisevaner og daglig bevægelse og inddragelse af egen omgivelser i målarbejdet

Huskeliste:

Procesevaluering for sessionen

Arbejdsark til notater om målarbejde

Kompendie (kopi)

Evalueringsskemaer

Sessionens forløb:

10.1 Hvordan er det gået siden sidst?

Hvor godt føler du, dine fysiske og sociale omgivelser understøtter dit målarbejde?

Hvilke tilpasninger skal der til for, at det fungerer? (ved behov)

Kunne du tænke dig at prøve mere/ andet i forhold til tilpasning af egne omgivelser?

12.1.1 Meningsfulde aktiviteter

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?”

12.1.2 Spisevaner

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?"

12.1.3 Daglig bevægelse

Eksempler på opfølgningsspørgsmål:

- Hvad har været nemt/ svært?
- Er der behov for tilpasning af målet?
- Er der behov for hjælpemidler?
- Er der behov for involvering af omgivelserne i eget hjem og omgangskreds?
- Er der behov for involvering af andre fagpersoner?"

12.2 Dagbog

"Hvordan fungerer det med notater i dagbogen?"

- Ergoterapeuten vejleder i forhold til det afprøvede og føring af dagbog

12.3 Evaluering

Læs op for deltageren fra evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes status på målarbejdet noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 13. Køkkenindretning, opbevaring af mad og indkøb

Gruppemøde i ergoterapien på Næstved sygehus

Formål med sessionen:

Formål med sessionen er at motivere deltagere til forsat refleksion over én måde at håndtere aktiviteter forbundet med valg, indkøb, tilberedning og opbevaring af mad.

Huskeliste:

Procesevaluering for sessionen

Kompendie (kopi)

Evalueringsskema

Book returkørsel med Flextrafik

Indkøb til analyse af varedeklarationer

Sessionens forløb:

13.1 Nudging i køkkenet og opbevaring af mad

"Vi har tidligere kigget på ergonomi i køkkenet, arbejdsstillinger og hjælpemidler til skrælle, skære og snitteopgaver. Der er flere ting som kan hjælpe én at foretage et sundere valg, bl.a. hvor og hvordan maden bliver opbevaret. Disse råd kan I også finde i jeres kompendie på s. 31:

Placér den sunde mad i øjenhøjde

Fordi: Der er 30% større chance for at ting placeret i øjenhøjde bliver valgt

Byt om på køleskabsindholdet, fx sæt syltetøj ned i grøntsagskuffen og grøntsager højere op

Fordi: Det bliver nemmere at vælge grønt

Lad maden ikke stå fremme

Fordi: Vi bliver unødvendigt fristet ved synet af mad

Pak sunde retter i husholdningsfilm frem for stanniol

Fordi: Det, vi hurtigt kan få øje på, bliver oftest vores første valg

Det som ikke skal friste skal i uigennemsigtige beholdere og væk fra synsfeltet

Fordi: Det hjælper at undgåfristelser

Ompak store poser til mindre portioner

Fordi:

- Jo større emballage, jo mere forbruger vi
- Tilfredshed er den samme, om vi får et lille bid eller en hel pose
- Det er de første få mundfulde der gør forskel, ikke resten

Stil kalorieholdige madvarer og drikke ud i skuret/ på de øverste hylder eller andet svært tilgængeligt sted

Fordi: svært tilgængelige ting tiltrækker mindre

13.2 Idéer til opbevaring af mad i egne omgivelser

”Nogle vil måske sige, at det nemmeste er ikke at købe usund mad. Men evidensen siger, at forbud kan gøre, at sunde livsstilsændringer ikke holder ret længe. Derfor er set sikrere at satse på små nemme forandringer. Åbn skemaet på s. 32 i kompendiet og skriv kort idéer til små forandringer hjemme hos jer selv, i jeres eget køleskab og køkken. Vi tager punkterne en ad gangen og deler tankerne med hinanden efter hvert punkt.”

1. *”Hvad i dit køleskab skal stå i øjenhøjde?”*
- Deltagerne reflekterer i plenum

2. *”Hvad i dit køleskab skal væk fra synet?”*
- Deltagerne reflekterer i plenum

3. *”Har du mad stående fremme? Hvilken type mad? Hvor kan den opbevares i stedet?”*
- Deltagerne reflekterer i plenum

4. *"Hvad skal pakkes ind i husholdningsfilm? Hvad skal ind i helst ikke-gennemsigtig beholder?"*

- Deltagerne reflekterer i plenum

5. *"Hvilke madvarer kan du ompakke i mindre portioner for at minimere forbrug?"*

- Deltagerne reflekterer i plenum

6. *"Hvilke madvarer skal helt ud i skuret (andet længst placeret sted)?"*

- Deltagerne reflekterer i plenum

13.3 Indkøb og næringsdeklarationer

"På s. 33 i kompendiet vil I finde gode råd til indkøbsture, så usunde valg bliver sværere at træffe. Men nu skal vi have fokus på valg af madvarer ud fra fødevaremærker og næringsdeklarationer."

13.3.1 Fødevaremærker: quiz "10 hurtige om Nøglehulsmærke: Hvilke udsagn passer?"

"På s. 34 finder i Nøglehulsmærkequiz. Brug lige et par minutter på at sætte kryds ved de korrekte svar".

- Deltagerne laver quizzen

"Nu vil jeg gennemgå svarene:

1. *___ Nøglehulsmærket tildeles kun økologiske madvarer (Nej, der sættes Ø-mærket på de økologiske madvarer)*
2. *___ Nøglehulsmærket betyder bæredygtig produktion (Nej, det fortæller ikke noget om produktionen)*
3. *___ Kun Nøglehulsmærket hjælper at skelne de sunde madvarer fra de usunde (Nej, der findes andre mærker, fx Fuldkornsmærket)*
4. *___ I nøglehulsmærkede mad er der max mulig mængde fuldkorn ((Nej, den slags mærkes med Fuldkornsmærket)*

5. *___ Nøglehulsmærket betyder mindre fedt sukker og salt, samt flere fuldkorn (Korrekt)*
6. *___ Nøglehulsmærket betyder et sundere valg inden for en bestemt varegruppe (Korrekt)*
7. *___ Nøglehulsmærket er Miljø- og Fødevareministeriets officielle ernæringsmærke (Korrekt)*
8. *___ Nøglehulsmærkede mad er mest for dem der har diabetes (Nej, Nøglehulsmærket har ikke noget med specialkost at gøre)*
9. *___ Nøglehulsmærke er fælles nordisk ernæringsmærke (Korrekt)*
10. *___ Man skal gå efter den grønne Nøglehulsmærke, den sorte er knap så god (Nej, farven har ingen betydning)*

Hvor mange korrekte svar har I fået?"

- *Deltagerne svarer*

"Kendskab til fødevaremærker kan spare tid og overskud på indkøbsture. Der er tre statslige fødevaremærker - Nøglehulsmærket, Fuldkornsmærket og Ø-mærket. Bag disse mærker står der stærkeste undersøgelser og kvalitetstest. Hvis I er i tvivl, hvilken vare er til at foretrække, vælg den med nøglehulsmærket eller de to andre, hvis I går efter fuldkorn og økologi!
Mærker fra forskellige organisationer som Dyrenes Beskyttelse, Astma-Allergi Forbundet, Fair Trade er ikke nødvendigvis mindre gode end de statslige mærker, men deres krav til produktet er knap så reglementerede.
Producenternes egne ernæringsmærker, fx Kellogs og Nestlé, har markedsføring som formål. Deres krav er endnu sværere at gennemskue."

Pause – 10 min.

(Ergoterapeuten henter et udvalg af madvarer til analyse af varedeklarationer fra køkkenet).

13.3.2 Næringsdeklarationer

"Næringsdeklaration er listen med ingredienser der er i maden. Den første ingrediens på listen er der mest af i den pågældende vare. Jo længere ned på listen er en ingrediens, jo mindre af den der er i denne vare.

"Energi- og næringsindholdet står angivet for 100 g/ 100 ml eller 1 portion af produktet. OBS på, hvor mange gram en portion er målt til (det er ikke sikkert, at mængden passer med det, du plejer at spise!) Energibehovet for en gennemsnitsdansker er ca. 2000 kcal for kvinder og 2500 kcal for mænd.
Anbefalingerne for fordelingen og mængden af fedt, kulhydrat og protein i det daglige energiindtag er: Kulhydrat - 45-60 %; Protein -10-20 %; Fedt - 25-40 %. Vær opmærksom på, at 1 gram fedt giver dobbelt så meget energi som 1 gram protein eller 1 gram kulhydrat. Selvom fedtholdige produkter som olie, mayonnaise osv. har højt kalorieindhold, bliver der typisk brugt lidt af dem.

