Occupational therapy for persons with chronic conditions

Effectiveness and process evaluation of the ABLE programme

Hagelskjær, Vita

DOI:
10.21996/7qn4-pa10

Publication date:
2022

Document version:
Final published version

Citation for pulished version (APA):
Hagelskjær, V. (2022). *Occupational therapy for persons with chronic conditions: Effectiveness and process evaluation of the ABLE programme*. [Ph.D. thesis, SDU]. Syddansk Universitet. Det Sundhedsvidenskabelige Fakultet. https://doi.org/10.21996/7qn4-pa10

Occupational therapy for persons with chronic conditions

Effectiveness and process evaluation of the ABLE programme

PhD thesis

Vita Hagelskjær

SDU
UNIVERSITY OF SOUTHERN DENMARK

Occupational Science, User Perspectives and Community-based Interventions, Department of Public Health, Southern Denmark University
Denmark
2022

Supervisors

Eva Ejlersen Wæhrens, Professor, OT, PhD
Occupational Science, User Perspectives and Community-based Interventions, Department of Public Health, University of Southern Denmark; The ADL unit, The Parker Institute, Bispebjerg and Frederiksberg Hospital, University of Copenhagen

Kristina Tomra Nielsen, OT, PhD
Department of Occupational Therapy, University College of Northern Denmark The ADL unit, The Parker Institute, Bispebjerg and Frederiksberg Hospital, University of Copenhagen

Cecilie von Bülow, OT, PhD
The ADL unit, The Parker Institute, Bispebjerg and Frederiksberg Hospital, University of Copenhagen; Occupational Science, User Perspectives and Community-based Interventions, Department of Public Health, University of Southern Denmark

Maud Graff, Professor, OT, PhD
Department of Rehabilitation & Scientific Institute for Quality of Care Research, Radboud University Medical Center Nijmegen, The Netherlands

Assessment Committee

Helle Ussing Timm, Professor, PhD (Chair)
National Institute of Public Health, Southern Denmark University

Eva Månsson Lexell, Docent, PhD,
Faculty of Medicine, Lund University

Thomas Bredgaard, Professor, PhD
Department of Politics and Society, Aalborg University

Front page illustration by Sarah Sonne Glatz

Printed by Print and Sign, Southern Denmark University, Odense, 2022

We have discovered the programme theory black box. Now comes the hard part. we have to get into it.

RAMESESPROJECT.ORG

Table of Contents

Abstract

Background: Problems related to performance of activities of daily living (ADL) tasks is associated with chronic conditions stressing a need to develop and evaluate intervention programmes addressing such problems. Guided by the United Kingdom Medical Research Council's (MRC) guidance on how to develop and evaluate complex interventions, the first version of the occupational therapy program (ABLE 1.0) was developed, aiming at enhancing ADL ability among persons with chronic conditions. ABLE incorporates knowledge based on existing evidence, clinical expertise of occupational therapists, and clients' experiences and needs. ABLE is a structured eight-week, generic, homebased, adaptational program, including five to eight individualised sessions, developed to be delivered in the client's home as part of community-based rehabilitation services. Following development of the programme, a feasibility study was conducted, showing that ABLE 1.0 was feasible in terms of content and delivery with minor adjustments to the intervention manual and recruitment procedures. Hence, pilot testing of the remaining uncertainties was recommended before proceeding to the evaluation phase. The aim of this doctoral thesis was to evaluate the remaining feasibility aspects prior to a randomised controlled trial (RCT), including minor revision of ABLE 1.0, and to conduct effectiveness and process evaluation of ABLE 2.0.

Methods: The MRC framework for developing and evaluating complex interventions was applied. Revision of ABLE 1.0 included conduction of a cognitive debriefing including n=5 occupational therapists to identify any aspect of the ABLE manual leading to confusion or misunderstanding. Further, relevant updates of theoretical models incorporated in ABLE 1.0 were implemented.

The pilot study was designed as a two-armed parallel RCT, planning a recruitment strategy including 20 persons with one or more chronic conditions and experiencing problems performing ADL tasks. The pilot study period was scheduled from December 2019 to April 2020. The following progression criteria were used to determine if a future full-scale RCT was feasible: (i) recruitment (50% met the eligibility criteria) and retention (80%), (ii) randomisation (80% accepted randomisation,

procedure was executed as planned), (iii) adherence to programme (100% followed the treatment protocol), (iv) outcome measurements (80% of the participants delivered relevantly and fully answered questionnaires), and (v) usual occupational therapy (extraction of needed information was successful).

The subsequent effectiveness evaluation was designed as a RCT with blinded assessors and investigators. Home-dwelling persons with chronic conditions experiencing ADL task performance problems were randomly allocated to ABLE 2.0 or usual occupational therapy. Data were collected at baseline (week 0), post intervention (week 10) and at follow-up (week 26). Co-primary outcomes were self-reported ADL ability (ADL-Interview (ADL-I) performance) and observed ADL motor ability (Assessment of Motor and Process Skills (AMPS)) at primary endpoint (week 10). Secondary outcomes were self-reported ADL ability (ADL-I performance), observed ADL motor ability (AMPS) at secondary endpoint (week 26) and perceived satisfaction with ADL ability (ADL-I satisfaction); and observed ADL process ability (AMPS) at primary and secondary endpoint. Explorative outcomes were occupational balance (Occupational Balance Questionnaire); perceived change (Client Weighted Problems Questionnaire) and general health (first question of the MOS 36-item Short Form Survey Instrument) at primary and secondary endpoint. All outcomes were analysed using the principles of Intention-To-Treat (ITT) analyses followed by sensitivity analyses in terms of Per Protocol (PP) analyses, applying analysis of covariance (ANCOVA) with time by programme as repeated measures. ADL-I at baseline was included as covariate.

In the process evaluation a realist evaluation approach was applied. A programme theory (ABLE 2.0 initial programme theory) was constructed expressing how contexts (C) and mechanisms (M) in the intervention programme were hypothesised to lead to certain outcomes (O), in so-called CMO configurations. The process evaluation was based on qualitative interview data from a sub-group of clients (n=8) and the occupational therapists delivering the programme (n=3), supplied by quantitative data from registration forms, filled in by clients receiving (n=38) and OTs delivering (n=3) ABLE 2.0.

Results: Based on data from the cognitive debriefing and updated theory the manual was revised resulting in ABLE 2.0. Due to the Covid-19 pandemic the pilot study was interrupted in March 2020, resulting in limited but sufficient data to answer most of the study questions. (i) Eighteen of 37 eligible persons (48.6%) were recruited; of those treated (n = 6), all remained in the programme (100%); (ii) 18 accepted randomisation (100%), and procedure was effective; (iii) ABLE was delivered with adherence (100%); (iv) 92.3–100% of the participants gave relevant and complete answers in two of three questionnaires; and (v) the needed information on usual occupational therapy was extractable in seven of nine aspects.

In the effectiveness evaluation ITT analysis of primary outcomes identified no statistically significant nor clinically relevant difference between group mean changes on self-reported, i.e. ADL-I performance (-0.16; 95 % CI: -0.38 to 0.06) and observed ADL ability, i.e. AMPS ADL motor ability (-0.1; 95 % CI: -0.3 to 0.1) from baseline to week 10. However, at the secondary endpoint (week 26) a statistically significant and clinically relevant difference was found in AMPS ADL motor ability (LS mean change = -0.3; 95% CI = -0.5 to -0.1) between groups. This was confirmed in the sensitivity analysis (LS mean change = -0.4; 95% CI = -0.7 to -0.1).

The process evaluation overall confirmed the initial programme theory, adding information on core mechanisms associated with the positive effects of the ABLE 2.0. These included active involvement of the client in the problem-solving process, a collaborative working relationship, mutual confidence, and a consultative occupation-based process using adaptational strategies. Several contextual factors were required to activate the desired mechanisms in terms of supportive management, referral procedures encouraging the problem-solving process, delivery in the client's home, skilled OTs, and clients feeling ready for making changes.

Conclusions: Based on the results it was concluded that the ABLE 2.0 was effective in improving observed ADL motor ability, reflecting a decreased level of effort in terms of clumsiness, physical effort, and fatigue among persons with chronic conditions. Sustainability of the improvements in ADL motor ability was obtained based on delivering the individualised systematic problem-solving process in the home of the client and by using adaptational strategies. Finally, because baseline ADL ability was identified as the only area were persons who benefitted differed from those who did not, and the

ABLE 2.0 otherwise was effective across age, gender and diagnoses, the idea of developing a generic programme was supported. Based on the conclusions it is recommended to proceed to planning of research activities aiming at implementing the ABLE intervention programme in clinical community-based rehabilitation settings.

Key words: Activities of daily living (ADL), Chronic conditions, Complex interventions, Occupational therapy, Occupation-based interventions, Occupational Therapy Intervention Process Model (OTIPM), Transactional Model of Occupation, Effectiveness evaluation, Process evaluation, Realistic evaluation.

Dansk sammenfatning (Summary in Danish)

Bakgrund: Det er velkendt at en række kroniske tilstande kan medføre nedsat evne til at varetage gøremål i hverdagen relateret til egenomsorg og huslige gøremål, også kaldet almindelig daglig levevis (ADL), og der er behov for at udvikle og evaluere interventionsprogrammer, der adresserer sådanne problemer. Med afsæt i Britiske Medicinske Forskningsråds vejledning (MRC guiden) for udvikling og evaluering af komplekse interventioner, blev den første version af det ergoterapeutiske program (ABLE 1.0) udviklet med det formål at forbedre ADL-evnen blandt personer med kroniske tilstande. ABLE inkorporerer viden baseret på eksisterende evidens, klinisk ekspertise hos ergoterapeuter og klienters erfaringer og behov. ABLE er et 8-ugers, struktureret og individualiseret forløb, som leveres i klientens hjem som en del af kommunal rehabiliteringspraksis. Forløbet består af 5-8 sessioner, og består af vurdering af ADL-evne, målsætning, intervention baseret på en kompensatorisk tilgang og afsluttes med revurdering af ADL evne. Desuden er programmet udviklet til at kunne anvendes på tværs af alder, køn og diagnoser, dvs. generisk. Et feasibility studie viste, at ABLE 1.0 var gennemførbar med hensyn til indhold og levering, med mindre justeringer af interventionsmanualen og procedurer for rekruttering. Det blev derfor anbefalet at gennemføre et pilot studie før planlægning og gennemførelse af evalueringsstudier. Formålet med denne afhandling var derfor at evaluere de resterende feasibility-aspekter forud for et randomiseret kontrolleret forsøg (RCT), inklusive revidering af ABLE 1.0, og at gennemføre effekt og proces evaluering af ABLE 2.0.

Metoder: MRC guiden blev anvendt som ramme. Revidering af ABLE 1.0 omfattede gennemførelse af en kognitiv debriefing med deltagelse af fem ergoterapeuter, med henblik på at identificere uklarheder i ABLE manualens opbygning og indhold, som potentielt kunne føre til forvirring eller misforståelser. Derudover omfattede det inkorporering af opdaterede versioner af teoretiske modeller i programmet.

Pilot studiet var designet som et randomiseret kontrolleret studie med to parallelle grupper. Planen var at inkludere 20 personer med én eller flere kroniske tilstande, som oplevede problemer med udførelse af ADL opgaver, i

perioden fra december 2019 til april 2020. Følgende progressionskriterier blev anvendt for at vurdere gennemførbarheden at et RCT studie: (i) rekruttering (50 % opfyldte inklusionskriterierne) og fastholdelse (80 %), (ii) randomisering (80 % accepterede randomisering og proceduren blev udført som planlagt), (iii) gennemførbarhed og accept i praksis (100 % fulgte manualen), (iv) resultatmålinger (80 % af deltagerne leverede relevante og fuldt besvarede spørgeskemaer) og (v) sædvanlig ergoterapi (udtræk af nødvendig information fra klientjournaler var vellykket).

Den efterfølgende effektevaluering havde et RCT design med blindede testere og forskere. Hjemmeboende klienter med kroniske tilstande og ADL problemer blev randomiseret og allokeret til ABLE 2.0 eller sædvanlig ergoterapi. Data blev indsamlet ved baseline (uge 0), efter endt intervention (uge 10) og ved followup (uge 26). Co-primære outcomes var selvrapporteret ADL evne, målt med ADL-Interviewet (ADL-I Udførelse) og observeret motorisk ADL evne målt med Assessment of Motor and Process Skills (AMPS) ved primært endpoint 10 uger efter baseline. Sekundære outcomes var selvrapporteret ADL evne, målt med ADL-I Udførelse, og observeret motorisk ADL evne, målt med AMPS, ved sekundære endpoint 26 uger efter baseline; og selvrapporteret tilfredshed med ADL evne, målt med ADL-I Tilfredshed, og observeret procesmæssig ADL evne, målt med AMPS, ved primært og sekundært endpoint. Eksplorative outcomes var aktivitetsbalance målt med Occupational Balance Questionnaire (OBQ11), oplevede forandringer målt med Client-Weighted-Problems Questionnaire (CWP-Q) og generelt helbred målt med det første spørgsmål i the MOS 36-item Short Form Survey Instrument (SF36-SF1) ved primært og sekundært endpoint. Alle outcomes blev analyseret i Intention-To-Treat analyser efterfulgt af sensitivitetsanalyser i form af Per-Protocol analyser ved hjælp af analyser af kovarians (ANCOVA) over tid mellem grupper som repeated measures. ADL-I Udførelse ved baseline blev brugt som kovariat.

Procesevalueringen var designet som en realistisk evaluering. Ved hjælp af en programteori blev hypoteser om hvordan kontekstuelle faktorer og mekanismer i interventionsprogrammet kunne lede til bestemte outcomes, i såkaldte CMO konfigurationer, beskrevet. Procesevalueringen var baseret på kvalitative data fra interview med 8 klienter, som havde modtaget ABLE 2.0, og de tre ergoterapeuter, der havde leveret det. Desuden blev der indsamlet kvantitative data ved hjælp af registreringsskemaer, som blev udfyldt af de klienter der modtog programmet og de tre ergoterapeuter der leverede det.

Resultater: Baseret på data fra kognitiv debriefing og opdateret teori blev manualen revideret, hvilket resulterede i ABLE 2.0. På grund af Covid-19 pandemien blev pilot studiet afbrudt i marts 2020, hvilket resulterede i et begrænset datasæt, som dog blev vurderet til at være tilstrækkeligt til at besvare studiets spørgsmål: (i) 18 ud af 37 som opfyldte inklusionskriterierne (48,6 %) blev rekrutteret; alle inkluderede (n = 6) forblev i programmet (100 %); (ii) 18 accepterede randomisering (100 %), og proceduren var effektiv; (iii) ABLE blev leveret som beskrevet i manualen (100%); (iv) 92,3-100 % af deltagerne gav relevante og fuldstændige svar i to af tre spørgeskemaer; og (v) information om sædvanlig ergoterapi var tilgængelig i syv ud af ni aspekter.

I effektevalueringens ITT analyser af primære outcomes fandt vi ingen statistisk signifikante eller klinisk relevante forskelle mellem grupper i gennemsnitlige forandringer i selvrapporteret (ADL-I Udførelse) (-0.16; 95 % CI: -0.38 to 0.06) eller observeret (AMPS) (-0.1; 95 % CI: -0.3 to 0.1) ADL evne fra baseline til uge 10. Ved sekundært endpoint 26 uger efter baseline, fandt vi en statistisk signifikant og klinisk relevant forskel i motorisk ADL evne (AMPS) (LS mean change = -0.3; 95% CI = -0.5 to -0.1) mellem grupperne. Dette fund blev bekræftet i sensitivitetsanalysen (LS mean change = -0.4; 95% CI = -0.7 to -0.1).

Procesevalueringen bekræftede overordnet set programteorien og tilføjede informationer om centrale mekanismer associeret med de positive resultater af ABLE 2.0: Aktiv involvering af klienten i problemløsningsprocessen, en velfungerende samarbejdsrelation, gensidig tillid og vejledning i en aktivitetsbaseret proces med brug af kompenserende tiltag. En række kontekstuelle faktorer, herunder understøttende ledelse, visitationsprocedurer der understøttede problemløsningsprocessen, levering i klientens hjem, ergoterapeuter med gode færdigheder, og klienter, der følte sig klar til forandringer, kunne aktivere mekanismerne.

Konklusioner: På baggrund af studiernes resultater kan det konkluderes, at ABLE 2.0 havde effekt i forhold til at opnå forbedringer i observeret motorisk ADL evne, det vil sige nedsat anstrengelse i form af klodsethed, fysisk udmattelse og træthed, blandt personer med kroniske tilstande. De opnåede langsigtede effekter på den observerede motoriske ADL evne tilskrives den systematiske tilgang til problemløsningsprocessen, at interventionen leveres i hjemmet og brugen af kompenserende tiltag. Slutteligt, fordi klienternes observerede ADL evne ved baseline var den

eneste identificerede forskel mellem de klienter, der opnåede forbedret ADL evne og de der ikke gjorde, og ABLE 2.0 således var effektiv på tværs af køn, alder og diagnoser, understøtter resultaterne ideen om et generisk program. Konklusionerne danner grundlag for at anbefale iværksættelse af forskningsaktiviteter, der sigter mod implementering af ABLE interventionsprogrammet i kommunal rehabiliteringspraksis.

Nøgleord: Almindelig daglig levevis (ADL), Kroniske tilstande, Komplekse interventioner, Ergoterapi, Aktivitetsbaserede interventioner, Occupational Therapy Intervention Process Model (OTIPM), Den transaktionelle model for aktivitet (TMO), Effektevaluering, Procesevaluering, Realistisk evaluering.

Abbreviations

ABLE	A better everyday life
ADL	Activities of daily living
ADL-I	Activities of daily living interview
ADL-Q	Activities of daily living questionnaire
AMPS	Assessment of motor and process skills
CMOC	Context-mechanism-outcome configuration
CWP-Q	Client-weighted-problems questionnaire
GAS	Goal attainment scaling
GCM	Group concept mapping
IADL	Instrumental activities of daily living
ICC-OT	intensive client-centred occupational therapy
IPT	Initial programme theory
OBQ	Occupational balance questionnaire
OT	Occupational therapist
MRC	Medical research council
OTIPM	Occupational therapy intervention process model
PADL	Personal activities of daily living
PEO	Person-environment-occupation
PROM	Patient reported outcome measure
RCT	Randomised controlled trial
SD	Standard deviation
SPSS	Statistical package for social sciences
TMO	Transactional model of occupation
UOT	Usual occupational therapy
WHO	World health organisation

List of figures and tables

Original Papers

This thesis is based on the following papers:

I Hagelskjær V, Nielsen KT, von Bulow C, Oestergaard LG, Graff M, Wæhrens EE. Evaluating a complex intervention addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a randomised controlled trial (ABLE). BMJ Open. 2021;11(11):e051722.

II Hagelskjær V, Nielsen KT, von Bülow C, Graff M, Wæhrens EE. Occupational therapy addressing the ability to perform activities of daily living among persons living with chronic conditions: a randomised controlled pilot study of ABLE 2.0. Pilot Feasibility Stud. 2021;7(1):122.

III Hagelskjær V, von Bülow C, Nielsen KT, Henriksen M, Wæhrens EE. Effectiveness of a systematic problem-solving individualised occupational therapy intervention programme using adaptational strategies on the ability to perform activities of daily living among persons with chronic conditions: a double-blinded randomised controlled trial of the ABLE programme (in draft)

IV Hagelskjær V, Nielsen KT, von Bülow C, Wæhrens EE. Realist evaluation of an occupational therapy intervention programme (ABLE), addressing ability to perform activities of daily living among persons with chronic conditions (in draft)

Preface

"*Occupation* is a wonderful word. Think of it – a noun of action – it is about "doing"!" (1)
(Anne Fisher, 1998)

This quote of Dr. Anne Fisher, professor in occupational therapy, captures very well the key idea of occupational therapy, to enable people to participate in the activities of everyday life, that also underpins this thesis. The conduction of the studies in this thesis has beyond all doubt strengthened my core as an occupational therapist and taken me to a new starting point for contributing to occupational therapy as an evidence-based profession.

In 1992, I graduated as occupational therapist, forming the foundation of my professional career and identity, that ever since, of course, was shaped by various events and people that I was involved in.

For several years I worked as a clinical occupational therapist and in development projects within rehabilitation among persons with acquired brain injuries. I met many persons within this field, who taught me about humans as occupational beings and confirmed the potential of using occupations as both means and ends. Specifically, being involved with engaged colleagues in providing interdisciplinary rehabilitation at the Activity- and Development Centre, including ongoing work striving to develop solid clinical occupational therapy practice, has had a great impact on my professional identity. Hence, from the beginning of my career, I was engaged in developing the quality of occupational therapy interventions.

My Master of Science in Social Sciences and Social Work in 2013, awakened my interest in evaluation history and evaluation models, and broadened my theoretical perspectives. It very well complemented my base in occupational therapy and occupational science. Especially the theories and method on how to address the complexity of the typical problems in focus of both social work and occupational therapy, became a kind of bridge-building between the two disciplines.

In 2013, I was employed at the Bachelor's Programme in Occupational Therapy at VIA University College. Being a lecturer, working with students and colleagues, collaborating with clinical practice, and being involved in

research and development projects, inspired me to further develop my academic career.

Going into the field of research by being involved in the “A Better Everyday Life” research programme has been a unique opportunity for me to acquire skills within complex interventions and evaluation research. In the “A Better Everyday Life” I was involved with persons with strong beliefs in occupational therapy. The first version of the ABLE intervention programme was already developed, and its feasibility evaluated, and it became my job to proceed plans according to the research programme and conduct pilot and evaluation studies. The ABLE intervention encapsulates many of the strengths of occupation-centred occupational therapy. The intervention programme reflects the transactional perspective on occupation and makes use of tools that origin from occupation-centred thinking.

Hence, the last three years of my life, working in depth with an intervention, that in a distinguished manner, encapsulates the core of occupational therapy, has further shaped me into what I am today. Being involved in this research makes me feel that I represent something unique for those persons, whose lives are affected by disease, disability, or other disruptions in their occupational identity.

What drives me is still a desire to contribute to development of occupational therapy for the benefit of the people who need occupational therapy.

/Vita Hagelskjær

Rationale

It is evident that persons with chronic conditions often experience problems related to performance of activities of daily living (ADL) tasks (2–10). While occupational therapy addresses occupational performance within several areas, including ADL, rest and sleep, education, work, play, leisure and social participation (11), many persons referred to occupational therapy experience problems related to performance of ADL tasks. Hence, working with ADL is core within occupational therapy (12,13).

The basic idea behind the launch of the "A Better Everyday Life" research programme in 2015 was to develop an occupation-centred, occupational therapy intervention programme i.e. a programme based on the philosophic foundation of the profession, aiming at enhancing the ADL ability among persons with chronic conditions (14). More specifically the programme should reflect how to practice focusing on occupation throughout the occupational therapy process, use occupation as both means and ends (13), and be applicable across diagnoses. The intention was that the intervention programme should be based on occupational therapy conceptual practice models, guiding the entire occupational therapy process, and explaining e.g., the complex relationship between person, occupation, and environment, to ensure a focus on these persons' occupational performance problems, regardless of their diagnosis (14).

Accordingly, the first version of the intervention programme, named ABLE, was developed based on transactional and process models of the Powerful Practice framework (13), existing evidence, clinical expertise of occupational therapists, and clients' experiences and needs. The intervention programme was found feasible in terms of content and delivery and there was a call for further research activities. Several uncertainties still needed investigation before proceeding to full-scale evaluation.

The rationale of this thesis was that to determine the relevance of future implementation of the ABLE intervention programme, piloting of remaining feasibility aspects and evaluation of effectiveness and process was warranted.

Introduction

The ABLE intervention programme is designed to enhance the ability to perform activities of daily living (ADL) tasks among persons with chronic conditions, to enable participation and engagement in everyday life. The first version of the ABLE programme (ABLE 1.0) was developed based on theoretical models of occupational therapy, research evidence, client perspectives, and clinical experience, and partly feasibility evaluated (14–16).

The focus of this doctoral thesis is evaluation of the remaining feasibility aspects, followed by evaluation of effectiveness and process of the ABLE intervention programme in a full-scale RCT design.

In this chapter the ADL task performance problems among persons with chronic conditions will be described; concepts of relevance for occupational therapy and ADL ability will be presented; the intervention programme evaluated will be described; and topics concerning evaluation of complex interventions will be discussed.

Persons with chronic conditions

In Denmark, more than 65% of the adult population lives with one or more chronic conditions (17). Worldwide, chronic conditions are prevalent and burdensome for individuals and societies (18,19) and the prevalence of persons living with multiple chronic conditions is increasing (20). According to an estimate by WHO 71 % of all deaths worldwide is caused by chronic conditions (18), with the four most common being cardiovascular diseases, cancer, chronic respiratory diseases and diabetes. Chronic conditions are by nature of long duration, and the probability of dying from one of these diseases between the ages of 30 and 70 decreased by 18 % globally between 2000 and 2016 (18), leaving an increasing number of persons living with such diseases.

Chronic conditions may be defined as *'conditions that last a year or more and require ongoing medical attention and/or limit activities of daily living*' (21), reflecting that decreased ability to perform activities of daily living (ADL) tasks is a widespread problem among persons with chronic conditions, which is supported by several studies (2–8,22,23).

In the following paragraph the concept of ADL and the ADL task performance problems among persons with chronic conditions is described.

Activities of Daily Living (ADL)

The concept of ADL

ADL involves tasks that most people need to perform in their everyday lives, and many definitions have been proposed (24–27). Within occupational therapy, the most widespread contemporary international understanding of the concept captures ADL tasks related to selfcare and household (28), excluding tasks related to work and leisure. Many definitions distinguish between personal ADL (PADL) and instrumental ADL (IADL) (26–28). PADL involves basic self-care tasks that are necessary to perform for all people across gender, age, culture, housing conditions and interests (27). Examples are eating, toileting, grooming and dressing (26,27). IADL involves more complex household chores, necessary for independent living, including shopping, cooking, cleaning and doing laundry (26,27).

Assessment of ADL ability typically involves determining the level of independence, but in a more complete evaluation of the quality of ADL task performance, the assessment also involves the person's use of time, amount of physical effort and/or fatigue, and potential safety risks (29).

ADL tasks performance problems among persons with chronic conditions

Persons with chronic conditions often report increased physical effort, increased use of time, safety risks and need for assistance when performing both personal and instrumental ADL tasks, reflecting decreased quality of performance (2,4,5,30).

In a group of persons with chronic obstructive pulmonary disease (2) decreased quality in ADL task performance seemed extremely common, as more than 90% reported increased physical effort and/or fatigue during performance of PADL tasks (2). Further, up to 88% reported a need for assistance during performance of IADL tasks or inability to perform tasks like cooking, shopping, cleaning, and doing laundry. Also, a group of persons with Parkinson's disease (7) reported early on limitations in ADL task performance and in a group of older persons with chronic heart failure (8) 75% needed assistance with one or more ADL task, especially within the IADL domain. And in a study including 47 persons with multiple sclerosis, (23) 366 problems related to occupational performance were identified, with 51% being within self-care.

In a study from 2021 including 593 persons with rheumatological disease, incurable cancer, chronic obstructive pulmonary disease and schizophrenia (30), the participants reported problems performing similar types of activities of daily living tasks across diagnostic sub-groups, especially within IADL. The problems reported were related to quality of performance as follows: using extra time/effort was frequently reported within both PADL (from 12 to 53% across tasks) and IADL (from 9 to 34% across tasks) and being at risk/needing help was frequently reported (from 24 to 37%) in relation to more complex IADL tasks, such as weekly shopping, weekly cleaning and washing heavy clothes (e.g., bed linen) in the washing machine.

Decreased quality in performance of ADL tasks may cause reduced energy and time for participation and engagement in other types of wanted and/or needed activities including work, leisure and social life; resulting in occupational imbalance, i.e. an experience of not having the right amount of and variation in everyday activities (31).

Community-based rehabilitation for persons with chronic conditions and ADL problems

In Denmark, persons with problems related to ADL task performance caused by chronic conditions are usually offered rehabilitation services delivered by interdisciplinary rehabilitation teams. The Danish White Paper on rehabilitation defines rehabilitation as:

> *"A goal-oriented, cooperative process involving a member of the public, his/her relatives, and professionals over a certain period of time. The aim of this process is to ensure that the person in question, who has, or is at risk of having, seriously diminished physical, mental, and social functions, can achieve independence and a meaningful life. Rehabilitation takes account of the person's situation as a whole and the decisions he or she must make, and comprises co-ordinated, coherent, and knowledge-based measures"* (32) .

Since 2015, the Danish legislation prescribes that *"the municipal council must offer rehabilitation to remedy decreased level of functioning, caused by diseases not treated under hospitalisation*" (33), and further "*must offer short-lived and time-limited rehabilitation for persons with decreased level of functioning, if such rehabilitation is judged to increase the person's level of functioning and thereby decrease the need for support"* (34). These services often include occupational therapy.

Rehabilitation services are often organised to address disease-specific needs, which represents a risk of treating individuals living with more than one chronic condition as individuals with 'a series of separate problems' (35). Further, Wade argues that by focusing on activity limitations, including problems related to performance of ADL tasks, rather than disease-specific symptoms, the rehabilitation process is the same across diagnostic groups, including phases of evaluation, goal setting, intervention, and re-evaluation (36). In line with Wade, (36), a scoping review on occupational therapy for chronic conditions (37) proposed that similar interventions addressing ADL may be applicable across a range of diagnoses. Accordingly, the rehabilitation approach as well as occupational therapy rely on the idea that, even though persons with different diagnoses may experience different courses of disease and different symptoms, they have similar needs to manage everyday life (35).

Occupational therapy for persons with chronic conditions and ADL task performance problems

ADL task performance problems among persons with chronic conditions are typically addressed by occupational therapists. This is supported by research suggesting that occupational therapy interventions in general may improve ADL ability among older persons with chronic conditions (37–40). Moreover, research has provided evidence to support a structured and individualised problem-solving process applied as a part of the occupational therapy process (37,38). Disease-specific occupational therapy interventions have been designed and evaluated using a methodologically sound approach, and proven to be effective for e.g., persons with Parkinson's disease or dementia (9,41). Still, research focusing on occupational therapy interventions for persons with various chronic conditions, developed and evaluated in methodologically sound processes with use of scientific expertise, involving key stakeholders in terms of experienced occupational therapists and persons with chronic conditions was needed (9,37,39,40,42). Moreover such research should include detailed description of the intervention, determine the contribution of occupational therapy in interdisciplinary rehabilitation services, and investigate the effectiveness and functioning of the intervention programmes (9,37,39,40,42).

Hence, the need for developing, evaluating and implementing an evidence-based occupational therapy intervention programme, directly focusing on enhancing the ADL ability among persons with chronic conditions was evident (37–39,43). Further, it seemed appropriate to develop such an intervention programme to be applicable across diagnoses, sex and age, i.e. to be generic (44). Moreover, to develop a feasible

intervention programme and determine its effectiveness, methodologically sound methods should be applied (45). Therefore, in 2015 the research programme 'A Better Everyday Life' was established to develop, evaluate, and implement an occupational therapy intervention to enhance the ADL ability among persons with chronic conditions experiencing problems related to ADL task performance. From early on, the research programme followed the UK Medical Research Council's (MRC) guidance on how to develop and evaluate complex interventions (45).

Before presenting the research program further, including a description of how the intervention programme was developed and how feasibility was tested, a brief introduction to the occupational therapy profession in terms of its foundation and basic assumptions including how the present thinking and practice is formed by history is provided below.

Occupational therapy

The occupational therapy profession was founded upon visionary ideas about the nature of human beings and their vital need for activity (46) and upon the power of occupation to transform people, whose lives were affected by illness and trauma (47).

Foundation and basic assumptions

One of the founders of the occupational therapy profession, the psychiatrist Adolf Meyer, expressed the basic assumption of occupational therapy already in the 1920s, that human health is promoted through occupation i.e. work, play, rest, and sleep (48). Understanding engagement in occupation as strongly related to human development, health, and wellbeing (49) is still reflected in the basic idea of occupational therapy. The profession is grounded in medical, social behavioural, psychological, psychosocial, and occupational sciences, preparing the occupational therapist to work collaboratively with people, in communities, in groups and individually (50); and the practise is focused on enabling individuals to change aspects of their person, the occupation, the environment, or a combination of these, to enhance occupational participation (50).

The occupational perspective permeating this thesis, i.e. the way of understanding and thinking about occupation and using occupation as both mean and end, is strongly founded in the occupation-centred reasoning described by Dr. Anne Fisher and Dr. Abbey Marterella in their model for authentic occupational therapy: Powerful Practice (13). They define occupation as doing, i.e. task performances that a person wants to, needs to

and/or is expected to perform. Occupation-centred reasoning builds on three core beliefs, referring to the philosophical base of the profession: occupational therapists 1) view people as occupational beings who may have occupational challenges; 2) recognise the importance of occupation in peoples' lives; and 3) think about how to focus on and use occupation throughout all phases of the therapeutic process (13). It serves as starting point of what we do as occupational therapists, and as a driver of implementing occupational therapy in clinical practice (13).

Paradigms and evidence-based practice

Since the establishment of the education for occupational therapy in Denmark in the early 1930s, the occupational therapy profession has developed under the influence of political reforms, economic opportunities of society, social and health conditions in the population, the growing amounts of research knowledge, and increasing demands for providing evidence-based services. Hence, the paradigms consolidating occupational therapy have undergone comprehensive changes throughout the years. After World War II, the biomedical perspective increasingly dominated within health services, and the occupational therapy profession became predominantly interested in inner body mechanisms. According to Gary Kielhofner (47) this led to a painful identity crisis for the profession in the 1970s, with a growing distance to the vision of our founders, resulting in a lack of common mission and shared vision of the profession, strongly expressed in this quote: "*We had almost lost the "occupation" in occupational therapy*" (47).

In the following years the field of occupational therapy underwent a renaissance in thought about the core of the profession, and rediscovered the values from the original paradigm, focusing on holism and occupation as both means and ends (12). This is also reflected in the definition of occupational therapy, presented by the World Federation of Occupational Therapists (WFOT) in 2012:

> *"Occupational therapy is a client-centred health profession concerned with promoting health and wellbeing through occupation. The primary goal of occupational therapy is to enable people to participate in the activities of everyday life. Occupational therapists achieve this outcome by working with people and communities to enhance their ability to engage in the occupations they want to, need to, or are expected to do, or*

by modifying the occupation or the environment to better support their occupational engagement" (50) .

Like health professionals in general, occupational therapists are expected to ground clinical practice in sound evidence (51). A classic definition of evidence-based medicine is: "*... the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research"* (52). The definition represents a process that synthesises clinical expertise, with the best evidence available from systematic research, and the values and preferences of patients (53). Subsequently, a new model for evidence-based clinical decision making was suggested (54), based on patients' circumstances, patients' preferences and actions, and best research evidence, with a central role for clinical expertise to integrate these components.

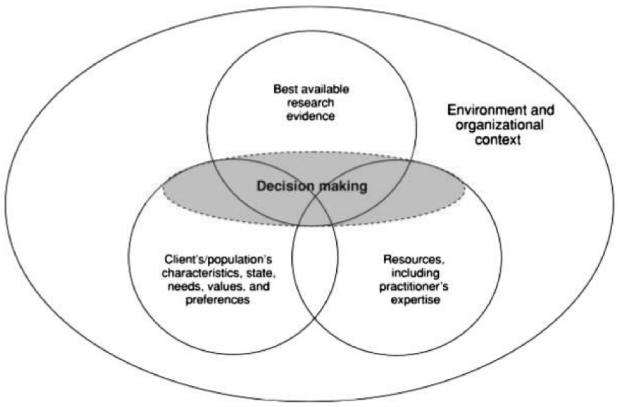


Figure 1 Evidence based clinical decision-making (54)

The model captures the importance of fitting the evidence to the single client, but is limited by not including the roles that society and healthcare organisations play in providing and limiting resources (55).

Occupation-centred reasoning

Over the years, to provide guidance on how to practice occupation-centred occupational therapy, several conceptual, process and intervention models has been developed (12,13,56). To promote the previously described occupation-centred reasoning, the Powerful Practise framework for

authentic occupational therapy by Fisher & Marterella was published in 2019 (13). The framework includes two central models; the Transactional Model of Occupation (TMO) and the Occupational Therapy Intervention Process Model (OTIPM).

The Transactional Model of Occupation

The TMO was developed to support client-centred reasoning and reflections on how occupations are continuous responses to situational elements, recognising a transactional perspective on occupation (57–59). In a transactional perspective, occupations are described as more than an individual experience. Rather, they are functionally integrated with the context (58). This context is not limited to physical forms, but includes social relationships, cultural contexts, and political aspects. Dickie et al (58) pronounce it this way: *"Occupation can be viewed as a transaction joining person and situation. In this sense, occupation becomes a way to functionally coordinate the intimate person–situation relationship"*. The transactional perspective on occupation is a cornerstone in this thesis. Hence, understanding the individual experiences of occupation is necessary, although insufficient, as occupation is considered to occur through complex contexts. In the TMO, this is illustrated by placing the client as part of, not separated from or in the center of, the intertwined transactional whole (13)

Figure 2 The Transactional Model of Occupation (TMO) (13)

The TMO illustrates occupation with three interwoven elements: occupational performance, occupational experience, and participation. Occupational performance refers to the observable aspects of doing, for example when the occupational therapist evaluates the quality of the client's performance during the standardised instrument Assessment og Motor and process Skills (AMPS). Within occupational performance, being a major focus for occupational therapy, we distinguish between two levels: a broad and a discrete level (13). The broader level captures engagement in various types of activities e.g., ADL, leisure activities or work activities; and performance of specific task, e.g., grooming, dressing, and eating. At the discrete level we focus on the smallest observable units of occupation, as links in a chain. The links are observable and goal-directed actions, referred to as performance skills. During a client's task performance we can observe each action with more or less skill (13).

Occupational experience refers to how occupation is experienced by the client (13). It is a central focus in occupational therapy to enable clients to engage in occupations, i.e., perform tasks they want to, needed to and/or are expected to perform (50). Hence, it is a core issue for the occupational

therapist to gain an understanding of the client's perspective on his/her doings, to determine if they represent relevant and meaningful occupations.

Participation refers to occupational engagement, i.e. combining the doing with the experienced value of that doing (13,60). Thus, when a person is doing something, and experience value (positive, neutral, or negative) in that doing, the person is participating (13). This includes individual or broader doings that are necessary, compulsory, ordinary, helpful, associated with commitment or responsibility, or make the person feel included, accepted, or socially connected (13).

The Occupational Therapy Intervention Process Model

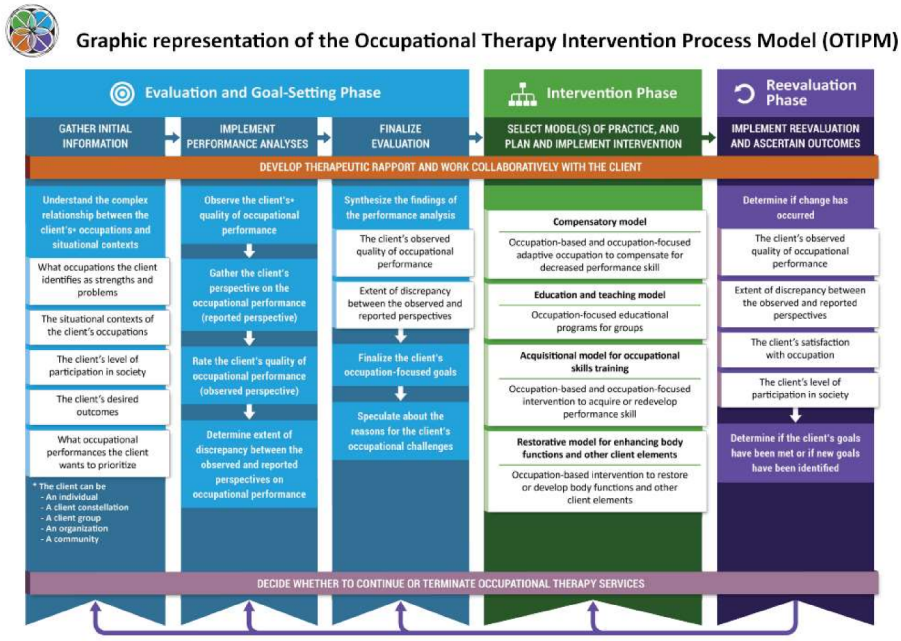
The TMO accompanies the Occupational Therapy Intervention Process Model (OTIPM) (13), outlining a practical process for planning and implementing client-centred, occupation-based and/or occupation-focused occupational therapy services. The first version of the OTIPM was presented by Anne Fisher (1) in 1998 at the Eleanor Clark Slaggle Lecture at the annual American Occupational Therapy Association (AJOT) conference.

The latest version of OTIPM was published in 2019 (13) (figure 3). The OTIPM depicts the occupational therapy process as occurring in three phases: a) Evaluation and Goal-Setting Phase, b) Intervention Phase, and c) Re-evaluation Phase (13). Each step within the phases may be occupation-based and/or occupation-focused to represent an occupation-centred reasoning (11,13). Occupation-based evaluation or intervention involves engaging the client in occupational performance, i.e. doing, whereas in occupation-focused methods the proximal focus is occupation, e.g., when the client and the occupational therapist discuss possible reasons for the client's occupational challenges (13). The OTIPM also represents a client-centred approach, i.e. establishment of a collaborate relationship that is respectful of the client's perspectives, preferences, values, and choices. The aspect of client-centredness is depicted graphically by the upper orange band in the graphical representation of the OTIPM.

Essentially the OTIPM represents a top-down approach to the entire occupational therapy process and defines methods and models appropriate for use in occupational therapy interventions (13). The entire occupational therapy process is initiated with a top-down approach to evaluation of the client's occupational performance. This includes a combination of gathering

information on the client's experienced occupational strengths and concerns, observing the client's occupational performance, formulating occupation-focused goals, and speculating about the reasons for the client's occupational challenges in a transactional perspective (13), conducted in the described order.

Four different intervention models are provided: compensatory, education and teaching, acquisitional, and restorative. To finalise the intervention the occupational therapist determines if change has occurred and the client has obtained his/her goal.



From Fisher, A. G., & Marterella, A. [2019]. *Powerful practice: A model for authentic occupational therapy*. Fort Collins, CO: Center for Innovative OT Solutions.

Figure 3 The Occupational Therapy Intervention Process Model (OTIPM) (13)

Conclusively, the OTIPM structures the occupation-centred reasoning, and incorporates the transactional nature of occupation, i.e. acknowledges occupation as a response to the situational context; that situational context extends beyond the environment; that occupation and situational context are intertwined; and that people cannot be separated from occupation nor their situational context (13).

Interventions to compensate for decreased performance skills

Previous studies support that the OTIPM is useful for structuring intervention programmes across diagnostic groups (61,62). Further, studies show that when addressing ADL task performance problems among persons with chronic conditions an adaptational approach is often preferred (30,63–65).

Adaptational strategies to compensate for decreased performance skills, by minimising the demands on the ineffective performance skills (13) may include changes in physical and social environment, use of assistive devices, and adjusting daily routines and habits. Moreover, when applying adaptational strategies, consultation and education are key features, prescribing that the OT discusses the available options with the client and engages the client in collaborative decision-making, i.e. consultation; and further engages the client in trying out, practising, and learning to use the chosen adaptational strategies aiming to incorporate them in daily routines, i.e. education (13). Hence, by means of an occupation-based approach and by altering one or more occupational or situational elements (13), using adaptational strategies aims to reduce effort and/or increase efficiency, safety, and independence in ADL task performance.

Development of the ABLE 1.0 intervention programme based on the MRC guidance

The MRC framework for development and evaluation of complex interventions to improve health was first published in 2000 (66) and updated in 2008 (45). In the following years a number of publications providing extended guidance on the subject was published (67–71). The development and feasibility phases of the 'A Better Everyday Life' research programme were conducted in the context of the MRC guidance from 2008, and the studies included in the present thesis were designed in accordance with the same guidance. The guidance (45) prescribes four stages: development, feasibility/piloting, evaluation, and implementation.

According to the 2008 MRC guidance (45), the development phase includes 'Identifying existing evidence', 'Identifying and developing theory', and 'Modelling process and outcomes'. To develop the desired intervention programme, several research activities were conducted, including:

- identification of occupational therapy theories and models supporting an occupation-centred approach

- a literature review on ADL interventions providing information on e.g. content and duration of existing ADL interventions (14);
- a descriptive study on self-reported quality of ADL task performance among persons across a variety of chronic conditions (30);
- a group concept mapping (GCM) study conducted among persons living with chronic conditions and occupational therapists experienced in working with this target group to identify and organise and prioritise ideas on how to improve ADL ability (63); and
- two expert workshops to synthesise all obtained information, modelling the intervention program, designing the specific intervention components, and developing logic models (14).

The descriptive study was conducted to further determine the relevance of a generic occupational therapy intervention programme, addressing ADL task performance problems among persons with chronic conditions. Hence, similarities and differences in ADL task performance problems across four diagnostic groups was explored (30). There was consistency in the PADL and IADL profiles of the entire group and the four subgroups, i.e. rheumatological disease, incurable cancer, chronic obstructive pulmonary disease, and schizophrenia concerning patterns of decreased quality of ADL task performance. Specifically, using extra time/effort was the dominating indicator of decreased quality of performance, and as the complexity of the tasks increased, the number of persons who reported to be competent generally decreased, and more persons perceived that their quality of performance decreased, changing from using extra time/effort, to being at risk/need help or being unable.

The GCM study was conducted to identify ideas on how to enhance the ADL ability among persons with chronic conditions, as experienced by persons with various chronic conditions and occupational therapists(63). Participants reported more than 100 unique ideas on how to enhance ADL ability, reflecting the necessity of delivering interventions that are individually tailored. Ideas were related to e.g., prioritising and planning in relation to time and tasks; receiving help from others; modifying physical environments; and using assistive devices (63). Hence, results indicated that the compensatory intervention model in the OTIPM would be relevant. Also, results revealed that similar ideas were presented by participants across diagnostic groups, supporting the idea of a generic intervention.

Conclusively, clients across chronic conditions experience similar problems related to ADL task performance, primarily in terms of increased use of time and physical effort (30) supporting to use the same methods, e.g.,

energy conversation, when intervening on particular types of ADL tasks performance problems, e.g., increased physical effort during cooking (15). Based on this information the first version of the ABLE intervention programme (ABLE 1.0) (14,63) was developed, incorporating knowledge based on existing evidence, clinical expertise of occupational therapists and clients' needs and preferences (4,14,30,63).

The ABLE 1.0 intervention programme

The purpose of the manualised ABLE 1.0 intervention programme was to compensate for long-term or permanent problems related to performance of ADL tasks among persons with chronic conditions (14). In short, ABLE 1.0 was a systematic, client-centred, 8-week occupational therapy intervention program applicable across diagnoses, sex, and age, characterised by offering an individualised combination of intervention components adapted to the single person.

The OTIPM, as described in 2009 (72), represented the theoretical frame of the intervention process. The phases of the OTIPM (72) provided the structure of the process and the design of each session. The focus on occupation was stressed throughout the programme and the intervention sessions applied the compensatory intervention model (72), characterised by using adaptational strategies to enable occupation (14).

Further, the Canadian Person-Environment-Occupation (PEO) model (73), explaining performance of everyday activities as doing shaped by the interaction between person, environment and occupation, was incorporated. The PEO was initially developed to explain and evaluate the complex relationship between a person (i.e. client, group, or organisation), an environment (i.e. physical, social, cultural, and institutional factors), and an occupation (here defined as clusters of tasks a person performs to carry out roles) reflecting how occupational performance relies on all three elements (73). The PEO model is in illustrated in figure 4.

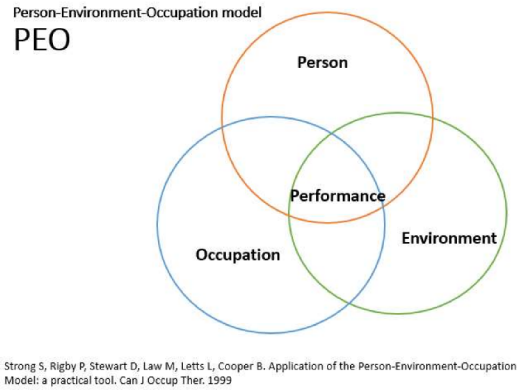


Figure 4 Person-Environment-Occupation (PEO) model

ABLE 1.0 consisted of five to eight sessions. Session 1 involved standardised evaluation of perceived and observed ADL ability by means of the ADL Interview (ADL-I) (74) and the Assessment of Motor and Process Skills (AMPS) (26,75), respectively. AMPS is an observation-based instrument measuring two aspects of ADL task performance: ADL motor ability (reflecting physical effort) and ADL process ability (reflecting efficiency, safety, and independence).

Session 2 concerned client-centred goal setting using Goal Attainment Scaling (GAS) (76,77). GAS is a tool for defining and monitoring individual goals. The client was to be actively involved in defining goals and describing levels of goal attainment. Goals were to be defined based on the ADL task performance problems identified and prioritised using ADL-I in session 1. Further, this session included clarification of reasons for ADL tasks performance problems, using the PEO model (73), in collaboration between the client and the OT.

Sessions 3–7 were intervention sessions, focusing on adaptation by employing a combination of nine intervention components to improve ADL task performance. The components were organised based on the PEO model (73). The personal (P) components included 'changing habits related to task performance (P1)'; 'changing attitude (P2)'; and 'plan, prioritise and reject (P3)'. The environmental (E) components included 'changing physical environment (E1)'; 'changing social environment (E2)'; 'use of tools, technology and/or helping aids (E3)'; and 'referring to other relevant services and opportunities (E4). And the occupational (O) components

included 'dividing the task into minor steps/distributing the task performance over longer time (O1)'; and 'simplifying the process or the task (O2)' (14). The intervention sessions were delivered face-to-face or by telephone, with or without homework (e.g. practicing strategies and trying out new ways of doing) between sessions.

The final session included re-evaluation of self-reported and observed ADL ability using the ADL-I and the AMPS, and evaluation of goal attainment using GAS. Sessions 1-4 and the final session were mandatory. The programme was developed to be delivered in the homes or local areas of the participants and was designed to be implemented as part of community-based rehabilitation services. As this was a newly developed intervention programme several uncertainties existed and a feasibility study was conducted.

Feasibility of the ABLE 1.0 intervention programme

According to the 2008 MRC guidance (45), the feasibility and piloting phase involved testing the primary uncertainties identified during the development phase. The framework by O'Cathain (67), suggesting to evaluate selected aspects of feasibility such as (a) content and delivery of an intervention; (b) design, conduct, and processes of an outcome trial; (c) identification and selection of outcomes; and (d) how to measure, was applied.

In a pre- and post-test design, n=30 persons with chronic conditions, received the ABLE 1.0 (15,16). Twenty clients (67 %) completed ABLE 1.0 and received four sessions (median = 4, range 4–7) and the most frequently applied component was 'changing habits related to task performance (P1)'. Deviations from the manual were made within evaluation of ADL ability and goal setting, and in some cases less than the mandatory number of 5 sessions were delivered. The occupational therapists reported confidence in delivering the programme and the clients receiving the ABLE 1.0 perceived the programme as meaningful and satisfying. Further, the clients experienced progress towards goal attainment, and goal attainment was reached in 52 % of the goals. Sixteen (80 %) of the clients completing the programme obtained clinically relevant improvements in self-reported or observed ADL ability.

The feasibility study showed that ABLE 1.0 was feasible in terms of content and delivery when delivered in a Danish municipality. More

specifically, the programme was feasible in terms of intervention development, intervention components, mechanisms of action, perceived value, benefits, harms or unintended consequences, feasibility and acceptability in practice and fidelity, and reach and dose of intervention (15).

However, the feasibility study also revealed a need to apply minor adjustments to the intervention manual and to adjust the recruitment procedure (15) before proceeding to an evaluation phase (45). Accordingly, a pilot RCT to evaluate the remaining feasibility aspects in terms of design, conduct and processes of an outcome trial, including recruitment, randomisation, adherence, and how to measure potential outcomes was recommended (15).

Choice of evaluation models

While both the original MRC framework (66) and the 2008 guideline (45) upheld the RCT as golden standard for testing complex interventions, the value of process evaluation within a trial, was recognised in the 2008 guideline stating that such an evaluation could *"be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors, associated with variation in outcomes"* (45). However, guidance on how to conduct process evaluations was not provided until 2015. In the guidance Moore et al (78) highly recommend a theory-driven approach, when conducting process evaluation. A theory-driven approach is considered vital when seeking to understand the causal assumptions underpinning an intervention and when building an evidence base to inform policy and/or practice on how an intervention works (78). Still, examples of how to conduct process evaluations within a trial were limited, and apart from being criticised for preferring experimental to observational design and for paying too little attention to understanding how and under what circumstances an intervention would bring about change, the MRC guidance was criticised for missing notion of historical change (79,80).

Taking a broader perspective on evaluation, it has been discussed for decades, how to best evaluate complex interventions. Evaluations of public health services, including rehabilitation services, are widespread, required, and varied (81). Evert Vedung defines evaluation as *"careful retrospective assessment of public-sector interventions, their organisation, content, implementation and outputs or outcomes, which is intended to play a role in future practical situations"* (81). According to this definition, evaluation serves to inform decision making, involves transparency concerning methods, systematic data collection, documentation and reporting in line

with research practice, and may include e.g., investigation of effects of interventions, implementation, processes, and organisation (81–83). Using a metaphor of waves depositing layers of sediments, Vedung describes how evaluation history has formed the contemporary evaluation thinking and practice (81).

Rolling from around the 1960s and earlier, the science-driven wave deposited high regard to experimental designs and randomised controlled trials (81,82). Following this call for objective science, the dialogue-oriented wave rolled in from the mid-1970s, depositing the idea of more pluralistic evaluations, including more dialogue and involvement of stakeholders at different levels (81). Around 1980, the neo-liberal wave entered the scene, approaching evaluation as accountability and value for money (81). The fourth wave, the evidence wave, started rolling in the late 1990s, as an effort to make government more scientific, e.g., reflected in ranking evidence in an evidence hierarchy with experimental designs as 'Gold Standard' (81,82). The evidence wave may be interpreted as a turnback to aspects of the first wave. However, as anticipated by Vedung, the power of the evidence wave would soon decrease (84) due to a growing discussion between the proponents of experimental designs and more responsive approaches, of the cornerstone in evidence-based knowledge, and of context dependent versus context independent knowledge (82). As a spin-off, the realistic evaluation approach was presented, suggesting ways to conduct evaluation of effect in real settings (82). In the 1990s, Ray Pawson and Nick Tilley were among the first researchers to present realistic evaluation addressing the question 'what works for whom, in which circumstances, and how' (85). The approach aimed at meeting the challenges of designing and evaluating complex interventions, requiring deeper insight into the nature of intervention programmes and the contexts of implementation (85).

At almost the same time, the MRC published the first version of their framework (66) addressing challenges related to defining, developing, documenting, and reproducing complex interventions. This first version presented sequential phases in developing randomised controlled trials of complex interventions (66), and hence represented a bio-medical approach to evaluation. Yet the authors stated that, "*we focus on randomised trials but believe that this approach could be adapted to other designs when they are more appropriate*" and hence acknowledged that variations in e.g., the intervention itself, in the expertise among health professionals and the persons receiving the intervention, and in the organisations entailed specific difficulties (66). However, the framework (66) provided only limited guidance. Due to critique concerning limited focus on piloting and feasibility testing, a linear approach, demands for integrating process and outcomes

evaluation, more focus on the role of context, and request for more information on the interventions a revision was published in 2008 (45). The definition of complex interventions was updated to also include complexity due to the persons receiving and delivering the intervention; the concept of context was elaborated and tailoring of the interventions to local circumstances was recognised. Moreover, the model itself was more dynamic. Still guidance was limited (79).

Within health services research the realistic evaluation approach has been increasingly used. Addressing the challenges of researchers within complex interventions, the RAMESES II project was established in 2017, funded by the UK National Institute of Health Research's Health Services and Delivery Research (NIHR HS&DR) (86). The project group, consisting of experienced researchers within realistic evaluation, developed quality and reporting standards and resources and training materials for realist evaluation (85,87).

Another key source contributing to designing the evaluation phase of the 'A Better Everyday Life' research programme was the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer) group (88). The DECIPHer group consists of researchers from a range of disciplines within public health with a particular focus on developing and evaluating multi-level interventions. DECIPHer is funded by Welsh Government through Health and Care Research Wales. The DECIPHer group outlines key principles guiding complex intervention development and evaluation, including the MRC framework (45,89) and realist principles (90). Hence, where MRC was lacking guidance, the DECIPHer group and the RAMESES II project delivered guidance, representing perspectives on complexity that was more updated and in line with Vedung's description of the present evaluation thinking and practice (81).

Frameworks for developing and evaluating the ABLE 2.0 intervention programme

As recommended by the MRC guidance (45) and further inspired by the DECIPHer group and the RAMESES II project, it was decided to apply evaluation of effectiveness, process evaluation (i.e. in terms of content and delivery; and functioning of the programme) and evaluation of cost-effectiveness in a nested design. The cost-effectiveness evaluation is not part of this thesis and will not be described further. For the process evaluation investigating the functioning of the next version of the ABLE intervention program (ABLE 2.0), i.e. to put focus on the role of context, associated with variation in outcomes (45), and to gain a deeper insight into the nature of the

intervention programme and the contexts of implementation (85,87) the realist logic was helpful. Realist evaluation is based on the assumption that intervention programmes work under certain conditions, i.e. contextual factors, and are influenced by the way different stakeholders, including deliverers and receivers of the intervention, respond to them (90,91).

Context is defined as material/social/organizational/economic/ technical/individual characteristic required for a mechanism to produce a desired outcome. It is "*the contextual conditioning of a causal mechanism which turns (or fails to turn) a causal potential into a causal outcome*" (90). Contexts operate at different levels (92):

1) an individual level (e.g., OT's skills, client's and OT's engagement, OT being familiar with the programme and acting as facilitator of change, client and OT characteristics),
2) an interpersonal level (e.g., the relationship between client and OT, the relationship between the research group and the OTs delivering the programme, and the relationship between the OTs and their administration),
3) an institutional level (e.g., culture in the municipality and how the institutional frames contribute to rehabilitation services), and
4) an infrastructural level (e.g., the extent of political support and how other administrations, such as the referral services contribute or counteract delivery of the programme). Furthermore, different types and levels of context interact and influence each other (92).

Mechanisms explain the impact of the interaction between the resources in the intervention programme and the persons' reasoning and choices (85,90,93). Mechanisms represent how persons receive, interpret and act upon programme resources, to produce outcomes (93). Examples of mechanisms are a therapeutic relationship, client feeling informed and involved, and collaboration between client and OT on finding solutions. Mechanisms do not work like an on/off switch, but rather like something you can turn up and down. Three essential indications on mechanisms are: 1) they are usually hidden (the black box), 2) they are sensitive to variations in context, and 3) they generate outcomes (94).

Outcomes are results of the interaction between a mechanism and its triggering context (85,90). They can be changes in behaviour, thinking or emotions in a client or OT. Outcomes include intended and unintended short-, medium- and long-term changes, resulting from intervention programmes. The understanding of how different contextual factors shape the mechanisms which leads to certain outcomes in a realistic evaluation can be expressed in context-mechanism-outcome configurations (CMOCs) (85).

The MRC framework 2021

In September 2021, the widely used MRC guidance (45) was replaced by a new framework (89) taking account of development in theory and methods in the intermediate years. The MRC framework for developing and evaluating complex interventions: update of Medical Research Council guidance (hereafter the MRC framework) (figure 5) (89) divides complex intervention research into four phases, i.e. development, feasibility, evaluation, and implementation. This is in line with the previous guideline (45), structuring the development phase and feasibility evaluation of ABLE 1.0.

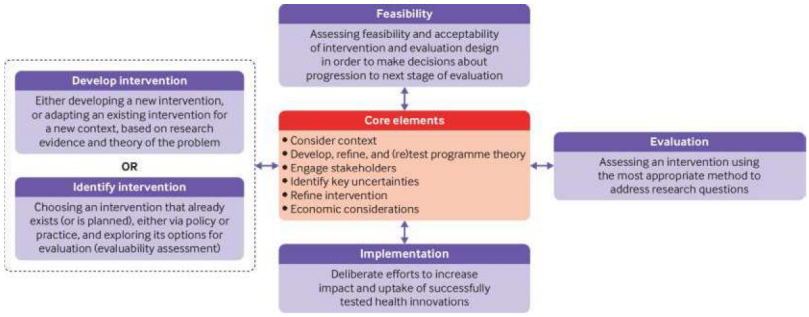


Figure 5 MRC Framework for developing and evaluating complex interventions (89)

In the MRC framework (89) key updates were included in terms of updating the definition of a complex intervention to include both the content of the intervention and the context in which it is conducted; adding systems thinking methods, taking wider contextual factors influencing an intervention into account, which implies a change in focus of evaluation from '*is it effective*?' to '*does it contribute*?'; and increased emphasis on engagement of various stakeholders in the research process including implementation considerations.

Consequently, an intervention is considered complex, when several components are involved in the intervention, when targeting a range of behaviours, or when a range of skills and expertise is required among those who receive and deliver the intervention. Further, to encapsulate the definition of complex, several settings, groups, and levels are targeted, or the intervention or its components permits a level of flexibility (89). Six core elements are suggested for consideration within each phase and in the transition between stages: context; develop, refine, and (re)test programme theory; engage stakeholders; identify key uncertainties; refine intervention, and economic considerations (89).

Summary

ADL task performance problems among persons with chronic conditions are widespread and the need to develop and evaluate occupational therapy interventions addressing such problems is evident. Previous research studies adopted the MRC guidance published in 2008, to structure development and feasibility evaluation of the first version of the ABLE intervention programme (ABLE 1.0). Feasibility in terms of content and delivery was established with minor adjustments to the intervention manual and recruitment procedures.

ABLE 1.0 was an 8-week occupational therapy intervention program consisting of evaluation of ADL ability (session 1); goal setting and clarification of causes for ADL problems (session 2); intervention building on an adaptational approach (sessions 3–7); and re-evaluation (final session). ABLE 1.0 was developed to be delivered in the homes of the clients.

At the starting point of this thesis, we were in possession of an intervention programme that was well described, tested, accompanied by a manual and continuously revised. The aims of this doctoral thesis were to revise the intervention programme as recommended in the feasibility evaluation, evaluate the remaining feasibility aspects of the ABLE intervention programme in a pilot RCT, and conduct effectiveness and process evaluations in a parallel design.

Aims of this Thesis

The overall aim of this thesis was to conduct effectiveness and process evaluations, initiated by conduction of a pilot study, on an occupational therapy intervention program applicable across diagnoses, sex, and age, aiming at enhancing performance of ADL tasks among persons with chronic conditions.

Underpinning aim of thesis

1. To revise the ABLE intervention programme

Specific aims of the pilot study (study 1)

2. To evaluate the remaining feasibility aspects of a randomised controlled trial in terms of
   a. assessing effectiveness of the recruitment process and retention in the context of a future trial

   b. assessing the randomisation procedure and determine the acceptability of randomisation among the participants

   c. assessing adherence to the intervention program in the same context as the future RCT trial

   d. assessing appropriateness of additional outcome measurements

   e. determine if needed information on usual occupational therapy (UOT) can be extracted from the client records in the municipality

Specific aims of the effectiveness evaluation (study 2)

3. To determine the effectiveness of ABLE 2.0, compared with UOT, in persons experiencing decreased ADL ability following chronic conditions. It was hypothesised that participants receiving ABLE 2.0 would achieve:

   a. a significantly higher increase in self-reported ADL task performance and/or a significantly higher increase in observed ADL motor ability (coprimary outcomes)
   b. a significantly higher increase in self-reported satisfaction with ADL task performance and/or a significantly higher increase in observed ADL process ability (secondary outcomes)

4. Explore outcomes related to occupational balance, perceived problems, and general health

Specific aim of the process evaluation (study 3)

5. To evaluate the interactions between context, mechanisms, and outcomes, and determine in what circumstances, for whom, why and how ABLE 2.0 enhanced the ADL ability in persons living with chronic conditions

Methods

In this chapter the methods applied in the research activities that make up this thesis are described.

Overview of thesis

Overall, this thesis was structured by the MRC framework (89), primarily concerning the feasibility and evaluation phases. Moreover, research activities concerning further development of the intervention programme and development of an initial programme theory underpinning the intervention programme were also conducted, reflecting an iterative process (78,89,90). The core elements outline in the MRC framework(89) were considered during research activities and studies, supporting the focus on complexity.

As prescribed in the MRC framework (89), considerations concerning the implementation phase were inherent in the applied research activities since the establishment of the 'A Better Everyday Life' research programme in 2015 (89), e.g., by involving persons with chronic conditions and occupational therapy clinicians in identifying intervention components, and by designing the studies in collaboration with the municipalities where they were to be conducted. Hence, it was continuously a purpose to gain knowledge on how to implement the ABLE programme in community-based rehabilitation services.

As this thesis is a continuation of several previously conducted studies developing and feasibility evaluating the ABLE 1.0, the initial research activities addressed some key uncertainties, and considerations related to context and programme theory (89) in the transition between past and future studies. This included revision of the intervention programme by incorporating updates of theory and results from the feasibility evaluation; transition to a realist evaluation approach when developing the ABLE 2.0 initial programme theory (IPT) expressing the relationship between context, mechanism, and outcomes; revision of the ABLE manual, including validation of the content by involving occupational therapists from clinical practice. Overall, these research activities resulted in ABLE 2.0.

Next, a pilot study (study 1) was designed and conducted evaluating the remaining feasibility aspects related to a future, full-scale trial. This step also

included establishment of cooperation with the municipality (89), where the evaluations where to take place, and involvement of several stakeholders.

At the final and most comprehensive step, a full-scale trial, to determine the effectiveness of ABLE 2.0 (study 2) was designed and conducted alongside a process evaluation (study 3) to investigate the functioning of ABLE 2.0. Table 1 provides an overview of the research activities forming the basis of this thesis, including their relationship to the different phases of the MRC framework (89), study aims, designs, stakeholder involvement, and data. As prescribed in the MRC framework, the specific studies are conducted in a non-linear order, which this thesis hopefully reflects.

Table 1 Overview of research activities

		Phase in MRC framework	Aim	Design	Stakeholder involvement	Data
Research activities (preparing for pilot and full-scale trial)	Refine ABLE intervention programme	Development and informing implementation	Incorporate updated theory and feasibility study results	n/a	n/a	Quantitative Qualitative (feasibility study data)
	Develop programme theory	Development and informing implementation	Develop ABLE 2.0 initial programme theory	Realistic evaluation	n/a	Quantitative Qualitative
	Revise the ABLE manual	Development	Update the manual resulting in the ABLE 2.0 manual	Cognitive debriefing	n=5 OTs	Qualitative
Study 1	Pilot study	Feasibility and informing implementation	Determine feasibility and acceptability of evaluation design in future full-scale trial	RCT	n=13 clients n=6 OTs	Quantitative
Study 2	Effectiveness evaluation	Evaluation	Evaluate effectiveness of ABLE 2.0 compared with UOT	RCT	n=78 clients n=9 OTs	Quantitative
Study 3	Process evaluation	Evaluation and informing implementation	Investigate delivery and functioning of ABLE 2.0	Realistic evaluation	n=8 clients n=3 OTs	Quantitative Qualitative

ABLE, a better everyday life; OT, occupational therapist; RCT, randomised controlled trial; UOT, usual occupational therapy

Figure 6 provides a more visual overview of the studies and how different research activities, in an iterative process (89), supported the work of refining the intervention programme, application of realist evaluation principles, design and planning of the evaluation phase all together leading towards future research aiming for contextually adapted implementation. The blue circle frames the studies within this thesis and serves to illustrate how context is essential to the intervention itself and to the potential effect, i.e. knowledge on the link between the ABLE intervention programme and its effect depends on the context, which is a core perspective in this thesis.

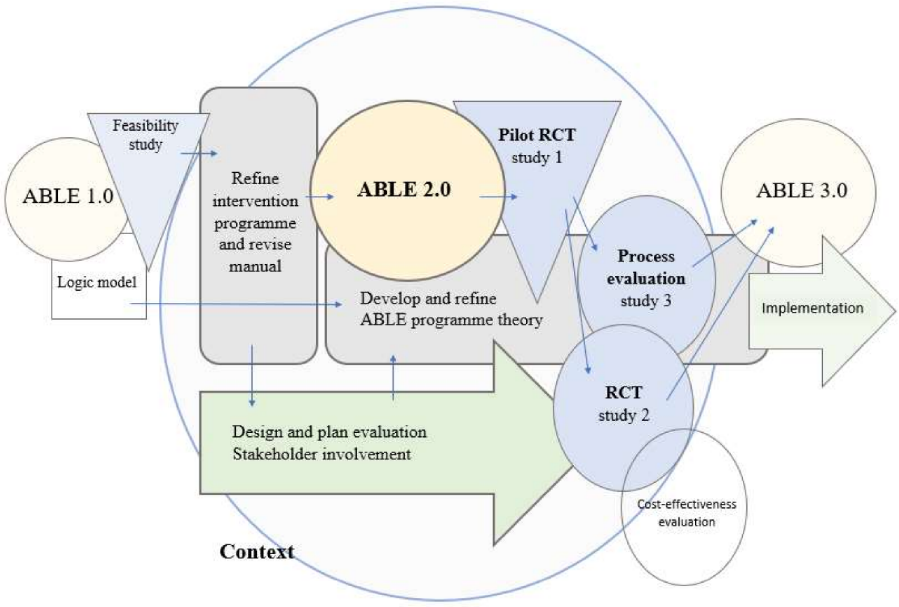


Figure 6 Research activities and studies in this thesis

In the following detailed descriptions of the applied methods are provided.

Revision of the ABLE intervention programme

Revision of the ABLE intervention programme involved a series of research activities including application of updated theories to the manual, strategies to increase adherence to the programme, and development of an initial programme theory. These research activities implied continuous revision of the manual, finalised by conducting a cognitive debriefing among OT clinicians to validate its content, resulting in the ABLE 2.0 manual.

Updated conceptual models

First, relevant updates of the conceptual practice models, i.e. OTIPM and the accompanying TMO (13) permeating the programme, were identified. Further, in the updated version of the OTIPM (13) the process of determining the extent of discrepancy between the observed and self-reported perspectives on the occupational performance (i.e. in the Evaluation and Goal-Setting Phase) had been specified (13). Accordingly, to support the dialogue between the client and the OT on this issue within the ABLE programme, an assessment form to determine how the client and the OT each perceived the quality of the client's ADL task performance during the AMPS evaluation, was developed, based on the OTIPM, and included in the updated ABLE manual (13).

Attempts to increase adherence

Based on qualitative interviews with clients receiving and OTs delivering ABLE 1.0 conducted as part of the feasibility evaluation (15,95) there was a need to apply minor adjustments to the intervention manual to further increase adherence. This included to:

- clarify that access to assistive devices would be a prerequisite for delivering the programme,
- provide more supportive description of the goal setting process, clarify the importance of tailoring and timing delivery to the individual client,
- clarify that consultation was to be part of all intervention components due to the compensatory model (13),
- clarify that GAS (76,77) is based on self-report,
- clarify that the intervention component 'changing habits related to task performance (P1)' often is combined with other components, and
- provide a clearer description of the concept of ADL (96).

To improve adherence to the programme, the training workshop for the ABLE OTs was planned to be extended to last three-and-a-half days and by spreading the workshops over a month, practicing the use of the instruments and delivery of the sessions would be allowed. Further, the manual was revised by adjusting the descriptions of how to evaluate the ADL ability and conduct the process of goal setting, and by supplying with more examples underpinning the importance of the use of the prescribed instruments. It was emphasised that evaluation of ADL ability was conducted before goal setting and intervention, and that dialogue on causes for the identified ADL problems was conducted before intervention. Further, it was clarified that consultation was not to be applied during the first 2 sessions. However, if an

OT would find it relevant for the client, intervention would be allowed at the end of session 2. The mandatory number of five sessions were maintained.

Development of programme theory

To address the question of what works in the ABLE 2.0 intervention programme, in which circumstances, for whom, why, and how, the realist evaluation approach was employed. Realistic evaluation begins with developing a programme theory (79,87,90), also illustrated in the realistic evaluation cycle (90) (figure 7).

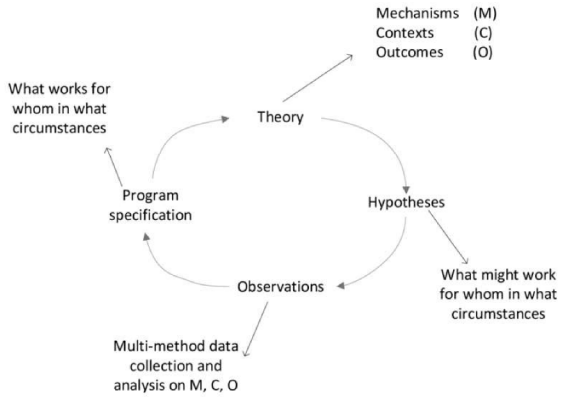


Figure 7 The realist evaluation cycle (90)

The ABLE 2.0 initial programme theory (IPT) was informed by the theory-of change-logic model (14), constructed during the development of the first version of ABLE intervention programme (14,30,63), and the results of the feasibility study (14–16). The ABLE 2.0 IPT captures the assumptions of ABLE 2.0 in terms of 'what works, for whom, in what circumstances, and how?' (85) and is expressed using the context-mechanism-outcome terminology.

The overarching ABLE 2.0 IPT assumed that ABLE 2.0 would improve clinical outcomes in terms of observed and/or self-reported ADL ability, based on a structured and individualised problem-solving process in the client's home. More specifically it was assumed that the overall occupation-centred approach informed by the models in the Powerful practice framework; the systematic problem-solving process based on the OTIPM facilitating evaluation of ADL ability and goal setting prior to intervention; the comprehensive involvement of the client during all sessions; skilled and engaged OTs delivering the programme; the adaptational approach in the

intervention sessions; and re-evaluation of ADL ability and determination of goal attainment, including feedback to the client, at the final session, would have particular impact in terms of sustainable changes. ABLE 2.0 IPT is illustrated in figure 8. As illustrated, some of the interactions between context, mechanisms, and outcomes in the IPT were assumed to work throughout the intervention programme, whereas others were assumed to function in specific sessions.

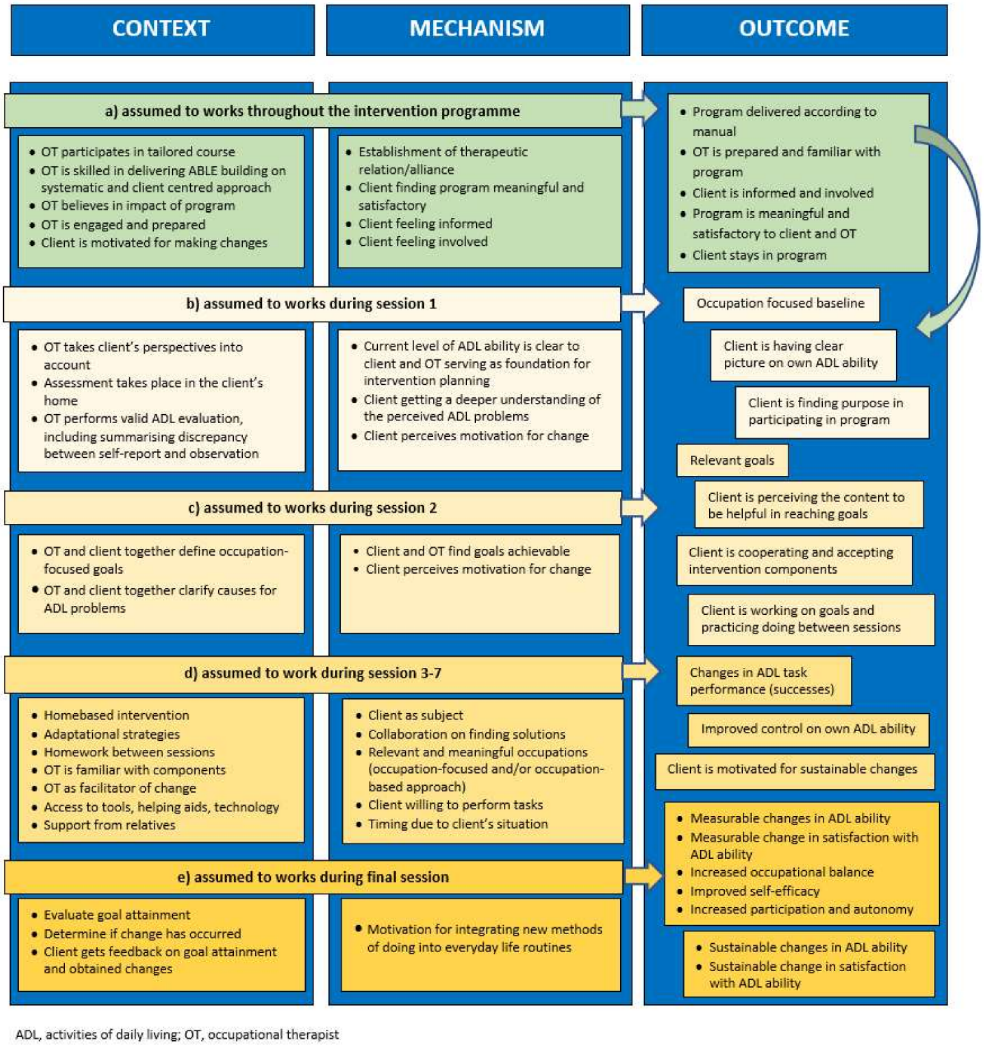


Figure 8 ABLE 2.0 initial programme theory

As the ABLE 2.0 IPT expressed the theoretical base of ABLE 2.0, it served as structure for data collection in the process evaluation (study 3).

Cognitive debriefing

To revise the ABLE manual a cognitive debriefing (97,98) was undertaken. During the revision of the manual the context in terms of OTs, considered to be core stakeholders (89), were involved and key uncertainties (89) in the manual were identified to aim for adherent delivery of the programme.

The cognitive debriefing was conducted in August 2019. The purpose of the cognitive debriefing was to examine the manual in terms of any aspect that could lead to confusion or misunderstanding, i.e. key uncertainties, among persons in the target group (89). Cognitive debriefing is a qualitative method by which a questionnaire, guide or manual is actively examined among representatives of the target group (97,99). The ABLE manual targets occupational therapists delivering the ABLE intervention programme. The intention was to assess if the occupational therapists understood and interpreted the content of the manual as intended, if they found it acceptable and contextually relevant, and to identify misunderstandings and confusions (97) leading to limited adherence. In cases of confusion or unclear descriptions we also wanted to obtain alternatives in terms of phrasing (98).

Completion of the cognitive debriefing involved a series of steps. First, the updated theories, the efforts to increase adherence, and the aspect of discrepancy including the developed assessment form, were incorporated in the manual. Then, an interview guide was developed to facilitate the cognitive debriefing including questions related to the structure and content of the manual, and to how the figures and boxes in the manual supported delivery of the intervention. E.g., the participants were asked about an illustration of the PEO model: '*How do you think the illustration works? Is it adequate or do you have any suggestions for revising it?*'

Occupational therapists (n=5) were invited to participate in the cognitive debriefing. Table 2 provides an overview of the inclusion and exclusion criteria. The sample of occupational therapists participating in the cognitive debriefing should cover a range from short-term to long-term experience from clinical practice and as occupational therapists in general, and represent different clinical areas, i.e. psychiatric and somatic areas, hence, aiming for variation in experience and age.

Table 2 Inclusion and exclusion criteria for participants in the cognitive debriefing

Inclusion criteria	Exclusion criteria
Occupational therapist experienced working with persons with chronic conditions	Employed in municipalities where feasibility or pilot studies were conducted
Experienced working with ADL problems, preferably both occupational therapists with little and a lot of experience	Experience from community-based clinical practice dates back more than 7 years (due to the ability of assessing the applicability of the manual in a current context)
Experience from community-based clinical practice	
Interested in participating in research	

Procedures

One week prior to the interview, the participants received a copy of the manual, as well as a guidance for their reading. They were prompted to prepare the cognitive debriefing by taking notes during their reading of the manual to help them remember details and ideas. We also asked for their permission to collect their notes after the interview.

The cognitive debriefing interview was facilitated by the researcher who developed, and feasibility tested ABLE 1.0 and I, and was recorded. Following the interview, the recording was listened through and all comments and ideas for revising the manual were extracted. The findings were reviewed and incorporated in the ABLE 1.0 manual (97,98), resulting in the ABLE 2.0 intervention programme. ABLE 2.0 is consistent with ABLE 1.0 in terms of the overall structure and intervention components. The manual was revised according to updated conceptual models and the results of the cognitive debriefing.

Design of studies 1-3

Alongside the research activities on revision of intervention programme and development of the programme theory, the design and planning of the pilot study (study 1), and the full-scale trial (study 2 and 3) was initiated. This section provides descriptions of methods applied in the pilot study (study 1), the effectiveness evaluation (study 2) and process evaluation (study 3).

The studies were conducted in the same municipality, and since the pilot study aimed to evaluate the remaining feasibility aspects of a full-scale trial, planning of the studies was intertwined. In the transition between the

feasibility and evaluation phase, core elements (89) in terms of context, involvement of stakeholders and key uncertainties were taken into account. The management in several departments of the municipality were involved in the design of the studies to overcome practical obstacles. For example, to make randomisation at an individual level possible in the effectiveness evaluation, delivery of the occupational therapy services had to be adapted in terms of planning of delivery of the interventions and the OTs transportation; and to make it possible to deliver the ABLE intervention programme as intended, adaptation of the usual referral procedure was adapted. Moreover, uncertainties included evaluation of trial procedures (recruitment and randomisation), adherence, access to information on UOT and feasibility of additional outcome measurements.

Design of the pilot study (study 1)

The pilot study was designed as two-armed, parallel, single-centre, randomised controlled trial with random and stratified allocation to ABLE 2.0 or UOT. The pilot study was scheduled to be conducted from December 2019 to May 2020. Twenty (n=20) persons were intended included in the pilot study, randomised equally (1:1) to receive either ABLE 2.0 or UOT.

Specific, pre-defined progression criteria to determine whether to proceed to a full-scale trial or not, were applied to optimise the pilot itself and the subsequent main trial, avoiding initiation of an un-realistic main trial (100) and for a transparent process of progression decision-making (101). Criteria for progression to full-scale RCT were determined using a framework by O'Cathain et al (67) and a checklist provided by Charlesworth et al (101). The following aspects were assessed: recruitment and retention, randomisation procedure, adherence to program, appropriateness of outcome measurements, and availability of information on UOT.

Design of the effectiveness evaluation (study 2)

In line with the pilot study, the effectiveness evaluation was designed as two-armed, parallel, single-centre, randomised controlled, outcome-assessor and investigator blinded trial, with two parallel groups, to compare ABLE 2.0 with UOT. In the effectiveness evaluation eighty (n=80) persons were to be included. The study investigated the outcomes of ABLE 2.0 with primary endpoint at 10 weeks from baseline, corresponding to the planned duration of ABLE 2.0 and the time when the largest improvement was expected. Secondary endpoint was at 26 weeks from baseline. The study was designed as a superiority trial. Participants were randomised equally (1:1) to receive either ABLE 2.0 or UOT (see below for details). The effectiveness and

process evaluations were conducted from December 2020 to October 2021. The overall design of the trial is illustrated graphically in figure 9.

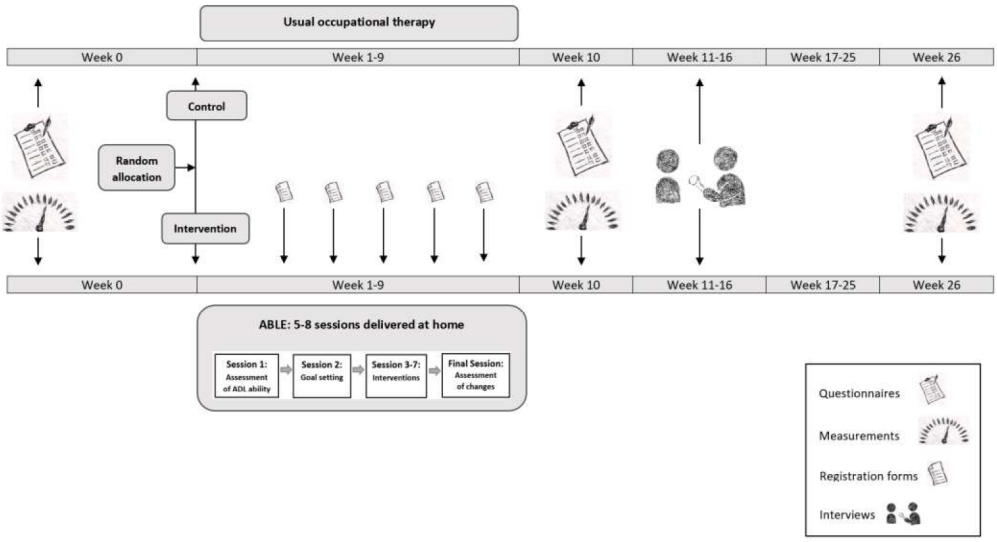


Figure 9 Graphical illustration of the ABLE 2.0 trial design

Design of process evaluation (study 3)

To seek contextualised understandings of how ABLE 2.0 produces change (89), a process evaluation was employed alongside the effectiveness evaluation. In the process evaluation (68), to investigate the quality of the implementation of ABLE 2.0 and how contexts triggered mechanisms to produce outcomes, and to facilitate further development of the programme theory (102), a theory-driven approach based on realist evaluation (90,103) was applied. The ABLE 2.0 IPT served as a structure for the process evaluation in terms of identifying questions and determining the types of data to be collected from where and from whom (85), to best support the process of further refinement of the intervention programme and inform on implementation. Quantitative and qualitative data were collected among participants receiving ABLE 2.0 and the OTs delivering ABLE 2.0 (ABLE OTs) during and after the intervention period.