Kostfiberindholdet viser, hvor groft produktet er. Kostfibre gavner fordøjelsen og forlænger mæthedsfølelsen. Fuldkornsmærkede produkter er rige på kostfibre. Betegnelsen "grov" giver derimod ikke automatisk garanti for, at der er højt indhold af kostfibre i produktet.

Allergener fremhæves med fed skrift eller blokbogstaver. Allergenerne er fx mælk, nødder, æg, hvedemel.

Tilsætningsstoffer (eller E-numre) tilfører maden mere farve, smag eller bedre konsistens. De kan både være naturlige og kemisk fremstillede. Hvis der ikke er E-numre i varedeklarationen, betyder det ikke, at der ikke er tilsætningsstoffer (fx kaldes E-300 citronsyre).

Mættet fedt, salt og sukker skal gerne holdes på et minimum. For højt indhold af disse i kosten kan føre til udvikling af kroniske tilstande.
Det mættede fedt findes i kød, smør, mælk og ost m.m. Mættet fedt kan føre til forhøjet kolesterol og udvikling ag hjerte-karsygdomme.

Salt bliver også angivet som Natrium (1g natrium = 2,5 gram salt). For stort indtag af salt påvirker blodtrykket. Jo mindre salt der tilsættes maden, jo bedre. Den maksimale daglige norm er 5-6 gram salt.
Sukker giver en hurtig energitilførsel og kortvarig lykkefølelse, hvor effekten forsvinder igen efter kort tid. Svingninger i blodsukkeret på baggrund af sukkerindtag kan føre til træthed, humørsvingninger og livsstilssygdomme. Der anbefales at spise så lidt tilsat sikker som muligt og max 50 g tilsat sukker om dagen for kvinder og 60 g – for mænd.

Light produkter bliver ofte tilsat stivelse for at bibeholde den gode konsistens, når sukker og fedt bliver fjernet (fx i yoghurt mm.) Stivelse og sukker har samme kaloriemængde, derfor er det ikke garanteret, at light-produkter vil give et lavere kalorieindtag.

Holdbarhedsdato ("Mindst holdbar til"/ "bedst før") angiver datoen, hvor produktet bevarer den rapporterede kvalitet. Produktet skal ikke nødvendigvis smides ud efter denne dato, men man skal vær opmærksom på dens smag, duft og farve og smide for gammel mad ud.
Sidste anvendelsesdato er derimod den frist, hvor maden han gøre dig dårlig, hvis den bliver spist efter datoen.

13.4 Evaluering

Deltageren udfylder evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes
Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form
Deltagernes status på målarbejdet noteres på arbejdsarket
Deltagelse/ fravær dokumenteres
Mono- og tværfaglig sparring opsøges efter behov

Session 14. Telefonisk konsultation

Formål med sessionen:

Afsluttende evaluering på målarbejdet med meningsfulde aktiviteter, spisevaner og daglig bevægelse, forberedelse til opsamling på gruppemødet

Huskeliste:

Procesevaluering for sessionen

Arbejdsark til notater om målarbejde

Kompendie (kopi)

Evalueringsskemaer

Sessionens forløb:

14.1 Den personlige fortælling

”På det fælles afslutningsmøde tager vi en runde, hvor I opsummerer hver især, hvordan I er kommet igennem forløbet – jeres historie om forandring. Vi tager de hverdagsområder, som I allerede kender fra tidligere - ’Egenomsorg’, ’Arbejde’, ’Fritid’ og Søvn/ Hvile’. Vi skal se på inspirationsarket i kompendiet på s. 39 og samle op på resultaterne.

- Ergoterapeuten spørger om, hvad deltagerens fortælling om forandring i relation til aktivitetsområderne i inspirationsarket vil indeholde. Stikord til fortællingen skrives ned.

14.1.1 Egenomsorg

”Hvilken forandring er der sket i forløbet i det, du gør for at passe på dig selv, og hvad du har brug for, for at møde livet?”

14.1.2 Arbejde/ produktivitet

”Hvilken forandring er der sket i forløbet i det, du skal gøre, fordi du føler dig forpligtet til at gøre det, eller fordi det er nødvendigt at gøre?”

14.1.3 Fritid

"Hvilken forandring er der sket i forløbet i det, du gør at lyst, for sjov eller af interesse?"

14.1.4 Søvn og hvile

" Hvilken forandring er der sket i forløbet omkring sin søvn- og hvilerutiner?"

14.2 Hjælpemiddelansøgning

Behov for yderligere afprøvning af relevante hjælpemidler eller hjælp med en hjælpemiddelansøgning til hjemmekommunen drøftes.

14.3 AMPS re-test aftale

To aktiviteter til follow-up undersøgelsen vælges i samarbejde med deltageren.

14.4 Dagbog-data til forskning

"Vil det være OK med dig, hvis vi tager en kopi af din dagbog til målarbejde?"

- *Patienten oplyser om muligheden for at få et blankt eksemplar til videre målarbejde*

12.3 Evaluering

Læs op for deltageren fra evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes status på målarbejdet noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

Session 15. Afslutning

Gruppemøde i ergoterapien på Næstved sygehus

Formål med sessionen:

Formål med sessionen er at evaluere og afslutte det ergoterapeutiske forløb.

Huskeliste:

Procesevaluering for sessionen

Kompendie (kopi)

Evalueringsskema

Book returkørsel med Flextrafik

Sessionens forløb:

15.1 Status på personlige mål

"Hvordan har I oplevet progression i forløbet fra første erfaringer med at blive opmærksom på aktiviteter der giver mening i jeres hverdag, bevægelsesaktivitet og spisevaner til nu? Hvilke successer og udfordringer har der været i forløbet? Hvilke fremtidige planer om forbedring af livskvaliteten har hver enkelte deltager?"

- Deltagerne fremlægger sin personlige fortælling for hinanden.

15.2 Evaluering af forløb

Deltageren udfylder evalueringsskema for sessionen. Skriv, hvilken session der evalueres på.

Efter sessionen:

Procesevalueringsskema udfyldes

Kommentarer fra deltagerne nederst på procesevalueringsskemaet noteres i fri form

Deltagernes mål noteres på arbejdsarket

Deltagelse/ fravær dokumenteres

Mono- og tværfaglig sparring opsøges efter behov

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Supplementary file 2

Poster, Occupational Science Europe Conference: Europe in Transition, Amsterdam, September 2019

Redesign your Everyday Activities and Lifestyle with Occupational Therapy [REVEAL (OT)]

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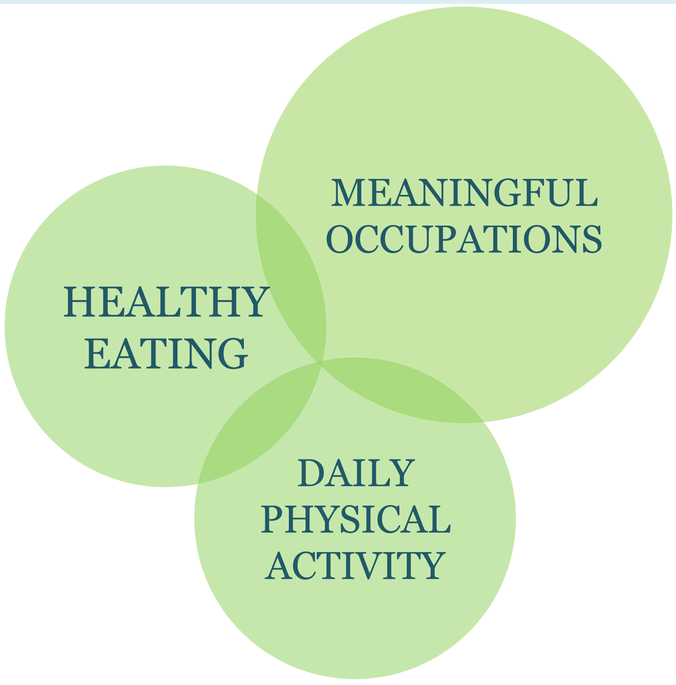
AIM

To investigate the effectiveness of a lifestyle-oriented occupational therapy intervention added to a multidisciplinary treatment for adults with chronic non-malignant pain



INTERVENTION METHODS

- **Education**
- **Group discussion**
- **Personal reflection**
- **Skill training**

INTERVENTION OUTCOMES

- **Quality of life**
- **Occupational performance**
- **Occupational Balance**
- **Pain self-efficacy**
- **Lifestyle-related anthropometrics**

INTRODUCTION

Chronic pain is a significant health issue that calls for proper non-pharmacological treatment alternatives, e.g. lifestyle interventions. Previous occupational therapy research showed the potential of occupational therapy in lifestyle management of chronic conditions. However, the effectiveness of an occupational therapy lifestyle intervention in the treatment of chronic non-malignant pain still needs further investigation.