Since the effectiveness and process evaluations were conducted in a parallel design, sometimes conflicting interests occurred. In the effectiveness evaluation the importance of randomisation at an individual level was prioritised, whereas the investigation of ABLE 2.0 in its context was more

important in the process evaluation. Hence, to ensure equal attention to participants in the two groups and avoid influencing follow-up measurements at week 26 in the effectiveness evaluation, individual participant interviews between week 10 and 26 were conducted in both the ABLE and the control group. The interviews in the control group were conducted by pre-graduate occupational therapy students in their bachelor thesis. Only data from the interviews with participants in the ABLE 2.0 group are reported in this thesis.

Participants and setting in studies 1-3

The pilot study (104), the effectiveness evaluation, and the process evaluation were all planned to be conducted in the same setting, namely a Danish municipality counting almost 90.000 inhabitants. About 50.000 persons lived in the main town, and the rest lived in villages or rural areas. All interventions were delivered by OTs employed in the municipality, with rehabilitation services organised in four demographically comparable geographic areas (North, East, South, and West), each with an interdisciplinary rehabilitation team. ABLE 2.0 was delivered by three OTs (ABLE OTs) affiliated with areas East or West, whereas UOT was delivered by any occupational therapist (UOT OT) from areas North or South.

Eligible participants for the pilot study lived with one or more medically diagnosed chronic condition, were aged ≥ 18 years; lived in own home; experienced ADL task performance problems; communicated independently and relevantly (without severe cognitive deficits); were motivated and ready for making changes in performance of ADL; motivated and ready for cooperating with OT in finding solutions to the experienced problems; and able to understand and relevantly answer a questionnaire. Exclusion criteria were known substance abuse; mental illness, and/or other acute illness effecting ADL task performance; or language barriers.

As the recruitment process, including criteria for inclusion and exclusion, was evaluated in the pilot study, minor revisions were applied before the main trial. An overview of the inclusion and exclusion criteria for the main trial is provided in table 3.

Table 3 Inclusion and exclusion criteria in the ABLE 2.0 trial

Inclusion criteria	Exclusion criteria
Lived with one or more medically diagnosed chronic conditions	Had PADL problems with acute, unmet need for help
Were aged ≥ 18 years	Had known substance abuse
Lived in their own home	Had mental illness, and/or other acute illness (<

	three months) effecting ADL task performance
Experienced ADL task performance problems	Had communication barriers (e.g. severe cognitive deficits; barriers that prevented receiving information on study)
Were motivated and ready for making changes in performance of ADL tasks	Received other occupational therapy services addressing decreased ADL ability during the intervention period (weeks 0-9)
Were motivated and ready to participate in an occupational therapy intervention	
Communicated independently and relevantly	
Were able to understand and relevantly answer a questionnaire	

ADL, activities of daily living; PADL, personal activities of daily living

ABLE OTs (n=3) were recruited among OTs in the municipality, provided they had ≥two years of experience working with the study target group and were calibrated AMPS raters. Assessors in the pilot study (n=2), conducting observation-based evaluation of ADL ability using the AMPS at baseline and post-intervention at week 10, were OTs trained and calibrated as AMPS raters recruited from a nearby Hospital Unit.

Assessors in the main trial (n=7), conducting observation-based evaluation of ADL ability using the AMPS and self-reported evaluation of ADL ability using the ADL-I at baseline, week 10, and week 26. During the first four months of the study, the same assessors as in the pilot study were involved. From the beginning of December 2020, the Covid-19 pandemic hindered the OTs from the Hospital Unit to visit the clients in their homes and they had to withdraw as assessors. Therefore, two OTs recruited from outside the municipality were trained and calibrated to conduct the assessments. In the meantime, to avoid interrupting the study, the ABLE OTs from the study municipality conducted the needed assessments. To avoid breaking blinding of assessors and biased measurements, they only conducted baseline tests and never in geographical areas where they delivered ABLE 2.0.

For the process evaluation the three ABLE OTs and a small sample of participants receiving the ABLE 2.0 intervention was invited. The participants in the sample should represent a variety in outcome reach (GAS) and process outcomes. The following criteria for the sample were proposed: ≥three males; ≥four participants with baseline AMPS ADL motor ability <1.0 logits; variation in number of sessions received; and variation in age.

Recruitment for studies 1-3

Participants in the pilot study (104) and the main trial were recruited from all four areas of the municipality among persons referred to or already receiving rehabilitation services using the same recruitment procedure.

As primary investigator, I coordinated the recruitment process. One (key) OT from each geographical area was involved in the process. The recruitment process was structured by guidelines, including a checklist on eligibility criteria. First, the key OT, potentially in collaboration with the rehabilitation team, assessed if persons referred to, or already receiving rehabilitation, immediately met the eligibility criteria. In a phone conversation or face-to-face, the key OT provided the client with initial information on the trial and asked for permission to forward contact information to me to conduct the remaining process of recruitment. Within three weekdays, I called the client to provide additional trial information and finalise screening of eligibility for inclusion, including confirmation of their motivation and readiness to make changes, and participate in occupational therapy delivered at home. If a person met the eligibility criteria, preliminary oral consent to participate was obtained.

Consent

Following the recruitment procedure, a letter was sent to the participant containing written information, consent form, and baseline questionnaires. At the baseline home visits, the participants were asked if they understood the written information, and if they had any related questions. Finally, they were asked to sign and hand over the consent form.

Interventions

The ABLE 2.0 intervention programme

The manualised ABLE 2.0 (105) was a systematic, client-centred, eight-week intervention program, applicable across sex, age, and chronic conditions. It was delivered by an ABLE OT in the client's home as part of community-based rehabilitation. The overall structure of ABLE 2.0 was informed by the OTIPM (13), prescribing a problem-solving process. The structured problem-solving process, included evaluation of ADL ability based on both self-report and observation; and involving the client in setting goals, clarifying reasons for the identified ADL task performance problems, and in finding solutions (13,105). ABLE 2.0 consisted of a maximum of eight sessions. Session 1

included evaluation of ADL ability using the ADL-I (29,74) and the AMPS (26,75); session 2 included goal setting, using Goal Attainment Scaling (GAS) (76,77), and clarification of reasons for ADL task performance problems using the TMO (13) or the PEO (73); sessions 3-7 included intervention sessions focused on adaptation by employing a combination of nine intervention components, consistent with ABLE 1.0, to improve ADL task performance; and the final session included re-evaluation of ADL ability using the ADL-I (29,74) and the AMPS (26,75) and determining goal attainment using GAS (76,77). However, to avoid too much burden on the participants, and because the AMPS (26,75) was performed by blinded assessors as part of collecting primary outcome data immediately after the intervention period, the AMPS was optional during re-evaluation within ABLE 2.0 intervention program. Detailed descriptions of ABLE 2.0, including a brief case example has been published (104).

Usual occupational therapy

Clients in the control group (i.e. the pilot study and the effectiveness evaluation) received standard UOT services as provided in the municipality. UOT services were framed similarly in the four geographical areas. To explore content and dose in UOT prior to the pilot study, being a key uncertainty (89), we extracted information from ten records representing clients similar to those to be recruited for the studies. For this purpose, a physiotherapist from the municipality, familiar with clinical practice and client records, was involved. Data suggested that the typical dose of UOT was 3 x 60 min and that the content of UOT seemed to vary based on client conditions and needs. However, observation of ADL task performance, counselling, and evaluation of the use of helping aids seemed common. Examples of established goals included “ability to bath independently” or “toilet safety”.

Hoffmann et al. (106) suggest that description of usual care in a trial should be provided at the same level of detail as in the intervention group, and thorough information on UOT is critical for investigating effectiveness of ABLE 2.0 (45). But usual care is by nature a dynamic phenomenon. It is unlikely that all participants will receive the same occupational therapy, as it reflects individual tailoring and locally adapted practices, and further, it may vary at different time points during the trial (107,108). Hence, description of UOT, based on retrospective investigation on what was delivered in the control group, was considered optimal in the trial. Accessibility to proper information on the control group intervention was investigated in the pilot study.

Training of Occupational Therapists delivering ABLE 2.0

Prior to the pilot study the ABLE OTs were trained in delivering ABLE 2.0 by attending a three-and-a-half-day course, conducted by the researchers who developed the program. Day 1 of the course consisted of introduction to the ABLE intervention programme including the background for its development, introduction to the OTIPM and the ADL-I, and a brush up on the AMPS. Day 2 of the course concerned the goal setting phase using GAS and application of PEO or TMO in the analysis of reasons for the occupational performance problems prioritised. Day 3 consisted of introduction to and practise of the nine intervention components and finally day 4 was set aside to focus on aspect that in the feasibility study was revealed to be challenging for the ABLE OTs, i.e. goal setting using GAS and the intervention sessions using adaptational occupation-based approaches. Finally, the ABLE OTs were introduced to their role in data collection (i.e. filling in registration forms immediately after each session delivered).

In between the course days the ABLE OTs trained the use of the introduced instruments and conceptual models to be applied during delivery of ABLE 2.0. To further support delivery of the program, feedback activities were offered in addition to the course throughout the intervention periods in the pilot study as well as in the main trial. Moreover, folders, containing the material (i.e. printouts of ADL-I schedule and PEO model) needed for the OT to deliver the ABLE 2.0 intervention programme to the single client, were provided.

Contamination

To minimise contamination between ABLE OTs and UOT OTs, ABLE OTs were recruited from West and East areas, while UOT OTs were recruited from South and North areas of the municipality. In the pilot study and the main trial periods, both the ABLE OTs and the UOT OTs delivered interventions in all four geographical areas, to make randomisation at an individual level possible. The ABLE OTs only rarely had contact with the UOT OTs, and they were informed not to share information of any kind on ABLE 2.0 with their colleagues.

Data collection

Demographic data (study 1-3)

At baseline, i.e. in the pilot study and the main trial, demographic data were collected including age, sex, types of chronic conditions, job situation, civic status, level of education, and whether they live alone or with others.

Pilot study (study 1)

As the feasibility study (15) revealed certain challenges related to recruitment and retention, reflecting key uncertainties (89), the recruitment procedure was revised in terms of determining the clients' motivation and readiness for change and for participating in the programme. This was reflected in the inclusion criteria and in the guideline used during recruitment. The participant flow during the pilot was registered. The progression criteria on recruitment was that 50% of the persons contacted met the eligibility criteria and accepted participation, and that 80% stayed in the programme.

To assess the randomisation procedure, designed in cooperation with involved stakeholders from the municipality (89), the randomisation progress was registered. Progression criterion was that 80% of the clients accepted randomisation and that the procedure was executed as planned.

To assess adherence registration forms were filled in after each session by both participant and ABLE OT informing on perceived engagement, participant involvement, meaningfulness, and satisfaction with intervention. Moreover, ABLE OT registration forms informed on the number of sessions delivered and time use in each session (dose), as well as what was delivered, including deviations from manual, goal setting and instruments applied for evaluation of ADL ability (fidelity); confidence in delivering the programme; unintended side effects; and practical and/or organisational facilitators and barriers. Aspects related to confidence in delivering the programme; involvement of participant; ABLE OT's and participant's engagement, meaningfulness and satisfaction with the programme, were scored using Likert scales from 1 to 5; 1 = very low degree, 2 = low degree, 3 = fair degree, 4 = high degree and 5 = very high degree. Progression criterion on adherence was ABLE 2.0 delivered as intended in terms of dose and fidelity.

Assessment of appropriateness of the outcome measurements planned for application in the main trial, i.e. those that were not assessed in the feasibility study, concerned aspects primarily related to context (89) in terms

of the participants' ability and opportunities to relevantly and independently answer questionnaires. The questionnaires included: the ADL-Questionnaire (ADL-Q) (29); the Occupational Balance Questionnaire (OBQ11) (31); and five questions specifically constructed for this study, named Client Weighted Problems questionnaire (CWP-Q). The number of relevantly and fully answered questionnaires were counted and the progression criterion was that 80% of the participants gave relevant and complete answers in the questionnaires.

To gather the needed information on UOT for comparison with ABLE 2.0, being a key uncertainty (89), the MRC guidance (78) was applied and the planning of the data collection was inspired by Erlen et al. (107) and Hoffmann et al. (106). Further, to identify the specific aspects of information needed, the ABLE 2.0 IPT was used, informing on the assumptions of the functioning of such interventions.

Aspects included:

- dose (duration of intervention, number of visits, length of visits),
- evaluation of ADL ability (use of standardised instruments, self-report and/or observation),
- goal setting (whether goals were formulated, how goals were negotiated),
- content of intervention phase (applied approaches including practicing performance of ADL tasks, counselling, focus on occupation/body functions/environment, involvement of home carer or relative),
- referral services (e.g. social services, group exercises or peer support groups) and
- programmatic and/or clinical changes during trial (changes applied based on e.g. new guidelines or participation in specialised courses) (107).

To monitor if the needed information was accessible, we investigated routinely collected records of participants receiving UOT in the ABLE pilot (n = 10). Data collection was conducted by a physiotherapist from the municipal Rehabilitation Unit and me. Her role as stakeholder (89) was reflected in her knowledge on the client records (i.e. expert) and the rehabilitation practices in the municipality (107). Progression criterion was access to information on the predefined aspects of UOT in 80% of the participants.

Effectiveness evaluation (study 2)

Co-primary outcomes were assessed at baseline and week 10 as self-reported ADL ability, measured using the ADL-I (29) and observed ADL motor ability

measured using the AMPS (26,75). This combination was chosen, as previous studies revealed limited relationship between measures of self-reported and observed ADL ability (4,5).

Secondary outcomes were assessed at baseline, week 10 and week 26 as perceived satisfaction with quality of ADL tasks performance (ADL-I Satisfaction) (29), and observed ADL process ability (AMPS) (26,75). Moreover, participants' self-reported quality of ADL task performance (ADL-I Performance) (29,74) and observed ADL motor ability (AMPS) were secondary outcomes assessed at week 26. Explorative outcomes were assessed at baseline, week 10 and 26 as participants' perceived occupational balance (OBQ11) (31), perceived problems (CWP-Q) (104) and general health (the first question (SF1) of the MOS 36-item Short Form Survey Instrument (SF36) (SF36-SF1)) (109). An overview of the assessment schedule is provided in table 4 and description of instruments is provided after the paragraph on data collection in the process evaluation.

Data on usual occupational therapy

Based on the results of the pilot study (104), we decided to collect data on UOT in the full-scale trial retrospectively on the following aspects:

- dose,
- methods applied for evaluation of ADL ability,
- goal setting,
- content of intervention phase,
- referral services, and
- programmatic and/or clinical changes during trial (e.g., new clinical guidelines).

The form developed for structuring data collection is provided in table 5.

Table 4 Schedule of enrolment, interventions, and outcome assessments

		Allocation	Post group allocation		
	Screening	Baseline	Intervention	Primary endpoint	Secondary endpoint
TIMEPOINT week	**-3 to -1**	**0**	**1-9**	**10**	**26**
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
ABLE			⟷		
UOT			⟷		
ASSESSMENTS:					
ADL-I		X		X	X
AMPS		X		X	X
OBQ11		X		X	X
CWP-Q		X		X	X
SF1 of SF-36		X		X	X

ABLE = A Better everyday LifE (experimental group)
ADL-I = Activities of Daily Living-Interview
AMPS = Assessment of Motor and Process Skills
CWP_Q = Client Weighted Problems Questionnaire
OBQ11=Occupational Balance Questionnaire
SF1 of SF36 = First question of the MOS 36-item Short Form Survey Instrument
UOT = Usual Occupational Therapy (control group).

Table 5 Form for collection of data on usual occupational therapy

General information			
Client	ID:	Month and year of birth:	Comments:
Reason for referral to rehabilitation			
Dose	Days:	Number of visits:	Sufficient dose: _ yes _ no

Evaluation			
Methods applied for evaluation of ADL ability	**0** = no information **1** = self-report **2** = observation	**0** = non-standardised instrument applied **1** = standardised instrument applied	**Name of standardised instrument if reported**

Goal setting			
Negotiated by	**Information on quality**		**Goals**
0 = no information **1** = OT and client in collaboration **2** = referral service	O Occupation-focused * O Body/environment focused* O Observable O Measurable O Realistic	O Who O What O How good O When	

Intervention							
Duration of session	**Content**						
	Doing occupation-based*	**Dialogue** occupation-focused*	**Dialogue** not occupation-focused*	**Exercise** focus on bodyfunction*	**Consultation**	**Collaboration** relatives and/or home carer	**Referral** to other services **
1							
2							
3							
4							
5							

Comments:

Finalising intervention			
Reevaluation of ADL-ability		**Type of session**	**Comments:**
O Yes O No	O Self-report O Observation	O Visit O Telephone	

* continua for proximal focus (13)
**e.g., social activities, user organisation, team training

Process evaluation (study 3)

To evaluate the interactions between context, mechanisms and outcomes both qualitative data, in terms of realist interviews (90,103), and quantitative data, in terms of registration forms and measures of ADL ability (110) were collected among participants who received, and ABLE OTs who delivered, ABLE 2.0. Pawson (79) points out that not using multi-methodological approaches in realistic evaluations is a common mistake resulting in limited opportunity to test the programme theory (83). Aiming to approach this realistic evaluation by using a combination of qualitative and quantitative data, and due to the lack of examples of how to conduct such programme theory testing, the qualitative data in this study are the primary data, whereas the quantitative data serve as more explorative data.

Qualitative data, realist interviews

Qualitative interviews were conducted to test and further refine the IPT and explore emerging CMOCs. Within realistic evaluation the purpose of an interview is to present the programme theory for the interviewees, for confirmation, refinement or rejection (90,111). The interchangeable roles in the teacher-learner relation described by Pawson and Tilley was used to allow good and full answers supported by examples, aiming to access and explain forms of theory (90) and refine the ABLE 2.0 IPT. The interviews focused on aspect in the ABLE 2.0 IPT, including the hypothesised CMOCs. However, because the registration forms provided comprehensive information on the hypothesised CMOCs, the interviews took a more open approach focusing on refinement of the ABLE 2.0 IPT.

First, individual interviews were conducted with the ABLE OTs, followed by individual interviews with the sub-sample of clients. Finally, a focus group interview with the ABLE OTs was conducted. The interviews with the ABLE OTs primarily focused on their experiences of what (mechanisms), for who and in which circumstances (context) successes and failures (outcomes) occurred (90), while the interviews with the clients primarily focused on the questions related to their experiences of whether ABLE 2.0 encouraged them to make changes in relation to ADL task performance (mechanisms) (90). The focus group interview with the ABLE OTs aimed to provide a deeper insight into what was revealed concerning the ABLE 2.0 IPT in the former interviews (90,111).

Interview guides were developed reflecting the realist approach. For example, to construct data on the impact of the ABLE OT's skills, the interviewer would first describe the IPT to the ABLE OT by saying: *"We had*

an assumption that your commitment and feeling skilled in delivering the programme were important for building a good relationship with the client, and for the client's experience that the content made sense and was satisfactory, and prior to delivering the programme you participated in a 3-an-a-half-day course learning about the programme". Then the interviewer would continue by asking: *"How were your prerequisites for delivering the programme? What was the impact of the course in your opinion? Is there anything you particularly want to highlight, good and bad"?* In the following interviews with client, the subject would be approached by saying: *"We would like to ask about your experience of the occupational therapist, both her professionalism and more personal* features" And further by asking: "*What do you immediately think about that? Did you find it overall professional? How did you feel that she listened to you and took you seriously? Did your opinions matter"?* Finally, the focus group interview served to validate or further explore the subject by giving a summery from the former interviews, asking for elaboration if relevant. All through the interviews the interviewees were prompted to give examples.

The realist evaluation approach (90,111) was reflected in the interview guides as well as during the interviews, to help identifying key contextual differences in outcome patterns (111). As I had consecutive contact with the ABLE OTs I did not participate in their individual interview. However, because of my insight into the ABLE 2.0 IPT, I participated in the remaining interviews.

Quantitative data, registration forms

To structure the collection of quantitative data, still following the realistic evaluation cycle (90), we derived five specific CMOCs (93) from the ABLE 2.0 IPT, serving as hypothesis to be tested (table 6). CMOC a) '*Relationship and collaboration*' was assumed to be active throughout the programme, whereas CMOC b), c), d), and e) were assumed to be active during specific sessions. For transparency, table 6 also provides information on numbering of contexts, mechanisms, and outcomes, and on data sources, e.g., that data on the mechanism '*client finding the program meaningful*' was given the number M2 within CMOC a), and data was collected from client registrations forms ($M2^{a}$).

Also, registration forms were developed to operationalise the CMOCs and to provide information on the perceived strengths of the hypothesised CMOCs, and on content and delivery. However, data on content and delivery is not part of this thesis and will reported in a future publication. Table 7 provides an overview of the questions asked in registration forms.

Table 6 Hypothesised CMO configurations to be tested in the ABLE 2.0 process evaluation (including information on data sources)

	Context	Mechanism	Outcome
CMOC a) Relationship and collaboration (session 1-8)	ABLE is delivered by an OT feeling engaged (C1[a]) and prepared(C2[a]) to deliver session content to a client motivated for making changes (C3[b]) ...	... activates a therapeutic relationship (M1[a]) and the client finding the program meaningful (M2[c]) and satisfactory (M3[c]) ...	... leading to client staying in the program (O1[a]) and increased ADL ability (O2[d])
CMOC b) Evaluation (session 1)	OT conducts valid occupation-focused and /or occupational-based evaluation in the client's home (C1[a]), taking client's perspectives into account (C2[a]) ...	... activates client getting a deeper understanding of his/her problems related to ADL task performance (M1[c]) and feeling informed (M2[c]) and involved (M3[c]) ...	... leading to occupation-focused and/or occupation-based starting point (O1[a]), client finding participation in session 1 satisfactory (O2[c]), and client finding the content of session 1 meaningful (O3[c])
CMOC c) Goal setting (session 2)	OT and client together define occupation-focused goals (C1[a]) and clarify causes for ADL problems (C2[a]) ...	... activates client feeling involved (M1[c]) ...	... leading to relevant goals (O1[c]), client finding participation in session 2 satisfactory (O2[c]), and client finding the content of session 2 meaningful (O3[c])
CMOC d) Intervention (session 3-7)	Adaptational intervention components delivered in the client's home (including optional homework) (C1[a]), delivered by an ABLE OT being familiar with components and acting as facilitator of change (C2[a]) ...	... activates collaboration between client and OT on finding solutions (M1[a]) and client being willing to try solutions during performance of ADL tasks (M2[a]) ...	... leading to commencing goal attainment (O1[c]), client finding participation in program purposeful (O2[c]), client finding participation in session 3-7 satisfactory (O3[c]), and client finding the content of session 3-7 meaningful (O4[c])
CMOC e) Reevaluation (final session)	Client gets feedback on goal attainment and obtained changes (C1[a]) ...	... activates motivation for integrating the new methods of doing into everyday life routines (M1[c]) ...	... leading to goal attainment (O1[a]), measurable changes in perceived and/or observed ADL task performance (O2a, O2b[d]), and satisfaction with obtained ADL ability (O3a, O3b[d])

ADL = activities of daily living; C = context; M = mechanism; O = outcome; CMOC = context-mechanisms-outcome configuration; OT = Occupational Therapist
Data sources: [a] OT registration form, [b] assessed at recruitment, [c] client registration form, [d] effectiveness evaluation

Table 7 Questions asked in registration forms

Aspect	Time-point	Questions for clients To what extent …*	Questions for ABLE OTs To what extent …*
Mechanism of impact	All sessions	**did** you feel informed? **did** you feel involved? **did** you find the content meaningful? **did** you feel satisfied with the content? **do** you feel that participation in the program has a purpose?	**was** the session meaningful to you? **was** the session in your opinion meaningful to the client? **was** delivery of this session satisfactory to you? **was** this session in your opinion satisfactory to the client?
	Session 1	**did** the interview and observation of your performance provide you with new knowledge on problems related to your activities of daily living? **did** the interview and practical testing contribute to clarification of focus for intervention? **did** you and the OT establish a good basis for further cooperation?	**did** you gain knowledge about problems related to the client's ADL tasks and skills? **did** the session clarify focus for intervention? **did** you and the client establish a good basis for further cooperation?
	Session 2	**did** you like setting goals for the intervention? **was** the conversation about reasons for your problems relevant?	**did** the conversation about discrepancies work well? **did** the conversation related to goal setting work well? **did** the conversation about reasons for ADL task performance problems work well?
	Session 3-7	**did** the session contribute to your goal attainment? **have** you currently reached your goals?	**did** the session contribute to client's goal attainment? **did** the client and you have a beneficial collaboration when finding solutions? **was** the client willing to practice the suggested solutions?

	Final session	**did** the program overall contribute to your goal attainment? **did** the program overall contribute to improved ability to perform activities of daily living? **will** you carry on using the new solutions?	**did** the intervention program overall contribute to client's goal attainment? **did** the intervention program overall contribute to enhancing client's ADL ability? **do** you believe the client will continue using the new solutions?
			Register:
Intervention delivery (dose, fidelity, adaptations)	All sessions		**Minutes** delivered **What** was delivered? **Did** you deliver according to manual?
Context	All sessions		**Did** you experience organizational barriers and/or facilitators?** **Did** you experience practical barriers and/or facilitators? ** **To** what extent did you feel prepared to deliver the session/familiar with content?* **To** what extent did you feel engaged during the session?* **To** what extent did you involve the client?*
Other	All sessions		**Did** you perceive positive / negative side effects?**

* a five-point ordinal scale is applied: 1=to a very low degree; 2=to a low degree; 3= to some degree; 4=to a high degree; 5=to a very high degree
** response categories: yes or no
ABLE, occupational therapy programme; ADL, activities of daily living; OT, occupational therapist.

The clients' registration forms informed on mechanisms of impact, e.g., *"to what extent was the conversation about reasons for your problems relevant"?* and on perceived outcomes, e.g., *"to what extent did you find the content meaningful"?* The ABLE OTs' registration forms informed on context, e.g., *"to what extent did you feel prepared to deliver the session/familiar with the content"?,* mechanisms, e.g., *"to what extent did the session clarify focus for intervention"?* and outcomes e.g., level of goal determined at the final session using GAS (76,77). The registration forms were answered using a 5-point Likert scale: 1 = 'to a very low degree', 2 = 'to a low degree', 3 = 'to some degree', 4 = 'to a high degree', and 5 = 'to a very high degree'. The registration forms were filled in after each session by client and ABLE OT separately.

Instruments

In this section the applied instruments are described. First the ADL-Questionnaire (ADL-Q) (29) applied in the pilot study, and its interview-based equivalent the ADL-I (29,74) are described. The ADL-I is incorporated in the ABLE intervention programme and as outcome measure in the effectiveness evaluation. Next is a description of AMPS (26,75), also applied in the ABLE intervention programme and the effectiveness evaluation. GAS (76,77) is used for goal setting and re-evaluation in the ABLE intervention and serves to measure process outcome. Finally, the explorative outcomes in the effectiveness evaluation, i.e. OBQ11 (31), CWP-Q (104,112), and SF36-SF1 (109).

The ADL-Q and ADL-I (performance and satisfaction)

ADL-Q (29) is a standardised questionnaire-based evaluation tool used by OTs to describe and measure self-reported quality of ADL task performance (29), in terms of physical effort and/or fatigue, efficiency, safety and independence. The ADL-I (29,74) is the interview-based equivalent.

In ADL-Q and ADL-I the persons report their perceived ADL ability for each of 47 ADL tasks using seven response categories: (a) *I perform the task independently without use of extra time or effort and without risk*; (b) *I perform the task independently, but I use helping aids*; (c) *I perform the task independently, but it takes me extra time*; (d) *I perform the task independently, but I use extra effort/get tired*; (e) *I perform the task independently, but there is a risk that I might injure myself*; (f) *I need assistance from someone but do participate*; and (g) *the task is performed by others for me—I cannot participate actively*. The person is instructed to use more than one response category if several apply to their perceived

performance of the specific ADL task (e.g. mark both c and d if they spend extra time and get tired). Finally, ratings for personal ADL tasks should be based on ADL task performances within the past 24 hours and for instrumental ADL tasks within the past 7 days (29).

To create an overall linear measure of self-reported quality of ADL task performance (reported in log-odds probability units; logits), based on the Rasch measurement methods, the mark given in the lowest response category on each task is re-scored using an ordinal rating scale from 0 to 3: *Competent* (score = 3) covering response categories (a) and (b), *Using extra time/effort* (score = 2) covering response categories (c) and (d), *At risk/need help* (score = 1) covering response categories (e) and (f) and *Unable* (score = 0) covering response category (g) (29). This reflects a continuum for quality of ADL task performance, illustrated in figure 10

Figure 10 Levels of quality in ADL task performance

Moreover, ADL-Q and ADL-I can be used to measure the client's perceived satisfaction with the quality of performance for each of the 47 ADL tasks, using a four-point ordinal satisfaction scale: 4='*very satisfied*', 3='*satisfied*', 2='*dissatisfied*' and 1='*very dissatisfied*' (29). As with ADL task performance, the satisfaction with quality performance measures are generated based on Rasch Measurement methods.

To measure change in self-reported quality of ADL task performance and satisfaction, the 47 ordinal quality of performance and satisfaction scores are transformed into overall linear (interval scale) measures of self-reported quality of ADL task performance and satisfaction, adjusted for the difficulty of the ADL tasks, based on Rasch measurement methods (29). The measures are expressed in logits (log-odds probability units) (5,29). Previous studies have indicated that ADL-I can be used to generate valid and reliable linear measures of self-reported quality of ADL task performance among persons with chronic conditions (2,4,29), and furthermore, that the instrument is sensitive to change post-intervention in older persons receiving a home-based reablement program (113). According to the ADL-I manual (74), a difference of ≥0.64 logits (based on mean SD=1.28) indicates a clinically relevant difference in self-reported ADL task performance. ADL-Q performance measures have demonstrated sensitivity to change, when applied in persons with rheumatoid arthritis (5).

The Assessment of Motor and Process Skills (AMPS)

The AMPS (26,75) is a standardised observation-based evaluation tool used by OTs to measure a persons observed ADL ability in term of physical effort and/or fatigue, efficiency, safety and independence, i.e. quality of ADL task performance. The person being evaluated chooses and performs at least two of the standardised ADL tasks that the person finds relevant and of appropriate challenge. During an AMPS evaluation, two domains of occupational performance are evaluated: motor skills (16 items) and process skills (20 items). After the observation, the quality of each skill is evaluated on a four-point ordinal scale according to the scoring criteria in the AMPS manual (75). The available AMPS software (114), based on Many-Faceted Rasch statistics, provides possibility to convert the ordinal raw scores into overall linear ADL motor and ADL process ability measures adjusted for task challenge, skill item difficulty and rater severity. The measures are expressed in logits (log-odds probability units) (26). ADL ability measures below the 1.5 logit independence cut-off on the ADL motor scale and below the 1.0 logit independence cut-off on the ADL process scale indicate a likely need for assistance (26). Measures below the lower independence cut-offs of 1.0 and 0.7 logits for ADL motor and ADL process ability, respectively, mark a need for moderate/maximal assistance (115). Several studies have supported that the AMPS ability measures are reliable and valid among persons with chronic conditions (4,5,116–118). Furthermore, several studies have revealed that the AMPS demonstrates sensitivity to change post-intervention (15,41,118,119). According to the AMPS manual (26) a difference of ≥0.3 logits on the ADL motor and/or ADL process scales defines a clinically relevant difference in ADL ability. AMPS can only be administered by calibrated assessors.

Goal attainment scaling (GAS)

Goal Attainment Scaling (GAS) (76,77) is a tool for defining and monitoring individual goals. The client is actively involved in defining the goals and describing the levels of goal attainment. When a goal is defined, measurable and observable indicators (e.g., independence, duration, and frequency) evaluating the progress towards goal attainment are used.

The level of goal attainment is described using an ordinal scale from −2 to +2. The actual level of performance is described at level −1, and the expected level is described at level 0. Level +1 and level +2 are descriptions of what the person will be able to if he or she achieves more than expected. Level −2 describes the level, where the person achieves less than expected. A

feasibility study (120) concluded that GAS was applicable among older adults with multiple chronic conditions living at home.

Occupational Balance Questionnaire (OBQ11)

Occupational balance Questionnaire (OBQ11) is a generic 11 item instrument measuring aspects necessary for the experience of and satisfaction with occupational balance, defined as as '*the experience of having the right amount of occupations and the right variation between occupations in the occupational pattern*' (31).

OBQ11 measures a person's experiences of their amount and variation of occupations, regardless of which these are (31). OBQ11 captures the perceived occupational balance for each of 11 items, using a four-category response scale: 0='*completely disagree*', 1='*tend to disagree*', 2='*tend to agree*', and 3='*completely agree*'. Scores are summed into a total score ranging from zero to 33, with 33 representing complete occupational balance. OBQ11 has been examined for internal construct validity in a general population using Rasch measurement theory (31), but not yet in clinical samples.

Client-Weighted Problems Questionnaire (CWP-Q)

To complete the investigation on how, from the participant's point of view, engagement in ADL task performance contribute to well-being, and how the participant perceives changes, five questions related to identified problems, need for help and hope for the future have been specifically constructed for this study:

Identified problems:

- *"To what extent is it a problem for you, that your chronic condition(s) affects your possibilities to perform and participate in everyday activities in and around your home? (e.g. shopping, cleaning, doing laundry, transport)?"*
- *"To what extent is it a problem for you, that your chronic condition(s) affects your possibilities to participate in social activities with friends and family?"*

Need for assistance:

- *"To what extent do you need help accepting your chronic condition(s)?"*
- *"To what extent do you need help to better cope with your everyday activities (e.g. perform them more securely, efficiently, with less effort or more independently?"*

Hope for the future:

- *"To what extent does your chronic condition(s) affect your hope for the future?"*

The perceived weight of the items is scored on an 11-point ordinal scale ranging from '0', representing "*not at all*" to '10', representing "*to a high extent*". The questionnaire was tested for appropriateness in the previous pilot study (104).

General Health (SF36-SF1)

General health was assessed using SF36-SF1 (109). The question is often used as an indicator of general health and well-being based on self-report. Thus, the following question was asked: "*In general, would you say your health is excellent* (=1), *very good* (=2), *good* (=3), *fair* (=4) or *poor* (=5)". Previous studies indicate that the question is applicable in persons with chronic conditions (109).

Sample size for evaluation of effectiveness (study 2)

Sample size was calculated based on prior studies (15). The calculation was performed using nQuery Advisor® (121). The portal "repeated measures for two means" was selected. The number of levels was set to be 3.

For the observation-based primary outcome, AMPS ADL motor ability, an average difference of 0.30 logits (i.e. a clinically relevant difference (26)) between the ABLE group and the control group was expected; the standard deviation (SD) is assumed to be 0.56 (15). With a sample size in each group of n=25, a two-sided test for the time averaged difference between two means in a repeated measure design with a significance level set to 5% ($p<0.05$) has a statistical power of 90%.

For the self-reported co-primary outcome, ADL-I performance, a clinically relevant difference of 0.64 logits (74) between the intervention and control group is expected; the SD is assumed to be 1.45 (15). With a sample size of n=34 in each group, a two-sided test for the time averaged difference between two means in a repeated measures design with a significance level set to 5% (<0.05), has a statistical power of 90%. Account for dropout is taken by recruiting 40 participants in each group.

Allocation (studies 1 and 2)

Randomisation and stratification

Participants were allocated in a 1:1 ratio to either ABLE 2.0 or UOT, taking into account their baseline level of observed ADL ability measured with the AMPS (26,75). Independence cut offs were applied, indicating a need for moderate to maximal assistance to live in the community: motor ADL ability (≤1.0 vs >1.0) and process ADL ability (≤0.7 vs >0.7) (26,75), i.e. four mutually independent randomised sequences. The stratification groups are illustrated in table 8.

Table 8 Stratification of participant in four subgroups using the AMPS

STRATIFICATION AMPS		L Process cut-off ≤ 0.7	H Process cut-off > 0.7
L	Motor cut-off ≤ 1.0	L-L Subgroup 1	L-H Subgroup 2
H	Motor cut-off > 1.0	H-L Subgroup 3	H-H Subgroup 4

AMPS, Assessment of Motor and process Skills; L, low; H, high

Following baseline assessment, I forwarded the pseudonymised ID and baseline AMPS measures on each participant to the principal investigator, who, blinded to coding of group allocation, allocated each participant to either '0' or '1' based on a randomisation list (i.e. sequence generation). The randomisation list was generated by an independent statistician before inclusion of participants based on permuted random blocks of variable size (2 to 6 in each block).

The central randomisation was done to achieve concealed group allocation. Following randomisation, information on allocation on each participant was returned to me to inform the ABLE OT or UOT OT to initiate and complete the intervention. Hence, I was unable to foresee group assignment when enrolling the participants.

Blinding

The nature of the trials precluded blinding of the therapists, who delivered the interventions. External assessors were blinded on allocation to intervention at post-intervention and follow-up. This was achieved by not informing them on the content of interventions delivered in the two groups

or the participants' group allocation. To avoid breaking the assessor-blinding at week 10 and 26 assessments, participants were reminded not to disclose information on their intervention to the outcome assessor. Intending to blind the participants, they were only informed that they would receive one of two occupational therapy programs, containing similar elements. Furthermore, assessors were prompted not to discuss the intervention with the participants. Finally, to blind the investigators on the participants' group allocations, participants were re-coded by an independent statistician before data analysis and a statistician who was not involved in the study conducted the statistical analyses.

Procedures

In the pilot study, immediately after inclusion, a letter was sent to the participants, containing written information on the study, informed consent form, and questionnaires. Within seven weekdays from the inclusion and oral consent, a baseline home visit by an assessor was conducted. First the participant was asked to hand in the signed informed consent form and the filled-in questionnaires. If the participant needed help to fill in any of these, the assessor offered and registered the need of help. Second the observation-based evaluation of ADL ability using the AMPS (26,75) was performed.

In the main trial the initial procedures, as employed in the pilot study, were replicated. Outcome measures were collected within 7 weekdays after inclusion and approximately 1 week before delivery of session 1 (week 0, baseline), 10 weeks after baseline (primary endpoint), and 26 weeks after baseline (secondary endpoint). At each timepoint, assessors visited participants in their homes to collect data. Participants received questionnaires 2–8 days before each visit. The filled in questionnaires were handed in to the assessor at each visit. Assessors were OTs, who were trained as AMPS raters, recalibrated (i.e., their testing skills were approved for use in research) prior to data collection, and were certified to use ADL-I. Data on UOT (i.e. information on dose, methods applied for evaluation of ADL ability, goal setting, content of intervention phase, referral services and programmatic and/or clinical changes during trial (e.g., new clinical guidelines) was extracted from client records after end of study period. Data extraction was conducted by a physiotherapist from the municipality, familiar with clinical practice and client records, and me. Information on duration of visits in minutes, which was not extractable from client records, was collected in registrations forms filled in by the UOT OTs. Description on UOT followed the TiDieR checklist (106).

For the process evaluation the registration forms were filled in after each session by client and ABLE OT separately. The qualitative interviews were conducted after completion of the intervention period of the study (figure 9). First the ABLE OTs were interviewed, then the clients were interviewed individually, and finally the focus group interview with the ABLE OTs was conducted. To focus on mechanisms and minimise recall bias, the sample of clients invited for interviews were composed among the last participants allocated to ABLE 2.0.

To minimise contamination between ABLE OTs and UOT OTs, ABLE 2.0 was delivered by OTs employed in Rehabilitation Unit areas West and East, whereas UOT was delivered by OTs employed in Rehabilitation Unit areas South and North. The OTs had rare contact across areas, and ABLE OTs were informed not to share information of any kind on ABLE 2.0 with their colleges. Furthermore, the OTs delivering ABLE 2.0 did not deliver UOT. Still, to be able to randomise at an individual level, both the ABLE OTs and the UOT OTs delivered interventions in all four geographical areas, depending on the outcome of the randomisation.

Data analyses

Demographics (studies 1-3)

Baseline participant characteristics were presented descriptively. Nominal data were reported based on numbers and percentages. Ordinal data were presented in medians, ranges, quartiles, absolute numbers, and frequencies. Continuous variables were reported in means and standard deviation (SD), if normally distributed. Continuous data with lack of normal distribution were presented based on medians and ranges.

Pilot study (study 1)

Data on recruitment, retention, and randomisation were presented in flowcharts. Number of relevantly and fully answered questionnaires were reported in numbers and percentages. Overview on accessibility to information on predefined aspects of UOT were provided in a table. Moreover, it was determined if the quality of the information related to goal setting and content of UOT was sufficient to be compared to similar types of information on ABLE 2.0

Effectiveness evaluation (study 2)

Statistical analysis

Minor adjustments were made to the analysis plan described in the protocol (104) by employing repeated measures mixed linear models handling missing data implicitly, i.e. more conservative principles were applied.

The primary analysis was performed in the intention-to-treat (ITT) population; participants were assessed and analysed according to their allocation, irrespective of adherence to the intervention. Continuous outcomes, including the co-primary outcomes, were analysed as change from baseline to week 10 and/or 26 using repeated measures mixed linear models, including participants as random effects, with fixed effect factors for group and week (including all timepoints respecting the ITT principle) and the corresponding interaction, while adjusting for baseline values (to increase precision) and the stratification factors (as part of the design). Results are reported as least squares means and Standard Errors (SEs). Differences between least squares means are reported with two-sided 95% Confidence Interval (95% CI) and associated p-values. Missing data were handled implicitly in the ITT analysis by the mixed linear models (122). Sensitivity analyses (123) were performed on the per-protocol (PP) population for all outcomes by repeating the primary analyses. The PP population included participants who attended assessments at primary endpoint (week 10) and received a minimum of three sessions of ABLE 2.0 (participants in the experimental group), or received sufficient UOT based on a professional estimate by the OTs after end of intervention (participants in the control group). If the primary analysis and the sensitivity analysis confirm each other, confidence in the results is increased.

Responder analysis

Responders were identified in the PP population as participants achieving a clinically relevant improvement in AMPS ADL motor ability (≥ 0.3 logits) (26) and/or ADL-I Performance (≥ 0.64 logits) (74) measures. The proportions (number and percentages) of responders were calculated and compared by Pearson's chi^2 test. Mean changes in observed and self-reported ADL ability for responders were analysed and compared using independent samples t-tests and reported in means and 95 % CI.

Data were analysed using IBM SPSS Statistics, version 25 (124) and SAS (version 9.4).

Process evaluation (study 3)

As prescribed within realistic evaluation the analysis was an iterative process (79,90,111), in fact starting ahead of data collection pursuing insights along the way to model understanding and explain patterns in the functioning of ABLE 2.0 (125).

Qualitative data were analysed by applying the standards by Wong et al (85) and inspired by Gilmore et al (126). Hence several steps were conducted. First the interview recordings were listened through and the transcripts read to gain an overview. Second each interview was examined and coded in terms of contextual factors, activated mechanisms, and perceived outcomes, followed by extracting paragraphs reflecting assumed and emergent CMOCs. Third a table on each type of interview, e.g., the individual client interviews, was produced including quotes. The final step examined the content across the tables to group data into contiguous units (themes) deriving prominent CMOCs, i.e. found in more than one data source, expressed with emphasis, or perceived to cause particularly positive or negative changes. As a parallel process the quantitative data were analysed.

Quantitative data were analysed through intra-group comparisons (91) to test the hypothesised CMOCs. To determine the strength of the hypothesised mechanisms, the relationship between the mechanisms and the process outcomes on different contextual factors was tested (table 6) by performing cross tabulations (127).

In preparation for data analysis, data from registration forms representing mechanisms and outcomes variables were dichotomised. Hence, data on mechanisms were grouped into 'weak' (covering 1= 'to a very low degree', and 2= 'to a low degree') and 'strong' (covering 3= 'to some degree', 4= 'to a high degree', and 5= 'to a very high degree'). Similarly, data on outcomes were grouped into 'low extent' (covering 1= 'to a very low extent', and 2= 'to a low extent') and 'high extent' (covering 3= 'to some extent', 4= 'to a high extent', and 5= 'to a very high extent'). Outcome variables on increased ADL ability were grouped into 'low extent' when less than clinically relevant change was obtained (i.e. ADL-I performance < 0.64, AMPS ADL motor ability < 0.3, ADL-I satisfaction < 0.5 SD (128)) and 'high extent' when clinically relevant change was obtained (i.e. ADL-I performance ≥ 0.64, AMPS ADL motor ability ≥ 0.3, ADL-I satisfaction ≥ 0.5 SD (128)). Goal attainment, i.e. GAS was grouped into 'low extent' when obtained level was < level 0 and 'high extent' when obtained level was ≥ level 0. When relevant, data from registration forms collected repeatedly across several

sessions were merged to provide a more comprehensive dataset. For example, data related to CMOC a) '*Relationship and collaboration*' (table 6), assumed to be active throughout the programme, was merged, and similarly, data related to CMOC d) '*Intervention*', assumed to be active during the intervention sessions (session 3-7) was merged.

Ethical considerations

The studies were conducted in accordance with the Helsinki Declaration. Study 1-3 were approved by the Danish Data Protection Service Agency: Journal-nr. P-2020-203. The Ethical Committee confirmed that no approval was needed for this study: Journal-nr.: 19045758.

All participants in the studies received both verbal and written information about the studies, including study purposes, the right to withdraw and guaranteed confidentiality. Informed consent was obtained from each participant in all studies, emphasising the right to withdraw. Participants in the pilot study and in the main trial were given an ID code, with which all data were pseudonymised and only accessed by authorised study personnel obliged to secrecy. After data collection was completed, personalised information was deleted, and all data was completely pseudonymised. Analyses were performed on anonymised data.

The study was registered at ClinicalTrials.gov (Identifier: NCT04295837) on December 5th, 2019.

Results

In this chapter the results of the conducted research activities and studies 1 to 3 are presented.

Revision of intervention programme

Since the launch of ABLE 1.0 an updated version of the OTIPM (13) was published and the TMO (13) was presented as a new model to accompany the OTIPM within the Powerful Practice framework. These models, described in detail in the introduction section, the rating form for determination on discrepancy, as well as results from the feasibility study (15,96) were incorporated in the manual.

Five OTs participated in the cognitive debriefing to test the structure and content of the manual among OTs who might be future deliverers of the ABLE programme. They were women, aged between 28 and 50 years, with five to 23 years of experience working with persons with chronic conditions, including children and adults with somatic and psychiatric diseases.

Overall, the manual was perceived to be well structured and informative. The OTs found it overall manageable with good illustrations and relevant examples. Overall, the structure of the manual, consisting of a part I (user manual) and a part II (theoretical background), and the content was perceived to provide comprehensive information on the intervention programme. Specifically, the front page, table of content, and preface were perceived to be informative and inspiring. In terms of the content, the importance of defining goals before intervention was perceived to be very clear, the use of boxes with examples was supportive, the description of how to clarify causes for the ADL task performance problems involving the client was perceived to be clear and instructive, and the section on the intervention components was good and needed no revision.

Still, the OTs identified elements to be improved. Aspects of confusion included the structure of the manual, making it challenging to overview the content (i.e. use the manual as a reference book). The content of part I (user manual) was perceived to be unclear in several aspects, including prerequisites needed among OTs delivering the programme, theoretical terms (i.e. ‘generic’, ‘session’), and why standardised instruments were preferred over non-standardised ones. Descriptions on how to involve the

client in the dialogue on discrepancy and how to summarise performance analysis (i.e. AMPS) was found too theoretical, and it was unclear how and when deviations from the manual were acceptable.

Concerning the content of part II (theoretical background), the OTs recommended more detailed description of the target group, as well as a clear definition of the term ADL. Further, instructions on how to apply quality indicators when defining levels of goal attainment needed clarification. It was suggested to number the headings and add information on how to use part I and II as complementary chapters. Further, it was suggested to clarify the content according to what was reported, including clarification of theoretical terms, and specifically to extent the use of figures to illustrate the process. Accordingly, the manual was revised resulting in ABLE 2.0 to be implemented in the pilot study.

Participants in studies 1 to 3

Baseline demographic and clinical characteristics for participants included in studies 1 -3 are presented in table 9. In the pilot study, a total of n = 37 persons with chronic conditions were assessed for eligibility, and n = 18 were enrolled. In the main trial, a total of n=149 persons with chronic conditions were assessed for eligibility, and n=78 were enrolled and allocated to ABLE 2.0 (n=38) or UOT (n=40). Demographic data indicated variation across diagnoses, age, sex, civic status, and educational level. More than half of the participants were diagnosed with more than one chronic condition and most were senior citizens, women, and living alone. Clients in the pilot study were slightly older than clients in the main trial.
At baseline, mean AMPS ADL motor and AMPS ADL process ability measures were below the scale specific competence cut-offs in both groups, i.e. < 2.0 logits and < 1.0 logit respectively. indicating decreased quality of performance in both groups i.e. increased physical effort, clumsiness and/or fatigue, ineffective use of time, space and objects, safety risk, and potential need for assistance in everyday life during ADL task performance (26,75). Moreover, baseline mean AMPS ADL motor and ADL process ability measures were below the scale specific independence cut-offs in both groups, i.e. < 1.5 logits and < 1.0 logit respectively, suggesting a need of assistance during ADL task performance. Only deviation from this pattern was the ABLE 2.0 ITT group being equal to competence cut-off in AMPS ADL process ability at baseline.

Table 9: Baseline characteristics for participants in thesis, grouped into ABLE 2.0 pilot RCT, ABLE RCT (intention-to-treat (ITT) and per-protocol (PP))

Variable	ABLE 2.0 pilot RCT	ABLE 2.0 RCT			
		ITT		PP	
	Total (n=13)	ABLE (n=38)	UOT (n=40)	ABLE (n=29)	UOT (n=28)
Age: median (range)	81.0 (46-99)	75.0 (34-88)	76.5 (29-92)	76.0 (51-88)	77.5 (36-92)
Sex: female, n (%)	10 (76.9)	29 (76.3)	27 (67.5)	21 (72.41)	20 (71.4)
Diagnosis[a]: n (%)					
Orthopaedic/musculosceletal[b]	5 (38.5)	18 (47.4)	24 (60.0)	14 (48.3)	16 (57.1)
Neurological[c]	6 (46.2)	6 (15.8)	9 (22.5)	4 (13.8)	7 (25.0)
Medical[d]	2 (15.4)	14 (36.8)	7 (17.5)	11 (37.9)	5 (17.9)
Multi morbidity[e]	10 (76.9)	24 (63.2)	26 (65.0)	19 (65.5)	19 (68.9)
Civic status: n (%)					
Living alone	6 (46.2)	26 (68.4)	26 (65.0)	20 (69.0)	17 (60.7)
Living with a partner	6 (46.2)	12 (31.6)	14 (35.0)	9 (31.0)	11 (39.3)
Living with children	1 (7.7)	2 (5.3)	3 (7.5)	1 (3.5)	1 (3.6)
Job situation: n (%)[f]					
Working	0 (0.0)	0 (0.0)	2 (5.0)	0 (0.0)	2 (6.90)
Sick leave	0 (0.0)	1 (2.6)	4 (10.0)	1 (3.5)	2 (7.1)
Senior citizen	13 (100.0)	36 (94.7)	34 (85.0)	28 (96.6)	24 (85.7)
Highest level of education: n (%)[g]					
Low	10 (76.9)	28 (73.9)	28 (70.0)	20 (69.0)	19 (67.9)
Middle	3 (23.1)	8 (21.1)	12 (30.0)	8 (27.6)	9 (32.1)
High	0 (0.0)	1 (2.6)	0 (0.0)	1 (3.5)	0 (0.00)
SF1 of SF36: Median (range)	4.0 (1-5)	4.0 (2-5)	4.0 (2-5)	4.0 (3-5)	4.0 (2-5)
ADL ability: mean (SD)					
AMPS motor	0,9 (0.4)	0.9 (0.6)	0.9 (0.6)	0.8 (0.6)	0.9 (0.6)
AMPS process	0.9 (0.3)	1.0 (0.5)	0.9 (0.5)	0.9 (0.5)	0.9 (0.5)
ADL-I Performance[h]	-	1.12 (1.10)	0.96 (0.80)	1.09 (1.16)	1.09 (0.85)
ADL-I Satisfaction[h]	-	0.97 (1.26)	0.77 (0.96)	0.83 (0.96)	0.90 (0.85)

OBQ11: median (range	22.5 (7-33)	23.0 (0-33)	23.0 (4-33)	23.0 (0-33)	23.0 (4-32)
CWP-Q: median (range)					
CC affect ADL	8.0 (0-10)	8.0 (0-10)	8.0 (2-10)	8.0 (0-10)	8.0 (2-10)
CC affect social life	5.0 (0-10)	7.0 (0-10)	6.0 (0-10)	7.0 (0-10)	5.5 (0-10)
Need help to accept CC	1.0 (0-10)	4.0 (0-10)	4.0 (0-10)	5.0 (0-10)	2.0 (0-10)
Need assistance in ADL	8.0 (0-10)	8.0 (0-10)	8.0 (0-10)	8.0 (1-10)	7.5 (0-10)
CC affect hope for future	5.0 (0-10)	8.0 (0-10)	9.0 (0-10)	8.0 (0-10)	7.5 (1-10)

ABLE: intervention group; UOT: control group (e.g., usual occupational therapy); SF1 of SF36: the first question (SF1) of The MOS 36-item Short Form Survey Instrument (SF36); ADL: activities of daily living; ADL-I: activities of daily living interview; AMPS: assessment of motor and process skills: OBQ: occupational balance questionnaire; CWP-Q: client weighted problems questionnaire; CC: chronic conditions

[a] The diagnosis in terms of orthopaedic/musculoskeletal, neurological and medical are the ones that the AMPS calibrated raters determined to affect the ADL ability the most at baseline
[b] The term 'orthopaedic/musculoskeletal' covers arthritis, chronic/long-term pain, and fracture/replacement
[c] The term 'neurological' covers stroke (i.e. right-/left-sided stroke, subarachnoid haemorrhage, cerebral aneurism) and non-stroke (i.e. cerebral palsy, traumatic brain injury, multiple sclerosis, parkinsonism)
[d] The term 'medical' covers cardiovascular disease, respiratory disease, diabetes, cancer, and obesity
[e] Participants with more than one chronic condition
[f] Data missing for one participant in the ABLE 2.0 RCT (ITT) group
[g] Based on the Danish educational system; low: primary education or low-level professional education; middle: secondary education or medium-level professional education; and high: tertiary education (bachelor's degree or higher)
[h] The instrument was not applied in ABLE 2.0 pilot RCT

Pilot study (study 1)

Figure 11 illustrates the flow of participants throughout study 1, including reasons for not completing the interventions.

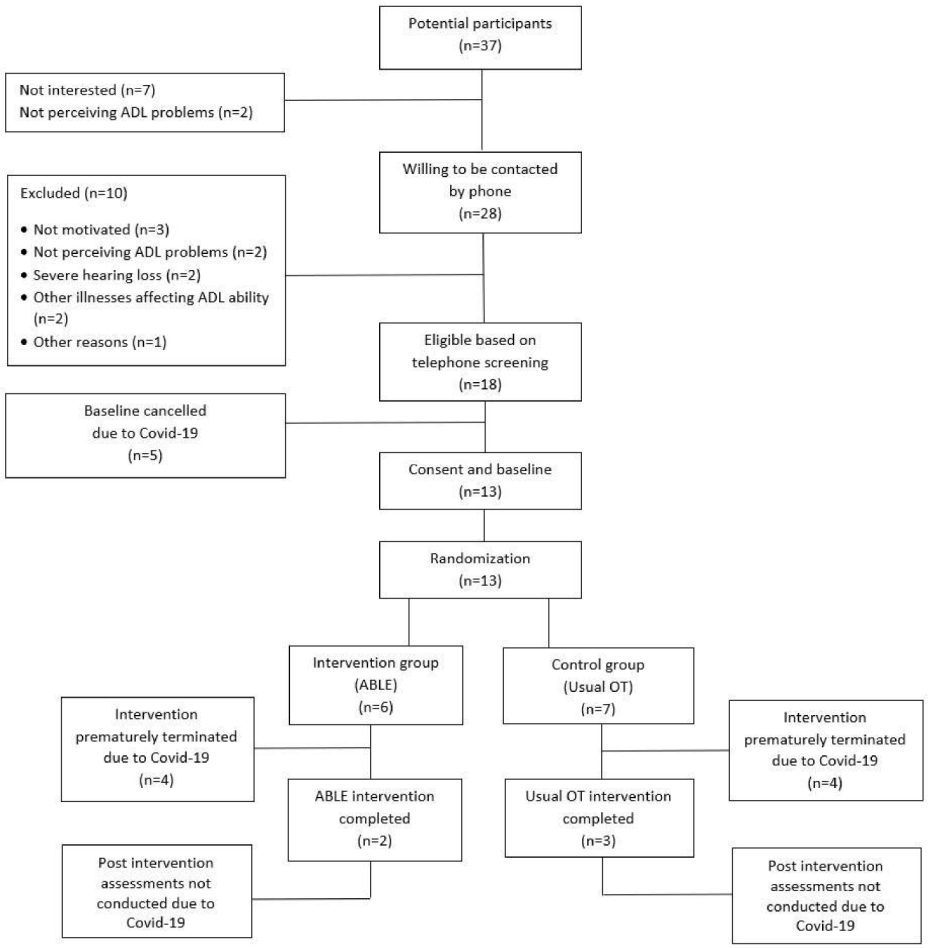


Figure 11 CONSORT diagram for pilot and feasibility trials: The ABLE 2.0 pilot RCT

The COVID-19 pandemic

The ABLE pilot RCT was discontinued and prevented from further conduction in March 2020 due to the COVID-19 pandemic lockdown. Consequently, we determined the extent to which the collected data was sufficient to address the aim of the study and launched additional actions where possible. Data related to monitoring recruitment and randomisation

procedures was considered sufficient. Information on retention was limited, and rates could not be determined. Also, data on adherence to ABLE 2.0 was limited with no opportunity to gather further data and hence data was based on information from registration forms related to two completed and three interrupted ABLE interventions. Data on appropriateness of outcome measurements was also limited, based on baseline evaluations of 13 participants. However, to supplement the limited data, a group interview was conducted with the assessors on their experiences from conducting baseline assessments. The number of baseline ADL-Q data was insufficient for generating ADL-Q measures, and they could not be reported. The extraction of information from client records on UOT was limited to three completed cases. To compensate for the limited data, we extracted and included information from client records on another seven clients, representative for the study sample and receiving UOT interventions before the pilot study. Conclusively, despite the interruption of the study, we judged that the pilot data were sufficient to answer the majority of the study questions.

Recruitment and retention

Of 37 persons contacted, 18 (48.6%) agreed to participate. Of these, 13 participants conducted baseline evaluations before the study was interrupted. Figure 11 provides an overview of the flow of participants in the pilot study. Seven of the 13 participants needed help filling out the questionnaires at baseline. In one case the participant had a limited use of the scale on ADL-Q performance, i.e. rated *'I perform the task independently without use of extra time or effort and without risk'* in 45 of 47 items. She explained her rating by saying: "*I can perform all tasks, but I tend to not get it done*". Hence, she rated being able to perform the tasks independently and competently despite receiving daily assistance from her spouse to initiate task performances. Furthermore, she was confused answering the CWP-Q and chose to reverse her answers completely after having received more information on the scale from the assessor. In terms of retention, no participants dropped out during the active data collection period.

Randomisation procedure

None of the 18 eligible participants refused randomisation. In five cases, further procedures were impossible due to the lockdown. Hence, 13 participants were randomised. Six (n=6) participants were allocated to ABLE 2.0 and seven (n=7) to UOT. All 13 participants stayed in their allocated program until the lockdown.

Adherent delivery of ABLE 2.0

Sessions delivered, instruments applied, intervention components implemented, and time used

Two (n=2) participants completed ABLE 2.0 with the minimum of five sessions, and one (n=1) participant completed all but the final session of ABLE 2.0. Another one (n=1) participant completed sessions 1 and 2. In all four cases, evaluation of ADL ability (AMPS and ADL-I) was conducted and GAS was used for negotiating and setting goals as prescribed in the manual (105). One more participant (n=1) completed session 1 including ADL evaluations. Finally, one randomised participant did not receive any sessions before the study was discontinued. The two participants (n=2) completing ABLE 2.0 went through ADL re-evaluation (AMPS and ADL-I) at the final session as prescribed in the manual (105). Eight of the nine potential intervention components to be employed in sessions 3–7, were applied across participants receiving ABLE 2.0. An overview of intervention components delivered is provided in table 10. The median number of minutes spent at the sessions delivered face-to-face varied between 27 and 135 minutes with a tendency to spend more time delivering the first (median = 93 min) and final sessions (median = 72 min).

Table 10 Frequency of implemented intervention components throughout sessions 3-7 in ABLE 2.0 pilot RCT

ABLE 2.0 intervention components[a] organised by PEO[b]	**Frequency**
P1: Changing habits related to task performance	3
P2: Changing attitude	3
P3: Plan, prioritise and reject	0
E1: Changing the physical environment	1
E2: Changing the social environment	1
E3: Use of tools, technology and/or helping aids	3
E4: Referring to other relevant services and opportunities	2
O1: Dividing the task into minor steps/distributing the task performance over longer time	1
O2: Simplifying the process/simplifying the task	1
Homework between sessions[c]	3

[a] Based on n=3 participants who completed the minimum of five intervention sessions
[b] Abbreviations: P: Person; E: Environment; O: Occupation
[c] Homework between session was applied in all three cases, examples were taking the bus with a friend; practice preparing lunch in smaller parts with rests in between; and practice using cordless vacuum cleaner

In the UOT group, n=3 participants completed their interventions. One (n=1) participant had the intervention process interrupted after one visit, and three (n=3) participants did not enter the UOT intervention process.

Deviations from the manual

The ABLE OTs reported no deviations from the manual apart from adjustments that were within the inherent flexibility of the program. Instruments and models were applied according to the manual.

Goal setting

Goals were negotiated for all participants completing session 2 (n=4). Two participants each defined two goals, and two participants each defined one goal. The ABLE OTs' perceived satisfaction with delivering session 2 was high (median=4.5; range: 3 to 5), whereas the ABLE OTs experience on how the dialogue on goal setting worked was somewhat lower (median=3; range: 2 to 5). Overview of aspects related to delivery in ABLE 2.0 pilot RCT is provided in table 11 and 12. The ABLE OTs reported to perceive some challenges related to goal setting, e.g., *"difficult to guide the participant on grading the goals"*; "*participant found it difficult to understand the scale*"; and "*it was difficult to explain GAS*". However, the participants all reported that they highly appreciated working with goal setting (median=4).

Confidence, engagement, involvement of participant, meaningfulness, and satisfaction with ABLE 2.0

The ABLE OTs reported a high level of confidence in delivering ABLE 2.0 and they felt highly engaged during the sessions (table 11). The degree of participant involvement was reported to be high, with similar ratings from ABLE OTs and participants. Moreover, participants and ABLE OTs found the content of the sessions highly meaningful and satisfactory.

Unintended side effects

The ABLE OTs registered a few examples of positive side effects: "*Based on the ADL task performance during the session, the participant was more able to describe the experienced problem related to the task*"; "*the participant seemed more motivated* [at the end of session 2]".

Practical and/or organizational facilitators and barriers

In terms of access to needed assistive devices no problems were reported.

Table 11 Delivery in ABLE 2.0 pilot RCT, OT registrations[a] (n=3)

		Session 1	Session 2	Sessions 3-7	Final session
Number of OT registrations: n (%)		5 (83) [b]	4 (100)	6 (100)	2 (67) [b]
Session 1 Median (range)	The session gave me knowledge on which ADL tasks and skills are problematic	4.0 (3-5)			
	The session clarified focus (ADL tasks and skills) for intervention	4.0 (3-5)			
	The participant and I established a good basis for further cooperation	4.0 (3-5)			
Session 2 Median (range)	The dialogue on discrepancy worked well		4.0 (3-5)		
	The dialogue on goal setting worked well		3.0 (2-5)		
	The dialogue on reasons for ADL problems worked well		4.0 (4)		
Sessions 3-7 Median (range)	The session contributed to goal attainment			3.0 (2-4)	
	The participant and I had a good cooperation on finding new strategies			4.0 (3-5)	
	The participant was willing to try new strategies			4.0 (2-5)	
Final session Median (range)	The intervention overall contributed to goal attainment				(3)
	The intervention overall contributed to better ADL ability				(4)
	I believe client will carry on using new strategies				(3-4)
All sessions Median (range)	Confidence in delivering	4.0 (4-5)	4.5 (3-5)	4.0 (3-5)	(4-5)
	OT engagement	4.5 (4-5)	5.0 (4-5)	4.0 (3-5)	(5)
	Involvement of client	3.5 (3-4)	4.0 (4)	4.0 (3-4)	(4-5)
	Perceived meaningfulness	4.0 (3-4)	4.5 (3-5)	4.0 (2-5)	(4-5)
	Perceived client meaningfulness	3.5 (3-4)	3.5 (3-5)	3.5 (3-4)	(4-5)
	Perceived satisfaction on delivery	3.5 (2-4)	3.5 (3-5)	4.0 (2-5)	(4-5)
	Perceived client satisfaction	4.0 (3-5)	3.5 (3-5)	4.0 (3-5)	(4-5)

ABLE, a better everyday life; ADL, activities of daily living; ADL-I, activities of daily living interview; AMPS, assessment of motor and process skills; OT, occupational therapist; RCT, randomised controlled trial, [a] Scored using Likert scales from 1-5; 1=very low degree, 2=low degree, 3=fair degree, 4=high degree and 5=very high degree
[b] One registration form was not completed

Table 12 Delivery in ABLE 2.0 pilot RCT, client registrations[a] (n=6)

		Session 1	Session 2	Sessions 3-7	Final session
Number of client registrations: n (%)		5 (83)	4 (100)	6 (100)	2 (67)
Session 1 Median (range)	ADL-I and AMPS gave me new knowledge on my ADL problems	2.0 (2-3)			
	ADL-I and AMPS clarified focus for intervention	4.0 (2-4)			
	OT and I established a good basis for further cooperation	4.0 (3-5)			
	I can see a purpose in participating in program	4.0 (2-5)			
Session 2 Median (range)	I liked the work on goal setting		4.0 (4)		
	It was relevant to talk about reasons for my ADL problems		4.0 (3-4)		
	I can see a purpose in participating in program		4.0 (4)		
Sessions 3-7 Median (range)	Session contributed to goal attainment			3.5 (3-5)	
	I have at this point attained my goals			3.0 (2-3)	
	I can see a purpose in participating in program			4.0 (3-5)	
Final session Median (range)	Intervention overall contributed to goal attainment				(3-4)
	Intervention overall contributed to better ADL ability				(3-4)
	I will carry on using the new strategies: (Range)				(3-4)
All sessions Median (range)	I felt informed	4.0 (3-5)	4.0 (4)	3.5 (3-5)	(3-4)
	I felt involved	4.0 (4-5)	4.0 (3-4)	4.0 (3-5)	(4)
	Session was meaningful to me	4.0 (3-5)	4.0 (4)	4.0 (3-5)	(4-5)
	Session was satisfactory to me	4.0 (3-5)	4.0 (4)	4.0 (4-5)	(4)

ABLE, a better everyday life; ADL, activities of daily living; ADL-I, activities of daily living interview; AMPS, assessment of motor and process skills; OT, occupational therapist;
RCT, randomised controlled trial
[a] Scored using Likert scales from 1-5; 1=very low degree, 2=low degree, 3=fair degree, 4=high degree and 5=very high degree

Appropriateness of outcome measurements

At baseline n=4 participants (30.7%) completed their ratings of performance in the ADL-Q, but only n=2 participants (15.4%) completed their ratings of satisfaction with ADL task performance in the ADL-Q. Twelve participants (92.3%) completed the OBQ11 at baseline, whereas all participants (100%) completed the CWP-Q at baseline. Thus, the progression criterion of 80% completely answered questionnaires was met in OBQ11 and CWP-Q, but not in ADL-Q. Seven participants needed assistance to fill in the questionnaires, one because of limited vision, another six for reasons like "*lack of overview*", "*it was overwhelming*", "*lack of energy*", "*receiving the questionnaires only the day before the meeting* [baseline assessment]" and "*not understanding a term* [occupational balance]". Two of the seven participants needing help received only minor assistance to complete the questionnaires, i.e. in less than 10% of the items.

Information on usual occupational therapy

Table 13 provides an overview of which of the predefined aspects of information on UOT was accessible. The quality of information related to goal setting and content of UOT was considered sufficient for comparison to similar types of information gathered during the ABLE intervention.

To summarise the results of the ABLE 2.0 pilot RCT, the procedures for recruitment and randomisation were feasible; the ABLE intervention program was adherently delivered and with no registered deviations from the manual; and almost all the desired information on UOT was accessible. The feasibility of outcome measurements in terms of the administration of the ADL-Q in the client population was associated with challenges, whereas the OBQ11 and CWP-Q were appropriate.

The process of deciding whether to proceed to a full-scale trial or not was based on the pre-defined progression criteria as illustrated in table 14 (results of ABLE 2.0 pilot RCT).

The study results implied a need for a few adjustments related to inclusion criteria, extraction of information on UOT and to the choice of outcome measurements. Further, based on the limited data on finalised interventions and the results of the feasibility study (15) that 60 % of the participants received less than the minimum number of five sessions, it was decided to reduce minimum dose to three (session 1, 2 and final session) sessions in future research.

Table 13 Accessible information on usual occupational therapy, client records (n=10)

Aspect	Prespecified information	Access to information (n)
Dose	Duration of intervention in days	10
	Number of visits	10
	Duration of visits in minutes	0[1]
Evaluation of ADL ability	Applied methods [2]	9
Goal setting	Whether goals were formulated	9
	How goals were negotiated	9
Content of treatment phase	Applied approaches [3]	10
Referral services		10
Programmatic and/or clinical changes[4]		0

[1] Scheduled time was accessible

[2] Use of standardised instruments; use of observation; use of self-report

[3] Practicing performance of ADL tasks; counselling; focus on occupation/body functions/environment; involvement of home carer or relative

[4] Changes applied based on e.g. new guidelines or participation in specialised courses

Table 14 Results of ABLE 2.0 pilot RCT

Aim	Aspect	Result	Decision
(i)	Recruitment	n=18; 48.6 %	+
	Retention	n=6; 100.0 %	
(ii)	Randomisation acceptance	n=18; 100.0 % procedure was effective	+
(iii)	Adherence	100.0 %	+
(iv)	Outcome measurements:	92.3-100.0 % in two of three questionnaires	+
(v)	Information on usual occupational therapy	extractable in seven of nine aspects	+

ABLE, a better everyday life; RCT, randomised controlled trial, Green colour reflects that the progression criteria were met, whereas yellow colour reflects a need for minor adjustments.

A full-scale randomised controlled trial was recommended.

Effectiveness evaluation (study 2)

Figure 12 illustrates the flow of participants throughout study 2, including time-points and reasons for not completing the interventions.

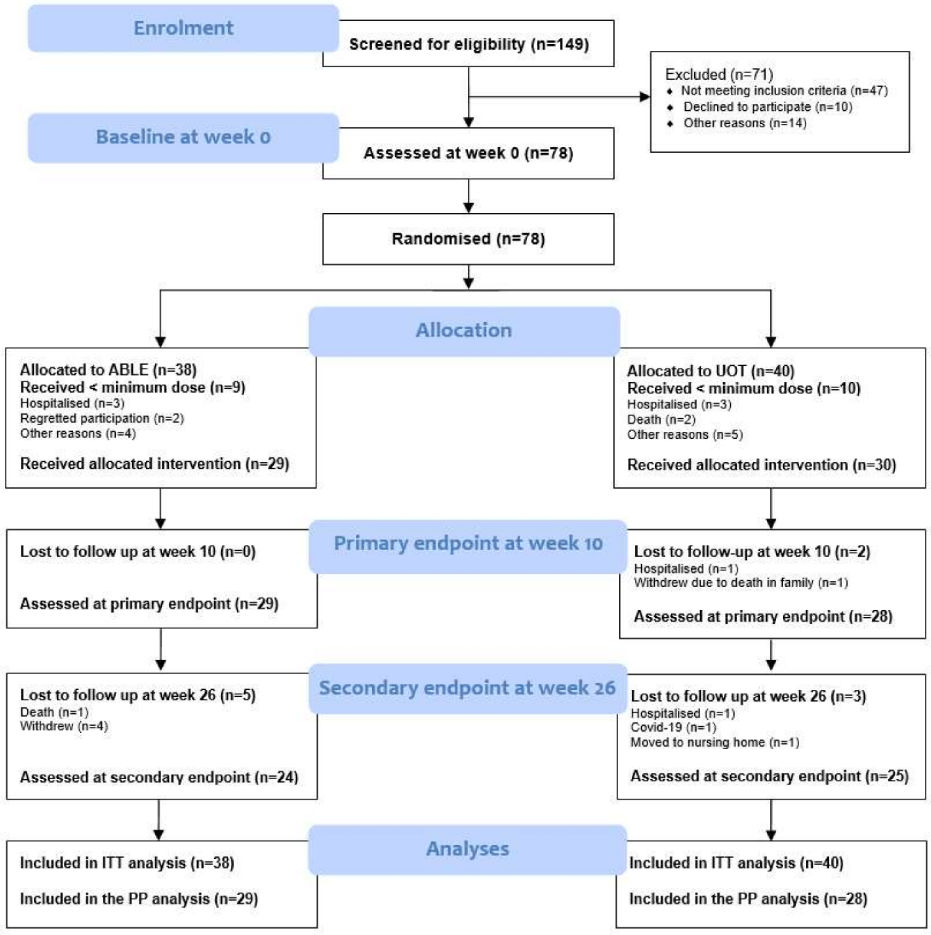


Figure 12 CONSORT 2010 Flow Diagram of the ABLE 2.0 trial

Usual occupational therapy

Thirty (n=30; 75%) of the participants in the UOT group completed the intervention. The median number of visits was 2 (range: 1 to 12) and the median duration of each visit was 60 minutes (range: 15 to 90). The median duration of the interventions were 14.5 days (range: 1 to 118). Six occupational therapists delivered UOT. One UOT OT, who delivered

intervention for one client, had <1 year of experience with the target group. The other five UOT OTs had >2 years of experience working with the target group. Overall, n=95 sessions were delivered. Of those, n=90 sessions (94.7%) were delivered in the home of the client, and n=5 sessions (5.3%) were delivered by telephone.

Client records overall indicated a non-standardised approach to evaluation of ADL ability, that included dialogue and trying out tasks. Moreover, the client records indicated that evaluation of ADL ability and intervention planning was conducted in a parallel order rather than employing evaluation as a basis for planning intervention. In n=12 cases (40.0%) the client records showed that focus/goals for the intervention was negotiated in collaboration between the OT and the client. Examples of areas of focus/goals were: *"Vacuuming", "preparing coffee", "cleaning the floor", "cooking", "dressing", "safer bathing", "independent bathing"*. In another n=17 cases (56.7%) goals were identified by the referral services, defining focus for the intervention. In a single case (3.3%) information on goal setting was not accessible. The information on the content of the delivered intervention sessions indicated that in n=18 cases (60.0%) the OTs facilitated practicing performance (i.e. occupation-based approach), of ADL tasks and/or employed counselling on ADL task performance, whereas in the remaining n=12 cases (40.0%) there was no information on performance of ADL tasks or application of counselling during the intervention. Furthermore, the client records indicated that interventions had various focus on the client's body functions, occupation and/or contextual factors (13). Moreover, involvement of home caregivers and/or relatives were occasionally described. According to the client records, n=9 (30.0%) clients were introduced to and/or referred to assistive devices and n=8 (26.7 %) clients were referred to receive assistance in the home. The interventions were finalised in various ways, including re-evaluation in n=7 (23.3%) cases using non-standardised methods.

Outcomes

Differences in mean changes between the ABLE 2.0 and the UOT group on primary, secondary, and explorative outcomes at primary and secondary endpoints are provided in table 15.

Table 15 Changes in primary, secondary, and explorative outcomes at primary and secondary endpoints in the intention-to treat (ITT) and per-protocol (PP) populations

	ITT				PP			
Variables	**ABLE (n=38)**	**UOT (n=40)**	**Estimated treatment difference**		**ABLE (n=29)**	**UOT (n=28)**	**Estimated treatment difference**	
	LSMean (SE)	LSMean (SE)	ΔLSMean (95% CI)	P value	LSMean(SE)	LSMean(SE)	ΔLSMean (95% CI)	P value
Primary outcomes at primary endpoint, week 10								
AMPS ADL motor ability	0.3 (0.1)	0.2 (0.1)	-0.1 (-0.3 to 0.1)	0.3430	0.4 (0.1)	0.1 (0.1)	-0.2 (-0.5 to 0.0)	0.0622
ADL-I Performance	0.17 (0.08)	0.01 (0.08)	-0.16 (-0.38 to 0.06)	0.1635	0.19 (0.09)	0.03 (0.09)	-0.15 (-0.41 to 0.10)	0.2384
Secondary outcomes at primary endpoint, week 10								
AMPS ADL process ability	0.1 (0.1)	0.1 (0.1)	-0.1 (-0.2 to 0.1)	0.4036	0.1 (0.1)	0.1 (0.1)	-0.1 (-0.2 to 0.1)	0.4350
ADL-I Satisfaction	-0.10 (0.13)	-0.20 (0.13)	-0.10 (-0.46 to 0.27)	0.6012	0.05 (0.10)	-0.16 (0.11)	-0.21 (-0.51 to 0.08)	0.1553
Secondary outcomes at secondary endpoint, week 26								
AMPS ADL motor ability	0.4 (0.1)	0.1 (0.1)	**-0.3 (-0.5 to -0.1)**	**0.0178**	0.5 (0.1)	0.1 (0.1)	**-0.4 (-0.7 to -0.1)**	**0.0027**
AMPS ADL process ability	0.1 (0.1)	0.1 (0.1)	0.0 (-0.2 to 0.1)	0.6062	0.2 (0.1)	0.0 (0.1)	-0.1 (-0.3 to 0.1)	0.2113
ADL-I Performance	0.19 (0.09)	0.28 (0.09)	0.09 (-0.15 to 0.34)	0.4381	0.14 (0.10)	0.31 (0.10)	0.18 (-0.10 to 0.46)	0.2050
ADL-I Satisfaction	0.22 (0.14)	-0.09 (0.14)	-0.31 (-0.71 to 0.08)	0.1204	0.17 (0.11)	-0.08 (0.11)	-0.25 (-0.57 to 0.07)	0.1245
Explorative outcomes at primary endpoint, week 10*								
OBQ11	1.62 (0.87)	1.01 (0.87)	-0.61 (-3.05 to 1.83)	0.6225	1.91 (1.00)	1.39 (1.00)	-0.52 (-3.31 to 2.28)	0.7140
CWP-Q1 - affects ADL	-0.80 (0.31)	-1.35 (0.32)	-0.56 (-1.44 to 0.33)	0.2182	-0.54 (0.35)	-1.37 (0.36)	-0.83 (-1.82 to 0.16)	0.0999
CWP-Q2 - affects social life	-0.09 (0.32)	-0.34 (0.32)	-0.26 (-1.16 to 0.65)	0.5763	0.10 (0.38)	-0.19 (0.38)	-0.29 (-1.35 to 0.77)	0.5903
CWP-Q3 - need help to accept	-1.44 (0.44)	-0.25 (0.43)	1.19 (-0.03 to 2.41)	0.0551	-1.34 (0.53)	-0.11 (0.50)	1.22 (-0.22 to 2.66)	0.0960
CWP-Q4 - need assistance in ADL	-2.16 (0.44)	-1.20 (0.44)	0.96 (-0.28 to 2.19)	0.1284	-2.41 (0.51)	-1.15 (0.50)	1.26 (-0.15 to 2.67)	0.0803
CWP-Q5 - affects hope for future	-0.29 (0.36)	-0.13 (0.35)	0.16 (-0.84 to 1.15)	0.7524	-0.47 (0.42)	-0.13 (0.42)	0.34 (-0.83 to 1.52)	0.5663
Explorative outcomes at secondary endpoint, week 26*								
OBQ11	1.14 (1.00)	0.97 (0.95)	-0.17 (-2.89 to 2.54)	0.9005	1.30 (1.10)	0.64 (1.08)	0.66 (-3.71 to 2.39)	0.6701
CWP-Q1 - affects ADL	-0.60 (0.36)	-1.19 (0.34)	-0.59 (-1.57 to 0.39)	0.2352	-0.37 (0.39)	-1.10 (0.38)	-0.73 (-1.81 to 0.35)	0.1834
CWP-Q2 - affects social life	-0.15 (0.41)	-0.25 (0.35)	-0.09 (-1.15 to 0.97)	0.8654	-0.06 (0.46)	-0.32 (0.41)	-0.27 (-1.48 to 0.95)	0.6657
CWP-Q3 - need help to accept	-1.05 (0.54)	-0.54 (0.46)	0.51 (-0.89 to 1.91)	0.4710	-0.88 (0.61)	-0.47 (0.54)	0.40 (-1.22 to 2.02)	0.6225
CWP-Q4 - need assistance in ADL	-2.08 (0.50)	-1.78 (0.46)	0.30 (-1.04 to 1.64)	0.6583	-1.81(0.55)	-2.20 (0.52)	-0.40 (-1.90 to 1.10)	0.6000
CWP-Q5 - affects hope for future	-0.48 (0.41)	-0.59 (0.38)	-0.12 (-1.2 to 0.99)	0.8355	-0.36 (0.47)	-0.74 (0.45)	-0.38 (-1.66 to 0.90)	0.5559

ABLE, a better everyday life (experimental group); ADL, activities of daily living; ADL-I, activities of daily living interview; AMPS, assessment of motor and process skills;
CI, confidence interval; CWP-Q, client weighted problems questionnaire; OBQ, occupational balance questionnaire; ITT, intention to treat; PP, per protocol; SE, standard error;
UOT, usual occupational therapy (control group)
* Data missing at baseline. OBQ: ABLE n=1, CWP-Q1: ABLE n=1, CWP-Q2: ABLE n=2, CW-Q3: ABLE n=4, UOT n=1, CWP-Q4: ABLE n=2, CWP-Q5: ABLE n=1

The primary analysis of the co-primary outcomes identified no statistically significant differences in mean changes between the groups at the primary endpoint (week 10) on AMPS ADL motor ability (LS mean difference = -0.1; 95%CI = -0.3 to 0.1) or ADL-I performance (LS mean difference = -0.16; 95%CI = -0.38 to 0.06). However, while both groups improved in AMPS ADL motor ability from baseline to week 10, only the ABLE 2.0 group obtained a clinically relevant change (LS mean change = 0.3; SE = 0.7). In contrast, in the primary analysis of AMPS ADL motor ability as a secondary outcome at the secondary endpoint (week 26), a statistically significant and clinically relevant difference in mean change between groups was found (LS mean difference = -0.3; 95% CI = -0.5 to -0.1). This was confirmed in the sensitivity analysis (LS mean difference = -0.4; 95% CI = -0.7 to -0.1), where the ABLE 2.0 group obtained a clinically relevant improvement from baseline to week 26 (LS mean change = 0.5; SE = 0.1). Figures 13 and 14 illustrates trajectories for the AMPS ADL motor ability and ADL-I performance respectively in both groups based on least square means. In the ABLE group the patterns in AMPS and ADL-I Performance over time were similar, with an increase from baseline to week 10 that continuous until week 26. Comparing the two groups in AMPS ADL motor only the participants in the ABLE 2.0 group obtained a clinically relevant mean change from baseline to week 10, and the at week 26 the between group difference in mean change was clinically relevant.