METHODS

The two-arm RCT will randomize outpatients (n=228) to either a lifestyle-oriented occupational therapy intervention added to other multidisciplinary treatment, or the other multidisciplinary treatment only. The intervention group is hypothesized to improve treatment outcomes significantly one year after intervention start (primary endpoint). Prior to the RCT, a feasibility study will be conducted to inform the design and the implementation of the RCT.

The authors have no conflicts of interests

AVAILABILITY OF THE RESULTS

Study results will be available ultimo 2019.
For more information please see ClinicalTrials.gov (NCT03903900) or scan the QR code.

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REGION ZEALAND

SDU University of Southern Denmark

ERGOTERAPEUT FORENINGEN

PROgrez

Supplementary file 3

Conference abstract (poster), Region Zealand Research Day 2019, Nykøbing Falster, September 2019

Abstract

Research Day, Region Zealand, September 18 2019

Abstract describing a research project in Region Zealand, including at least preliminary results.
Times New Roman | Size 12 | Max 2 A4 pages | in English | deadline August 1, 2019
Please submit to: saabi@regionsjaelland.dk

Title:
Lifestyle-oriented occupational therapy intervention for patients with chronic non-malignant pain – A randomized controlled trial (Ergoterapeutisk livsstilsintervention til patienter med kroniske non-maligne smerter - et randomiseret kontrolleret forsøg)

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Place where the project is carried out: *Hospital, department*
Dept. for Physioterapy and Occupational Therapy, Slagelse Hospital in collaboration with Occupational Therapy Dept. at Naestved Hospital and The Multidisciplinary Pain Centre at Naestved Hospital

Status: *ongoing / planned completion / completed*
Ongoing

Purpose and Background:
The study aims to investigate the effectiveness of a lifestyle-oriented Occupational Therapy intervention in adults with chronic non-malignant pain. Chronic pain is a significant health issue that calls for proper non-pharmacological treatment alternatives. Current evidence suggests that the bio-psychosocial approach delivered by multidisciplinary teams is the most effective, and potentially cost-effective in the longer term, in the treatment of chronic non-malignant pain. However, evidence is still missing on the optimal treatment composition, dose and duration, as well as the effectiveness of the particular treatment components in different patient subgroups. Some treatment approaches have not yet been sufficiently tested, e.g. lifestyle interventions. The need for improvement in lifestyle among individuals with chronic non-malignant pain has been underpinned. Previous Occupational Therapy research in lifestyle management showed the potential of Occupational Therapy. However, the effectiveness of an Occupational Therapy lifestyle intervention in the treatment of chronic non-malignant pain still needs further investigation.
The randomized controlled trial (RCT) will bring new evidence on the effectiveness of a lifestyle-oriented intervention to chronic non-malignant pain and describe the contribution of Occupational Therapy. The lifestyle-oriented Occupational Therapy intervention is expected to enhance the resilience, adaptivity and flexibility towards societal transformations among the participants who will learn how to practice value-based self-management of occupations in their everyday life.

Material and Methods:
The two-arm RCT will randomize outpatients (n=228) referred to the Multidisciplinary Pain Center (MPC), Zealand, Denmark, to either a lifestyle-oriented intervention added to the current multidisciplinary treatment at the MPC, or the current treatment only. Initially, a feasibility study among the outpatients (n=24) will be conducted to inform the RCT. Differences in change in the primary outcome (Quality of life, EQ-5D-5L) and secondary outcomes (occupational performance, occupational balance, meaningful activity participation, pain self-efficacy and lifestyle-related anthropometrics) between the groups will be analyzed by repeated measures mixed model from baseline to 12, 24 and 52 weeks. Primary endpoint for the study will be 52 weeks from baseline.
ClinicalTrials.gov Identifier: NCT03903900 – "Redesign of Everyday Activities and Lifestyle with Occupational Therapy for Chronic Pain Patients (REVEAL (OT)"

Results:
Preliminary results from the feasibility study will be available to present at Research Day, Region Zealand, since the half of the participants will be through the feasibility study by that time.

Discussion and Conclusion:
The ongoing feasibility study has been an important step in the development of the future RCT. The feasibility study has already given the research group plenty of new knowledge and experience, e.g. highlighted the necessity of a qualitative follow-up to support the forthcoming quantitative results. The new knowledge would be relevant to implement in the future study process.

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Funding:
Naestved, Slagelse and Ringsted Hospitals' Research Funds and The Danish Association of Occupational therapists

Please indicate if you are interested in oral presentation, poster participation, or both.

	Mark with Y=yes, N=no
Oral presentation only	N
Poster exhibition only	Y
Both oral presentation and poster exhibition	N

Supplementary file 4

Conference abstract (oral), Region Zealand Research Day 2019, Holbæk, September 2021 (A)

Abstract

Research Day, Region Zealand, September 15 2021

Abstract describing a research project in Region Zealand, including at least preliminary results.Times New Roman | Size 12 | Max 2 A4 pages | in Danish or English |deadline June 25, 2021 Please submit to: hol-forsk-hus@regionsjaelland.dk

Title: Associations of health-related quality of life with sociodemographic characteristics, health, pain, and lifestyle and motivation for changing lifestyle in adults living with chronic pain: a cross-sectional study [Research project SJ-703: Lifestyle-oriented occupational therapy intervention for patients with chronic non-malignant pain]

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Place where the project is carried out: *Hospital, department*

Naestved Hospital (The Multidisciplinary Pain Center)

Status: *ongoing / completed*

Completed

Purpose and Background: Recent evidence highlights the need for comprehensive non-pharmacological interventions aimed at multiple lifestyle factors to prevent chronicity in people living with chronic pain. Lifestyle factors, such as physical activity, physical fitness, healthy eating, Body Mass Index (BMI), tobacco and alcohol consumption, sleep quality, and stress, are considered modifiable and relevant for lifestyle management of chronic pain. However, healthcare interventions can also approach lifestyle by targeting everyday human activities and interpreting lifestyle as the way of living based on habitual occupational choices and routines regarding such life areas as physical activity, eating, and sleeping. Occupational therapists can improve health and well-being in self-care, work and leisure in people living with chronic pain by assisting them to a more balanced occupational performance and participation in daily activities while taking current recommendations on a healthy lifestyle into consideration. Considering lifestyle from an occupational therapy perspective may broaden the focus in lifestyle interventions from improving metabolic health to overall well-being and quality of life. Health-related quality of life (HRQoL) has been considered a relevant effect measure in chronic pain interventions because of its ability to capture the overall improvement in health and well-being, despite possible fluctuations in the self-perceived

HRQoL in specific life areas. To inform the development of a lifestyle occupational therapy intervention (REVEAL (OT)) for adults living with chronic pain referred to a Danish pain center, we wanted to investigate how their HRQoL is associated with sociodemographic characteristics, health, pain, lifestyle and motivation for changing lifestyle.

Material and Methods: A total of 144 outpatients completed a questionnaire on HRQoL (EQ-5D-5L), health, pain, physical activity, physical fitness, healthy eating, Body Mass Index (BMI), tobacco and alcohol consumption, sleep quality, stress, and motivation for lifestyle changes. We used multiple linear regression analyses to assess associations between HRQoL and the independent variables.

Results: The participants had a mean age of 50 years, 81% were females, 93% had ≥2 body pain sites, 64% had a BMI≥25, and 43% had a sedentary lifestyle. In the participants, 58% had multiple (n≥2) elevated metabolic risk factors, 72% considered lifestyle important for HRQoL, and 92% expressed moderate to very high motivation for changing lifestyle. Poorer HRQoL in the study population was significantly associated with higher pain intensity in the most painful body site (ß=-0.316, *P*=0.001) and very poor sleep quality (ß=-0.410, *P*=0.024). Serious-to-extreme problems in usual activities were associated with significantly poorer health (ß=-0.328, *P*=0.030).

Discussion and Conclusion: Elevated pain intensity and poor sleep quality were associated with a poorer self-evaluated HRQoL, and severe-to-extreme difficulties in usual activities, such as work, study, housework, family, and leisure, were associated with poorer general health in adults living with chronic pain. We observed high frequencies of overweight, obesity, and sedentary lifestyle in the study population. Although suffering from pain in multiple body sites and multiple lifestyle-related risk factors, most adults living with chronic pain found lifestyle important for having satisfactory HRQoL and were highly motivated for improving their lifestyle. Further research aiming at pain alleviation, sleep quality, usual activities, and lifestyle in adults living with chronic pain is needed.

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Funding:
Lokal Research Fund, Naestved, Slagelse & Ringsted Hospitals
Region Zealand Health Science Research Fondation
The University of Southern Denmark
The Danish Occupational Therapy Association

Please indicate if you are interested in oral presentation or poster participation or bothOral (virtual) presentation, 7 min ☐
Poster (virtual) only, 2 min ☒

- After a review procedure, 8 abstracts will be selected for oral presentation. The oral presentation is virtual, lasting max 7 minutes followed by 2 minutes for a quick q & a.
- All authors, who have their abstract accepted for a poster presentation, will be asked to produce a presentation of their study/project in the format of two PowerPoint slides including 2 minutes speech and if possible video. Further instructions for this will follow indue time.

Please note the following deadlines:
Abstract submission: June 25, 2021 – Response in your mail by July 10, 2021
Pp-slides submission: August 10, 2021

Supplementary file 5

Conference abstract (oral), Region Zealand Research Day 2019, Holbæk, September 2021 (online) (B)

Abstract

Research Day, Region Zealand, September 15 2021

Abstract describing a research project in Region Zealand, including at least preliminary results.Times New Roman | Size 12 | Max 2 A4 pages | in Danish or English |deadline June 25, 2021 Please submit to: hol-forsk-hus@regionsjaelland.dk

Title: Quantitative and qualitative feasibility evaluation of a lifestyle-oriented occupational therapy intervention REVEAL(OT) for patients with chronic non-malignant pain [Research project SJ-703: Lifestyle-oriented occupational therapy intervention for patients with chronic non-malignant pain]

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Jeanette Reffstrup Christensen, PhD, main supervisor, University of Southern Denmark, jrchristensen@health.sdu.dk

Place where the project is carried out: *Hospital, department*
Naestved Hospital (Occupational therapy unit & the Multidisciplinary Pain Centre)

Status: *ongoing / completed*
Ongoing

Purpose and Background: Comprehensive interventions addressing daily activities and lifestyle seem to be relevant and needed in people living with chronic pain. Previous research showed the potential of occupational therapy in lifestyle management. However, the impact of lifestyle-oriented occupational therapy on chronic pain population still needs investigation. Occupational therapy intervention REVEAL(OT) [Redesign your EVEryday Activities and Lifestyle with Occupational Therapy] targeting occupational performance, physical activity and eating habits was developed and added to multidisciplinary cognitive-behavioural therapy-based treatment at a Danish pain center. Neither occupational therapy nor lifestyle management was included in the current treatment before. Thus, to inform a future randomized controlled trial, the REVEAL(OT) was evaluated and tested for feasibility.

Material and Methods:
A total of 40 outpatients (≥18<65 years old, 34 females) with chronic pain≥3 months were divided into eight groups and participated in a lifestyle-oriented occupational therapy program added to the current multidisciplinary treatment. Three feasibility rounds were carried out with structural adjustments between the rounds according to the outpatients and clinicians' feedback. The three-fold program focus on occupational performance, physical activity and healthy eating, and the treatments methods used remained unchanged between the feasibility rounds.
Clinical utility was evaluated quantitatively and qualitatively. Primary outcomes were pre-defined research progression criteria including recruitment rate (acceptable: 5 participants/group), assessment procedure acceptance (min. 75% acceptance rate), participant retention (min. 75% completion rate), program adherence (min. 75% adhere to >50% of sessions), adverse events (acceptable: minor events with no participants discontinuing the study), the fidelity of delivery (min. 75% of manualized intervention content delivered), and patients' self-perceived relevance, timing, and form of delivery (min. 75% satisfaction rate). Secondary outcomes were self-reported health-related quality of life, occupational performance, occupational balance, body anthropometrics and pain sensitization. Preliminary differences in changes before-after the intervention in occupational performance and satisfaction (COPM) were evaluated by analysing means and standard deviations (SD).
The qualitative midterm evaluation included three focus group interviews (two with the outpatients (n=8) and one with the clinicians (n=4)) involved in the REVEAL(OT) 1.0 and 2.0, to provide a deeper insight into group opinions about the participation. The qualitative results were subject to thematical analysis and inspired to further improve the REVEAL(OT).

Results: Preliminary results showed 95% assessment procedure acceptance; satisfactory patients' perceived relevance, timing, and form of delivery of the intervention; ≥75% recruitment rate, fidelity of delivery, completion, and adherence; and acceptable adverse events. The pre-post assessments of 23 participants showed a trend to significantly improved pre-post mean COPM scores for occupational performance by 1.88 (95% CI 1.20; 2.56), p<0.001, and satisfaction with an occupational performance by 1.97 (95% CI 0.86; 3.08), p<0.005, indicating overall successful and satisfactory resolution of the identified everyday occupational problems. However, only 17.4% reached the recommended cut-off for minimal clinical important difference (MCID) in occupational performance and 26.1% - in satisfaction with occupational performance. Frequency of COPM change scores above MCID raised in the REVEAL(OT) 3.0 compared to versions 1.0-2.0 by 44.1% in occupational performance and 32.4% in satisfaction with occupational performance. Qualitative mid-term evaluation showed the outpatients´ satisfaction with the intervention and a greater acceptance of living with chronic pain through increased understanding of pain mechanisms, more effective daily planning and improved social interaction. The outpatients felt empowered to change lifestyle habits by restarting habitual interests, prioritising joyful occupations for improved occupational balance, and lifestyle modifications. The REVEAL(OT) was considered relevant, though, needed improvements, such as reduced information and treatment load and a higher degree of communication and cooperation among the clinicians involved in the intervention. The feasibility phase will be completed in August 2021.

Discussion and Conclusion: Preliminary evaluation of the lifestyle-oriented occupational therapy program demonstrated that it was satisfactory and feasible in assisting adults living with chronic pain in working with lifestyle goals and promoting occupational performance and satisfaction, adding this novel focus to the current chronic pain treatment. Several areas for further improvement were detected to inform future research activities. Randomized trials are needed to determine the effectiveness of the intervention compared to a control group.

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Naestved, Slagelse & Ringsted Hospital's Research Fund
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The Danish Occupational Therapy Association

Please indicate if you are interested in oral presentation or poster participation or both

Oral (virtual) presentation, 7 min □
Poster (virtual) only, 2 min x

- After a review procedure, 8 abstracts will be selected for oral presentation. The oral presentation is virtual, lasting max 7 minutes followed by 2 minutes for a quick q & a.
- All authors, who have their abstract accepted for a poster presentation, will be asked to produce a presentation of their study/project in the format of two PowerPoint slides including 2 minutes speech and if possible video. Further instructions for this will follow in due time.

Please note the following deadlines:

Abstract submission: June 25, 2021 – Response in your mail by July 10, 2021
Pp-slides submission: August 10, 2021

Supplementary file 6

Conference abstract (oral), Rehabilitation International 24th World Congress, Aarhus, September 2021

Title: Moving forward: a lifestyle-oriented occupational therapy intervention for chronic pain

Authors: Svetlana Solgaard Nielsen[1,2], Søren Thorgaard Skou[2,3], Anette Enemark Larsen[4], Vicki Oldenschläger Mogensen[5], Charlotte Simonÿ[6], Jens Søndergaard[7], Jeanette Reffstrup Christensen[1]

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Abstract for Forum of Various Projects and Practice (oral presentation)

Presenting author: Svetlana Solgaard Nielsen

Life situation: Individuals/groups with chronic health-related problems

Keywords: Care and Health Issues, Hospital-based Rehabilitation, Rehabilitation in Research and Education

Moving forward: a lifestyle-oriented occupational therapy intervention for chronic pain

Background: A lifestyle-oriented occupational therapy intervention REVEAL(OT) [Redesign your EVEryday Activities and Lifestyle with Occupational Therapy] was developed and tested for feasibility as an add-on treatment modality to usual care for adults living with chronic pain.

Purpose: To provide a deeper insight into the user perspectives on the delivery process and outputs of the REVEAL(OT) at a Danish pain center, to complete the evaluation process and adapt the intervention in preparation for a randomized controlled trial.