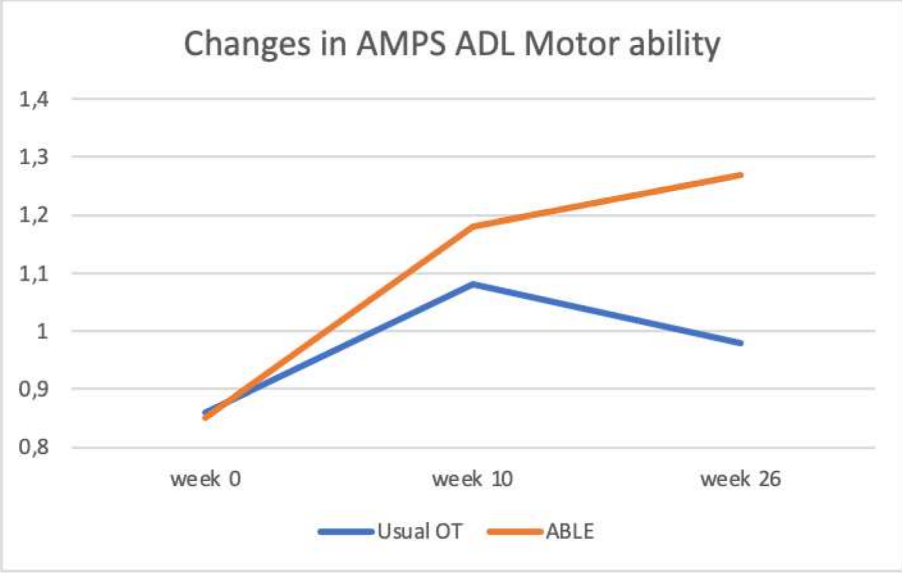


Figure 13 Trajectories of the AMPS ADL motor ability in both groups, based on least square means. Higher values represent more observed ADL motor ability

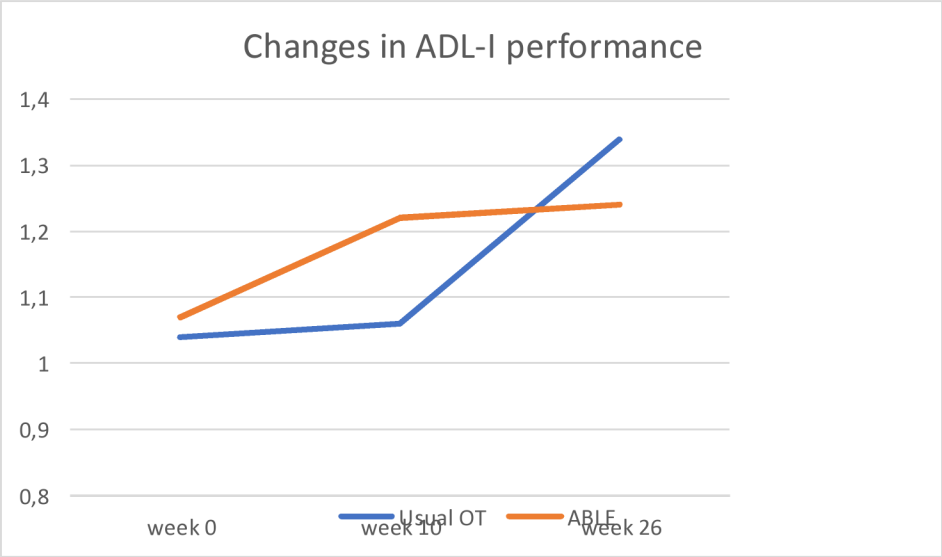


Figure 14 Trajectories of the ADL-I Performance ability in both groups, based on least square means. Higher values represent more self-reported ADL ability

In the primary analysis of the secondary and exploratory outcomes no statistically significant nor clinically relevant changes were revealed in self-reported ADL ability (ADL-I Performance and Satisfaction), observed ADL process ability (AMPS process), occupational balance (OBQ11), and client weighted problems (CWP-Q). Further, logistic regression analysis on overall health measured by the SF36-SF1 showed no association between allocation to ABLE 2.0 (vs. UOT) and self-reported improvement in health (odds ratio = 1.3; 95% CI = 0.09 to 22.66; p = 0.8249).

The per protocol analyses confirmed the primary analyses.

Responder analysis

In total, n=57 participants received ≥minimum doses and attended assessments at week 10, constituting the PP population. Baseline demographics on responders and non-responders at primary endpoint in the two groups are presented in table 16, and an overview of the proportion of responders and mean changes in ADL ability at primary and secondary endpoints is provided in table 17.

Table 16 Baseline demographics on responders and non-responders at primary endpoint in the ABLE 2.0 and the usual occupational therapy (UOT) groups

Variable	ABLE		UOT	
	Responders n=16	**Non-responders n=13**	**Responders n=14**	**Non-responders n=14**
Age: median (range)	76.0 (66-86)	76.0 (51-88)	77.5 (36-92)	75.5 (57-89)
Sex: female, n (%)	12 (75.0)	9 (69.2)	8 (57.1)	12 (85.7)
Diagnosis[a]: n (%)				
Orthopaedic/musculosceletal[b]	7 (43.8)	7 (53.8)	6 (42.9)	10 (71.4)
Neurological[c]	2 (12.5)	2 (15.9)	4 (28.6)	3 (21.4)
Medical[d]	7 (43.8)	4 (30.8)	4 (28.6)	1 (7.1)
Multi morbidity	11 (68.8)	8 (61.5)	9 (64.3)	10 (71.4)
Civic status: n (%)				
Living alone	11 (68.8)	9 (69.2)	9 (64.3)	8 (57.1)
Living with a partner	5 (31.3)	4 (30.8)	5 (35.7)	6 (42.9)
Living with children	0 (0.0)	1 (7.7)	1 (7.1)	0 (0.0)
Job situation: n (%)				
Working	0 (0.0)	0 (0.0)	0 (0.0)	2 (14.3)
Sick leave	0 (0.0)	1 (7.7)	1 (7.1)	1 (7.1)
Senior citizen	16 (100.0)	12 (92.3)	13 (92.9)	11 (78.6)
Highest level of education: n (%)[e]				
Low	11 (68.8)	9 (69.2)	10 (71.4)	8 (57.1)
Middle	4 (25.0)	4 (30.8)	4 (28.6)	6 (42.9)
High	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)
SF1 of SF36: median (range)	4.0 (4-5)	4.0 (3-5)	4.5 (2-5)	4.0 (3-5)
ADL ability: mean (SD)				
AMPS ADL motor	0.6 (0.6)	1.1 (0.4)	0.6 (0.7)	1.2 (0.4)
AMPS ADL process	0.8 (0.5)	1.1 (0.4)	0.9 (0.5)	1.0 (0.5)
ADL-I Performance	0.91 (1.23)	1.32 (1.08)	0.88 (0.76)	1.31 (0.91)
ADL-I Satisfaction	0.73 (0.93)	0.95 (1.02)	0.66 (0.77)	1.13 (0.88)
OBQ11: median (range)	22 (0-33)	25 (12-33)	23 (10-30)	26 (4-32)
CWP-Q: median (range)				
CC affects ADL	8.0 (5-10)	8.0 (0-10)	8.0 (5-10)	8.0 (2-10)
CC affects social life	8.0 (0-10)	6.0 (0-10)	6.0 (0-10)	4.0 (0-10)
Need help to accept CC	5.0 (0-10)	5.0 (0-9)	4.0 (0-10)	1.0 (0-10)
Need assistance in ADL	9.0 (4-10)	6.0 (1-10)	6.5 (0-10)	8.0 (3-10)
CC affects hope for future	8.0 (2-10)	8.0 (1-10)	9.0 (2-10)	6.0 (1-10)

ABLE: experimental group; UOT: control group (e.g., usual occupational therapy); SF1 of SF36: the first question (SF1) of The MOS 36-item Short Form Survey Instrument (SF36); ADL: activities of daily living; ADL-I: activities of daily living interview; AMPS: Assessment of Motor and Process Skills: OBQ: occupational balance questionnaire; CWP-Q: client weighted problems questionnaire; CC: chronic condition.

[a] the diagnosis (orthopaedic/musculoskeletal, neurological and medical) that the assessor determined to affect the ADL ability most at baseline
[b] defined as arthritis, chronic/long-term pain, and fracture/replacement
[c] defined as stroke (i.e. right-/left-sided stroke, subarachnoid haemorrhage, cerebral aneurism) and non-stroke (i.e. cerebral palsy, traumatic brain injury, multiple sclerosis, parkinsonism)
[d] defined as cardiovascular disease, respiratory disease, diabetes, cancer, and obesity
[e] based on the Danish educational system; low: primary education or low-level professional education; middle: secondary education or medium-level professional education; and high: tertiary education (bachelor's degree or higher)

Table 17 Proportion of responders and mean changes in ADL ability at primary and secondary endpoints

	ABLE n=29	**UOT** n=28	**Group differences**
Responders on co-primary outcomes at primary endpoint (week 0-10)			
AMPS ADL motor ability			
n (%)	14 (48.3)	10 (35.7)	Chi^2=0.92; df=1; p=0.34
Mean change (95 % CI)	0.8 (0.5-1.1)	0.8 (0.5-1.1)	0.0 (-0.4 to 0.4)
ADL-I performance			
n (%)	6 (20.7)	4 (13.8)	Chi^2=0.40; df=1; p=0.34
Mean change (95 % CI)	1.15 (0.41-1.88)	1.04 (0.82-1.26)	-0.10 (-0.94 to 0.73)
AMPS ADL motor ability and/or ADL-I performance			
n (%)	16 (55.2)	14 (50.0)	Chi^2=0.19; df=1; p=0.89
Responders on co-primary outcomes at secondary endpoint (week 0-26)			
AMPS ADL motor ability			
n (%)	13 (44.8)	10 (35.7)	Chi^2=0.50; df=1; p=0.48
Mean change (95 % CI)	1.0 (0.7-1.3)	0.8 (0.4-1.1)	-0.2 (-0.7 to 0.2)
ADL-I performance			
n (%)	6 (20.7)	9 (32.1)	Chi^2=0.96; df=1; p=0.33
Mean change (95 % CI)	1.06 (0.08-1.33)	1.05 (0.82-1.27)	00.02 (-0.34 to 0.30)
AMPS ADL motor ability and/or ADL-I performance			
n (%)	14 (48.3)	17 (60.7)	Chi^2=0.89; df=1; p=0.35

ABLE: experimental group; UOT: control group (e.g., usual occupational therapy); ADL: activities of daily living; ADL-I: activities of daily living interview; AMPS: Assessment of Motor and Process Skills

Sixteen (55.2%) of the clients completing ABLE 2.0 obtained a clinically relevant improvement in ADL ability, i.e. were responders, based on self-report (ADL-I Performance) and/or observation (AMPS ADL motor) measured as change from baseline to primary endpoint at week 10. Of these, n=4 (25.0%) achieved a clinically relevant improvement based on both measures. In comparison, in the UOT group n=14 (50.0%) of the clients completing their programmes obtained a clinically relevant improvement in ADL ability at week 10. None of these participants achieved a clinically relevant improvement based on both measures. Differences in proportion of responders between groups were not statistically significant.

At the secondary endpoint n=14 (48.3%) of the clients completing ABLE 2.0 obtained a clinically relevant improvement in ADL ability based on self-report (ADL-I Performance) and/or observation (AMPS ADL motor). Of these, n=5 (17.2%) achieved a clinically relevant improvement based on both measures. In comparison, n=17 (60.7%) of the participants in the usual occupational group obtained a clinically relevant improvement in ADL ability. Of these, n=2 (7.1%) achieved a clinically relevant improvement based on both measures. As with the results at primary endpoint, the differences in proportion of responders between groups were not statistically significant. Finally, at primary and secondary endpoints, mean changes in AMPS ADL motor ability and ADL-I Performance measures were not significantly different between groups of responders.

In the ABLE 2.0 group all responders were senior citizens, whereas participants with other job situations were either non-responders or responders in the UOT group. The baseline mean AMPS ADL motor ability among responders in the ABLE 2.0 group was 0.5 logits lower compared to non-responders, representing a clinically relevant difference (i.e. ≥ 0.3 logits) (26). In the UOT group similar differences (0.6 logits) were seen between responders and non-responders at baseline. Moreover, a clinically relevant difference in baseline mean AMPS ADL process ability (0.3 logits) was seen between responders and non-responders in the ABLE 2.0 group (26), whereas in the UOT group the mean difference was 0.1 logits in favour of non-responders, but not clinically relevant.

Baseline mean ADL-I Performance measures among the responders in the ABLE 2.0 group was 0.41 logits lower than among the non-responders, whereas in the UOT group the mean difference was 0.43 logits in the favour of non-responders. Still, none of these differences represented a clinically relevant difference (i.e. ≥ 0.64 logits).

The results of the CWP-Q showed that responders in both groups at baseline perceived that their chronic conditions affected their ADL ability, social life, and hope for the future more than among non-responders; that the perceived need for help accepting their chronic conditions was lower among clients in the UOT group compared to the ABLE 2.0 group, and very low among the non-responders; and that the perceived need for assistance was highest among responders in the ABLE 2.0 group.

Process evaluation (study 3)

Overall, the n=38 clients, randomised to the ABLE group and the three ABLE OTs were included in the process evaluation. Filled in registration forms were collected from the delivered sessions informing on the hypothesised CMOCs, i.e. CMOC a) *Relationship and collaboration* (sessions 1-8; n=144); CMOC b) *Evaluation* (session 1, n=33); CMOC c) *Goal setting* (session 2, n=29); CMOC d) *Intervention* (sessions 3-7, n=53); CMOC e) *Re-evaluation* (final session, n=29; goals defined, n=67).

Realist individual interviews were conducted with the three ABLE OTs followed by interviewing n=8 clients having received ABLE 2.0. The ABLE OTs were women, aged between 35 to 43 years, with 7 to 11 years of experience working as OTs with ADL ability among persons with chronic conditions. Characteristics on the interviewed clients are presented in table 18. In total, n=22 goals were defined by the eight clients (median n=3, range 1-5). In n=20 (90.9 %) goals the client reached the expected, more, or much more than expected level of goal attainment. In n=1 (4.5%) goal, the client remained at the baseline level. Finally, a focus group interview was conducted among the three ABLE OTs.

The results of the analyses of quantitative and qualitative data are presented within four themes derived from the qualitative data: 1) building a foundation for the entire intervention, 2) establishing the focus for further intervention, 3) identifying and implementing relevant compensatory solutions, and 4) re-evaluating ADL ability to finalise intervention. The results are documented with quotes as follows: ABLE OT interviews (numbered OT1-3), client interviews (numbered C1-8) and the focus group (FG).

Table 18 Characteristics on clients who participated in interview

Client number	Sex	Age	Diagnosis	AMPS ADL motor	Number of

				ability at baseline	sessions received
1	Female	84	Medical[c] Orthopaedic/musculosceletal[a]	0.8	3
2	Male	74	Medical[c] Orthopaedic/musculosceletal[a]	0.7	4
3	Female	69	Orthopaedic/musculosceletal[a]	1.1	5
4	Female	74	Medical[c] Neurological[b]	0.7	5
5	Female	75	Neurological[b]	1.1	4
6	Male	70	Medical[c]	0.8	4
7	Male	75	Medical[c] Orthopaedic/musculosceletal[a]	1.3	4
8	Female	85	Medical[d] Orthopaedic/musculosceletal[a]	1.4	4

ADL: activities of daily living; AMPS: assessment of motor and process skills
[a]'orthopaedic/musculoskeletal' covers arthritis, chronic/long-term pain, and fracture/replacement
[b] 'neurological' covers stroke (i.e. right-/left-sided stroke, subarachnoid haemorrhage, cerebral aneurism) and non-stroke (i.e. cerebral palsy, traumatic brain injury, multiple sclerosis, parkinsonism)
[c] 'medical' covers cardiovascular disease, respiratory disease, diabetes, cancer, and obesity

Each theme includes descriptions of how ABLE 2.0 was perceived to function including determination of whether aspects of the IPT was confirmed, refined or rejected, supplied with selected findings concerning the strength of the hypothesised CMOCs where relevant (Table 19 provides an overview of the selected results of the intra-group comparisons; appendix 1 provides an overview of all intra-group comparisons). The prominent CMOCs, derived through the analyses and across data sources are presented in table 20.

Building a foundation for the entire intervention

Data reflected that during sessions 1 and 2 contextual factors at different levels facilitated or constrained the process of building a solid foundation for the entire intervention. This was framed and structured by the thorough evaluation of the client's ADL ability, by actively involving the client in this process, and by taking the client's perspective into account.

At the infrastructural level, the client's pathway to rehabilitation services played a role in building a foundation for the entire intervention. The following paragraph describes how this refines the IPT. The clients' pathways affected their motivation for participating in the intervention programme and readiness for making changes. In the municipality a client could be referred from the referral services (e.g., when applying for support

in the home), or from the rehabilitation team (e.g., if a physiotherapist identified that a client experienced ADL task performance problems). As part of the usual workflow in the municipality, the referral service typically defined goals for the intervention when granting the intervention. This tended to prevent building a foundation for the entire process, by counteracting the certain order of the content of ABLE 2.0, prescribing evaluation of ADL ability prior to goal setting. An ABLE OT said: "*If the client was referred from the referral service, for example 'needing help bathing', this is what they expect us to take care of ... but sometimes some completely different problems appear... then we must return to the referral service with other needs ... how do we solve that? Who is the authority? There is something in relation to the way we are organised ...*" (OT3). Another ABLE OT agreed: "*It is confusing for the clients, they expect us to work on* [goals related to] *bathing* [as defined by the referral service], *and then we also ask about dressing and cooking* [as prescribed in ABLE manual] *... the order of things in ABLE involves the client a lot more"* (FG). Hence, when a client was referred from the referral services, and goals were defined prior to initiating the occupational therapy intervention process, and prior to evaluating the client's perceived and observed ADL ability, building a foundation for the entire intervention was obstructed.

At the institutional level, the support from the management in prioritising time for training ABLE OTs in delivering ABLE 2.0 in accordance with the manual, and in legitimising deviations from usual practice, facilitated the OTs feeling obliged and responsible. This refines the IPT and led to increased effort and engagement related to delivering what the ABLE OTs called '*quality occupational therapy*', and a sense of being skilled among the ABLE OTs. Furthermore, the described management resulted in important support from colleagues in terms of accepting new ways of working, and in referring relevant clients to occupational therapy. Sometimes the ABLE OTs perceived lack of understanding of the new way of working among their colleagues, especially related to delivery of session 1, taking more time than a usual start-up. An ABLE OT said: " *... of course the manager's attitude* [matters], *the fact that you have an employer who thinks it's important to deliver these interventions, and that we get enough time for it"* (OT2). Another ABLE OT said: "*Some of our colleagues said, well it was good you finished it* [participating in the research] *... they thought it took a lot of time and that we were less available ...*" (FG). Another contextual factor at the institutional level, confirming the IPT (a), was related to training and support in delivering the intervention, i.e. the three-and-a-half-day course, the exchange of questions and experiences between the ABLE OTs, and the access to supervision on delivery from the research group in relation to occurring challenges. This activated the ABLE

OTs feeling confident in delivering the programme, leading to ABLE OTs feeling satisfied and engaged. An ABLE OT said: "*I have used her* [the primary investigator] *very much, to make sure I was on the right track. It has just meant a lot ... I have also had two colleagues who have been involved in it* [delivering ABLE], *and we have shared many things ...*" (OT1).

At the interpersonal level, ABLE 2.0 provided a frame for building confidence and collaborative relationships between the client and the OT, overall confirming the IPT in terms of triggering the therapeutic relationship as a mechanism (a, b). Such relationships were found core in building the foundation for the intervention process and led to satisfaction and engagement among both clients and ABLE OTs. A client said: *"She was nice and straightforward, she listened to me, and I was straightforward too, and then we just got started ... we were on wavelength right away, yes, we were, and that has helped a lot"* (C2). Administration of evaluations based on both self-report and observation of ADL ability at session 1 was found to be a prerequisite for initiating the problem-solving process. This systematic approach framing the first meeting between the client and the OT, activated involvement of the client. A client said: "*I think it was really good, especially because of those forms* [AMPS and ADL-I] *we used. I got something out of it. I think it made a lot of sense. I even got an insight – thinking in a different way. We put it into words, whether I needed help, or it was hard or easy for me, whether I felt pain, - I could see it. And I saw that yes, it is actually true that I need help*" (C7).

This was supported by the results of the intra-group comparison (table 19) on the hypothesised CMOC b), showing that in most cases the mechanisms '*clients getting a deeper understanding of his/her ADL ability*' and '*client feeling involved*' was triggered by the combined methods in evaluating their ADL ability, leading to the client perceiving satisfaction with session 1 and finding content of session 1 meaningful, respectively. In 23 (72%) of 32 clients '*satisfaction with session 1*' was related to '*getting a deeper understanding of their ADL problems*'; and in 29 (97%) of 30 clients '*finding content of session 1 meaningful*' was related to '*feeling involved*'.

Table 19 Intra group comparisons of hypothesised context[a]-mechanism[b]-outcome[c] configurations

CMOC a) Relationship and collaboration			
ABLE is delivered by an OT feeling engaged and prepared to deliver session content to a client motivated for making changes (C)			
Client finding programme meaningful (M2)	Increased ADL ability (O2)[d]		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	48 (37)	80 (63)	128 (100)
Weak: n (%)	2 (40)	3 (60)	5 (100)
Delivered sessions with complete data, n	50	83	133 (100)
CMOC b) Evaluation			
Valid evaluations of ADL ability conducted in the client's home, including taking the clients perspective into account (C)			
Client getting a deeper understanding of his/her ADL problems (M1)	Client finding participation in session 1 satisfactory (O2)		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	0 (0)	23 (100)	23 (100)
Weak: n (%)	0 (0)	9 (100)	9 (100)
Delivered session 1 with complete data, n	0	32	32 (100)
Client feeling involved (M3)	Client finding the content of session 1 meaningful (O3)		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	1 (3)	29 (97)	30 (100)
Weak: n (%)	0 (0)	0 (0)	0 (100)
Delivered session 1 with complete data, n	1	29	30 (100)
CMO c) Goal setting			
ABLE OT and client together define occupation-focused goals and clarify causes for ADL problems (C)			
Client feeling involved (M1)	Client finding participation in session 2 satisfactory (O2)		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	0 (0)	27 (100)	27 (100)
Weak: n (%)	0 (0)	0 (0)	0 (100)
Delivered session 2 with complete data, n	0	27	27 (100)
Client feeling involved (M1)	Client finding the content of session 2 meaningful (O3)		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	0 (0)	26 (100)	26 (100)
Weak: n (%)	0 (0)	0 (0)	0 (100)
Delivered session 2 with complete data, n	0	26	26 (100)
CMOC d) Intervention			
Adaptive intervention components delivered in the client's home (including optional homework), and the ABLE OT being familiar with components and acting as facilitator of change (C)			
Collaboration between client and OT on finding solutions (M1)	Commencing goal attainment (O1)		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	3 (7)	42 (93)	45 (100)
Weak: n (%)	0 (0)	2 (100)	2 (100)
Delivered session 3-7 with complete data,	3	44	47 (100)

n			
Collaboration between client and OT on finding solutions (M1)	Client finding participation in programme purposeful (O2)		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	2 (4)	43 (96)	45 (100)
Weak: n (%)	0 (0)	2 (4)	2 (100)
Delivered session 3-7 (complete data), n	2	45	47 (100)
Client being willing to try solutions during performance of ADL tasks (M2)	Commencing goal attainment (O1)		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	3 (7)	38 (93)	41 (100)
Weak: n (%)	0 (0)	6 (14)	6 (100)
Delivered session 3-7 (complete data), n	3	44	47 (100)
Client being willing to try solutions during performance of ADL tasks (M2)	Client finding participation in programme purposeful (O2)		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	2 (5)	39 (95)	41 (100)
Weak: n (%)	0 (0)	6 (100)	6 (100)
Delivered session 3-7 (complete data), n	2	45	47 (100)
CMOC e) Re-evaluation			
Client gets feedback on goal attainment and obtained changes (C)			
Client expecting to carry on using the new solutions (M1)	Goal attainment (O1)		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	5 (8)	55 (92)	60 (100)
Weak: n (%)	1 (50)	1 (50)	2 (100)
Goals defined with complete data, n=62	6	56	62 (100)
Client expecting to carry on using the new solutions (M1)	Satisfaction with obtained ADL ability (week 0-10) (O3a)[e]		
	low extent	**high extent**	**total n (%)**
Strong: n (%)	21 (78)	6 (22)	27 (100)
Weak: n (%)	1 (100)	0 (0)	1 (100)
Delivered final session, n=	22	6	28 (100)

ADL, activities of daily living; CMOC, context-mechanism-outcome configuration; C, context; M, mechanism; O, outcome

[a] Contextual factors were all over scored to be highly presented, reflecting successful implementation of ABLE 2.0
[b] Data on mechanisms were dichotomised: 'weak' covers 'to a very low degree' and 'to a low degree'; 'strong'covers 'to some degree', 'to a high degree', and 'to a very high degree'
[c] Data on outcomes were dichotomised: 'low extent' covers 'to a very low extent' and 'to a low extent'; 'high extent' covers 'to some extent', 'to a high extent', and to a very high extent'
[d] Data on obtained ADL ability was dichotomised: low extent=less than clinically relevant change; high extent=more than clinically relevant change (i.e. in ADL-I Performance and/or AMPS ADL motor ability at week 10)
[e]Data on satisfaction was dichotomised: low extent=less than clinically relevant change; high extent=more than clinically relevant change (i.e. in ADL-I Satisfaction at week 10)

Data also showed that when the ABLE OT was feeling skilled and engaged in delivering ABLE 2.0, e.g., using the instruments for evaluating the ADL ability, it led to the client feeling satisfied, engaged, listened to, seen and

understood. Further, this led to revealing the client's perspective on his/her ADL ability. An OT said: "*You feel well informed* [after having conducted ADL-I and AMPS] *to move forward, and you really feel you have established a common starting point to move forward, because we got in depth with* [understanding] *the client's everyday life …*" (OT2). Also, the ABLE 2.0 manual provided guidelines for identifying potential discrepancies between the client's and the OT's perspectives on the ADL ability. This dialogue was found to activate the client feeling confident in the collaborative relationship, leading to a common foundation for further intervention. This dialogue was especially important in cases where discrepancy occurred. An OT said: "*Having both the client's perspective and the therapeutic perspective has a huge impact … it shows a very clear picture of the situation. If we only see one perspective, then the assessment of the need for intervention will be completely different*" (OT2).

Relatives may have facilitated or constrained the intervention process. In one case a spouse was ill and needed special care from the client, causing lack of energy to actively participate in ABLE 2.0, limiting the process of establishing a foundation for the intervention process. On the other hand, when another relative actively supported the process of a client by e.g., helping to describe how certain ADL problems occurred in the home, the intervention process was facilitated.

At the individual level the most influential contextual factors confirming the IPT (a, b) were the ABLE OTs being skilled and professional, activating that they felt they delivered '*true*' occupational therapy, and a sense of believing in the impact of the programme. The skills also involved being able to communicate about the programme and thereby actively involve the client. The skills that the ABLE OTs built during the three-and-a-half day course and by practising delivery of the programme, simultaneously improved their ability to communicate with the client about the different parts of the intervention, e.g., the instruments used for evaluation of ADL ability. Hence, when the OT felt confident in explaining how and why the models or instruments were used, it activated a fruitful communication and the client perceiving that the ABLE OT was professional, leading to the client finding content meaningful and to establishing a foundation and agreement on focus for further intervention. An ABLE OT said: "*…being forced to professionally stick to the manual, to use those tools, and have to use some professional terms when communicating with the client …*" (OT1). Furthermore, the client's motivation and readiness for making changes, and his/her positive expectations, seemed to have activated mechanisms in terms of the OT being more engaged in the evaluation of ADL ability, leading to establishing a therapeutic relationship as basis for further collaboration.

Establishing the focus for further intervention

Data reflected that contextual factors at different levels facilitated or constrained the process of establishing the focus for further intervention, provided that the previously described foundation was built during the first sessions. A strength in ABLE 2.0 was perceived to be the coherence between the different parts, the logical order of the sessions and the way each step led to the next step. All together involving the client in the problem-solving process and establishing the focus for further intervention. The focus for the further process was primarily established during session 2, framed by using GAS for goal setting and PEO and/or TMO when clarifying causes for the ADL problems, including an active involvement of the client and taking the client's perspectives into account.

At the institutional level, delivery of the intervention in the home of the client was important for establishing the focus for further intervention, promoting the ABLE OT's knowledge of the client's ADL ability, everyday life, and preferences; and affecting the client's engagement and experience of meaningfulness. A client said: "*She saw how I did things in my bedroom, in my own bed. That was good because I know how it works for me here*" (C3). This confirmed the IPT (b, c) concerning the impact of delivering ABLE 2.0 in the client's home. Delivery in the home of the client was the ideal context to facilitate a dialogue focusing on ADL task performance (i.e. occupation-focused dialogue), involving the client in an analytic approach, and in setting occupation-focused goals based on the client's priorities. An OT said: "*They were more relaxed in their own surroundings; it was the most natural set-up and it was always an advantage to be in the client's home*" (OT3). Discussing and determining the focus for the further process in the home of the client led to more knowledge on the ADL task performance problems and served as an eyeopener for new ideas for possible solutions. Hence, it pointed towards content in the future occupation-based (i.e. engaging the client in performing ADL tasks), intervention sessions. Further, delivering the interventions in the homes of the clients, supported the inherent element of flexibility in terms of how the OT planned and timed the intervention, facilitating the ABLE OTs feeling obliged and responsible, and the client being more relaxed, leading to client empowerment, fruitful dialogues, and relevant goals.

At the interpersonal level the ABLE 2.0 provided a frame for focusing the further intervention by facilitating a collaborative and occupation-focused dialogue between the OT and the client, in defining goals and discussing causes for the ADL problems. This refined the IPT, on the functioning of session 2, to be elaborated in the following. In most cases the clients were

actively involved in defining goals and levels of goal attainment, which activated the ABLE OT's and the client's reasoning and served as a starting point for focusing the process. The ABLE OTs agreed: "*You cannot conduct an ABLE intervention if you don't use GAS or the other tools. It just wouldn't work … you cannot get from A to Z if you do not use K or F. You must practice and practice and become proficient in using them*" (FG). Further they said: "*GAS is a good tool. It is complicated to use though. And some clients are difficult to involve, especially those with cognitive deficits*" (FG). When applied as intended, the goal setting process activated a dialogue on both parties' notions of expected outcomes. This led to relevant and clear goals framing and targeting the intervention and establishing the basis for monitoring the progress. An OT said: *"The levels* [in GAS] *helped me to think in steps and made it* [the focus] *clear to the clients. So, GAS helped to set the frame for the intervention and to align expectations"* (OT2). Another OT said: *"Most of my clients were really involved in defining the different levels … it became concrete … and at the end of the intervention it was easy to monitor"* (OT3). In the context of discussing causes for the ADL problems, data showed that the use of PEO and TMO offered an opportunity to move from a disease-oriented to a more transactional perspective on the clients ADL problems. An OT said: *"Many of the elderly tend to point to themselves* [when talking about causes for ADL problems] saying "*It's because I'm an old one". Using the PEO model was a way of opening the dialogue on this. We could talk about other causes than those pointing at themselves".* Another OT said: *"If you find it hard to explain to the client, then the model* [PEO] *helps you. Some clients never thought about other reasons than their disease. It becomes clear, how we can find resources in the environment and they can find opportunities to be able to do the things they want to be able to do … this talk just means everything for the further focus*". Hence, the dialogue based on a transactional perspective led to involving the client in the problem-solving process and facilitated the use of adaptive occupation and environmental opportunities to compensate ineffective occupational skills. This was an eye opener and of great importance for establishing a focus for the intervention in terms of relevant and clear goals pointing towards potential compensatory solutions.

At the individual level the most influential contextual factors in establishing the focus for further intervention were the OTs' skills in facilitating dialogue on goal setting and causes for ADL task performance problems, refining the IPT. Moreover, client characteristics were influential, also refining the IPT. The ABLE 2.0 offered models that supported the ABLE OT in communicating about goal setting and clarification of causes for ADL problems. For example, by applying GAS for goal setting, the OT was provided with a vocabulary to communicate with the client about setting

goals. Hence, in the context of being a skilled OT, mastering the use of GAS and involvement of the client, having words to facilitate a dialogue on causes, the collaborative relationship between client and OT was activated, establishing the focus for further intervention. However, there was also cases where involving the client in defining goals and levels of goal attainment failed, i.e. implementation failure. An OT said: "*The main goal is fairly easy to define in collaboration with the client, but those sub-goals … it is something I usually do by myself, you know, the client says his or her main goal, and then I formulate the sub-goals, in relation to time, energy, risk of falling and those things* [quality of performance]. *I* [sometimes] *found it difficult to define in detail* [the levels in GAS] *with the client"* (OT1). The OTs described that they sometimes perceived lack of skills in using GAS and specifically in supporting the client in expressing his/her desired level of task performance. This was amplified by the usual workflow in the municipality, with the OTs having to follow the goals defined by the referral service, and hence did not involve the clients in goal setting and/or in a dialogue on causes for ADL problems. The intra-group comparison related to goal setting (CMOC c)) revealed somehow different results. Here the mechanism '*client feeling involved*' was triggered by the collaboration on defining goals and clarifying reasons for ADL problems in all cases, leading to all clients finding participation in session 2 satisfactory and meaningful. In all 27 clients, satisfaction with session 2, was related to '*feeling involved*'; and in all 26 clients '*finding content of session 2 meaningful*', was related to '*feeling involved*'.

When the implementation failure on goal setting occurred there was a tendency that the intended problem-solving process was interrupted, as goals were formulated as concrete solutions (e.g., be able to vacuum the kitchen floor with a cordless vacuum cleaner) rather than as quality of functioning (e.g., be able to vacuum the kitchen floor without risk of falling) as prescribed in the manual.

The interviewed clients only rarely recalled the dialogue on goal setting. They recalled the focus for the intervention, but not the intended dialogue and formulation of levels in goal attainment. This might be due to examples of implementation failure in goal setting (e.g., the ABLE OTs sometimes did not include the clients in the goal setting process and formulated goals including the solution rather than the functional level to be attained).

Identifying and implementing relevant compensatory solutions

Data revealed that contextual factors at different levels facilitated or constrained the process of identifying and implementing relevant compensatory solutions to enhance the clients' ADL ability, provided that the previously described foundation for the entire intervention was built and the focus for further intervention was established. Identification and implementation of relevant compensatory solutions was done during the intervention sessions (sessions 3-7). This was framed by the ABLE 2.0 intervention components and conducted in collaboration and dialogue between the client and the ABLE OT by actively involving the client in the problem-solving process, and by trying out possible solutions in the client's home.

At the institutional level, the use of the environment (here the client's home) facilitated the process of finding and trying out solutions, confirming the IPT (d). When the intervention sessions were delivered in the client's home, it supported how the client could both explain and demonstrate issues related to his/her ADL task performance in the actual environment. Thus, the consultative process of finding effective and sustainable solutions was facilitated. Further, the ABLE OTs perceived that clients were less likely to cancel appointments, as they did not have to leave the home. An ABLE OTs said: "*I think it* [finding solutions in the home] *gives them peace and makes them feel confident, that it is exactly in their everyday duties and their environment … I do not find it possible to do it* [practice solutions] *in other ways … and when we come to them, there is a greater chance that they will accept it … if they have to come to us, we sometimes experience dropouts*" (OT2). In addition, which refined the IPT, when the collaboration across the community-based organisation (i.e. rehabilitation service, referral service, helping aids service, home care service) was timed on the client's premises and was experienced to be smooth and effective, the clients and the ABLE OTs felt that it was worth their effort, that solutions could be adjusted to the client and client's context, and that they were successful. This was satisfying and motivating for the client. E.g., it was important to have access to a suggested assistive device. A client said: *"It happened pretty fast. They came and lined them up* [assistive devices], *I was completely surprised it happened so fast, … I thought there was a wait for something like that. A lot of things happened … I am very happy about it*" (C1). On the other hand, when ABLE 2.0 was carried out on the system's premises, with delay in delivery of sessions due to a wait for assistive devices, it had consequences for the problem-solving process, for consultation of the client in using the assistive device, and for the clients confidence with the system, potentially

resulting in decreased benefit of the intervention. An ABLE OT said: *"... the client may lose function and loose ability to use the assistive device or lose confidence in our help. Or maybe they will need more home care. I had a case that was completely interrupted. I was not able to introduce it* [the assistive device]. *Maybe she thought 'what does she* [the OT] *do good for at all?'*"(FG).

At the interpersonal level, data revealed that collaboration, dialogue and discussion between client and OT were crucial and facilitated the process of finding and implementing solutions. Hence, several solutions were discussed and tried out to determine which to apply. Further, when the ABLE OT had a non-directive approach suggesting different solutions, it led to the client feeling actively involved in the problem-solving process and having the power to accept or reject suggested solutions, and it was associated with the experience that the content was meaningful. A client said: *"We discussed it, whether it was the right solution"* (C5). This refined the IPT and was supported by the results of the intra-group comparison related to intervention sessions (CMOC d)), showing that the mechanism '*beneficial collaboration between client and ABLE OT on finding solutions*' was triggered by '*adaptive intervention components delivered in the client's home (including optional homework), and the ABLE OT being familiar with components and acting as facilitator of change*', leading to '*client perceiving commencing goal attainment and finding participation in programme purposeful*' (CMOC d). In 42 of 47 cases a high extent of '*commencing goal attainment*' was related to strong '*collaboration between client and OT on finding solutions*'; and in 43 out of 47 cases a high extent of '*client finding participation in programme purposeful*' was related to strong '*collaboration between client and OT on finding solutions*'.

Further the mechanism '*client being willing to try out solutions during performance of ADL tasks*' was also triggered by the context '*adaptive intervention components delivered in the client's home (including optional homework), and the ABLE OT being familiar with components and acting as facilitator of change*', leading to high extent of '*commenced goal attainment*' and '*client finding participation in programme purposeful*' respectively. In 38 of 47 cases a high extent of '*commencing goal attainment*' was related to strong '*client being willing to try out solutions during performance of ADL tasks*'; and in 39 of 47 cases a high extent of '*client finding participation in programme purposeful*' was related to strong '*being willing to try solutions during performance of ADL tasks*'.

Several clients also highlighted the fact that the OT observed their ADL task performance during the problem-solving process, confirming the IPT

(d). As the ABLE OT observed the client being engaged in e.g., watering flowers or cleaning the floor, she had the opportunity to suggest and guide in new ways of doing. One of the clients described this as an *"eye-opener"* (C7). Another client expressed the value of being observed during engagement in ADL task performance like this: *"I think it was good. Because as I said, talking does not help it all. I prefer some action too, and it was good"* (C1). When the ABLE OT observed the client's performance, the clients sometimes considered it a validation of their needs which to some extend legitimised e.g., applications for assistive devices. One of the clients said: *"I feel that there was really someone who could see that I needed it, that it was not just something I asked for. But she could really see that I needed it too"* (C7).

At the individual level, the most influential contextual factors in identifying and implementing relevant compensatory solutions were related to the characteristics of the ABLE OTs and the clients. For example, that the OTs was empathetic, kind, skilled and competent, refining the IPT. The skills and competencies were primarily related to communication and collaboration on relevant solutions. One client said*: "She was nice, kind, and straightforward, and we could just get to the point"* (C5). Another client said: *"She was nice and understanding, and she was on the marks when I claimed about the toilet and the sheets, … I felt she heard me … and it was fixed right away"* (C8). Further, based on the initial sessions in ABLE 2.0 the ABLE OT had a solid foundation for planning and implementing interventions in a competent way. A client said: *"It was the same form* [ADL-I] *we used every time, and then when she saw me do it* [water my flowers]*, using my new chair, she could guide me. It was an eye opener … Now I can just do it, I can just roll over to my flowers here and fix it, and it does not hurt, when I do it anymore"* (C7). Client characteristics in terms of motivation, readiness for making changes, and his/her expectations to the programme, were perceived to have an impact when finding solutions. A client said: *"I was not expecting certain things* [prior to the intervention]*, I was just waiting for what was going to happen … positive thinking you know … I am sure that meant a lot* [for the benefit of the intervention]*"* (C5). And an ABLE OT said: *"The clients' motivation mattered to finding goals and solutions, to how I could help them make changes … and their engagement mattered a lot to the benefits"* (OT2). These individual level contextual factors seemed to activate professionalism both experienced by the ABLE OTs and the clients and a sense of joint commitment, refining the IPT. Further, these factors lead to the ABLE OT being engaged in suggesting targeted and sustainable solutions adjusted to the specific client and his/her tasks and environment. Thus, potentially leading to improved ADL ability. On the other hand, when a client specifically had applied for help with, for example cleaning, the client's motivation for finding other compensatory

solutions, e.g., using assistive devices or changing the physical environment, was sometimes lacking, which was perceived to impede the collaboration on trying out different solutions. Further, when a client lacked insight, due to age or cognitive deficits, involving the client in the problem-solving process was a challenge. An ABLE OT said: *"In a few clients, if they had decreased insight in their own situation ... sometimes they had difficulties seeing the problems. Even though they had reported it in the ADL-I, still they did not remember it in the next sessions and when trying to find solutions. They kind of carried it along during the whole intervention"* (OT3).

Re-evaluating ADL ability to finalise intervention

During intra-group comparison the relationship between the context '*ABLE is delivered by an OT feeling engaged and prepared to deliver session content to a client motivated for making changes*' and the mechanism '*client finding the programme meaningful*' was investigated on its impact on ADL ability, i.e. increased ADL ability defined as clinically relevant change in AMPS ADL motor ability and/or ADL-I performance from baseline (week 0) to week 10 measured in the effectiveness evaluation (CMOC a). The results show that a low extent of '*increased ADL ability*' was related to '*client finding the programme meaningful*' in 48 of 128 cases and a high extent of '*increased ADL ability*' was related to '*client finding the programme meaningful*' in 80 of 128 cases.

The ABLE 2.0 IPT included assumptions concerning the functioning of the final session confirming and refining the IPT (a, e). Due to the study design, with evaluation of effectiveness conducted alongside this process evaluation, the re-evaluation session was conducted somewhat different than originally intended in ABLE 2.0. Because AMPS was performed by blinded assessors as part of collecting primary outcome data for the RCT, the AMPS was optional at the final session, resulting in primarily performing re-evaluation based on the ADL-I and the GAS. Hence data on the final session is limited. However, data reflected that contextual factors at different contextual levels facilitated or constrained the process of re-evaluation to finalise the intervention. According to the ABLE OTs, the three instruments applied during the final session seemed to serve different purposes which refined the IPT; for the clients, the most important purpose seemed to be feedback contributing to insight and motivation for sustainable changes; for the rehabilitation service, the most important purpose seemed to be to provide the client with useful feedback and to document the impact of the occupational therapy intervention in the client records; for the referral services, the most important purpose seemed to be to receive documentation for the level of functioning at the end of the intervention, which was

necessary in case of the client applying for home care or assistive devises at the end of the intervention.