Methods: Focus group interviews with the patients and clinicians involved in REVEAL(OT) were conducted from November 2019 to January 2020.

Results: The patients were satisfied with the REVEAL(OT) and reported a better acceptance of living with chronic pain through increased understanding of pain mechanisms, more effective daily planning and improved social interaction. The patients felt empowered for changing habits, e.g., restarting habitual interests, prioritizing joyful occupations for better occupational balance, and lifestyle modifications. Contacts with occupational therapists and peer support were important empowering factors. The clinicians found the REVEAL(OT) beneficial as an add-on to the usual care, pointing out the need for adjustments, such as a reduction of the information load and treatment intensity, and improved multidisciplinary cooperation.

Conclusion: The patients and clinicians found the lifestyle-oriented occupational therapy program relevant as an add-on treatment option within the multidisciplinary chronic pain management course. Reduced information and treatment load, more effective monitoring of lifestyle goals, better management of group dynamics, and a higher degree of communication and cooperation among the clinicians involved in the intervention were needed, which would support adding the lifestyle-oriented occupational therapy program to usual care.

Perspectives: The new knowledge will support the planning and conduct of the future randomized controlled trial, to investigate the effectiveness of the lifestyle-oriented occupational therapy intervention REVEAL(OT) added usual care for adults living with chronic pain.

Supplementary file 7

Conference abstract (oral), 2nd COTEC-ENOTHE congress 2020, Prague, September 2021 (A)

Abstract 1 accepted for oral presentation, COTEC/ ENOTHE 2021

Authors: **Svetlana Solgaard Nielsen[1], Soeren Thorgaard Skou[2], Jens Soendergaard[3], Jeanette Reffstrup Christensen[4]**

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Lifestyle, occupational performance and quality of life as markers of resilience in chronic pain patients

Background: Unhealthy lifestyle may negatively affect the quality of life, and thus the resilience to everyday stressors among individuals with chronic pain. A lifestyle-oriented occupational therapy intervention focusing on the quality of life and changing lifestyle through meaningful activities was developed for outpatients at a Danish pain center.

Objective: The study aimed to reveal current lifestyle status, the association between quality of life and occupational performance, and motivation to participate in a lifestyle-oriented intervention in chronic pain patients, to inform the design and conduct of a future randomized controlled trial.

Methods: A convenience sample of 146 patients answered a questionnaire developed for the study.

Results: Lifestyle was considered important for the quality of life in 77% of the respondents. Over 64% of the sample was overweight or obese. More than every second did not meet the recommendations for weekly physical activity for adults. Having more difficulties when performing usual activities was associated with a poorer quality of life. Moderate to high motivation for changing lifestyle was reported by 97% of the respondents.

Conclusions: An occupational therapy intervention with an impact on lifestyle and occupational performance is needed to improve the quality of life for better resilience in chronic pain patients.

Supplementary file 8

Conference abstract (oral), 2nd COTEC-ENOTHE congress 2020, Prague, September 2021 (B)

Abstract 2 accepted for oral presentation, COTEC/ ENOTHE 2021,

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Improving Resilience Through Lifestyle-oriented Occupational Therapy for Adults with Chronic Pain

Background: Lifestyle-related issues adversely affect the quality of life and occupational performance, thereby weakening the overall resilience in adults with chronic pain. Previous occupational therapy research showed the potential of occupational therapy in lifestyle management. However, the impact of lifestyle-oriented occupational therapy on chronic pain population still needs investigation.

Objective: A randomized controlled trial (RCT) was planned to investigate the effectiveness of a lifestyle-oriented occupational therapy intervention in chronic pain patients. Enhanced resilience through improved quality of life and occupational performance in the participants was expected. To inform the RCT, the intervention was tested for feasibility.

Methods: Outpatients (n=20) referred to a Danish pain center participated in a 12-weeks occupational therapy program. Pre-post changes in occupational performance and lifestyle-related anthropometrics were measured.

Results: Preliminary results of 13 participants showed significantly improved Canadian Occupational Performance Measure scores for occupational performance (1,57 [95% CI: 0.8; 2.4], p=.0004) and satisfaction (1.25 [95% CI: 0.17; 2.34], p=.0133). No significant changes in occupational performance function (Assessment of Motor and Process Skills) and bio-impedance were detected. Areas for further justifications in the intervention design were pointed out.

Conclusions: The lifestyle-oriented occupational therapy program was able to improve occupational performance and satisfaction in chronic pain patients.

Supplementary file 9

Conference abstract (oral), ERGO 2022: “Ergo22: Styrket Forskning – Styrket Praksis”, Nyborg, June 2022 (accepted)

ERGO 2022

Abstrakt til en kortere mundtlig præsentation i parallelsession

Titel: Ergoterapi i den tværfaglige behandling af kroniske smerter– erfaringer fra en pilotafprøvning

Forfattere: Svetlana Solgaard Nielsen[1,2], Søren T. Skou[2,3], Anette Enemark Larsen[4], Henrik Bjarke Vægter[5,6], Rikke Lyshøj Jensen[7], Lise Vincentz Lundgreen Mikkelsen[7], Romanas Polianskis[8], Charlotte Simonÿ[2,9], Jens Søndergaard[10], Jeanette Reffstrup Christensen[1,10]

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Oplægsholder: Svetlana Solgaard Nielsen

Nøgleord: kroniske smerter, livsstil, aktivitetsudførelse, komplekse interventioner

Ergoterapi i den tværfaglige behandling af kroniske smerter– erfaringer fra en pilotafprøvning

Baggrund: Patienter med kroniske smerter kan have behov for at arbejde med livsstilsforbedringer som en del af den tværfaglige rehabilitering. Tidligere studier har vist ergoterapiens potentiale i en livsstilsorienteret tilgang til smertebehandling, men der er behov for yderligere forskning i dansk kontekst.

Formål: Som forberedelse til et randomiseret kontrolleret studie, blev den ergoterapeutiske intervention REVEAL(OT) [Redesign your EVEryday Activities and Lifestyle with Occupational Therapy] pilotafprøvet som et tillæg til det nuværende tværfaglige behandlingstilbud på et regionalt smertecenter i Region Sjælland.

Metoder: Ambulante patienter med kroniske smerter (n=40) mellem 18 og 65 år (85% kvinder) henvist til Tværfagligt Smertecenter på Næstved sygehus deltog i undersøgelsen. Ergoterapeuter har samarbejdet med deltagerne omkring deres personlige mål i relation til daglige aktiviteter, regelmæssig bevægelse og spisevaner. Primære effektmål for studiet var prædefinerede progressionskriterier (ift. progression til det randomiserede studie) for rekruttering, accept af undersøgelsesprocedurer, retention, deltagelsesprocent, uønskede hændelser og planmæssig levering af programmet. Sekundære effektmål var helbredsrelateret livskvalitet, aktivitetsudførelse, aktivitetsbalance, kroppens antropometri og smertesensitisering. Tendenser blev monitoreret ved at sammenligne før- og eftermålingerne. Fokusgruppeinterviews med 8 patienter og 4 klinikere blev gennemført for en dybere indsigt i, hvordan REVEAL(OT) blev oplevet.

Resultater: Foreløbige analyser af data fra deltagere (n=30) som har afsluttet programmet, demonstrerede acceptabelt-til-godt niveau i opfyldelsen af de primære effektmål, samt en tendens til signifikant forbedring i de sekundære mål: aktivitetsudførelse (1.76 [95% CI 1.22;

2.29]) og tilfredsheden med aktivitetsudførelsen (1.88 [95% CI 1.01; 2.75]). REVEAL(OT) medvirkede til øget accept af livet med kroniske smerter hos patienterne og deres empowerment for livsstilsændringer. Patienter og klinikere foreslog en række forbedringer i interventionen.

Konklusioner: Pilotafprøvningen af det ergoterapeutiske program REVEAL(OT) har givet et indblik i, hvordan der kan arbejdes med daglige aktiviteter og livsstil som led i den tværfaglige smertebehandling. Et randomiseret studie skal afdække effekten af det ergoterapeutiske livsstilsorienterede program for kroniske smertepatienter.

Supplementary file 10

Conference abstract (oral), 18th WFOT Congress, Paris, August 2022 (accepted)

WFOT 2022 – Oral

Title: Occupational engagement used as a tool of impact on lifestyle in chronic pain management – a systematic review and meta-analysis

Authors: Svetlana Solgaard Nielsen[1,2], Søren Thorgaard Skou[2,3], Anette Enemark Larsen[4], Jens Søndergaard[5], Jeanette Reffstrup Christensen[1]
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Presenting author: Svetlana Solgaard Nielsen

Themes prioritized: (1) Quality, effectiveness and outcome measures, (2) Health promotion, public health and health services, (3) Revolutionising rehabilitation

Occupational engagement used as a tool of impact on lifestyle in chronic pain management – a systematic review and meta-analysis

Introduction: Occupational therapists can help people living with chronic pain change their lifestyle. However, whether engagement in everyday occupations can support the effectiveness of lifestyle interventions for people living with chronic pain is unclear.

Objectives: To study the effect of occupational engagement on lifestyle and occupational performance and participation in adults living with chronic pain.

Methods: In a systematic review, we searched the databases Ovid MEDLINE, Embase, PsycINFO, CINAHL, Cochrane, Scopus, Web of Science, OTseeker, ClinicalTrials.gov, OpenGray, and Google Scholar and evaluated the evidence quality using the GRADE approach. We performed a meta-analysis when two or more studies reported on an outcome of interest.

Results: Six randomised controlled trials comprising 685 adults were included. Despite improvements in physical activity observed, no significant overall effect (Hedge's g) of occupational engagement was detected in trials reporting on physical activity level (n=2), post-treatment 0.24 (-0.11; 0.59) and at follow-up 0.11 (-0.25; 0.46), or sleep quality (n=2), post-treatment 0.20 (-0.20; 0.61) and at follow-up 0.47 (0.05; 0.90). The other two trials reporting a significant decrease in stress and improved occupational performance were not subject to the meta-analysis. The overall evidence quality was low.

Conclusion: The overall evidence quality on occupational engagement used in intervention targeting physical activity, stress, and occupational performance in adults with chronic pain was low, not allowing for a firm effect size estimation. The impact of occupational engagement applied to other lifestyle factors remained unclear. Further trials on occupational engagement as a treatment tool in lifestyle-oriented chronic pain management are warranted.

Supplementary file 11

Conference abstract (poster), 18th WFOT Congress, Paris, August 2022 (accepted)

WFOT 2022 - Oral

Title: Comprehensive value-based occupational and lifestyle goal setting and achievement in adults living with chronic pain assisted by occupational therapists – a feasibility study

Authors: Svetlana Solgaard Nielsen[1,2], Søren Thorgaard Skou[2,3], Anette Enemark Larsen[4], Charlotte Simonÿ[2,5], Jens Søndergaard[6], Jeanette Reffstrup Christensen[1]
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Presenting author: Svetlana Solgaard Nielsen

Themes, prioritized: (1) User perspectives and experiences, (2) Health promotion, public health and health services

Comprehensive value-based occupational and lifestyle goal setting and achievement in adults living with chronic pain assisted by occupational therapists – a feasibility study

Introduction: People living with chronic pain seem to find a healthy lifestyle important for their quality of life and need comprehensive, individually tailored interventions tackling multiple lifestyle factors. Enhanced occupational engagement can support lifestyle changes. However, lack of surplus may challenge setting and achieving realistic lifestyle goals.

Objectives: To investigate the feasibility of a lifestyle-oriented treatment program, where occupational therapists assisted adults living with chronic pain in setting and achieving value-based goals related to everyday living, physical activity and eating habits.

Methods: A total of 22 outpatients referred to a Danish pain centre participated in the feasibility study. Occupational therapists assisted the participants in making value-based occupational choices based on data from the Canadian Occupational Performance Measure (COPM) assessed at baseline and identifying prioritised occupational problems.

Results: Mid-term qualitative evaluation showed that the occupational therapy program benefited the participants' acceptance of living with chronic pain and empowered them to change their lifestyle. The participants evaluated weekly support from the occupational therapists in the intervention essential for their participation. Preliminary results from 20 participants demonstrated significantly improved pre-post mean COPM scores for occupational performance at 1.25 (95% CI 0.59; 1.91) and satisfaction at 1.01 (95% CI 0.98; 1.92), indicating successful resolution of the identified everyday occupational problems.

Conclusion: The occupational therapy program was feasible in assisting adults living with chronic pain in setting and achieving multiple value-based occupational and lifestyle goals, promoting occupational performance and satisfaction in the participants. Randomised trials are needed to determine the effectiveness of the intervention.

Thesis attachments

Declaration of co-authorship (PhD thesis)

Under Section 12 (4) of the *PhD order**, a declaration on the extent and nature of the relative contributions, signed by the collaborators and the author, must accompany the PhD thesis if the dissertation or parts of it are the result of collaboration.

Co-authors should fulfil the requirements of the Vancouver rules**

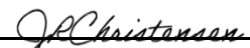
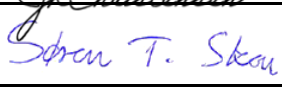
1. **General information**	
Candidate's name	Svetlana Solgaard Nielsen
Title of PhD thesis	Occupational therapy lifestyle intervention REVEAL(OT) added to multidisciplinary chronic pain treatment at a Danish pain center

2. **This co-author's declaration applies to the following article/manuscript No. 1**
The effect of occupational engagement on lifestyle in adults living with chronic pain – A systematic review and meta-analysis

The extent of the candidate's contribution to the article is assessed on the following scale

A. has contributed to the work (0-33%)
B. has made a substantial contribution (34-66%)
C. did the majority of the work (67-100%)

3. **Declaration on the individual elements**		Extent (A, B, C)
1.	Formulation in the concept phase of the basic scientific problem on the basis of theoretical questions which require clarification, including a summary of the general questions which it is assumed will be answered via analyses or concrete experiments/investigations.	B
2.	Planning of experiments/analyses and formulation of investigative methodology in such a way that the questions asked under (1) can be expected to be answered, including choice of method and independent methodological development.	A
3.	Involvement in the analysis or the concrete experiments/investigation.	B
4.	Presentation, interpretation and discussion of the results obtained in the form of an article or manuscript.	A

4. **Co-authors' signatures**			
Date	Name	Title	Signature
21.12.21	Jeanette Reffstrup Christensen	PhD	
21.12.21	Søren Thorgaard Skou	PhD, Professor	
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5. **Candidate's signature**


*The Danish *Ministerial Order on the PhD Programme at the Universities (PhD order)*, no. 18 of 14 January 2008

**Vancouver rules: "All persons named as authors must satisfy the authorship requirement. The order of names must be a joint decision taken by all the authors. The individual author must have participated in the work to a sufficient extent to be able to accept public liability for the content of the scientific work. Authorship can only be based on substantial contribution with regard to: 1) conception and design or analysis and interpretation of data, 2) drafting the article or revising it critically for important intellectual content, and 3) final approval of the version to be published. *Involvement based only on obtaining funding for the work or collecting data does not qualify for authorship. Neither does general supervision of the research group in itself qualify as authorship.* If the authorship is collective, key persons who are responsible for the article must be identified. The editors of the scientific periodical may ask authors to account for their part in the authorship."

Declaration of co-authorship (PhD thesis)

Under Section 12 (4) of the *PhD order**, a declaration on the extent and nature of the relative contributions, signed by the collaborators and the author, must accompany the PhD thesis if the dissertation or parts of it are the result of collaboration.