At the institutional level ABLE 2.0 provided a frame for documenting occurred changes and obtained ADL ability refining the IPT (e). The documentation based on the AMPS was especially useful when the clients applied for e.g., home care services and/or assistive devices. An OT expressed it this way: "*The ADL-I … sometimes it can easily stand completely alone … and I can document without the AMPS. But it depends a lot on what the client is applying for … when I used AMPS* [at the final session] *it was because the referral service should make a decision on the client's need for assistance in tasks related to cleaning …"* (OT1). Further one of the OTs expressed it like this: *"Using the AMPS for re-evaluation is especially relevant when you need to document to the referral service, to the general practitioner or the nurse, and where I as OT can see, that even though we worked on this for eight weeks, nothing changed, and we need to apply for some assistance in the home".* (FG). Moreover, the AMPS was found useful as documentation in the client records, in the case of future referral to rehabilitation services, which was expressed like this: *"I will absolutely use it in the future* [AMPS to document]. *It might be a client we will hear more about later …* (OT1).

At the interpersonal level ABLE 2.0 provided a frame for re-evaluation of the client's ADL ability by facilitating a dialogue between the client and the ABLE OT on goal attainment, obtained changes and ADL ability at the final session, confirming the IPT (e). Finalising ABLE 2.0, applying the prescribed instruments, had an impact on how to provide feedback to the client. The ABLE OTs agreed that GAS was the preferred instrument for providing feedback to the client on obtained changes, because it assessed the attainment of the specific goals in focus. In comparison, the ADL-I was found less relevant in terms of providing feedback, focusing on the ADL ability at the end of the intervention, but without comparison to the ADL ability at session 1. An OT said: "*My experiences of using GAS* [for monitoring attainment of goals] *are good … it provided an awareness for the client on the current level and what was achieved*" (OT2). Further she said: "*I have had a little bit of a harder time seeing the meaning of using it* [ADL-I] *in the final session … GAS is kind of a better summary for the client. In the ADL-I, I think, the clients are not asked if they felt they improved. We did not compare the scores* [at the beginning of the intervention with scores and at the final session]. *I also think the ADL-I was a little too comprehensive for the clients"* (OT2). An OT explained how she experienced that ADL-I was less useful for providing feedback to clients: *"Even though the intervention ran over several weeks, they still saw*

themselves as they functioned before the intervention. As if they had too little time to understand the implementation of their new habits" (OT3).

These results were somehow confirmed in the intra-group comparisons concerning CMOC e) re-evaluation. First, a low extent of '*goal attainment*', i.e. having obtained the expected level in GAS to a low extent (< level 0) was related to a strong mechanism '*client expecting to carry on using the new solutions*' in 5 of 62 cases, whereas a high extent of '*goal attainment*', i.e. having obtained the expected level in GAS to a high extent (≥ level 0) was related to a strong mechanism in 55 of 62 cases. Second, a low extent of '*satisfaction with obtained ADL ability*', i.e. no clinically relevant change in ADL-I satisfaction from baseline to week 10, was related to a strong mechanism '*client expecting to carry on using the new solutions*' in 21 of 28 cases, whereas a high extent of '*satisfaction with obtained ADL ability*', i.e. a clinically relevant change in ADL-I satisfaction from baseline to week 10, was related to a strong mechanism '*client expecting to carry on using the new solutions*' in 6 of 28 cases.

At the individual level the ABLE 2.0 provided a frame for the ABLE OT to perform valid re-evaluation to finalise the intervention, confirming the IPT (a, e). When the final session was delivered in the context of an ABLE OT being skilled in interpreting the results, and when the ABLE OT supported the dissemination of the results with visual material (e.g., the graph in the AMPS report) to the client, it activated the client's insight in occurred changes and motivation for carrying on using the new strategies, potentially contributing to sustainable changes. An ABLE OT said: "*The ADL-I is good, and in a few cases I also performed AMPS, showing to them, how they did during these eight weeks. I prefer to use the graph from AMPS* [from session 1]*, to compare … it makes a huge difference"* (OT1).

Table 20 Prominent context-mechanism-outcome configurations (CMOCs) in the ABLE 2.0

Context	Mechanism	Outcome
Building a foundation for the entire intervention		
If ABLE 2.0 is delivered in the context of a supportive collaboration between the departments in the municipality in terms of the municipal guidelines for referring to rehabilitation services (i.e., the client's pathway to intervention), allowing the logic order of the intervention (i.e. assessment prior to goal setting and dialogue on causes) ...	... it may activate the client being actively involved in the problem-solving process ...	... contributing to client being motivated for participating in the intervention programme and being ready for making changes
If ABLE 2.0 is delivered in a context of goals defined by the referral service ...	... it may activate limited involvement of the client ...	... contributing to obstruction of building a foundation for the entire intervention
If ABLE 2.0 is delivered in a context of supportive management ...	... it may activate the ABLE OT feeling obliged and responsible, and supportive colleagues ...	... contributing to the ABLE OT feeling skilled and professional when delivering the programme ...
If ABLE 2.0 is delivered in a context of training and support, i.e. supervision and exchanging experiences among ABLE OTs ...	... it may activate the ABLE OT feeling confident in delivering the programme ...	... leading to ABLE OT feeling satisfied and engaged
If ABLE 2.0 is delivered in a context of the client and the OT initially perceiving to be 'on wavelength', share thoughts, and the client finds that the ABLE OT is professional ...	... it may activate mutual confidence and openness ...	... contributing to the ABLE OT being vigorous and client feeling his/her problems are being acknowledged
If a systematic approach is applied in the initial sessions, including a mandatory structured dialogue on eventual discrepancy ...	... it may activate the client feeling confident and involved, perceiving to gain insight, and a collaborative relationship between the client and the ABLE OT ...	... contributing to building a foundation for the intervention, initiating a problem-solving process, and client and ABLE OT gaining a common understanding of the

		client's ADL ability
If ABLE 2.0 is delivered in the context of involved relatives ...	... it may activate the client being more/less engaged ...	... contributing to a facilitated/limited process
If ABLE 2.0 is delivered in the context of a skilled ABLE OT ...	... it may activate a sense of believing in the programme and in the ABLE OT ...	... contributing to the client finding content of programme meaningful
If ABLE 2.0 is delivered in the context of an ABLE OT feeling confident in explaining how and why the models were used ...	... it may activate a fruitful communication and the client perceiving that the ABLE OT was professional ...	... contributing to the client finding content of the programme meaningful and to establishing a foundation and agreement on focus for further intervention
If ABLE 2.0 is delivered in the context of a client with positive/less expectations ...	... it may activate the ABLE OT being more/less engaged ...	... contributing to easier/constrained establishment of a therapeutic relationship
Establishing the focus for further intervention		
If ABLE 2.0 is delivered in the home of the client ...	... it may activate an increased knowledge of the client's everyday life and preferences, client feeling relaxed, flexible planning and timing, ABLE OT feeling obliged and responsible ...	... contributing to client empowerment, defining relevant and occupation-focused goals, and future occupation-based intervention
If ABLE 2.0 is delivered in the context of an ABLE OT being skilled in communicating and administrating GAS ...	... it may activate a collaborative relationship, goal setting primarily based on the client's priorities (including that the client has the power to define and formulate goals and levels of goal attainment) ...	... contributing to establishment of basis for monitoring progress, and relevant and clear goals
If ABLE 2.0 is delivered in the context of an ABLE OT perceiving to lack skills administrating GAS or goals being defined by the referral service ...	... it may activate limited involvement of the client in defining goals and levels of goal attainment and in dialogue on causes for ADL problems ...	... contributing to interruption of the logic order in the intervention, interruption of the coherence and the problem-solving process
If ABLE 2.0 is delivered in the context of collaboration and dialogue between client and OT, when clarifying causes for the ADL problems using a transactional perspective ...	... it may activate involvement of the client in the analytic approach to understanding the ADL problems from a more transactional perspective (e.g., taking other perspectives than diagnosis into account) ...	... contributing to more perspectives and new insights on the ADL problems, and to revealing new, other and more ideas for solutions

If ABLE 2.0 is delivered in a context of a client with cognitive deficits ...	... it may activate limited involvement of the client in dialogues related to goal setting, causes for ADL problems and in the overall problem-solving process	... contributing to less relevant and clear goals, lack of framing of the further intervention
Identifying and implementing relevant compensatory solutions		
If ABLE 2.0 is delivered in the context of the client's home when finding solutions ...	... it may activate the consultative process ...	... contributing to finding effective and sustainable solutions
If ABLE 2.0 is delivered in the context of a system working on the client's premises, including effective coordination between services and access to assistive devices ...	... it may activate the client's confidence with the system, and client and ABLE OT feeling successful ...	... contributing to client feeling motivated for changes and feeling satisfied with the content of the sessions; and to solutions adjusted to the client's context
If ABLE 2.0 is delivered in the context of delivery in the terms of the system ...	... it may activate decreased confidence with the system's ability to help and ABLE OT feeling powerless ...	... contributing to interruption of the problem-solving process, decreased ADL ability, and decreased benefit of assistive devise
If ABLE 2.0 is delivered in the context of dialogue between client and ABLE OT; and the ABLE OT has a non-directive approach to this collaboration ...	... it may activate the client feeling involved and having the power to accept or reject suggestions ...	... contributing to client finding content of sessions meaningful
If ABLE 2.0 is delivered in the context of the ABLE OT observing the client trying out solutions during performance of ADL tasks ...	... it may activate the ABLE OT acting as facilitator of change using an adaptational approach and the client feeling that his/her needs are legitimised ...	...contributing to client feeling satisfied with content of sessions
If ABLE 2.0 is delivered in a context of a client with insight in own ADL ability, and who is able to understand, remember and maintain knowledge on his/her ADL ability and the causes for the ADL problems in focus (revealed during the first sessions) ...	... it may activate the client being actively involved in the problem-solving process ...	... contributing to finding relevant solutions and goal attainment
If ABLE 2.0 is delivered in the context of a client being openminded to finding other	... it may activate an occupation-based approach where the client is willing to try out	... contributing to client finding the programme content meaningful;

solutions than he/she expected in advance ...	solutions and the client and OT discuss and exchange ideas primarily based on the clients priorities, and the client having the power to accept or reject solutions ...	motivation for staying in the programme; and finding focused, targeted, and potentially sustainable solutions
If ABLE 2.0 is delivered in the context of a client having applied for specific practical assistance, e.g., for cleaning ...	... it may activate limited motivation for making other types of changes ...	... contributing to challenges in finding relevant solutions
If ABLE 2.0 is delivered in the context of a client with cognitive deficits ...	... it may activate limited involvement in the problem-solving process ...	... contributing to limited benefit of intervention
If the ABLE 2.0 is delivered in the context of an ABLE OT being empathetic, kind, skilled and competent ...	... it may activate focused communication and collaboration between client and ABLE OT ...	... contributing to finding relevant solutions and improved ADL ability
Re-evaluation		
If ABLE 2.0 is delivered in the context of giving concrete feedback in terms of comparing level of obtained goals with level at session 1 ...	... it may activate the client perceiving that the intervention made a difference and feeling motivated for integrating the new methods into everyday life routines ...	... contributing to sustainable changes
If ABLE 2.0 is delivered in the context of an ABLE OT being skilled in interpreting and explaining the results ...	... it may activate the client getting insight in occurred changes and motivation for carrying on using the new strategies ...	... contributing to sustainable changes
If ABLE 2.0 is delivered in the context of an OT conducting systematic re-evaluation using standardised instruments ...	... it may activate clarity on obtained changes ...	... contributing to demanded documentation

ABLE, a better everyday life; ADL, activities of daily living; CMO, context-mechanism-outcome; OT, occupational therapist

Discussion

This thesis was initiated by conducting several research activities in preparation for a pilot RCT evaluating the remaining feasibility aspects before a randomised controlled trial. Based on the results of the ABLE 2.0 pilot RCT, conducted between December 2019 and March 2020 in a Danish municipality, proceeding to a full-scale trial was recommended with a few adjustments on outcome measurement instruments, inclusion criteria and extraction of information on usual occupational therapy.

The full-scale trial, including evaluation of effectiveness and process conducted alongside each other, was completed in the same municipality as the ABLE 2.0 pilot RCT, between August 2020 and October 2021. Overall, the studies provide important information for future implementation of the ABLE intervention programme in other contexts. In the following the results will be discussed as well as aspects of prominent impact on the effectiveness and outcomes of ABLE 2.0, followed by some methodological considerations.

Effectiveness of ABLE 2.0

Main results

In the effectiveness evaluation the outcomes of the ABLE 2.0 intervention were compared with outcomes of UOT in the municipality. It was hypothesised that the ABLE 2.0 intervention programme would be significantly more effective than UOT already at end of intervention. This, however, was not the case. The main result was that participants in both groups overall displayed an increase in observed ADL motor ability immediately after intervention, reflecting decreased effort, clumsiness, and fatigue during ADL task performance. Consequently, differences between groups at end of intervention were small and statistically non-significant, suggesting that both types of occupational therapy had some impact on observed ADL ability. Still, mean change in observed ADL motor ability in the group receiving ABLE 2.0 reached the level of clinical relevance i.e. an observable change in ADL ability. In contrast, mean changes in ADL motor ability in the group receiving UOT never reached clinical relevance.

Generally, evaluating the outcomes of a new intervention by comparing it with the intervention usually offered, or even another new active intervention, represents a challenge, since some improvements may be expected from both interventions. This was the case in a study, where the , in terms of observed ADL motor ability, of an 11-week intensive client-centred

occupational therapy intervention (the ICC-OT study) was compared with usual brief (maximum three sessions) occupational therapy in a sample of home-dwelling older adults (129). In line with our findings, they found no significant differences in observed change in ADL motor ability between groups post intervention, but in contrast to our results both groups obtained clinically relevant changes in AMPS ADL motor ability immediately after the intervention period (129). Similarly, a study comparing the outcomes of a two-week, group-based interdisciplinary rehabilitation programme followed by either 16 weeks of occupational therapy or physiotherapy (the IMPROvE phase-two study) (62), among women with fibromyalgia, also identified a clinically relevant difference in observed change in ADL motor ability in both groups immediately after the intervention period, with no significant differences between groups (62). In line with ABLE 2.0, the occupational therapy intervention (ADAPT) in this study (62,130) was structured by the OTIPM (13) and aimed to improve ADL ability by means of adaptation. Hence, the individual home-based ABLE intervention and the group-based ADAPT intervention, both based on the structured approach provided in the OTIPM and the application of adaptational strategies to resolve ADL task performance problems, seem to improve ADL motor ability immediately after the intervention period in people with chronic conditions.

Sustainable changes

In our study, observed ADL motor ability continued to increase in the group receiving ABLE 2.0 from end of intervention to 26 weeks from baseline. In contrast, in the group receiving UOT, the observed ADL motor ability decreased again to a level close to baseline. These differences between groups in ADL motor ability were statistically significant at week 26, suggesting that sustainable changes were only obtained in the ABLE 2.0 group.

A similar pattern was found in the ICC-OT study (129). They identified a further increase in ADL motor ability from end of intervention to 6 months from baseline (129). The ICC-OT intervention is comparable to the ABLE intervention in delivering a home-based, client-centred individualised occupational therapy intervention programme, and in emphasising collaboration with the client on goal setting and practising performance, i.e. occupation-based approach. Hence, such elements may support sustainable changes.

Commonly, studies evaluating long-term effectiveness of interventions for people with chronic conditions, report that improvements achieved are not sustainable. This was the case in the follow-up study on the IMPROvE

trial (42,62). They reported a clinically relevant and statistically significant increase in AMPS ADL motor ability immediately after the intervention period (62), followed by a decrease to a level close to baseline at week 88 from baseline (42). The occupational therapy intervention in the IMPROvE trial, ADAPT, differs from the ABLE 2.0 intervention in being group-based and delivered in a clinical rehabilitation setting. Hence, differences in long-term outcomes between the ADAPT and the ICC-OT and ABLE interventions may be explained by the fact that the ICC-OT and ABLE are individualised interventions delivered in the home.

Evaluating ADL ability based on self-report

In terms of change over time in self-reported ADL ability, a pattern similar to changes in observed ADL ability was seen in the ABLE 2.0 group. Thus, self-reported ADL ability increased immediately after intervention, and increased slightly at week 26. Still, mean change in self-reported ADL ability did not reach clinical relevance. A contrasting pattern was seen in the group receiving UOT with no change from baseline to primary endpoint followed by an increase in self-reported ADL ability at week 26, still not reaching a level of clinical relevance. Between group differences in self-reported ADL ability on the ADL-I performance, and in the remaining secondary and explorative outcomes based on self-report, were all statistically insignificant.

The challenge of verifying changes based on self-report has been highlighted in studies documenting changes based on observation (62,119,129,131). In the ICC-OT study, the Canadian Occupational Performance Measure (COPM), a self-report instrument based on interview, was employed as primary outcome (129). Results indicated a statistically significant difference between groups, but neither differences between groups nor changes over time reached the recommended minimal important change of 3.5 points (132). In the IMPROvE trial, in both the phase 1 and 2 study, statistically significant changes over time between groups were seen in observation-based ADL ability, whereas no differences were seen in self-reported outcomes (62,131). Similarly, in a study comparing hand-exercise as an add on to UOT with UOT alone in women with rheumatoid arthritis, both groups improved in observed ADL motor ability, but no changes were documented in self-reported outcomes (119). In fact, if any of these studies had omitted observation-based outcomes, the risk would have been that the interventions had been considered ineffective.

Poor relationships between self-reported and observation-based outcomes has previously been found in comparable samples, e.g., persons

with chronic widespread pain (62,131), persons with inflammatory rheumatoid diseases (5,133), and persons with chronic low back pain (134,135). There may be several reasons for this lack of relation. While self-report represents the insider's perspective, observation represents the outsider's perspective. Information based on observation is characterized by being 'here-and-now', describing the person's ability at a certain point in time in a certain place. This 'picture' is just one single example of the person's ability and influenced by e.g. how the observer was doing that day and if the physical and social environment felt secure and relevant to the person. In contrast, information based on self-report is the person's image of his/her ability, typically over time and across places. This image may be influenced by a range of factors, including memory, coping ability, personal style (optimist/pessimist, careful/careless etc.). Also, if self-report is based on interview rather than questionnaire, the interviewer may influence the person in various ways.

Acknowledging that information about ADL ability based on self-report and observation are distinct but related and therefore should be gathered using methods of both self-report and observation to represent both the insider's and outsider's perspective, the AMPS and the ADL-I were employed in the ABLE 2.0 RCT. While the ADL-I would take a broader perspective on the ADL ability, reflecting the client's perceived ability over a period of time, naturally influenced by various other factors, the AMPS would reflect the exact moment of the task performance, as observed by the assessor.

Another explanation was revealed in the process evaluation suggesting that these clients often needed extended time to experience changes in ADL ability. When living several years with one or more chronic condition influencing the ability to perform ADL, many may become accustomed to the decreased ADL ability i.e. paying less attention to the ADL performance problems. So, if the ADL ability improves during or after intervention, they simply may need extra time to internalise their new level of ability in their consciousness, to be reflected in self-report. This point is core in the Stages of Change theory (136) which originates from the idea that changing behaviour goes through distinct stages, including a temporal dimension. Regarding the temporal dimension as basis for the Stages of Change (137), a new behaviour has to be conducted for an extended period to become habitual. Acknowledging that self-report and observation-based measures provide distinct information and serve different purposes, including both methods in clinical trials is suggested valuable.

Another reason for not reaching statistically significant changes in the ADL-I might be loss of power. Our sample size calculation suggested 68

participants to reach a power of 90 % in the ADL-I Performance. By planning to include 80 participants a 15% drop-out rate was allowed. However, only 58 participants were assessed at primary endpoint resulting in loss of statistical power in terms of ADL-I Performance, decreasing the chance of detecting a true difference between groups.

Looking at the trajectories in ADL-I over time in figure 14, the pattern shows a difference in the two groups in the favour of ABLE 2.0 at the primary endpoint. Based on the results (p=0.1635; 95% CI = -0.38 to 0.06) it may have been possible to reach a statistically significant difference in changes between the two groups at the primary endpoint with a larger sample.

Stability in ADL process ability

While the AMPS ADL motor ability measures increased, the AMPS ADL process ability measures overall remained stable over time in both groups. Similar results of stability in ADL process ability in both groups over time were found in the ICC-OT study (129); and in both phases of the IMPROvE trial (62,131).

ADL process ability reflects among other things a person's ability to efficiently use time, space and objects, and adapt when problems occur. The ABLE 2.0 involves solutions to decrease effort during performance such as slowing down performance speed, sitting rather than standing or taking breaks during task performance. Therefore, such solutions could potentially result in lower ratings on the ADL process skills addressing use of time. Still, other elements in the ABLE intervention programme involves introducing the client to a problem-solving process of problem identification, goals setting, and finding solutions. This may have resulted in higher ratings on the ADL process skills concerning the clients' ability to adapt. Hence, the stable ADL process ability measures are considered a positive result. As for the similar pattern in the group receiving UOT intervention, it is hard to determine reasons for this result. In the ADAPT intervention (62,130) the applied types of adaptational solutions and ways of collaborating with the clients were similar to those described in ABLE 2.0, supporting the involvement of the client in the problem-solving process and application of adaptational strategies. The ICC-OT (129) however is not comparable to ABLE and ADAPT. In terms of content it addresses occupational performance problems in general and not ADL specifically. It builds on acquisitional, compensatory, and restorative intervention models (13), and provides up to 22-week intensive intervention programme. Overall, the

results provide support for considering stability in ADL process ability over time an overall positive result among persons with chronic conditions.

Responders

So, who seems to benefit from the ABLE intervention? Clients in the ABLE 2.0 group who obtained a clinically relevant improvement in self-reported and/or observed ADL ability had a clinically relevant lower observation-based ADL motor and ADL process ability at baseline, suggesting room for improvement. Similar results were found in the feasibility study of ABLE 1.0 (15), supporting that persons with low observed ADL motor ability may benefit from ABLE 2.0. In fact, the responders in the ABLE 2.0 group represented a baseline level of AMPS ADL ability below the independence cut off (1.5 logits) indicating increased effort, fatigue, inappropriate use of time, space, or objects, and decreased ability to adapt actions efficiently during performance of ADL tasks. Further the level of ADL ability indicated a need for assistance to live in the community (26). That is the responders had an overall lower level of ADL ability, i.e. they used more effort, were less efficient and more dependent during ADL task performance at baseline, compared to non-responders.

Further, the IMPROvE phase-two study (62), targeting persons with fibromyalgia receiving the group-based occupational therapy programme ADAPT, applying adaptational strategies found that the ability measures were clinically and statistically significantly lower among responders compared to non-responders at baseline. These results all over increase the confidence in the systematic approach by means of the OTIPM and application of the principles of the compensatory intervention model using adaptational strategies (13).

The clinically relevant lower ADL process ability at baseline among responders in the ABLE 2.0 group compared to non-responders indicates that these persons at start have decreased skills for problem-solving (26). Therefore, they were more likely to benefit from working with the OT to identify and prioritise perceived ADL task performance problems and find solutions during the problem-solving process of the ABLE 2.0 intervention. Lower ADL process ability might in some, but not all, cases be related to diminished cognitive functioning. The process evaluation revealed that the ABLE OTs found it particularly challenging to involve clients with cognitive deficits in the problem-solving process. Recognising the challenge of proper involvement of such clients in a collaborative problem-solving process, this study stresses the importance of OTs possessing effective collaborative and communication skills when delivering the ABLE intervention programme.

Especially, when collaborating and communicating about goal setting and clarification of causes for the ADL problems, to ensure that the intended and coherent problem-solving process is implemented.

Patient reported outcome measures

In the effectiveness evaluation we used the generic ADL-I Performance scale (29,74), an instrument developed to measure ADL ability based on self-report. Also, a range of self-report, questionnaire-based instruments were employed as secondary and exploratory outcomes. These instruments all may be classified as patient reported outcome measures (PROMs). Use of PROMs is highly recommended within health research (138,139), to determine the outcome of an intervention from a client's perspective (140). Still, systematic reviews have found that while using PROMs is clinically meaningful, the impact of PROMs in finding evidence is limited (139,141).

The occupational therapy intervention process model, OTIPM, also prescribes evaluation of tasks performance based on both self-report and observation, to ensure that both the 'insiders' and 'outsiders' perspectives are represented, when evaluating change following intervention (13). The relationship between the two methods of data collection has been thoroughly investigated (135,142–144). Especially, studies examining the relationship between measures based on ADL-I and AMPS found hardly any relationship between measures of self-reported and observed quality of ADL task performance, supporting the idea of using both methods as part of evaluation of ADL ability (4,5,29). In support, the responder analysis in this study revealed limited relation between responders on the AMPS ADL motor and the ADL-I Performance. In fact, at week 10 and week 26, only 4 and 7 participants, respectively, obtained clinically relevant improvements in both observed ADL motor (AMPS) and self-reported ADL (ADL-I Performance) ability.

In a realist synthesis Greenhalgh et al (145) found, that using PROMs can change how patients think about their condition, and that the way clinicians use PROMs is shaped by their relationships with the clients and their professional roles. Hence, the impact of using PROMS is highly influenced by contextual factors, which was also found in our process evaluation. When re-evaluating ADL ability at the final session, the ABLE OTs found that the ADL-I only to a limited extent captured the obtained changes, by means of the 47 predefined tasks. It was suggested that the persons having received ABLE 2.0 needed more time to experience obtained changes, supporting that PROMs such as the ADL-I Performance is less sensitive to short term changes. A recent study looking at the use of PROMs from a patient

perspective showed that also clients themselves seem to doubt that PROMs can accurately convey their experience of symptoms and functional limitations (146). Still, they recognised their advantages in communicating symptoms and disease impact (146).

The processes of ABLE 2.0

What works?

The process evaluation, designed as a realistic evaluation, supported the results of the effectiveness evaluation, and showed that ABLE 2.0 had the potential to enhance the ADL ability among persons with chronic conditions. Specifically, the process evaluation revealed several contextual factors that had an impact on the enhanced ADL ability and therefore should be recommended as prerequisites for successful implementation of the ABLE intervention programme. Hence, it is recommended that ABLE is delivered in a municipal structure that supports delivery of a problem-solving process involving the client throughout the intervention, and including initial evaluation of the client's ADL ability, clarification of causes for the ADL task performance problems, goal setting and identification of relevant solutions. Further, delivery should be supported by the management; OTs should be skilled in administrating the prescribed instruments and in collaboration with their clients; and the clients should be prepared for and ready to make changes in performance of ADL tasks.

Differences between ABLE 2.0 and usual occupational therapy

As described above, the results of the process evaluation suggest that the long-term differences between ABLE 2.0 and UOT may be due to differences in the therapeutic approaches applied. But what constitutes the differences between the ABLE 2.0 intervention and UOT, which might explain the differences in long-term outcomes?

The structure and content of the ABLE 2.0 intervention programme is composed of standardised instruments and conceptual practise models. In that respect ABLE 2.0 does not differ from what can be implemented in any clinical occupational therapy practice and does not imply special knowledge or skills. However, ABLE 2.0 is unique in outlining *how* the underpinning theories, conceptual practice models and instruments are applied and *how* the content interdependently work together to provide a coherent client-centred individualised occupational therapy process.

The UOT interventions as reflected in the client records were characterised by a variation in content and delivery. All over, a non-standardised approach to evaluation of ADL ability was found, and, in many cases, goal setting was conducted by the referral service instead of being an integrated part of the occupational therapy process. Hence the focus for the intervention was not emerged from a collaborative process between the client and the OT as prescribed in client-centred practise (13). Further, when goals included levels of goal attainment these typically referred to independency and there were no examples of describing levels of goal attainment in terms of quality of performance. Occupation-based approaches were reported applied in 60% of the cases and hence may not have been a standard part of the occupational therapy practice in these interventions. Finally, the median number of delivered sessions were 2 (range 1-12), leaving limited space for practising and learning to use the new solutions. All over the UOT interventions seemed to vary in structure and there was no sign of following a standard occupational therapy process model. This overall indicates that the coherent problem-solving process that was highlighted as unique in the ABLE 2.0 was generally not implemented in the UOT interventions delivered.

The impact of an adaptational approach

One of the core intervention components in ABLE 2.0 has been suggested to be 'change habits (P1)' (14,105). It was the most frequently implemented intervention component in the feasibility study (14,15) and also among the most frequently implemented in the pilot study (104). The component includes to introduce the client to new ways of doing, e.g., the use of pauses before, during, or after task performance; or adjusting the pace during task performance (14). Further the manual (105) prescribed that the 'change habits' component often was to be implemented alongside other components, e.g., 'plan, prioritise and reject (P3)' involving discussions on how to plan performance of demanding tasks (e.g., time of the day, overcoming barriers, ask for help) (14). A compensatory intervention approach (13), embraces introduction of adaptational strategies, consultation, and education (13), and emphasises that the OT engages the client to *"try out, practice, and learn to use their chosen adaptation strategies and ensure that they will be able to incorporate them into their daily life routines"* (13). Hence, a compensatory approach involves some kind of habit change, and when aiming for sustainable changes even habit formation. In the context of a person's doing, specifically performance of ADL tasks, habits may be understood as *"behaviour patterns operating below conscious awareness that are acquired through context-dependent repetition*" (147). Modifying habits by making changes in the physical or

social contexts have been suggested to be the most effective and straightforward way of disrupting, developing, or changing habits (147,148). In the ABLE 2.0 this is extended to also include adapting the task, reflected in one of the prominent CMOCs that emerged, saying that when a client is openminded to other solutions than he/she expected in advance, it may trigger an occupation-based approach where the client is willing to try out solutions, and the client and the OT discuss and exchange ideas primarily based on the clients priorities. This includes discussing ways of doing the task differently, e.g., sitting down during task performance instead of standing or using pauses before, during, or after task performance. This may lead to more efficient performance in terms of reducing physical effort during tasks performance, contributing to finding potentially sustainable solutions. Still, changing habits require that the person with a need for changing habits is in possession of cognitive, emotional, and material resources (147). In other words, addressing habits formation in the ABLE 2.0 includes all three aspects of the PEO model (73). Further, the fact that persons vary in the capacity to make contextual changes themselves (149) and that many persons need assistance identifying deficits and potential solutions (147,148) adds to the complexity (89) in interventions aiming to enhance the ADL ability among persons with chronic conditions.

The impact of a problem-solving process

According to the IPT, ABLE 2.0 would improve the ADL ability based on a structured, individualised problem-solving process in the client's home. We found that the administration of initial evaluations, based on both self-report and observation of ADL ability at session 1, was a prerequisite for initiating the problem-solving process and that supportive management, a system working on the client's premises, and the OTs' skills in facilitating a dialogue on goal setting and clarification of causes for ADL task performance problems were core contextual factors.

The support provided by the managers in terms of ensuring resources demanded for delivering this new programme, and ensuring acceptance among colleagues regarding its implementation in the study period, was underpinned by the OTs as important for their commitment and responsibility in delivering high quality ABLE 2.0 interventions. Caldwell et al (150) found that managers can enhance the results of practice changes by working to develop e.g., teamwork, tolerance for mistakes, and team support when new things are tried, to increase the readiness for change within the group. Managers actions can facilitate implementation and reduce barriers to change, e.g., by communicating clearly and directly, by ensuring the needed knowledge and resources, by serving as facilitators, and by building a

culture among staff where quality improvement is an expectation. Hence, the managers play a key role in implementing the ABLE 2.0 in existing rehabilitation settings.

Based on evidence established during development of the ABLE intervention programme (14,37,38) the problem-solving approach was incorporated in the intervention programme and in the manual (105), as prescribed in the OTIPM (13). We found that the problem-solving process was a comprehensive reason for the outcomes and improvements achieved among clients receiving ABLE 2.0, which is in line with the results of a systematic review by Steultjens et al (38), finding evidence to support efficacy of occupational therapy for elderly persons and persons with stroke and arthritis, and that this benefit mainly relates to the unique occupational therapy process, characterised by a problem-solving process. Involving the client in the problem-solving process and facilitating adaptive occupation in the client's home to compensate ineffective occupational skills was called "*an eye-opening process*" that facilitated the prescribed occupation-focused dialogue, involving the client in the analytic process. We also found that the logical order of sessions in the ABLE intervention programme and the coherence between its different parts were unique. The different parts were each other's prerequisites. Hence, the contribution of evaluation of ADL ability, using the AMPS and the ADL-I in building a solid foundation for the entire intervention was crucial.

The functioning of the evaluation of ADL ability

The impact of the systematic approach to evaluation of ADL ability in initiating the problem-solving process was emphasised by both clients and OTs, and was reflected in one of the prominent CMOCs, saying that the systematic approach, including a mandatory structured dialogue on eventual discrepancy, may trigger the client's confidence and feeling involved, the client's perceiving gaining insight, and a collaborative relationship between the client and the OT, and hence may contribute to building a foundation for the intervention, initiating a problem-solving process, and that the client and the ABLE OT gain a common understanding of the client's ADL ability. The previous feasibility study found supportive results (15), that clients and OTs found the formal and standardised evaluations highly meaningful and supportive of client involvement in the process, and suggested that a thorough initial evaluation, based on both self-report and observation, provides a solid foundation for planning and implementing goal-directed, time-efficient interventions. Moreover, the pilot study (104) confirmed the findings with overall high scores on the impact of session 1 in clarifying focus for intervention and establishment of a good basis for further cooperation.

Further, the process evaluation revealed that the strength of the mandatory dialogue on discrepancy lay in the fact that there was a guideline on how to approach the dialogue on potential areas of disagreement or different perspectives on the observed performance. It was one part of the coherent process that could not be taken out. Specifically, it was an important part of the evaluation and in building the foundation for the entire intervention, that both parties at this point of the intervention process, became aware of the other person's perspective. Overall, the findings provide evidence to support a crucial impact of the initial evaluation phase outlined in the OTIPM (13) and reflected in ABLE 2.0 session 1 including evaluating the ADL ability combining self-reported and observation-based methods as basis for setting goals and planning of purposeful intervention.

Further it was found that an OT skilled in administering the instruments may trigger the client's sense of believing in the programme and in the OT, and hence may contribute to the client finding the content of the programme meaningful. In the feasibility study (15) as well as in the pilot study (104) the OTs felt highly confident in delivering the initial session, confirming that their experience in conducting the evaluations were sufficient. This was a subject of priority in the three-and-a-half-day training course and should remain so in case of future implementation in other contexts.

In terms of the impact of the coherence between the different parts of the intervention process it was found, that if one part was left out e.g., not involving the client in defining goals and defining levels of goal attainment at session 2, the problem-solving process was obstructed, resulting in implementation failure. Especially the process of goal setting was considered a challenge and hearth for the examples of implementation failure.

The functioning of collaborative goal setting

Overall, the process of goal setting was found core in establishing the focus for the further process, framed by using GAS for goal setting and PEO and/or TMO in clarifying causes for the ADL problems. As reflected in a prominent CMOC, the goal setting process contributes to establishment of basis for monitoring progress and to relevant and clear goals, provided that the OT is skilled in communicating and administrating GAS, triggering a collaborative relationship and goal setting primarily based on the client's priorities.

In terms of the implementation failure, with regards to goal setting, three explanations are proposed: 1) OTs were not experienced in goal setting, due to the usual referral procedure in the municipality including that goals

typically were defined by the referral service; 2) OTs sometimes perceived to lack communication and collaboration skills to involve the client in using GAS, 3) clients with cognitive deficits were a challenge to involve.

To ensure implementation of ABLE 2.0 in the municipality, during the pilot and RCT study periods, the referral procedure was adapted, and hence, the approaches to goal setting were different in the two groups. It can be argued that the lack of experience in goal setting as part of the problem-solving process among the ABLE OTs explains their perceived challenges.

Regarding the perceived challenges in involving the clients in goal setting the complexity in goal setting among persons with chronic conditions is recognised (151–154). Still, based on the process evaluation, the importance of the goal setting process was beyond doubt. This is supported by Wade (155), claiming that goal setting is and should be a central feature in rehabilitation and should be a core competence of members of rehabilitation teams. The UOT approach to goal setting, in terms of those cases where goals were defined by the referral service, may represent absence of negotiation and client-involvement which contrasts with a rehabilitation approach and with the recommendation of applying collaborative goal setting with elderly persons with chronic conditions (151).

The impact of the goal setting process in establishing the focus for further intervention and in the overall problem-solving process is underpinned by the findings in the UOT group with goals defined by the referral service in almost half of the cases. The client records overall indicated a non-standardised approach to evaluation of ADL ability in the UOT group, further that the evaluation of ADL ability was not conducted before intervention planning, but in a parallel order. This indicates that when goal setting is taken out of the coherent intervention process it may facilitate a clinical practice where evaluation is attributed low priority because the main purpose of it is eliminated. In a systems perspective, implementing ABLE 2.0 was a disruption to the complex system in the municipality (89) and it serves as an example of how complexity can arise from the context in which the intervention is delivered. To better understand the dynamic interaction between ABLE and context, future implementation research should apply a systems thinking perspective (89) to further investigate this interaction as a source of complexity affecting how ABLE may contribute to changes.

Recognising the challenges in goal setting, future research activities related to the ABLE intervention programme should address the OTs' skills in communicating around goal setting. It is suggested to revise the ABLE 2.0 intervention programme concerning how to facilitate the dialogue with the

client on the desired level of ADL task performance, including prioritising the quality aspect of performance, e.g., use of time, physical effort/fatigue and/or safety risks (29). For example, if the client presented a marked level of increased physical effort during preparation of a meal when evaluating the ADL ability, a dialogue facilitating clarification of whether achievement of moderate or minimal level of increased effort would be satisfying for the client, would contribute to establishing the focus for the further process. Moreover, specific focus on how to intentionally develop a fruitful therapeutic relationship during delivery of the ABLE intervention programme is suggested.

The collaborative working relationship

The OTIPM (13) emphasises that the collaborative working relationship between the client and the OT is a critical component of the therapeutic process. Studies show that clients' perception of the therapeutic relationship, defined as "*a personally interpreted interaction process between the therapist and the client*" (156) is associated with changes in the clients' engagement and satisfaction with occupational performance by awarding the client a more active role (157–160). Further, practising client-centred communication is considered one of the mechanisms through which improved well-being and health outcomes will be realised (161,162). The process evaluation revealed that the ABLE OTs were sometimes challenged communicating and collaborating with different clients, which may call for a variety of different skills among OTs delivering the programme. Delivering ABLE is not simply applying the tools, instruments, and models prescribed in the ABLE manual (105). The impact is found in *the way* OTs deliver the ABLE intervention programme. Drawing on the work of Dr. Gary Kielhofner, Dr. Renee Taylor (156) offers a theoretical model to facilitate OTs' reasoning on approaches to intentionally develop the therapeutic relationship. In the Intentional Relationship Model (IRM) six distinct ways, i.e. therapeutic modes (i.e. advocating, collaborating, emphasising, encouraging, instructing, and problem-solving mode) of relating are described (156). For example by utilising the *advocating mode*, reflecting that the OT speaks for the client's rights and help to secure resources (156) may be appropriate in case of inappropriate wait for assistive devises or home care; or when involving the client in finding relevant solutions the *collaborating mode,* reflecting that the OT works on an egalitarian level with the client, entrusting that the client lead the decision-making process (156) may be particularly appropriate.

The idea of applying the IRM (156) is emphasised by the fact that the responder analysis revealed that responders in the ABLE group had a clinically relevant lower AMPS ADL process ability at baseline compared to

non-responders, indicating that persons with low ADL process skills benefit the most. Further, the process evaluation revealed that the ABLE OTs found it particularly challenging to involve clients with cognitive deficits in the problem-solving process. Recognising that lower ADL process ability not in all cases is related to diminished cognitive functioning, the results point to the advantage of OTs that are skilled in involving clients with low ADL process ability in identifying and understanding their ADL problems and finding relevant solutions.

The impact of a transactional perspective

When involving the client in clarification of causes for the ADL problems, by using the PEO (73) and/or the TMO (13) during session 2, it reflected a transactional perspective on occupation. The process evaluation revealed that this dialogue between the client and the ABLE OT triggered a core mechanism of change, i.e. understanding occupation as a response to the situational context (13). It was found that using the models (i.e. PEO and/or TMO) offered an opportunity to move from a disease-oriented to a more transactional perspective on the clients' ADL problems, and that this facilitated the use of environmental opportunities and/or adaptive occupations to compensate ineffective occupational skills, hence reflecting a compensatory intervention approach. The ABLE OTs found that focusing on the chronic conditions did not explain the client's decreased ADL ability. As prescribed in the OTIPM, we need to understand why the ADL task performance problems occur to help the client improve his/her ADL ability. Thus, we need to consider, what it is in the situational context of this person's ADL task performance, including elements related to the client, the task, temporal, geopolitical and sociocultural elements, as well as the physical and social environment, that makes this ineffective response? In the transactional perspective on occupation, *"occupation is a response to situational elements that naturally shape each other"* (13). By moving away from understanding the ADL problems as solely individual problems towards understanding the problems as response to the situational context (13) we get access to more efficient solutions and sustainable changes in the client's behaviour. This is in line with Dickie et al (58) arguing that occupations should be described as more than an individual experience, and rather as functionally integrated with the context. We need to stop thinking, that when a problem occurs in a client, this is also where the solution is too be found. Rather we should strive to understand in what circumstances, i.e. in response to which situational elements (13), the problems occur. Further, a study exploring persons' experiences of their adjustments to chronic conditions found, that they always described their occupations in relation to the context (163). The personal context of doing included the person's

values, interests, and abilities, guiding the persons' preference of certain occupations, that were influenced by the opportunities and resources in their environmental context (163). Hence, indicating, that persons with chronic conditions subscribe to a transactional perspective on occupation themselves.

Based on the process evaluation it was also clear, that one of the strengths in ABLE 2.0 was the logic order of the sessions and the coherence between the different parts, all together involving the client in the problem-solving. Hence it can be argued that apart from a context of dialogue between the client and the OT, important contextual factors are the infrastructural and institutional level contextual factors in terms of the municipal guidelines for referring to rehabilitation services, supportive management, supportive teamwork, a systematic approach to evaluation of ADL ability, and a mandatory structured dialogue on eventual discrepancy. This serves as an example of how occupation and elements of the situational context, e.g., task, temporal, sociocultural, and social environmental elements are intertwined (13) and confirms the importance of considering the situational context as a core element within research in relation to complex interventions, as emphasised by the MRC framework (89).

Somehow this was already pronounced by the American occupational therapist, Elizabeth Yerxa in 1988 arguing that problems seen by occupational therapists are by definition complex, and that *"oversimplification is the process by which inherently complex phenomena are reduced to parts or fragments which are more easily seen, understood and /or controlled"* (164). A purpose in delivering rehabilitation services is to understand the person referred in this person's specific context, which is reflected in the definition of rehabilitation: "*... rehabilitation takes account of the person's situation as a whole ...*" (32). Hence there is evidence to support understanding and approaching ADL task performance problems among persons with chronic conditions within rehabilitation, based on a transactional perspective.