Co-authors should fulfil the requirements of the Vancouver rules**

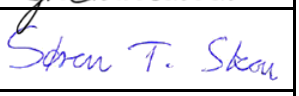
1. **General information**	
Candidate's name	Svetlana Solgaard Nielsen
Title of PhD thesis	Occupational therapy lifestyle intervention REVEAL(OT) added to multidisciplinary chronic pain treatment at a Danish pain center

2. **This co-author's declaration applies to the following article/manuscript No. 2**
Associations of health-related quality of life with sociodemographic characteristics, health, pain, and lifestyle factors, and motivation for changing lifestyle in adults living with chronic pain: a cross-sectional exploratory study

The extent of the candidate's contribution to the article is assessed on the following scale

A. has contributed to the work (0-33%)
B. has made a substantial contribution (34-66%)
C. did the majority of the work (67-100%)

3. **Declaration on the individual elements**	Extent (A, B, C)
1. Formulation in the concept phase of the basic scientific problem on the basis of theoretical questions which require clarification, including a summary of the general questions which it is assumed will be answered via analyses or concrete experiments/investigations.	A
2. Planning of experiments/analyses and formulation of investigative methodology in such a way that the questions asked under (1) can be expected to be answered, including choice of method and independent methodological development.	A
3. Involvement in the analysis or the concrete experiments/investigation.	A
4. Presentation, interpretation and discussion of the results obtained in the form of an article or manuscript.	A

4. **Co-authors' signatures**			
Date	Name	Title	Signature
21.12.21	Jeanette Reffstrup Christensen	PhD	
21.12.21	Søren Thorgaard Skou	PhD, Professor	
21.12.21	Jens Søndergaard	PhD, Professor	
21.12.21	Anette Enemark Larsen	PhD	

5. **Candidate's signature**


*The Danish *Ministerial Order on the PhD Programme at the Universities (PhD order)*, no. 18 of 14 January 2008

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Co-authors should fulfil the requirements of the Vancouver rules**

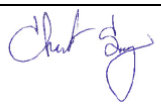
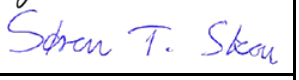
1. **General information**	
Candidate's name	Svetlana Solgaard Nielsen
Title of PhD thesis	Occupational therapy lifestyle intervention REVEAL(OT) added to multidisciplinary chronic pain treatment at a Danish pain center

2. **This co-author's declaration applies to the following article/manuscript No. 3**
Feasibility assessment of an occupational therapy lifestyle intervention added to multidisciplinary chronic pain treatment at a Danish pain centre: a qualitative evaluation from the perspectives of patients and clinicians

The extent of the candidate's contribution to the article is assessed on the following scale

A. has contributed to the work (0-33%)
B. has made a substantial contribution (34-66%)
C. did the majority of the work (67-100%)

3. **Declaration on the individual elements**		Extent (A, B, C)
1.	Formulation in the concept phase of the basic scientific problem on the basis of theoretical questions which require clarification, including a summary of the general questions which it is assumed will be answered via analyses or concrete experiments/investigations.	A
2.	Planning of experiments/analyses and formulation of investigative methodology in such a way that the questions asked under (1) can be expected to be answered, including choice of method and independent methodological development.	B
3.	Involvement in the analysis or the concrete experiments/investigation.	B
4.	Presentation, interpretation and discussion of the results obtained in the form of an article or manuscript.	A

4. **Co-authors' signatures**			
Date	Name	Title	Signature
21.12.21	Charlotte Simonÿ	PhD, Associate Professor	
21.12.21	Jeanette Reffstrup Christensen	PhD	
21.12.21	Søren Thorgaard Skou	PhD, Professor	
21.12.21	Jens Søndergaard	PhD, Professor	
21.12.21	Anette Enemark Larsen	PhD	
21.12.21	Vicki Oldenschläger Mortensen	Master in Health (OT)	

5. **Candidate's signature**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Co-authors should fulfil the requirements of the Vancouver rules**

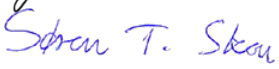
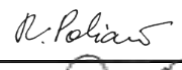
1. **General information**	
Candidate's name	Svetlana Solgaard Nielsen
Title of PhD thesis	Occupational therapy lifestyle intervention REVEAL(OT) added to multidisciplinary chronic pain treatment at a Danish pain center

2. **This co-author's declaration applies to the following article/manuscript No. 4**
Occupational therapy lifestyle intervention added to multidisciplinary treatment for adults living with chronic pain: A feasibility study

The extent of the candidate's contribution to the article is assessed on the following scale

A. has contributed to the work (0-33%)
B. has made a substantial contribution (34-66%)
C. did the majority of the work (67-100%)

3. **Declaration on the individual elements**	Extent (A, B, C)
1. Formulation in the concept phase of the basic scientific problem on the basis of theoretical questions which require clarification, including a summary of the general questions which it is assumed will be answered via analyses or concrete experiments/investigations.	B
2. Planning of experiments/analyses and formulation of investigative methodology in such a way that the questions asked under (1) can be expected to be answered, including choice of method and independent methodological development.	B
3. Involvement in the analysis or the concrete experiments/investigation.	A
4. Presentation, interpretation and discussion of the results obtained in the form of an article or manuscript.	A

4. **Co-authors' signatures**			
Date	Name	Title	Signature
21.12.21	Jeanette Reffstrup Christensen	PhD	
21.12.21	Søren Thorgaard Skou	PhD, Professor	
21.12.21	Jens Søndergaard	PhD, Professor	
21.12.21	Anette Enemark Larsen	PhD	
21.12.21	Henrik Bjarke Vægter	PhD, lektor	
21.12.21	Romanas Polianskis	PhD,MD	
21.12.21	Wojciech Zbigniew Pawlak	PhD,MD	

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Forskerskolen
Det Sundhedsvidenskabelige Fakultet
Syddansk universitet

22. december 2021

Udtalelse vedrørende Svetlana Solgaard Nielsens ph.d.- uddannelse

Ph.d.- studerende Svetlana Solgaard Nielsen har færdiggjort sin ph.d. -uddannelse med indlevering af sin ph.d. - afhandlingen den 31.12.2021.

Titlen på afhandlingen er: "*Occupational therapy lifestyle intervention REVEAL(OT) added to multidisciplinary chronic pain treatment at a Danish pain centre".*

Undertegnede Jeanette Reffstrup Christensen, lektor ved Forskningsenheden for Almen Praksis, og ved Brugerperspektiver og borgernære indsatser, Institut for Sundhedstjenesteforskning, Det Sundhedsvidenskabelige Fakultet, SDU, har fungeret som hovedvejleder.

Medvejledere har været:
Søren Thorgaard Skou, Professor ved Sygehusene i Næstved, Slagelse og Ringsted, og ved Muskuloskeletal Funktion og Fysioterapi, Institut for Idræt og Biomekanik, Det Sundhedsvidenskabelige Fakultet, SDU.

Anette Enemark Larsen, Lektor ved Ergoterapeutuddannelsen, Københavns Professionshøjskole.

Jens Søndergaard, Professor ved Forskningsenheden for Almen Praksis, Institut for Sundhedstjenesteforskning, Det Sundhedsvidenskabelige Fakultet, SDU.

Som hovevejleder kan jeg bekræfte, at Svetlana Solgaard Nielsen til overmål har opfyldt kravene vedr. antal ECTS-point (36,7). Hun har som ph.d.-studerende været aktiv med vidensformidling gennem såvel undervisning som foredrag/forelæsninger og videnskabelige publikationer. Kravet om ophold ved et udenlandsk universitet er grundet Corona-situationen ikke indfriet. Til gengæld har den ph.d. -studerende haft et tæt samarbejde med en håndfuld internationale forskere, hvorfor jeg mener at samarbejde med eksterne forskningsmiljøer er indfriet. Den ph.d.-studerende har fulgt forskningsplanen for projektet.

Der er således tale om et fuldt tilfredsstillende studieforløb.

Bilag: Oversigt over kurser, vidensformidling og samarbejde med eksterne forskningsmiljøer.

Med venlig hilsen

Jeanette Reffstrup Christensen
Ergoterapeut, Lektor, Ph.d.

Description of the Ph.D. programme for Svetlana Solgaard Nielsen

List of completed courses

Dates	Course	Place	ECTS
2019			
20.03 + 27.03	Responsible Conduct of Research	SDU	2.0
07-08.05	GRASPH Summer School, Korsør	KU	1.4
21.05	Introduction to health research	SDU	0.7
9-10.09	Datamanagement & STATA	AU	1.4
13-19-26.09 + 3-8.10	Biostatistics I	SDU	5.0
07. + 09.10	Complex interventions addressing health behaviour change on multiple levels	AU	2.1
22-23.10	Using news media and social media to increase the awareness and dissemination of your research	SDU	2.0
28-30.10	Randomized controlled trial in health sciences – why and how to run a high quality trial	SDU	2.5
18-21.11	Conducting a systematic review – meta-analysis and a meta-synthesis Sandbjerg Manor, Sandbjergvej 102, 6400 Sønderborg	AU	3.0
25-26.11	What is pain and how should it be measured?	AU	1.6
2020			
22-23.01	Bootcamp Advanced Statistical Methods in Health Sciences	SDU	1.5
25.02.-10.03	Hey, let me tell you about my research	SDU	2.0
14-15.05	English grammar in context	SDU	2.0
Jan-June 2020	Academic writing	AU	5.0
2021			
9.04 + 21.05	Advanced Course in Written English	AU	2.6
10 + 24.08	Effective presentation of medical results	SDU	1.9
Total			**36.7**

Teaching activities

2019

Teaching:
Evidensbasering og Kvalitetsudvikling modul, Master of Health Science (Occupational Therapy) programme, SDU