Methodological considerations

The pilot study (study 1)

The 2008 guidance on developing and evaluating complex interventions (45) emphasised the importance of conducting feasibility and pilot studies before proceeding to a full-scale trial to examine key uncertainties in terms of acceptability, compliance, delivery, recruitment and retention, effect sizes, and understanding context. A previous feasibility study (15) was followed by

conduction of the pilot RCT (104) in this thesis, evaluating the remaining feasibility aspects of a full-scale trial. The transparency and the quality of the process of deciding whether a future trial was relevant was strengthened by applying pre-defined progression criteria, which later was recommended in the updated MRC framework (89). Further, also strengthening the confidence in the results of the pilot study, it was conducted in the same municipality as was planned for the full-scale trial, and by involving core stakeholders from the municipality in designing the study, we gained valuable knowledge about contextual factors to be considered in the design of the evaluations of effectiveness and process.

A limitation of the pilot study was the incomplete dataset caused by the Covid-19 pandemic lockdown that interrupted and terminated the study earlier than planned. This resulted in reduced evidence on some of the pilot aspects, primarily on adherence to the intervention programme and appropriateness of outcome measurements. A more complete dataset on adherence, may have revealed the challenges related to goal setting identified in the process evaluation, and may in that respect have led to revision of the manual and/or the training course, preventing occurrence of implementation failure. Still, the pilot study revealed important findings that the procedures for recruitment and randomisation were effective and that it was possible to recruit a sample representing the population targeted by ABLE 2.0. Despite the limited dataset, it was also important that the intervention was delivered according to the manual and that the first five persons included completed the mandatory sessions and stayed in the program.

The effectiveness evaluation (study 2)

Conduction of the study in an RCT design in a real-world setting provided valuable understanding of how ABLE 2.0 may work in usual conditions, despite challenges in terms of designing the study. Involvement of stakeholders from the municipality enabled randomisation at an individual level, by adapting some of the usual procedures, e.g., referral procedures and transportation, and hence we achieved balance between the groups and limited the risk of selection bias. Further, it strengthened the study that assessors, and the researcher conducting statistical analyses were blinded on allocation to intervention.

Several limitations concerning the RCT could be considered. A relatively large number of persons withdrew from the study before completion of the intervention programme and week 10 assessments, in most cases due to hospitalisation or death. Still, information concerning other reasons to

withdraw would have been beneficial in terms of future implementation. Recruitment and retention of elderly persons in RCTs are known to be challenging (165), representing a potential source for biased samples and results. The loss of power related to the co-primary outcome ADL-I Performance probably resulted in non-significant results and decreased chances of detecting a true difference between groups. Further, the study was conducted in a single municipality and hence generalisation of the results should be done with caution.

Due to the poor relationships between self-reported and observation-based outcomes when measuring the ADL ability among persons with chronic conditions (62,131,133–135), using the two methods as co-primary outcomes is considered to have strengthen the study. Further the OTs conducting the assessments were trained and re-calibrated as AMPS raters and certified in using ADL-I prior to collection of data.

The ABLE OTs were trained and supervised in delivering the ABLE 2.0 and we also provided a manual describing how the ABLE 2.0 was intended to be delivered. The manual was feasibility evaluated in a previous study (15) and revised based on the results and a cognitive debriefing. Overall, probably improving the delivery quality of the intervention.

Aiming to describe UOT with a level of detail similar to the description of the ABLE 2.0, as suggested by Hoffmann et al (106) this was based on retrospective investigation of client records. By doing that, data on UOT informed on what was delivered to the participants in the control group as reflected in the client records. Hence, we avoided some typical uncertainties concerning the dynamic nature of usual care including local adaptations and variations over time (107,108).

The conduction of this study during the Covid-19 pandemic is considered a success. However, the inclusion period was extended, and information on how the study might have been affected by the pandemic e.g., in terms of affecting the clients' everyday lives, or whether the patterns on recruitment deviated from usual conditions, are unknown.

The process evaluation (study 3)

In the process evaluation, using realistic evaluation principles, a multi methodological approach was employed, strengthening the confidence in the results. Based on the initial programme theory, expressing the ideas of how the intervention works, we facilitated conversation with the persons receiving and delivering the intervention during collection of qualitative and

quantitative data, and with existing evidence. This reflects triangulation and resulted in comprehensive knowledge about the functioning of the ABLE intervention programme.

Some quantitative data were collected to follow up on the previous evaluation of feasibility of the ABLE 1.0 program in terms of content and delivery. While these results will be reported later, the data were also used to further explore the hypothesised CMOCs. The CMOCs were tested despite limited examples to guide the process. The idea was to conduct intra-group comparisons using cross tabulations as suggested by Ravn (127). While the analysis supported a successful implementation and served as supplemental information on the qualitative analysis, this analysis mostly served as a pilot testing of the method. That is, our dataset was relatively small, and we did not collect data from clients who withdrew from the study. The latter would have provided useful information concerning how contextual factors may or may not have triggered mechanisms. In case of future realist evaluation including quantitative testing of the CMOCs, it is recommended to include few and core mechanisms with a larger sample over broader CMOCs with smaller sample (127).

The qualitative data served as prominent information on the functioning of the programme, strengthened by the longitudinal conduction of the series of realist interviews. However, in the interviews with clients having received ABLE 2.0 we experienced several examples of clients having difficulties remembering details from their intervention process. This may be because it has been a while since they finalised their intervention (due to the parallel design with the effectiveness intervention, conduction of interviews was exposed to after the intervention period) or because the clients typically had many persons coming in their homes for different reasons, resulting in mixing up persons and experiences. Consequently, information on the clients' perspectives on how they perceived that the ABLE 2.0 may have facilitated changes in their daily lives are limited. In future studies it should be considered to conduct client interviews immediately after a session, or alternatively consider conduction of focus group interviews with a group of clients selected for the purpose of informing on mechanisms of change.

Considerations concerning application of the MRC guidance and framework

The application of first the 2008 MRC guidance (45), and recently the MRC framework (89) in the 'A Better everyday LifE' research programme has overall strengthened the studies. However, as described in the introduction chapter, we found it necessary to apply recommendations from

other sources, including the DECIPHeR group (88) and RAMESES II projects (86). This, to accommodate the needs for taking wider contextual factors of impact into account, specifically reflected in the use of programme theory and realistic evaluation. Moreover, confirming that our choices of evaluation models were relevant, the authors of the recently updated MRC framework (89) argue that investigating how interventions work, including interactions with contextual factors, is equally important to investigation of effectiveness. The parallel design of evaluation of effectiveness and process is considered a strength.

Implications for practice

This thesis provides immediate implications for clinical occupational therapy practice:

- First, employing an established occupational therapy intervention process model, promoting a client-centred, occupation-focused and occupation-based, collaborative, problem-solving approach resulted in clients feeling involved and in OTs feeling more confident in delivering occupation-centred occupational therapy. Delivering systematic individualised problem-solving occupational therapy implies that rehabilitation services might consider implementation of supportive process models. Further, based on what was revealed about the importance of supportive management, such implementation is largely a management task and responsibility

- Second, employing an established occupational therapy intervention process model, prescribing conduction of systematic evaluation of occupational performance based on both self-report and observation prior to goal-setting and intervention, was found to have crucial impact on the remaining part of the intervention process and outcomes. Hence, implementation of systematic evaluation as standard procedure in clinical practice may be recommended

- Third, the findings concerning how the occupational therapy services and the referral services were organised in the municipality, serving as a barrier in providing a coherent problem-solving occupational therapy process, implies that municipalities consider modifications to their referral procedures

- Fourth, the effectiveness of the ABLE 2.0 attributed to the application of adaptational strategies emphasises the importance of using such

approaches in clinical practice when aiming at enhancing the ADL ability among persons with chronic conditions

- Fifth, because the coherence in the problem-solving process was found to be crucial in obtaining sustainable changes in ADL ability, it is recommended to pay specific attention to how the circumstances in which interventions are delivered may bring about the desired changes

Recommendations for future research/activities

Overall, based on the results of the studies in this thesis, it is recommended to proceed to planning research activities aiming at implementing the ABLE intervention programme in clinical community-based rehabilitation settings. This includes a number of preparing research activities addressing certain aspects of uncertainty (89) informing development of an implementation plan. However, first the remaining studies on evaluation of the ABLE 2.0 should be conducted.

The following studies are recommended:

- First, it is recommended to finalise the remaining studies related to the evaluation of ABLE 2.0. That is, to conduct the second part of the process evaluation, concerning content and delivery, and conduct the evaluation of cost-effectiveness. In addition it is recommended to revise the manual and the initial programme theory (89)

- Second it is recommended to identify known facilitators and barriers described in international research, for implementing the ABLE intervention programme in clinical practice, based on a systematic review of existing research

- Third, it is recommended to map current clinical practice and identify potential facilitators and barriers for implementing the ABLE intervention programme in clinical practice, based on a survey

- Fourth, it is recommended to investigate and identify general and specific attitudes on implementation of evidence-based interventions in clinical practice, representing potential facilitators and barriers for implementing the ABLE intervention programme in clinical practice, based on a vignette study

- Fifth, it is recommended to identify ideas on how to address potential barriers, and how potential facilitators may support, implementation in clinical practice, based on a GCM study

Based on a synthesis of the results of the preparing studies, a detailed implementation plan may be developed, including to engage relevant stakeholders (89).

Conclusions

The following conclusions may be drawn based on the results of the studies included in this thesis:

- Evidence of the effectiveness of the ABLE 2.0 intervention programme was established among persons experiencing decreased ADL ability following chronic conditions. Overall, participants receiving the ABLE intervention obtained a clinically relevant increase (i.e. improved) in observed ADL motor ability from baseline to post intervention, reflecting a decreased level of effort in terms of clumsiness, physical effort, and fatigue. This improvement was sustained 26 weeks from baseline. In contrast, participants receiving UOT obtained an increase in observed ADL ability not reaching the level of clinical relevance, and their ADL ability decreased to almost baseline level after 26 weeks.
- The ABLE 2.0 intervention programme represents a systematic problem-solving individualised occupational therapy process using a compensatory intervention model addressing problems related to performance of ADL tasks among persons with chronic conditions. The ABLE 2.0 was effective in achieving sustainable improvements in observed ADL motor ability when including standardised evaluation of the ADL ability based on self-report and observation, followed by collaborative goal setting and application of adaptational strategies in the home of the client, to resolve the perceived ADL task performance problems
- Knowledge informing on in what circumstances, for whom, how, and why the ABLE 2.0 intervention programme functions was acquired. The ABLE 2.0 initial programme theory was confirmed adding information on core mechanisms associated with the positive effects of the ABLE 2.0, including active involvement of the client in the problem-solving process, a collaborative working relationship between the client and the OT, mutual confidence between the client and the OT, and a consultative occupation-based process using adaptational strategies. These desired mechanisms required activation by supportive management, referral procedures encouraging the coherent problem-solving occupational therapy process, and delivery in the client's home. Further, skilled OTs being confident in administrating the applied instruments, intervention

components, and conceptual models in a client-centred manner, and clients feeling ready for making changes also seemed to be required

- At the individual level, participants benefitting from the ABLE 2.0 intervention (i.e. obtaining a clinically relevant increase in ADL ability) had significantly lower observed ADL motor and ADL process ability at baseline than participants not benefitting, suggesting need of help and a larger room for improvement. No other differences between persons responding and not responding to the ABLE intervention were seen in baseline characteristics including age, sex, and diagnoses. Hence, the ABLE 2.0 intervention programme was effective among persons with lower levels of ADL ability and need of help across age, sex, and diagnoses, supporting the initial arguments for developing a generic ADL intervention

Acknowledgements

This thesis is a result of fruitful collaboration between The Parker Institute, Southern Denmark University, and VIA University College.

I gratefully acknowledge financial support from Local Government Denmark and The Danish Health Confederation; VIA University College; Southern Denmark University; The Parker Institute; and The Danish Association of Occupational Therapists.

Having the opportunity to enter the field of research and conduct the doctoral studies in this thesis was kind of a dream coming true for me. I am humble and proud of the confidence that was given to me. The journey has been challenging, joyful, and very educational. Please let me express my gratitude to everyone who contributed, supported, and encouraged me in various ways.

My sincere gratitude to:

The participants in the studies. The persons with chronic conditions for being willing to participate in this research and share your experiences; the nine occupational therapists who delivered the ABLE 2.0 or UOT during the pilot study and the main trial in the municipality of Herning for continuous effort recruiting clients and delivering interventions, and for sharing your experiences; *Vibeke Machmüller, Kirstine Buelund Fyhn*, and *Vibeke Pedersen*, for your engagement in delivering ABLE 2.0; and the occupational therapists who participated in the cognitive debriefing on the ABLE manual.

Partners in Herning municipality, for entering this research programme with positive attitudes. I always felt this was a common project and never doubted your engagement. *Hanne Volsgaard Nielsen*, head of professions, for being key person establishing the collaboration, and for working with me on fundraising. *Elin Mogensen*, head of Health Promotion, Rehabilitation, and Assistive Devises, for supporting the project behind the scenes and always being there when needed. A special thanks to *Allis Lunde*, head of Rehabilitation Unit East, for invaluable collaboration in solving various challenges along the way and in coordinating the studies all the way through. *Lars Østergård, Trine Rold, Kirsten Fugl Matthiasen*, heads of

Rehabilitation Units South, North, and West respectively, for continuous collaboration and dialogue coordinating the activities in the field and for ongoing support to keep things going. *Birgitte Nystrup Andersen*, head of the Referral Service, for contributing to designing the study in terms of recruitment and for being willing to adapt usual procedures in the study periods. *Jytte Hoffmann,* physiotherapist, for working with me extracting data from client records.

Peter Seebach, former head of Department for Occupational Therapy and Physiotherapy, Regional Hospital West Jutland, for seeing the potential in this research and being willing to enter an agreement on providing assessors; and *Susan Bjerrum Nielsen*, head of therapists, for continuing support of the project and collaboration until, unfortunately, covid-19 prevented the occupational therapists from the hospital visiting clients in their homes and hence had to withdraw from the research project.

Lillian Noe, Bettina Hvas Busk, Mette Mondrup, and *Linda Trier Hald*, for thoroughly conducting all assessments in the pilot study and the main trial. Thank you for your engagement. Your contributions are comprehensive.

Eva Ejlersen Wæhrens, my main supervisor. So dedicated, knowledgeable, and skilled in occupational therapy and research, and so willing to share. Thank you so much for inviting me as your phd student. I haven't stopped being humble and happy that I accepted. I feel that you walked the path with me, and most important - that you believe in me. I really learned a lot from you. Your supervision has been professional, engaged, timed, and customised to me. Thank you, *Eva*. Thanks also for hospitality to you and *Niels*.

Kristina Tomra Nielsen, my co-supervisor. You are probably the person I know, who believes most in occupational therapy. Thank you for sharing your enthusiasm, and for valuable support – it has meant a lot. I took over on the work on the precious ABLE after you, and you have been an important partner and supervisor for me in getting familiar with and revising the programme. Especially thank you for hard-working, eye-opening, and joyful collaboration during analysis of process evaluation data. Those were good days.

Cecilie von Bülow, my co-supervisor. We need persons like you in occupational therapy research. Thank you for sharing your knowledge, for asking thousands of questions, and for being the guarantor of broadening the perspectives. Especially thank you for helping me understand (at least some of) the possibilities of statistics. Your engagement is impressive – thank you *Cecilie*.

Maud Graff, my co-supervisor. Thank you for seeing the potential in the ABLE intervention programme and the research programme. Thank you for sharing your knowledge and experience on complex ADL interventions and for contributing to conduction of the pilot study and designing the effectiveness and process evaluations. Thank you for your input and acknowledging feedback on my work.

Colleagues at the Parker Institute. Such a wonderful group of persons. It has been a privilege to be part of the research unit, with the admirable balance between humour, warmth, and serious solid research. Due to Covid-19 lockdowns I had the opportunity to participate in the weekly virtual meetings, despite the distance. However, I wish I had the chance of getting to know you better – you are much more than what the computer-screen captures. My special gratitude to *Claus Bomhoff* and *Marius Henriksen*. *Claus*, administrator at the Parker Institute, for seeing the potential in having long-distance PhD student situated in the Western part of Jutland. Thank you for always "running the business", for your welcoming attitude, and for never making things unnecessarily complicated; and *Marius*, professor, PT, PhD, for letting us benefit from your vast competencies in statistics.

Colleagues at Occupational Science, User Perspectives and Community-based interventions. It has been quite a transition to finally become a research group. I was happy to experience that with you all. Thank you for engagement and constructive discussions on occupational therapy, occupational science, and research methodology. Thanks for inspiring journal clubs and research seminars, and for valuable feedback on my work. I truly appreciate that. Thanks for meetings every Tuesday morning – mostly on the screen. Thanks for inspiring collaboration in teaching planning.

*Colleagues at VIA University College, the department of occupational therapy in Holstebro***,** for ongoing support and interest in me (and my research) and for always finding time for a cup of coffee and a talk when I

had a need to socialise. I am looking forward to returning “home” to you all. Especially thank you to *Anne Lise Voss*, head of the Occupational Therapy Department, for invaluable support, for confidentiality, and for providing me optimal conditions. I am very grateful to you.

Jette Tietze and *Ida Jensen* occupational therapy students at VIA University College, for assisting me in data processing.

Family and friends. Thank you for being present in my life, for doing important things with me, and for keeping on asking and being truly interested in my work, my successes, failures, and struggles; to *Rasmus, Carina*, *Sigrid, Emilie, Johan* and *Olivia*, for your presence and interest, and not least crazy whims (and a special thanks to my daughter *Emilie*, for keeping alive my nerve that every human being has the right to be engaged in meaningful and purposeful occupations); and *Jørgen*, my beloved husband, for all your support during hard days and for celebrating every little milestone and victory along the way.

References

1. Fisher AG. Uniting Practice and Theory in an Occupational Framework. 1998 Eleanor Clarke Slagle Lecture. Am J Occup Ther. 1998;52(7):509–21.
2. Bendixen HJ, Wæhrens EE, Wilcke JT, Sørensen LV. Self-reported quality of ADL task performance among patients with COPD exacerbations. Scand J Occup Ther. 2014 Jul 21;21(4):313–20.
3. Lindahl-Jacobsen L, Hansen DG, Wæhrens EE, la Cour K, Søndergaard J. Performance of activities of daily living among hospitalized cancer patients. Scand J Occup Ther. 2015 Mar 1;22(2):137–46.
4. Nielsen KT, Wæhrens EE. Occupational therapy evaluation: Use of self-report and/or observation? Scand J Occup Ther. 2015;22(1):13–23.
5. Wæhrens EE, Bliddal H, Danneskiold-Samsøe B, Lund H, Fisher AG. Differences between questionnaire-and interview-based measures of activities of daily living (ADL) ability and their association with observed ADL ability in women with rheumatoid arthritis, knee osteoarthritis, and fibromyalgia. Scand J Rheumatol. 2012;41(2):95–102.
6. Daving Y, Claesson L, Sunnerhagen KS. Agreement in activities of daily living performance after stroke in a postal questionnaire and interview of community-living persons. Acta Neurol Scand. 2009;119(6):390–6.
7. Hariz GM, Forsgren L. Activities of daily living and quality of life in persons with newly diagnosed Parkinson's disease according to subtype of disease, and in comparison to healthy controls. Acta Neurol Scand. 2011;123(1):20–7.
8. Norberg EB, Boman K, Löfgren B. Activities of daily living for old persons in primary health care with chronic heart failure. Scand J Caring Sci. 2008;22(2):203–10.
9. Sturkenboom IHWM, Graff MJL, Hendriks JCM, Veenhuizen Y, Munneke M, Bloem BR, et al. Efficacy of occupational therapy for patients with Parkinson's disease: a randomised controlled trial. Lancet Neurol. 2014 Jun 1;13(6):557–66.
10. Storeng SH, Vinjerui KH, Sund ER, Krokstad S. Associations between complex multimorbidity, activities of daily living and mortality among older Norwegians. A prospective cohort study: The HUNT Study, Norway. BMC Geriatr. 2020;20(1):1–8.

11. Fisher AG. Occupation-centred, occupation-based, occupation-focused: Same, same or different? Scand J Occup Ther. 2014;21(S1):96–107.

12. Kielhofner G. Conceptual foundations of occupational therapy practice. 4th editio. F. A. Davis Company; 2009.

13. Fisher AG, Marterella A. Powerful practice : A Model for Authentic Occupational Therapy. Fort Collins: CIOTS - Center for Innovative OT Solutions; 2019.

14. Nielsen KT. Occupational therapy for persons living with chronic conditions - Development and feasibility of the ABLE program. Thesis. Southern Denmark University; 2018.

15. Nielsen KT, Guidetti S, von Bülow C, Klokker L, Wæhrens EE. Feasibility of ABLE 1.0—a program aiming at enhancing the ability to perform activities of daily living in persons with chronic conditions. Pilot Feasibility Stud. 2021;7(1):1–15.

16. Guidetti S, Nielsen KT, von Bülow C, Pilegaard MS, Klokker L, Wæhrens EE. Evaluation of an intervention programme addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a feasibility trial (ABLE). BMJ Open. 2018;8(5):e020812.

17. Hvidberg MF, Johnsen SP, Davidsen M, Ehlers L. A Nationwide Study of Prevalence Rates and Characteristics of 199 Chronic Conditions in Denmark. PharmacoEconomics - Open. 2019;4:361–380.

18. World Health Organization. Worlds Health Statistics 2020: Monitoring health for the SDG, sustainable development goals. Geneva; 2020.

19. Goodman RA, Posner SF, Huang ES, Parekh A, Koh HK. Defining and Measuring Chronic Conditions : Imperatives for Research , Policy , Program , and Practice Conceptual Model for Standardizing the Analysis of Health Data Sets for Selected Chronic Conditions. Prev Chronic Dis. 2013;10(Mcc):1–16.

20. Møller SP, Laursen B, Johannesen CK, Schramm S. Multisygdom i Danmark [Multi-disease in Denmark]. Statens Institut for Folkesundhed, SDU. 2019. 5–18 p.

21. Goodman RA, Posner SF, Huang ES, Parekh AK, Koh HK. Defining and Measuring Chronic Conditions: Imperatives for Research, Policy, Program, and Practice. Prev Chronic Dis. 2013 Apr 25;10:120239.

22. Portela D, Almada M, Midão L, Costa E. Instrumental activities of daily living (IADL) limitations in Europe: An assessment of share data. Int J Environ Res Public Health. 2020;17(20):1–15.

23. Månsson Lexell E, Iwarsson S, Lexell J. The complexity of daily occupations in multiple sclerosis. Scand J Occup Ther. 2006;13(4):241–8.

24. Kielhofner G. The Model of Human Occupation. 4th ed. Philidelphia, USA: Lippincott, William & Wilkins; 2008.

25. Tjørnov J. Ergoterapi. Baggrund og udvikling [Occupational therapy. Background and development]. Copenhagen: FADL; 1987.

26. Fisher AG, Jones KB. Assessment of motor and process skills. Volume 1: Development, standardization, and administration manual. 7th ed. Fort Collins, Colorado, USA: Three Star Press; 2012.

27. Avlund K. Disability in old age. Longitudinal population-based studies of the disablement process. Dan Med Bull. 2004;51(4):315–49.

28. Wæhrens EE. Almindelig daglig levevis: ADL [Activities of daily living: ADL]. Munksgaard; 2015.

29. Wæhrens EE. Measuring quality of occupational performance based on self-report and observation. Development and validation of instruments to evaluate ADL task performance [Internet]. Thesis. Department of Community Medicine and Rehabilitation, Umeå University; 2010. Available from: http://umu.diva-portal.org/smash/record.jsf?pid=diva2%3A318271&dswid=3508

30. Nielsen KT, Klokker L, Wæhrens EE. Self-reported quality of activities of daily living task performance in four diagnostic groups with chronic conditions. IJTR. 2021;28(4):1–10.

31. Håkansson C, Wagman P, Hagell P. Construct validity of a revised version of the Occupational Balance Questionnaire. Scand J Occup Ther. 2019;0(0):1–9.

32. Marselisborgcentret; Rehabiliteringsforum Danmark. Hvidbog om rehabiliteringsbegrebet - Rehabilitering i Danmark [White Paper on the Concept of Rehabilitation - Rehabilitation in Denmark]. Århus; Marselisborgcentret; 2004.

33. Serviceloven [Law on Social Services] § 86. (SEL) [Internet]. [cited 2021 Dec 14]. Available from: https://danskelove.dk/serviceloven/86

34. Serviceloven [Law on Social Services] § 83a. (SEL) [Internet]. [cited 2021 Dec 14]. Available from: https://danskelove.dk/serviceloven/83a

35. Wade D. Rehabilitation-a new approach. Part four: A new paradigm, and its implications. Clin Rehabil. 2016;30(2):109–18.

36. Wade DT. Describing rehabilitation interventions. Clin Rehabil. 2005;19(8):811–8.

37. Hand C, Law M, McColl MA. Occupational therapy interventions for chronic diseases: A scoping review. Am J Occup Ther. 2011;65(4):428–36.

38. Steultjens E, Dekker J, Bouter L, Leemrijse C, Ende C van den. Evidence of the efficacy of occupational therapy in different conditions: an overview of systematic reviews. Clin Rehabil. 2005;19(3):247–54.

39. Guidetti S, Ranner M, Tham K, Andersson M, Ytterberg C, Von Koch L. A 'client-centred activities of daily living' intervention for persons with stroke: One-year follow-up of a randomized controlled trial. J Rehabil Med. 2015;47(7):605–11.

40. Nielsen TL, Petersen KS, Nielsen CV, Strøm J, Ehlers MM, Bjerrum M. What are the short-term and long-term effects of occupation-focused and occupation-based occupational therapy in the home on older adults' occupational performance? A systematic review. Scand J Occup Ther. 2017 Jul 4;24(4):235–48.

41. Graff MJL, Vernooij-Dassen MJM, Thijssen M, Dekker J, Hoefnagels WHL, Rikkert MGMO. Community based occupational therapy for patients with dementia and their care givers: Randomised controlled trial. Br Med J. 2006;333(7580):1196–9.

42. Amris K, Bülow C von, Christensen R, Bandak E, Rasmussen MU, Danneskiold-Samsøe B, et al. The benefit of adding a physiotherapy or occupational therapy intervention programme to a standardized group-based interdisciplinary rehabilitation programme for patients with chronic widespread pain: a randomized active-controlled non-blinded trial. Clin Rehabil. 2019;33(8):1367–81.

43. Waehrens EE, Fisher A. Improving quality of ADL performance after rehabilitation among people with acquired brain injury. Scand J Occup Ther. 2007;14(4):250–7.

44. Nielsen TL, Bjerrum M, Nielsen CV, Petersen KS. Older adults' experiences and expectations after discharge from home-based occupational therapy. Br J Occup Ther. 2018 Aug 20;81(8):450–9.

45. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337(7676):979–83.

46. Yerxa EJ. Some implications of occupational therapy's history for its epistemology, values, and relation to medicine. Am J Occup Ther. 1992 Jan;46(1):79–83.

47. Kielhofner G. Respecting both the 'occupation' and the 'therapy' in our field. Am J Occup Ther. 2007;61(4):479–82.

48. Meyer A. The Philosophy of Occupational Therrapy. Arch Occup

Ther. 1921;1(1).

49. Jonsson H. A new direction in the conceptualization and categorization of occupation. J Occup Sci. 2008;15(1):3–8.

50. The World Federation of Occupational Therapists. Definitions of Occupational Therapy [Internet]. 2018 [cited 2021 Dec 6]. Available from: https://wfot.org/resources/definitions-of-occupational-therapy-from-member-organisations

51. Therapists TDA of O. Professionsgrundlag for ergoterapi [the Foundation of the Occupational Therapy Profession]. 2008.

52. Sackett DL, Rosenberg WM, Gray J, Haynes RB, Richardson WS. Evidence Based Medicine: What it is and what it isn't. Bmj. 1996;312(7023):71–2.

53. Bennett S, Bennett JW. The process of evidence-based practice in occupational therapy: informing clinical decisions. Aust Occup Ther J. 2000;(47):171–80.

54. Satterfield JM, Spring B, Brownson RC, Mullen EJ, Newhouse RP, Walker BB, et al. Toward a Transdisciplinary Model of Evidence-Based Practice. Milbank Q. 2009;87(2):368–90.

55. Haynes RB, Devereaux PJ, Guyatt GH. Clinical expertise in the era of evidence-based medicine and patient choice EBM notebook Clinical expertise in the era of evidence-based medicine and patient choice. 2002;(July 2005):7–10.

56. Townsend, E., & Polatajko H. Enabling occupation II: Advancing an occupational therapy vision for health, well-being, & justice through occupation. Ottawa: CAOT Publishers; 2007.

57. Aldrich B, Cutchin M. Deweys concepts of embodiment, growth and occupation: Extended base for a transactional perspective. In Cutcin & Dickie: Transactional Perspectives on Health. New York: Springer; 2012.

58. Dickie V, Cutchin MP, Humphry R. Occupation as transactional experience: A critique of individualism in occupational science. J Occup Sci. 2006;13(1):83–93.

59. Fritz H, Cutchin MP. The transactional perspective on occupation: A way to transcend the individual in health promotion interventions and research. 2017;7591.

60. Hammell KW. Quality of life, participation and occupational rights: A capabilities perspective. Aust Occup Ther J. 2015;62(2):78–85.

61. Norberg EB, Löfgren B, Boman K, Wennberg P, Brännström M. A client-centred programme focusing energy conservation for people with heart failure. Scand J Occup Ther. 2017 Nov 2;24(6):455–67.

62. Von Bülow C, Amris K, Bandak E, Danneskiold-Samsøe B, Wæhrens EE. Improving activities of daily living ability in women with fibromyalgia: An exploratory, quasi-randomized, phase-two study, improve trial. J Rehabil Med. 2017;49(3):241–50.

63. Nielsen KT, Klokker L, Guidetti S, Wæhrens EE. Identifying, organizing and prioritizing ideas on how to enhance ADL ability. Scand J Occup Ther. 2018;26(5):382–93.

64. Kjeken I, Darre S, Slatkowsky-Cristensen B, Hermann M, Nilsen T, Eriksen CS, et al. Self-management strategies to support performance of daily activities in hand osteoarthritis. Scand J Occup Ther. 2013;20(1):29–36.

65. Norberg EB, Boman K, Löfgren B, Brännström M. Occupational performance and strategies for managing daily life among the elderly with heart failure. Scand J Occup Ther. 2014;21(5):392–9.

66. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. BMJ. 2000 Sep 16;321(7262):694–6.

67. O'Cathain A, Hoddinott P, Lewin S, Thomas KJ, Young B, Adamson J, et al. Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: Guidance for researchers. Pilot Feasibility Stud. 2015;1(1):O88.

68. Moore G, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Guidance on process evaluation of complex interventions. Br Med J. 2015;350:h1258.

69. Craig P, Cooper C, Gunnell D, Haw S, Lawson K, Macintyre S, et al. Using natural experiments to evaluate population health interventions. 2010;(November):29–30.

70. Craig P, Di Ruggiero E, Frolich KL, Mykhalovskiy E, White M, Campbell R, et al. Taking account of context in population health intervention research: guidance for producers, users and funders of research. 2018.

71. Moore G, Campbell M, Copeland L, Craig P, Movsisyan A, Hoddinott P, et al. Adapting interventions to new contexts-the ADAPT guidance. BMJ. 2021;374(fig 1).

72. Fisher A. Occupational Therapy Intervention Process Model - A model for planning and implementing top-down, client-centered and occupation-based interventions. Fort Collins, Colorado, USA: Three Star Press, Inc.; 2009.

73. Strong, S.; Rigby, P.; Stewart, D.; Law, M.; Letts, L.; Cooper B. Application of the Person-Environment-Occupation Model: A

practical tool. Can J Occup Ther. 1999;

74. Wæhrens EE, Nielsen KT. ADL-Interview (ADL-I). Klinisk version 1.0 - Introduktion, ADL-I og administration [Clinical version 1.0 - Introduction, ADL-I, and administration]. ACE Copenhagen. 2020.

75. Fisher AG, Jones KB. Assessment of motor and process skills. Volume 2: User manual. 7th ed. Fort Collins, Colorado, USA: Three Star Press; 2012.

76. Krasny-Pacini A, Hiebel J, Pauly F, Godon S, Chevignard M. Goal Attainment Scaling in rehabilitation: A literature-based update. Ann Phys Rehabil Med. 2013;56(3):212–30.

77. Kiresuk TJ, Smith A, Cardillo JE. Goal Attainment Scaling : Applications, theory, and measurement. Hillsdale, N.J.: L. Erlbaum Associates; 1994.

78. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. Bmj. 2015;350(mar19 6):h1258–h1258.

79. Pawson R. The Science of Evalation. A realist manifesto. SAGE Publications; 2013.

80. Greenhalgh T, Papoutsi C. Studying complexity in health services research: desperately seeking an overdue paradigm shift. BMC Med. 2018;16:95.

81. Vedung E. Four waves of evaluation diffusion. Evaluation. 2010;16(3):263–77.

82. Krogstrup HK. Kampen om evidens [The struggle for evidence]. Hans Reitzels Forlag; 2011.

83. Bredgaard T. Evaluering af offentlig politik og administration [Evaluation of public policy and administration]. Kbh.: Hans Reitzel; 2016. 375 sider.

84. Vedung E. Fire evalueringsbølger [Four waves of evaluation]. In: Bredgaard Thomas, editor. Evaluering af offentlig politik og administration [Evaluation of public policy and administration]. Hans Reitzels Forlag; 2016. p. 37–68.

85. Wong G, Westhorp G, Manzano A, Greenhalgh J, Jagosh J, Greenhalgh T. RAMESES II reporting standards for realist evaluations. BMC Med. 2016;14(1):1–18.

86. The RAMESES Projects [Internet]. [cited 2022 Jan 9]. Available from: https://www.ramesesproject.org/

87. Greenhalgh T, Wong G, Jagosh J, Greenhalgh J, Manzano A, Westhorp G, et al. Protocol-the RAMESES II study: Developing

guidance and reporting standards for realist evaluation. BMJ Open. 2015;5(8).

88. Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer) group [Internet]. [cited 2022 Jan 9]. Available from: https://decipher.uk.net/

89. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. BMJ. 2021;374(2018):1–11.

90. Pawson R, Tilley N. Realistic evaluation. Reprint. London: Sage; 1997. xvii, 235 s., illustreret.

91. Westhorp G. Realist Impact Evaluation. Res Policy Dev. 2014;(September):1–12.

92. The RAMESES II Project. RAMESES II Context Report. 2017;1–4.

93. Salter KL, Kothari A. Using realist evaluation to open the black box of knowledge translation: A state-of-the-art review. Implement Sci. 2014;9(1):1–14.

94. Dalkin SM, Greenhalgh J, Jones D, Cunningham B, Lhussier M. What's in a mechanism? Development of a key concept in realist evaluation. Implement Sci. 2015;10(1):1–7.

95. Nielsen K, Bang M, Pilegaard M, Hagelskjær V, Wæhrens E. Perspectives on content and delivery of the ABLE 1.0. intervention program. Unpubl Work.

96. Nielsen KT, Hagelskjær V, Pilegaard MS, von Bülow C, Wæhrens EE. The development of the A better Everyday LifE (ABLE) intervention program. Unpubl Work.

97. Willis Gordon B. Cognitive Interviewing. Sage Publications; 2011.

98. Wild D, Alyson G, Mona M, Sonya E, Sandra M, Verjee-Lorenz A, et al. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures. Value Heal. 2005;8(2):95–104.

99. Bonsaksen T, Kvarsnes H, Eirum MN, Torgrimsen S, Hussain RA. Development and content validity of the Norwegian Self-Assessment of Modes Questionnaire (N-SAMQ). Scand J Occup Ther. 2016;23(4):253–9.

100. Avery KNL, Williamson PR, Gamble C, Francischetto EOC, Metcalfe C, Davidson P, et al. Informing efficient randomised controlled trials: Exploration of challenges in developing progression criteria for internal pilot studies. BMJ Open. 2017;7(2).

101. Charlesworth G, Burnell K, Hoe J, Orrell M, Russell I. Acceptance checklist for clinical effectiveness pilot trials: A systematic approach. BMC Med Res Methodol. 2013;13(1).

102. Fletcher A, Jamal F, Moore G, Evans RE, Murphy S, Bonell C. Realist complex intervention science: Applying realist principles across all phases of the Medical Research Council framework for developing and evaluating complex interventions. Evaluation. 2016;22(3):286–303.

103. Mansoor A. F. Kazi & Lucy J. Spurling. Realist Evaluation for evidence-based practice. Pap Present Eur Eval Soc Fourth Conf Lausanne, Switzerland, Oct 2000.

104. Hagelskjær V, Nielsen KT, von Bülow C, Graff M, Wæhrens EE. Occupational therapy addressing the ability to perform activities of daily living among persons living with chronic conditions: a randomised controlled pilot study of ABLE 2.0. Pilot Feasibility Stud. 2021;7(1):122.

105. Nielsen KT, Hagelskjær V, Wæhrens EE. Manual: ABLE 2.0 - et ergoterapeutisk interventionsprogram for personer med kroniske tilstande [ABLE 2.0 - an occupational therapy intervention programme for persons with chronic conditions]. Unpubl Work. 2020;

106. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348(March):1–12.

107. Erlen JA, Tamres LK, Reynolds N, Golin CE, Rosen MI, Remien RH, et al. Assessing Usual Care in Clinical Trials. West J Nurs Res. 2015;37(3):288–98.

108. Yorganci E, Evans CJ, Johnson H, Barclay S, Murtagh FEM, Yi D, et al. Understanding usual care in randomised controlled trials of complex interventions: A multi-method approach. Palliat Med. 2020;667–79.

109. Gill TK, Broderick D, Avery JC, Dal Grande E, Taylor AW. Self reported overall health status: Implications for intervention strategies. Australas Med J. 2009;2(8):44–57.

110. Moore GF, Raisanen L, Moore L, Din NU, Murphy S. Mixed-method process evaluation of the Welsh National Exercise Referral Scheme. Health Educ. 2013;113(6):476–501.

111. Manzano A. The craft of interviewing in realist evaluation. Evaluation. 2016;22(3):342–60.

112. Hagelskjær V, Nielsen KT, von Bulow C, Oestergaard LG, Graff M,

Wæhrens EE. Evaluating a complex intervention addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a randomised controlled trial (ABLE). BMJ Open. 2021;11(11):e051722.

113. Winkel A, Langberg H, Wæhrens EE. Reablement in a community setting. Disabil Rehabil. 2015;37(15):1347–52.

114. OT Assessment Package (OTAP). Fort Cloons, Colorado, USA: Center for Innovative OT Solutions; 2016.

115. Merritt BK. Utilizing AMPS ability measures to predict level of community dependence. Scand J Occup Ther. 2010;17(1):70–6.

116. Moore K, Merritt B, Doble SE. ADL skill profiles across three psychiatric diagnoses. Scand J Occup Ther. 2010;17(1):77–85.

117. Von Bülow C, Amris K, La Cour K, Danneskiold-Samsøe B, Wæhrens EE. Ineffective ADL skills in women with fibromyalgia: a cross-sectional study. Scand J Occup Ther. 2016;23(5):391–7.

118. Wæhrens EE, Amris K, Fisher AG. Performance-based assessment of activities of daily living (ADL) ability among women with chronic widespread pain. Pain. 2010;150(3):535–41.

119. Ellegaard K, von Bülow C, Røpke A, Bartholdy C, Hansen IS, Rifbjerg-Madsen S, et al. Hand exercise for women with rheumatoid arthritis and decreased hand function: An exploratory randomized controlled trial. Arthritis Res Ther. 2019;21(1):1–9.

120. Toto PE, Skidmore ER, Terhorst L, Rosen J, Weiner DK. Goal attainment scaling (GAS) in geriatric primary care: A feasibility study. Arch Gerontol Geriatr. 2015;60(1):16–21.

121. Statistical Solutions, Saugus, MA U. nQuery Advisor®, version 8.5.0.0. computer program [Internet]. [cited 2021 Jan 20]. Available from: https://www.statsols.com/

122. Detry MA, Ma Y. Analyzing repeated measurements using mixed models. JAMA - J Am Med Assoc. 2016;315(4):407–8.

123. Little RJ, Ph D, Agostino RD, Ph D, Cohen ML, Ph D, et al. The Prevention and Treatment of Missing Data in Clinical Trials. 2012;367:1355–60.

124. IBM Corp. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.;

125. The RAMESES II Project. Retroduction in realist evaluation. Nihr. 2017;(p 207):1–3.

126. Gilmore B, McAuliffe E, Power J, Vallières F. Data Analysis and Synthesis Within a Realist Evaluation: Toward More Transparent

Methodological Approaches. Int J Qual Methods. 2019;18:1–11.

127. Ravn R. Testing mechanisms in large-N realistic evaluations. Evaluation. 2019;25(2):171–88.

128. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, et al. Interpreting the Clinical Importance of Treatment Outcomes in Chronic Pain Clinical Trials: IMMPACT Recommendations. J Pain. 2008;9(2):105–21.

129. Nielsen TL, Andersen NT, Petersen KS, Polatajko H, Nielsen CV. Intensive client-centred occupational therapy in the home improves older adults' occupational performance. Results from a Danish randomized controlled trial. Scand J Occup Ther. 2018;0(0):1–17.

130. von Bülow C. Development and Evaluation of an Adaptational Program, Occupational Therapy for People with Chronic Health Conditions. PhD thesis. Southern Denmark University; 2015.

131. Amris K, Wæhrens EE, Christensen R, Bliddal H, Danneskiold-Samsøe B. Interdisciplinary rehabilitation of patients with chronic widespread pain: Primary endpoint of the randomized, nonblinded, parallel-group IMPROvE trial. Pain. 2014;155(7):1356–64.

132. Larsen AE, Christensen JR, Wehberg S. The responsiveness of the Danish version of the Canadian Occupational Performance Measure. Br J Occup Ther. 2022;

133. Poole JL, Atanasoff G, Pelsor JC, Sibbitt WL. Comparison of a self-report and performance-based test of disability in people with systemic lupus erythematosus. Disabil Rehabil. 2006;28(10):653–8.

134. Reneman MF, Jorritsma W, Schellekens JMH, Göeken LNH. Concurrent validity of questionnaire and performance-based disability measurements in patients with chronic nonspecific low back pain. J Occup Rehabil. 2002;12(3):119–29.

135. Wittink H, Rogers W, Sukiennik A, Carr DB. Physical functioning: Self-report and performance measures are related but distinct. Spine (Phila Pa 1976). 2003;28(20):2407–13.

136. Prochaska JO, DiClimente C. Stages and processes of self-change of smoking: Toward an integrative model of change. ournal Consult Clin Psychol. 1983;51(3):390–5.

137. Funnell SC, Rogers PJ. Purposeful Program Theory : Effective Use of Theories of Change and Logic Models. San Francisco, CA : Jossey-Bass; 2011.