Supervision:
Co-supervisor, Master Thesis
Lykke Dam Nielsen og Trine Hjort Laursen
Titel: Hverdagslivet med non-maligne kroniske smerter
Master of Health Science (Occupational Therapy) programme, SDU

2020

Teaching:
Evidensbasering og Kvalitetsudvikling modul, Master of Health Science (Occupational Therapy) programme, SDU
The University of Southern California, USA – International module, online (summer Master course)

Exam:
Evidensbasering og Kvalitetsudvikling, Master of Health Science (Occupational Therapy) programme, SDU

Supervision:
Clinical supervisor, Bachelor thesis
Clara Buttenschøn, Karoline Kromann Jensen, Maja Helene Hornum, Simone Britta Søndergaard Larsen
Titel: "Et indblik i sanseprofilen hos personer med kroniske non-maligne smerter – et tværsnitsstudie"
Bachelor of Occupational Therapy programme, University College Absalon, Naestved

2021

Teaching:
Evidensbasering og Kvalitetsudvikling modul, Master of Health Science (Occupational Therapy) programme, SDU
Aktivitetsvidenskab og hverdagslivsteori, Master of Health Science (Occupational Therapy) programme, SDU
Studiestartsopgave (Supervisor), Medicine (Master of Science), SDU

Exam:
Evidensbasering og Kvalitetsudvikling modul, Master of Health Science (Occupational Therapy) programme, SDU
Aktivitetsvidenskab og hverdagslivsteori, Master of Health Science (Occupational Therapy) programme, SDU
Studiestartsopgave, Medicine (Master of Science), SDU

Supervision:
Main supervisor, Master Thesis
Mette Tækker Jensen
Titel: "The effectiveness of interventions targeting social relations in weight loss treatment of adults with overweight or obesity - A systematic review and meta-analysis"
Master of Health Science (Occupational Therapy) programme, SDU

Dissemination activities

Peer-reviewed publications

Nielsen, SS; Skou, ST; Larsen, AE; Soendergaard, J; Christensen, JR. Associations of health-related quality of life with sociodemographic characteristics, health, pain, and lifestyle factors, and motivation for changing lifestyle in adults living with chronic pain: a cross-sectional exploratory study. Scandinavian Journal of Pain, vol., no., 2021, pp. 000010151520210062. https://doi.org/10.1515/sjpain-2021-0062

Nielsen, SS; Christensen, JR; Soendergaard, J; Mogensen, VO; Larsen, AE; Skou, ST; Simonÿ, C. Feasibility assessment of an occupational therapy lifestyle intervention added to multidisciplinary chronic pain treatment at a Danish pain centre: a qualitative evaluation from the perspectives of patients and clinicians, International Journal of Qualitative Studies on Health and Well-being, 16:1, DOI: 10.1080/17482631.2021.1949900

(In review)

Nielsen, SS; Skou, ST; Larsen, AE; Bricca, A; Soendergaard, J; Christensen, JR. The effect of occupational engagement on lifestyle in adults living with chronic pain – A systematic review and meta-analysis. Occupational Therapy International, in review

Nielsen, SS; Skou, ST; Larsen, AE; Polianskis, R; Pawlak, WZ; Vægter, HB; Soendergaard, J; Christensen, JR. Programme development and feasibility study of an occupational therapy lifestyle management programme added usual care for adults living with chronic pain. Scandinavian Journal of Occupational Therapy, in review

Peer-reviewed abstracts

Nielsen, SS; Skou, ST; Soendergaard, J; Christensen, JR. Lifestyle-oriented Occupationa Therapy Intervention for Patients with Chronic Non-malignant Pain. 'Europe in transition', Occupational Science Europe 2019, Amsterdam, The Netherlands, 29th August – 01st September, 2019. Peer-review abstract. Poster presentation

Nielsen, SS; Skou, ST; Soendergaard, J; Christensen, JR. Lifestyle-oriented Occupational Therapy Intervention for Patients with Chronic Non-malignant Pain. Region Zealand Research Day 2019, Nykoebing Falster, Denmark, 18th September, 2019. Peer-review abstract. Poster presentation

Nielsen, SS; Skou, ST; Larsen, AE; Mogensen, VO; Soendergaard, J; Christensen, JR. Moving forward: a lifestyle-oriented occupational therapy intervention for chronic pain. 'Moving Societies', Rehabilitation World Congress, Aarhus, Denmark, 7-9th September, 2021 (revised date). Peer-review abstract. Oral presentation

Nielsen, SS; Skou, ST; Larsen AE; Polianskis, R; Vaegter, HB; Pawlak, WZ; Simonÿ, C; Soendergaard, J; Christensen, JR. Feasibility evaluation of a lifestyle-oriented occupational therapy intervention for patients with chronic non-malignant pain. Region Zealand Research Day 2021, Holbaek Hospital, Denmark, 15th September, 2021. Peer-review abstract. Poster presentation

Nielsen, SS; Skou, ST; Larsen AE; Pawlak, WZ; Polianskis, R; Soendergaard, J; Christensen, JR. Associations of health-related quality of life with sociodemographic characteristics, health, pain, and lifestyle and motivation for changing lifestyle in adults living with chronic pain: a cross-sectional study. Region Zealand Research Day 2021, Holbaek Hospital, Denmark, 15th September, 2021. Peer-review abstract. Poster presentation

Nielsen, SS; Skou, ST; Soendergaard, J; Christensen, JR. Lifestyle, occupational performance and quality of life as markers of resilience in chronic pain patients. 'Occupational Therapy Europe – building resilience in individuals, communities and countries', 2nd COTEC-ENOTHE Congress 2021, Prague, Czech Republic, 15-18th September, 2021 (revised date). Peer-review abstract. Oral presentation

Nielsen, SS; Skou, ST; Soendergaard, J; Christensen, JR. Improving Resilience Through Lifestyle-oriented Occupational Therapy for Adults with Chronic Pain. 'Occupational Therapy Europe – building resilience in individuals, communities and countries', 2nd COTEC-ENOTHE Congress 2021, Prague, Czech Republic, 15-18th September, 2021 (revised date). Peer-review abstract. Oral presentation

(Upcoming – abstracts accepted)

Nielsen, SS; Skou, ST; Larsen AE; Vaegter, HB; Jensen, RL; Mikkelsen, LVL; Polianskis, R; Simonÿ, C; Soendergaard, J; Christensen, JR. 'Ergoterapi i den tværfaglige behandling af kroniske smerter– erfaringer fra en pilotafprøvning', ERGO 2022: "Ergo22: Styrket Forskning – Styrket Praksis", Nyborg, Denmark, 2-3rd June 2022. Oral presentation

'Comprehensive value-based occupational and lifestyle goal setting and achievement in adults living with chronic pain assisted by occupational therapists – a feasibility study', 18th WFOT Congress, Paris, France, August 2022. Poster presentation

'Occupational engagement used as a tool of impact on lifestyle in chronic pain treatment – a systematic review and meta-analysis', 18th WFOT Congress, Paris, France, August 2022. Oral presentation

<u>Publications in media</u>

Nielsen SS. Debat: Ergoterapi har plads i smertebehandlingen [Internet]. Sundhedsmonitor. Sundhedsmonitor; 2021 [cited 2021Dec22]. Available from: http://sundhedsmonitor.dk/8357590

Contacts with other research environments during the PhD programme

The Research Unit PROgrez [Patient-Related Objectives: Generating better Rehabilitation, Treatment, Exercise and Diagnostics - Region Zealand]
Department of Physiotherapy and Occupational Therapy at Næstved, Slagelse, Ringsted Hospital
Contact: Søren T. Skou, Professor, PhD, Head of Research

User Perspectives and Community-based Interventions
University of Southern Denmark
Contacts: Birgitte Nørgaard, Associate Professor, PhD, Head of Research Unit

Research Unit of General Practice, Research Group for Health Promotion
University of Southern Denmark
Contact: Trine Thilsing, Associate Professor, Senior Researcher, PhD, DVM, Associate Professor

Research Unit of General Practice, Research Group MOVE
Aarhus University
Contact: Rasmus Østergaard Nielsen, Associate Professor, Senior Researcher, PhD

Study abroad (planned for 2020-21, postponed due to COVID-19 pandemic)

Chan Division of Occupational Science and Occupational Therapy, University of Southern California (USA)
Contact: Daniel Park, OTD, OTR/L, MSW, Associate Professor of Clinical Occupational Therapy/ Director, USC Chan Global Initiatives, University of Southern California