138. Anker SD, Agewall S, Borggrefe M, Calvert M, Caro JJ, Cowie MR, et al. The importance of patient-reported outcomes: A call for their comprehensive integration in cardiovascular clinical trials. Eur Heart

J. 2014;35(30):2001–9.

139. Valderas AJM, Kotzeva A, Espallargues M, Guyatt G, Ferrans CE, Revicki DA, et al. The Impact of Measuring Patient-Reported Outcomes in Clinical Practice: A Systematic Review of the Literature. 2008;17(2):179–93.

140. England NHS. 01| BITE-SIZE GUIDE TO PATIENT INSIGHT. THE NATIONAL PATIENT REPORTED OUTCOME MEASURES (PROMS) PROGRAMME [Internet]. [cited 2022 Feb 11]. Available from: https://www.england.nhs.uk/wp-content/uploads/2018/08/proms-guide-aug-18-v3.pdf

141. Greenhalgh J, Meadows K. The effectiveness of the use of patient-based measures of health in routine practice in improving the process and outcomes of patient care: A literature review. J Eval Clin Pract. 1999;5(4):401–16.

142. Latham NK, Mehta V, Nguyen AM, Jette AM, Olarsch S, Papanicolaou D, et al. Performance-Based or Self-Report Measures of Physical Function: Which Should Be Used in Clinical Trials of Hip Fracture Patients? Arch Phys Med Rehabil. 2008;89(11):2146–55.

143. Abraha I, Cherubini A, Cozzolino F, De Florio R, Luchetta ML, Rimland JM, et al. Deviation from intention to treat analysis in randomised trials and treatment effect estimates: Meta-epidemiological study. BMJ. 2015;350.

144. Hidding A. Comparison between self-report measures and clinical observations of functional disability in ankylosing spondylitis. J Rheumatol. 1994;21(5):818–23.

145. Greenhalgh J, Gooding K, Gibbons E, Dalkin S, Wright J, Valderas J, et al. How do patient reported outcome measures (PROMs) support clinician-patient communication and patient care? a realist synthesis. J Patient-Reported Outcomes. 2018;2.

146. Shaw Y, Zhang C, Bradley M, Simon TA, Schumacher R, McDonald D, et al. Acceptability and Content Validity of Patient-Reported Outcome Measures Considered From the Perspective of Patients With Rheumatoid Arthritis. Arthritis Care Res. 2021;73(4):510–9.

147. Fritz H, Cutchin M. Integrating the science of habit: Opportunities for occupational therapy. OTJR Occup Particip Heal. 2016;36(2):92–8.

148. Neal DT, Wood W, Drolet A. How do people adhere to goals when willpower is low? The profits (and pitfalls) of strong habits. J Pers Soc Psychol. 2013;104(6):959–75.

149. Fritz HA. Learning to do Better: The Transactional Model of Diabetes Self-Management Integration. Qual Health Res. 2015;25(7):875–86.

150. Caldwell DF, Chatman J, O'Reilly CA, Ormiston M, Lapiz M. Implementing strategic change in a health care system. Health Care Manage Rev. 2008;33(2):124–33.

151. Vermunt NPCA, Harmsen M, Westert GP, Olde Rikkert MGM, Faber MJ. Collaborative goal setting with elderly patients with chronic disease or multimorbidity: A systematic review. BMC Geriatr. 2017;17(1):1–12.

152. Ranner M, Von Koch L, Guidetti S, Tham K. Client-centred ADL intervention after stroke: Occupational therapists experiences. Scand J Occup Ther. 2016;23(2):81–90.

153. Kessler D, Walker I, Sauvé-Schenk K, Egan M. Goal setting dynamics that facilitate or impede a client-centered approach. Scand J Occup Ther. 2019;26(5):315–24.

154. Cameron LJ, Somerville LM, Naismith CE, Watterson D, Maric V, Lannin NA. A qualitative investigation into the patient-centered goal-setting practices of allied health clinicians working in rehabilitation. Clin Rehabil. 2018;32(6):827–40.

155. Wade DT. Goal setting in rehabilitation: An overview of what, why and how. Clin Rehabil. 2009;23(4):291–5.

156. Taylor RR. The intentional relationship: occupational therapy and the use of self. Philadelphia (PA): F.A. Davis Co.; 2008.

157. Gunnarsson AB, Eklund M. The tree theme method as an intervention in psychosocial occupational therapy: Client acceptability and outcomes. Aust Occup Ther J. 2009;56(3):167–76.

158. Palmadottir G. Client-therapist relationships: Experiences of occupational therapy clients in rehabilitation. Br J Occup Ther. 2006;69(9):394–401.

159. Cole MB, McLean V. Therapeutic Relationships Re-defined. Learn about Ment Heal Pract. 2003;19 (2):33–56.

160. Taylor RR, Lee SW, Kielhofner G, Ketkar M. Therapeutic use of self: A nationwide survey of Practitioners' attitudes and experiences. Am J Occup Ther. 2009;63(2):198–207.

161. McDonald A, Sherlock J. A long and winding road. Improving communication with patients in the NHS. London: Marie Curie. 2016;

162. Street RL. How clinician-patient communication contributes to health improvement: Modeling pathways from talk to outcome. Patient Educ Couns. 2013;92(3):286–91.

163. White C, Lentin P, Farnworth L. 'I know what I am doing': A grounded theory investigation into the activities and occupations of

adults living with chronic conditions. Scand J Occup Ther. 2019;0(0):1–10.

164. Yerxa E. Oversimplification: The Hobgoblin of Theory and Practice in Occupational Therapy. Can J Occup Ther. 1988;55(4):161–2.

165. Michelet M, Lund A, Sveen U. Strategies to recruit and retain older adults in intervention studies: A quantitative comparative study. Arch Gerontol Geriatr. 2014;59(1):25–31.

Appendix 1 Intra-group comparison of hypothesised context-mechanism-outcome configurations

CMO a) Relationship and collaboration (session 1-8; n=144) **Context[1]:** ABLE is delivered by an OT feeling engaged[a] (C1) and prepared[a] (C2) to deliver session content to a client motivated for making changes[b] (C3) … **Mechanism:** activates a therapeutic relationship[e] (M1) and the client finding the programme meaningful[c] (M2) and satisfactory[c] (M3) … **Outcome:** leading to client staying in the programme[a2] (O1) and increased ADL ability[d3] (O2)			
Strength of client finding programme meaningful (M2)	**Client staying in programme (O1) low extent**	**Client staying in programme (O1) high extent**	**Total n (%)**
Strong: n (%)	4 (3)	124 (97)	128 (100)
Weak: n (%)	0 (0)	5 (100)	5 (100)
Delivered sessions with complete data, n	4	129	133 (100)
Strength of client finding programme meaningful (M2)	**Increased ADL ability (O2) low extent**	**Increased ADL ability (O2) high extent**	**Total n (%)**
Strong: n (%)	48 (37)	80 (63)	128 (100)
Weak: n (%)	2 (40)	3 (60)	5 (100)
Delivered sessions with complete data, n	50	83	133 (100)
Strength of client finding programme satisfactory (M3)	**Client staying in programme (O1) low extent**	**Client staying in programme (O1) high extent**	**Total n (%)**
Strong: n (%)	4 (3)	128 (97)	132 (100)
Weak: n (%)	0 (0)	3 (100)	3 (100)
Delivered sessions with complete data, n	4	131	135 (100)
Strength of client finding programme satisfactory (M3)	**Increased ADL ability (O2) low extent**	**Increased ADL ability (O2) high extent**	**Total n (%)**
Strong: n (%)	52 (39)	80 (61)	132 (100)
Weak: n (%)	0 (0)	3 (100)	3 (100)
Delivered sessions with complete data, n	52	83	135 (100)
CMO b) Valid assessment (session 1, n=33) **Context[1]:** OT conducts valid occupation-focused and /or occupation-based assessments in the client's home[a] (C1), taking client's perspectives into account[a] (C2) … **Mechanism:** activates client getting a deeper understanding of his/ her problems related to ADL task performance[c] (M1) and feeling informed[c] (M2) and involved[c] (M3) … **Outcome:** leading to occupation-focused and/or occupation-based starting point[a] (O1), client finding participation in session 1 satisfactory[c] (O2), and client finding the content of session 1 meaningful[c] (O3)			
Strength of client getting a deeper understanding of his/her ADL problems (M1)	**Occupation-focused and/or occupation-based starting point (O1) low extent**	**Occupation-focused and/or occupation-based starting point (O1) high extent**	**Total n (%)**
Strong: n (%)	4 (17)	19 (83)	23 (100)

Weak: n (%)	3 (33)	6 (67)	9 (100)
Delivered session 1 with complete data, n	7	25	32 (100)
Strength of client getting a deeper understanding of his/her ADL problems (M1)	**Client finding participation in session 1 satisfactory (O2) low extent**	**Client finding participation in session 1 satisfactory (O2) high extent**	**Total n (%)**
Strong: n (%)	0 (0)	23 (100)	23 (100)
Weak: n (%)	0 (0)	9 (100)	9 (100)
Delivered session 1 with complete data, n	0	32	32 (100)
Strength of client getting a deeper understanding of his/her ADL problems (M1)	**Client finding the content of session 1 meaningful (O3) low extent**	**Client finding the content of session 1 meaningful (O3) high extent**	**Total n (%)**
Strong: n (%)	0 (0)	22 (100)	22 (100)
Weak: n (%)	1 (11)	8 (89)	9 (100)
Delivered session 1 with complete data, n	1	30	31 (100)
Strength of client feeling informed (M2)	**Occupation-focused and/or occupation-based starting point (O1) low extent**	**Occupation-focused and/or occupation-based starting point (O1) high extent**	**Total n (%)**
Strong: n (%)	6 (20)	24 (80)	30 (100)
Weak: n (%)	1 (50)	1 (50)	2 (100)
Delivered session 1 with complete data, n	7	25	32 (100)
Strength of client feeling informed (M2)	**Client finding participation in session 1 satisfactory (O2) low extent**	**Client finding participation in session 1 satisfactory (O2) high extent**	**Total n (%)**
Strong: n (%)	0 (0)	30 (100)	30 (100)
Weak: n (%)	0 (0)	2 (100)	2 (100)
Delivered session 1 with complete data, n	0	32	32 (100)
Strength of client feeling informed (M2)	**Client finding the content of session 1 meaningful (O3) low extent**	**Client finding the content of session 1 meaningful (O3) high extent**	**Total n (%)**
Strong: n (%)	1 (3)	28 (97)	29 (100)
Weak: n (%)	0 (0)	2 (100)	2 (100)
Delivered session 1 with complete data, n	1	30	31 (100)
Strength of client feeling involved (M3)	**Occupation-focused and/or occupation-based starting point (O1) low extent**	**Occupation-focused and/or occupation-based starting point (O1) high extent**	**Total n (%)**
Strong: n (%)	7 (23)	24 (77)	31 (100)
Weak: n (%)	0 (0)	0 (0)	0 (100)
Delivered session 1 with complete data, n	7	24	31 (100)

Strength of client feeling involved (M3)	**Client finding participation in session 1 satisfactory (O2) low extent**	**Client finding participation in session 1 satisfactory (O2) high extent**	**Total n (%)**
Strong: n (%)	0 (0)	31 (100)	31 (100)
Weak: n (%)	0 (0)	0 (0)	0 (100)
Delivered session 1 with complete data, n	0	31	31 (100)
Strength of client feeling involved (M3)	**Client finding the content of session 1 meaningful (O3) low extent**	**Client finding the content of session 1 meaningful (O3) high extent**	**Total n (%)**
Strong: n (%)	1 (3)	29 (97)	30 (100)
Weak: n (%)	0 (0)	0 (0)	0 (100)
Delivered session 1 with complete data, n	1	29	30 (100)
CMO c) Goal setting (session 2, n=29) **Context[1]:** OT and client together define occupation-focused goals[a] (C1) and clarify causes for ADL problems[a] (C2) … **Mechanism:** activates client feeling involved[c] (M1) … **Outcome:** leading to relevant goals[e] (O1) client finding participation in session 2 satisfactory[c] (O2) and client finding the content of session 2 meaningful[c] (O3)			
Strength of client feeling involved (M1)	**Client finding participation in session 2 satisfactory (O2) low extent**	**Client finding participation in session 2 satisfactory (O2) high extent**	**Total n (%)**
Strong: n (%)	0 (0)	27 (100)	27 (100)
Weak: n (%)	0 (0)	0 (0)	0 (100)
Delivered session 2 with complete data, n	0	27	27 (100)
Strength of client feeling involved (M1)	**Client finding the content of session 2 meaningful (O3) low extent**	**Client finding the content of session 2 meaningful (O3) high extent**	**Total n (%)**
Strong: n (%)	0 (0)	26 (100)	26 (100)
Weak: n (%)	0 (0)	0 (0)	0 (100)
Delivered session 2 with complete data, n	0	26	26 (100)
CMO d) Interventions (adaptational approach) (session 3-7, n=53) **Context[1]:** Adaptive intervention components delivered in the client's home (including optional homework)[a] (C1), delivered by OT familiar with components and acting as facilitator of change[a] (C2) … **Mechanism:** activates collaboration between client and OT on finding solutions[a] (M1) and client being willing to try solutions during performance of ADL tasks[a] (M2) … **Outcome:** leading to commencing goal attainment[c] (O1), client finding participation in programme purposeful[c] (O2), client finding participation in session 3–7 satisfactory[c] (O3), and client finding the content of session 3–7 meaningful[c] (O4)			
Strength of collaboration between client and OT on finding solutions (M1)	**Commencing goal attainment (O1) low extent**	**Commencing goal attainment (O1) high extent**	**Total n (%)**

Strong: n (%)	3 (7)	42 (93)	45 (100)
Weak: n (%)	0 (0)	2 (100)	2 (100)
Delivered session 3-7 with complete data, n	3	44	47 (100)
Strength of collaboration between client and OT on finding solutions (M1)	**Client finding participation in programme purposeful (O2) low extent**	**Client finding participation in programme purposeful (O2) high extent**	**Total n (%)**
Strong: n (%)	2 (4)	43 (96)	45 (100)
Weak: n (%)	0 (0)	2 (4)	2 (100)
Delivered session 3-7 with complete data, n	2	45	47 (100)
Strength of collaboration between client and OT on finding solutions (M1)	**Client finding participation in session 3–7 satisfactory (O3) low extent**	**Client finding participation in session 3–7 satisfactory (O3) high extent**	**Total n (%)**
Strong: n (%)	1 (2)	43 (98)	44 (100)
Weak: n (%)	0 (0)	2 (100)	2 (100)
Delivered session 3-7 with complete data, n	1	45	46 (100)
Strength of collaboration between client and OT on finding solutions (M1)	**Client finding the content of session 3–7 meaningful (O4) low extent**	**Client finding the content of session 3–7 meaningful (O4) high extent**	**Total n (%)**
Strong: n (%)	2 (5)	41 (95)	43 (100)
Weak: n (%)	0 (0)	2 (5)	2 (100)
Delivered session 3-7 with complete data, n	2	43	45 (100)
Strength of client being willing to try solutions during performance of ADL tasks (M2)	**Commencing goal attainment (O1) low extent**	**Commencing goal attainment (O1) high extent**	**Total n (%)**
Strong: n (%)	3 (7)	38 (93)	41 (100)
Weak: n (%)	0 (0)	6 (14)	6 (100)
Delivered session 3-7 with complete data, n	3	44	47 (100)
Strength of client being willing to try solutions during performance of ADL tasks (M2)	**Client finding participation in programme purposeful (O2) low extent**	**Client finding participation in programme purposeful (O2) high extent**	**Total n (%)**
Strong: n (%)	2 (5)	39 (95)	41 (100)
Weak: n (%)	0 (0)	6 (100)	6 (100)
Delivered session 3-7 with complete data, n	2	45	47 (100)
Strength of client being willing to try solutions during performance of ADL tasks (M2)	**Client finding participation in session 3–7 satisfactory (O3) low extent**	**Client finding participation in session 3–7 satisfactory (O3) high extent**	**Total n (%)**
Strong: n (%)	1 (2)	39 (98)	40 (100)
Weak: n (%)	0 (0)	6 (100)	6 (100)

Delivered session 3-7 with complete data, n	1	45	46 (100)
Strength of client being willing to try solutions during performance of ADL tasks (M2)	**Client finding the content of session 3–7 meaningful (O4) low extent**	**Client finding the content of session 3–7 meaningful (O4) high extent**	**Total n (%)**
Strong: n (%)	2 (5)	37 (95)	39 (100)
Weak: n (%)	0 (0)	6 (100)	6 (100)
Delivered session 3-7 with complete data, n	2	43	45 (100)
CMO e) Reevaluation (final session, n=29; goals defined, n=67) **Context**[1]**:** Client gets feedback on goal attainment and obtained changes[a] (C1) … **Mechanism:** activates motivation for integrating the new methods of doing into everyday life routines[c] (M1) … **Outcome:** leading to goal attainment[a4] (O1), measurable changes in perceived and/or observed ADL task performance[d5] (O2a, O2b), and satisfaction with obtained ADL ability[d6] (O3a, O3b)			
Strength of client expecting to carry on using the new solutions (M1)	**Goal attainment (O1) low extent**	**Goal attainment (O1) high extent**	**Total n (%)**
Strong: n (%)	5 (8)	55 (92)	60 (100)
Weak: n (%)	1 (50)	1 (50)	2 (100)
Goals defined with complete data, n=67	6	56	62 (100)
Strength of client expecting to carry on using the new solutions (M1)	**Measurable changes in perceived and/or observed ADL task performance (week 0-10) (O2a) low extent**	**Measurable changes in perceived and/or observed ADL task performance (week 0-10) (O2a) high extent**	**Total n (%)**
Strong: n (%)	14 (52)	13 (48)	27 (100)
Weak: n (%)	0 (0)	1 (100)	1 (100)
Delivered final session with complete data, n=	14	14	28 (100)
Strength of client expecting to carry on using the new solutions (M1)	**Measurable changes in perceived and/or observed ADL task performance (week 0-26) (O2b) low extent**	**Measurable changes in perceived and/or observed ADL task performance (week 0-26) (O2b) high extent**	**Total n (%)**
Strong: n (%)	10 (45)	12 (55)	22 (100)
Weak: n (%)	0 (0)	1 (100)	1 (100)
Delivered final session, n=	10	13	23 (100)
Strength of client expecting to carry on using the new solutions (M1)	**Satisfaction with obtained ADL ability (week 0-10) (O3a) low extent**	**Satisfaction with obtained ADL ability (week 0-10) (O3a) high extent**	**Total n (%)**
Strong: n (%)	21 (78)	6 (22)	27 (100)
Weak: n (%)	1 (100)	0 (0)	1 (100)
Delivered final session, n=	22	6	28 (100)

Strength of client expecting to carry on using the new solutions (M1)	Satisfaction with obtained ADL ability (week 0-26) (O3b) low extent	Satisfaction with obtained ADL ability (week 0-26) (O3b) high extent	Total n (%)
Strong: n (%)	21 (84)	4 (16)	25 (100)
Weak: n (%)	0 (0)	1 (100)	1 (100)
Delivered final session, n=	21	5	26 (100)

Abbreviations:
ABLE, intervention programme; ADL, activities of daily living; CMO, context-mechanism-outcomes; OT, occupational therapist

Data sources:
[a] OT registration form
[b] assessed at recruitment
[c] client registration form
[d] effectiveness evaluation
[e] no data

Comments and definitions:
[1] Contextual factors were all over scored to be present to a high degree (hence were left out, not used as layers)
[2] Client staying in programme was defined as having received ≥ 3 sessions
[3] Increased ADL ability was defined as clinically relevant change in AMPS ADL motor ability and/or ADL-I performance from baseline (week 0) to week 10 measured in the effectiveness evaluation
[4] Goal attainment was defined as having obtained the expected level in GAS (low extent < level 0; high extent ≥ level 0)
[5] Measurable changes in perceived and/or observed ADL ability was defined as clinically relevant change in AMPS motor ADL ability and/or ADL-I performance from baseline (week 0) to week 10 (i.e. O2a); or from week 0 to week 26 (i.e. O2b) measured in the effectiveness evaluation
[6] Satisfaction with obtained ADL ability was defined as clinically relevant change in ADL-I satisfaction from baseline (week 0) to week 10 (i.e. O3a); or from baseline (week 0) to week 26 (i.e. O3b) measured in the effectiveness evaluation (low extent < 0.63; high extent ≥ 0.63)

Paper I

BMJ Open

Evaluating a complex intervention addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a randomised controlled trial (ABLE)

Vita Hagelskjær ,[1,2,3] Kristina Tomra Nielsen ,[1,4] Cecilie von Bulow,[1,2] Lisa Gregersen Oestergaard ,[2,5,6] Maud Graff,[7] Eva Ejlersen Wæhrens[1,2]

To cite: Hagelskjær V, Nielsen KT, von Bulow C, *et al*. Evaluating a complex intervention addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a randomised controlled trial (ABLE). *BMJ Open* 2021;**11**:e051722. doi:10.1136/bmjopen-2021-051722

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-051722).

Received 29 March 2021
Accepted 01 November 2021

For numbered affiliations see end of article.

Correspondence to
Dr Vita Hagelskjær;
vita.hagelskjaer@regionh.dk

ABSTRACT

Introduction The need to develop and evaluate interventions, addressing problems performing activities of daily living (ADL) among persons with chronic conditions, is evident. Guided by the British Medical Research Council's guidance on how to develop and evaluate complex interventions, the occupational therapy programme (ABLE) was developed and feasibility tested. The aim of this protocol is to report the planned design and methods for evaluating effectiveness, process and cost-effectiveness of the programme.

Methods and analysis The evaluation is designed as a randomised controlled trial with blinded assessors and investigators. Eighty participants with chronic conditions and ADL problems are randomly allocated to ABLE or usual occupational therapy. Data for effectiveness and cost-effectiveness evaluations are collected at baseline (week 0), post intervention (week 10) and follow-up (week 26). Coprimary outcomes are self-reported ADL ability (ADL-Interview (ADL-I) performance) and observed ADL motor ability (Assessment of Motor and Process Skills (AMPS)). Secondary outcomes are perceived satisfaction with ADL ability (ADL-I satisfaction); and observed ADL process ability (AMPS). Explorative outcomes are occupational balance (Occupational Balance Questionnaire); perceived change (Client-Weighted Problems Questionnaire) and general health (first question of the MOS 36-item Short Form Survey Instrument). The process evaluation is based on quantitative data from registration forms and qualitative interview data, collected during and after the intervention period. A realist evaluation approach is applied. A programme theory expresses how context (C) and mechanisms (M) in the programme may lead to certain outcomes (O), in so-called CMO configurations. Outcomes in the cost-effectiveness evaluation are quality-adjusted life years (EuroQool 5-dimension) and changes in ADL ability (AMPS, ADL-I). Costs are estimated from microcosting and national registers.

Ethics and dissemination Danish Data Protection Service Agency approval: Journal-nr.: P-2020-203. The Ethical Committee confirmed no approval needed: Journal-nr.: 19045758. Dissemination for study participants, in peer-reviewed journals and conferences.

Strengths and limitations of this study

- The occupational therapy intervention programme (ABLE 2.0) is developed based on research evidence, client perspectives and clinical experience, resulting in a programme applicable across gender, age and chronic conditions, aiming at enhancing the ability to perform activities of daily living among persons living with chronic conditions.
- This protocol, informed by two previous studies, covers the evaluation of ABLE 2.0 in terms of effectiveness, process and cost-effectiveness, using a randomised controlled trial design.
- Conducting this trial, comprising three evaluations alongside each other, in a community-based rehabilitation setting involving clinicians in assessment and intervention represents challenges on blinding, adherence, inclusion procedures and outcomes assessment.
- Conducting this trial in a clinical setting, including clients, already referred to rehabilitation and offering an intervention programme delivered by occupational therapists employed in the municipality, increase the external validity of the study findings.
- The study is part of the research programme "A Better Everyday Life' systematically following the British Medical Research Council's guidance on how to develop and evaluate complex interventions, supporting the choice of appropriate methods.

Trial registration number NCT04295837

INTRODUCTION

Existing research have documented the need to develop, evaluate and implement evidence-based occupational therapy interventions, directly focusing on enhancing ability to perform activities of daily living (ADL) tasks among persons living with chronic conditions.[1–4] Consequently, the research programme 'A Better Everyday Life'

was established to develop and evaluate such an intervention programme.

Recent statistics from the WHO estimate that 71% of all deaths worldwide is caused by chronic conditions,[5] with the four most common being cardiovascular diseases, cancer, chronic respiratory diseases and diabetes. Further, a recent study revealed that more than 65% of the Danish population, aged 16 or above, live with one or more chronic conditions.[6] However, the probability of dying from one of these diseases between the ages of 30 and 70 decreased globally by 18% between 2000 and 2016,[5] leaving an increasing number of persons living with such diseases. This entails an increasing financial burden for community-based rehabilitation services[7–9] and potentially decreased quality of life for the persons concerned.

Chronic conditions have been defined as 'conditions that last a year or more and require ongoing medical attention and/or limit ADL'.[10] Performing ADL tasks is a widespread problem among persons living with chronic conditions.[11–18] ADL involve tasks that most people need to perform in their everyday lives, including personal and instrumental ADL tasks.[19] Personal ADL involve basic self-care tasks necessary to perform for all people across gender, age, culture and interests, for example, eating, toileting, grooming and dressing. Instrumental ADL tasks involve more complex household chores, necessary for independent living, including shopping, cooking, cleaning and doing laundry.[20] Persons living with chronic conditions report increased physical effort, increased use of time, safety risks and need for assistance when performing both personal and instrumental ADL tasks, reflecting decreased quality of performance.[11 13 14] Decreased quality in performance of ADL tasks may cause reduced energy and time for participation and engagement in other types of wanted and/or needed activities including work, leisure and social life[21]; resulting in occupational imbalance, that is, an experience of not having the right amount of and variation in daily activities.[22] Adressing such ADL task performance problems, among persons with various diseases, is a core area for occupational therapy.

Research suggests that occupational therapy interventions in general may improve ADL ability among older persons with chronic conditions.[1 2 4 23] Further, research provides evidence to support a structured and individualised problem-solving process applied as a part of the occupational therapy process.[1 2] Occupational therapy interventions have been designed for specific diagnostic groups, for example, persons with Parkinson's disease or dementia.[18 24] Still, research investigating the effectiveness and functioning of occupational therapy interventions for persons with various chronic conditions, detailed description of the intervention, and determination of the contribution of occupational therapy in multidisciplinary rehabilitation services is needed.[2 4 18 23 25]

Based on a scoping review on occupational therapy for chronic conditions, Hand *et al*[2] suggested that similar interventions addressing ADL may be applicable across a range of diagnoses. To investigate this further, our research group examined self-reported quality of ADL tasks performance among n=593 persons living with chronic conditions, and found similar types of ADL task performance problems across chronic conditions.[26 27] Accordingly, the first version of an occupational therapy intervention programme (termed ABLE 1.0) was developed, addressing decreased ADL ability across chronic conditions causing disability. To our knowledge, ABLE 1.0 is the first intervention programme addressing ADL task performance problems, for use across gender, age and chronic conditions. The idea of using a programme applicable across gender, age and chronic conditions is in accordance with Wade's[28] bio-psycho-social approach within rehabilitation, suggesting to focus on limitations in relation to activities rather than diagnosis during the process of rehabilitation.

The development and evaluation of the ABLE intervention programme is guided by the British Medical Research Council's (MRC) guidance on how to develop and evaluate complex interventions.[29] The guidance prescribes four stages: development, feasibility/piloting, evaluation and implementation.[29] The first phase of the research programme was conducted during 2015–2018 focusing on the development and feasibility of ABLE 1.0[21 27 30]. This resulted in an 8-week occupational therapy programme, applicable across gender, age and chronic conditions, and addressing ADL task performance problems among persons living with chronic conditions at home. It consists of five to eight individualised sessions, based on an adaptational approach. The programme flexibly allows an individualised approach by employing a combination of intervention components adapted to the single client, the types of ADL task performance problems and the local settings. The programme is designed as a home-based service to be implemented as part of community-based rehabilitation.

The feasibility study showed that ABLE 1.0 was feasible in terms of content and delivery with minor adjustments to the intervention manual and recruitment procedures.[30] Accordingly, the intervention manual was revised, resulting in ABLE 2.0. Following the feasibility study, a randomised controlled pilot study was conducted in the same context as the potential full-scale trial. The pilot study assessed feasibility in terms of trial procedures, adherence, appropriateness of additional outcome measurements and accessability to information on what was delivered in the control group (usual occupational therapy).[31] The results suggested few adjustments on outcome measurements, inclusion criteria and extraction of information on usual occupational therapy.[31] Moreover, information gathered in the pilot study suggested that ABLE 2.0 differs from usual occupational therapy by building on a systematic, profession-specific, client-centred, problem-solving approach, including assessments, goalsetting and specified intervention components.[31] Therefore, ABLE 2.0 is considered superior to usual occupational therapy. Proceeding to full-scale trial was recommended.[31]

This trial is designed to evaluate the ABLE 2.0 in terms of effectiveness, process and cost-effectiveness, according to the MRC guidance recommendations.[29] Assessing effectiveness is considered important due to prevention of selection bias.[29] A process evaluation within the trial is valuable to investigate how the intervention programme is delivered, how it functions, and to inform interpretation of the outcomes.[29 32] Evaluation of cost-effectiveness makes it possible to compare cost of intervention versus its advantages.[29 32]

Aims and hypotheses

The aims of the ABLE 2.0 randomised controlled trial are to:

1. Determine the effectiveness of ABLE 2.0, compared with usual occupational therapy, in persons experiencing decreased ADL ability following chronic conditions. It is hypothesised that participants receiving ABLE 2.0 will achieve:
   a. A significantly higher increase in self-reported ADL task performance and/or a significantly higher increase in observed ADL motor ability (coprimary outcomes).
   b. A significantly higher increase in self-reported satisfaction with ADL task performance and/or a significantly higher increase in observed ADL process ability (secondary outcomes).
2. Explore outcomes related to occupational balance, perceived problems and general health.
3. Evaluate the processes of ABLE 2.0, including:
   a. Delivery of ABLE 2.0 in terms of fidelity, dose, adaptations and reach.
   b. Interactions between context, mechanisms and outcomes, and determine under what circumstances, for whom, why and how ABLE 2.0 enhances the ADL ability in persons living with chronic conditions.
4. Investigate the cost-effectiveness of ABLE 2.0 compared with usual occupational therapy from a societal perspective.

METHODS AND ANALYSES

Design

For the purpose of effectiveness and cost-effectiveness evaluation, this is a single-centre, randomised controlled, outcome-assessor and investigator-blinded superiority trial, with two parallel groups, designed to compare ABLE 2.0 with usual occupational therapy in two phases. Reporting of the protocol follows the Standard Protocol Items: Recommendations for Interventional Trials statement[33] and the Template for Intervention Description and Replication (TiDieR checklist).[34]

The first phase includes the main trial with a baseline and a 10-week follow-up, corresponding to the planned duration of ABLE 2.0. Primary endpoint of change is at the end of intervention 10 weeks from baseline, since this is the time when the largest improvement is expected. The second phase includes the secondary endpoint being 26 weeks from baseline. Participants are randomised equally (1:1) to receive either ABLE 2.0 or usual occupational therapy (see below for details). The design is illustrated graphically in figure 1.

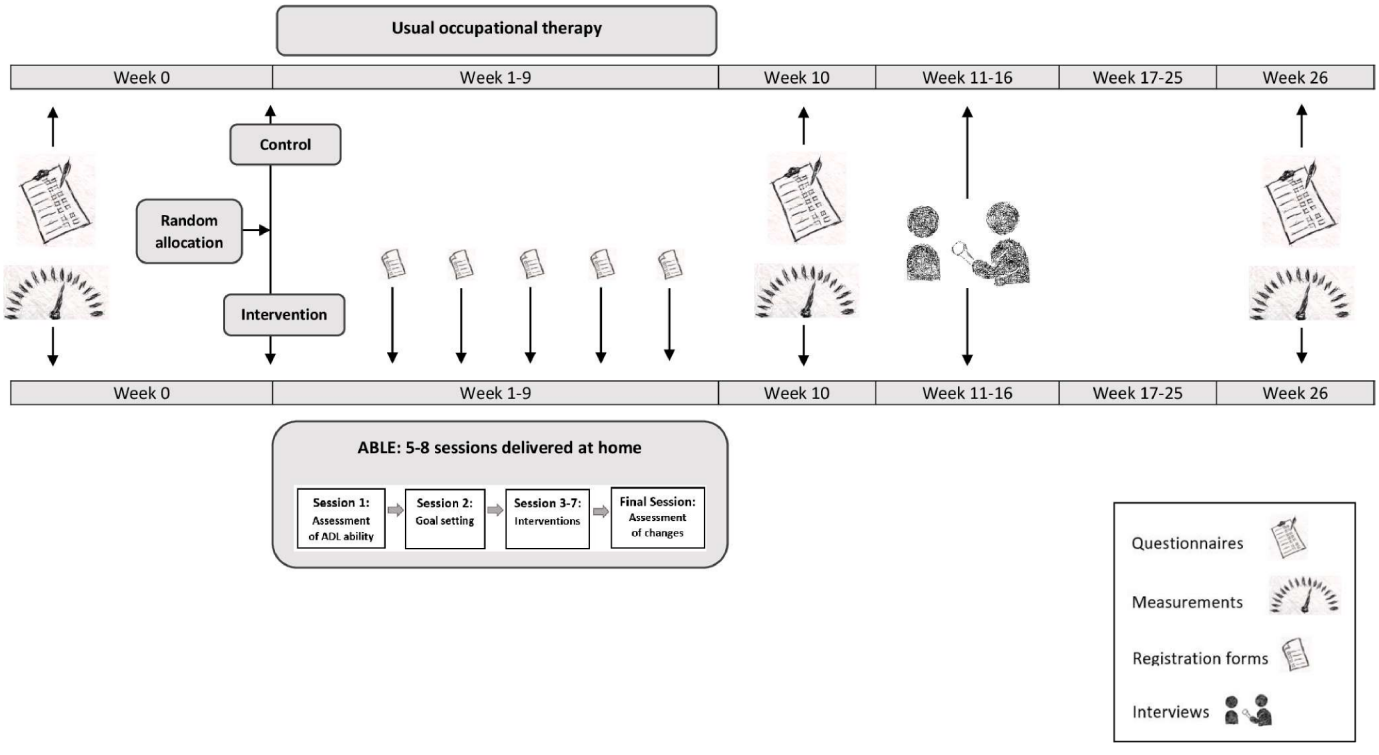


Figure 1 Graphical illustration of the A Better everyday LifE (ABLE) 2.0 trial.

Alongside, investigating the effectiveness and cost-effectiveness of ABLE 2.0, data are collected to conduct a process evaluation in the ABLE group. A theory-driven approach, based on realist evaluation,[35 36] is applied during data collection and analyses.[37] Quantitative and qualitative data are collected among participants receiving ABLE 2.0 and the ABLE occupational therapists (ABLE OTs) during and after the intervention period. To ensure equal attention to participants in the two groups and avoid influencing 26-week follow-up measurements in this parallel design, individual participant interviews between week 10 and 26 are conducted in both the ABLE and the control group. Results from interviews with participants in the control group will be reported elsewhere.

Setting

The study is conducted in the same setting as the pilot study,[31] a Danish municipality counting almost 90 000 inhabitants. About 50 000 live in the main town, and the rest lives in villages or in the countryside. Rehabilitation services in the municipality are organised in four demographically comparable geographic areas (North, East, South and West). Participants are recruited from all four areas. Delivery of intervention sessions and data collection take place in the homes of the participants.

Participants

Eligibility criteria

Participants living with one or more medically diagnosed chronic conditions must: be aged≥18 years, live in own home, experience ADL task performance problems, be motivated and ready for making changes in performance of ADL tasks, be motivated and ready to participate in an occupational therapy intervention, communicate independently and relevantly and be able to understand and relevantly answer a questionnaire. Exclusion criteria are: personal ADL problems with acute, unmet need for help, known substance abuse, mental illness and/or other acute illness (<three months) effecting ADL task performance, communication barriers (eg, severe cognitive deficits; barriers that prevent receiving information on study), receiving other occupational therapy services addressing decreased ADL ability during the intervention period (weeks 0–9).

OTs delivering ABLE 2.0 (n=3) are recruited among OTs in the municipality, provided they have ≥2 years of experience working with the study target group, are calibrated Assessment of Motor and Process Skills (AMPS) raters, and that they also delivered ABLE 2.0 in the pilot study.[31]

Recruitment

Persons referred to, or already receiving rehabilitation services, are assessed for eligibility. One OT from each geographic area assesses participants for eligibility. The recruitment process is structured by guidelines, including a checklist on eligibility criteria (online supplemental appendix A). In a phone conversation, the OT provides the client with initial information on the trial and asks for permission to forward contact information to the primary investigator. Within 3 weekdays, the primary investigator calls to provide potential participants with additional trial information and finalise screening of eligibility for inclusion, including confirmation of their motivation and readiness to make changes, and participate in occupational therapy delivered at home. If a person meets the eligibility criteria, preliminary oral consent to participate is obtained.

Consent

Following recruitment, a letter is sent to the participants containing written information, consent form and baseline questionnaires. At the baseline home visits, the participants are asked if they understand the written information, and if they have any related questions. Finally, they are asked to sign and hand over the consent form.

Allocation

Randomisation and stratification

Participants are allocated in a 1:1 ratio to either ABLE 2.0 or usual occupational therapy, taking into account their baseline level of observed ADL ability measured with the AMPS.[38 39] Independence cut-offs, indicating need of moderate to maximal assistance to live in the community, are applied: motor ADL ability (≤1.0 vs >1.0) and process ADL ability (≤0.7 vs >0.7),[38 39] that is, four mutually independent randomised sequences. Following baseline assessment, the primary investigator forward ID and baseline AMPS measures for each participant, to the principal investigator, who (blinded to coding of group allocation) allocates each participant to either '0' or '1' based on a randomisation list (ie, sequence generation). The randomisation list is generated by an independent statistician before inclusion of participants based on permuted random blocks of variable size (2–6 in each block).

The group allocation is concealed, as the primary investigator enrolling participants is not able to foresee group assignment, due to central randomisation. Following randomisation, information on allocation is returned to the primary investigator, who will then inform the ABLE or usual occupational therapy OT to initiate and complete the intervention.

Blinding

The nature of the trial precludes blinding of the therapists delivering the interventions. Outcomes assessors are not informed about the content of interventions delivered in the two groups and are blinded to the participants' group allocation. We aim not to break this assessor blinding at 10-week and 26-week assessments. With the intent to blind the participants, they are only informed that they will receive one of two occupational therapy programmes, containing similar elements. Hence, should they refer to these when talking to outcome assessors, it is not likely to affect blinding. Still, participants are reminded not to disclose information about their intervention to the

outcomes assessor, and assessors are prompted not to discuss the intervention with participants. Finally, to blind the investigators on the participants' group allocations, groups are recoded by an independent statistician before data analyses.

Interventions

The manualised ABLE 2.0 is a systematic, client-centred, 8-week intervention programme, applicable across gender, age and chronic conditions, delivered by an OT in the client's home as part of community-based rehabilitation. The overall structure of ABLE 2.0 is informed by the Occupational Therapy Intervention Process Model,[40] prescribing a problem-solving process. The problem-solving process serves as a structure for ABLE 2.0, including to evaluate ADL ability based on both self-report and observation; and to involve the client in setting goals, clarifying reasons for the identified ADL task performance problems, and in finding solutions[40] . ABLE 2.0 consists of a maximum of eight sessions including ADL assessment, using the ADL-Interview (ADL-I)[41] and AMPS[38 39] (session 1); goal setting, using Goal Attainment Scaling (GAS),[42 43] and clarification of reasons for ADL task performance problems (session 2); intervention sessions focused on adaptation by employing a combination of intervention components to improve ADL task performance (sessions 3–7); and re-evaluation of overall ADL ability (final session). The nine intervention components[30] are organised according to the Person–Environment–Occupation model.[44] Detailed description on the intervention programme, including a brief case example, is provided elsewhere.[31]

Clients in the control group receive usual occupational therapy services. These services are framed similarly in the four geographical areas, while content and dose vary based on the individual client's condition and needs. See 'Procedures—effectiveness evaluation' for information on how data on usual occupational therapy is collected.

Training of OTs delivering ABLE 2.0

The ABLE OTs are trained in delivering ABLE 2.0 by attending a three-and-a-half-day course, conducted by the researchers who developed the programme. The course consists of introduction to ABLE 2.0 and the underlying theories and models, practising the use of ADL-I, AMPS and GAS, and training delivery of ABLE sessions. To further support delivery of the programme, feedback activities are offered in addition to the course throughout the intervention period, and a folder, containing the material needed for each session in ABLE 2.0, is provided for each client.

Contamination

To minimise contamination between ABLE OTs and usual occupational therapy OTs, ABLE OTs are recruited from West and East areas, while usual occupational therapy OTs are recruited from South and North areas of the municipality. This is in line with the recruitement procedure in the pilot study.[31] In the study period, both the ABLE OTs and the usual occupational therapy OTs deliver interventions in all four geographical areas, to make randomisation at an individual level possible. The ABLE OTs rarely have contact with the usual occupational therapy OTs, and they are informed not to share information of any kind on ABLE 2.0 with their colleagues.

		Allocation	Post group allocation		
	Screening	Baseline	Interventions	Primary endpoint	Secondary endpoint
TIMEPOINT week	-3 to -1	0	1-9	10	26
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
ABLE			⟷		
UOT			⟷		
ASSESSMENTS:					
ADL-I		X		X	X
AMPS		X		X	X
OBQ11		X		X	X
CWP-Q		X		X	X
SF1 of SF-36		X		X	X
EQ-5D		X		X	X
Dutch cost diary		X		X	X

Figure 2 Schedule of enrolment, interventions, and outcome assessments. ABLE, A Better everyday LifE (experimental group); ADL-I, activities of daily living-Interview; AMPS, Assessment of Motor and Process Skills; CWP-Q, Client-Weighted Problems Questionnaire; EQ5D, EuroQool 5-dimension; OBQ11, Occupational Balance Questionnaire; SF1 of SF36, First question of the MOS 36-item Short Form Survey Instrument; UOT, usual occupational therapy (control group).

Demographic data

At baseline, demographic data are collected including age, gender, types of chronic conditions, job situation, civic status, level of education and whether they live alone or with others.

Outcomes

Effectiveness evaluation

The assessment schedule is presented in figure 2. The applied instruments are briefly described below. Complete descriptions are provided in online supplemental appendix B.

Primary outcomes

Coprimary outcomes are assessed at week 10 as change from baseline in participants' self-reported ADL ability, measured using the ADL-I[41] and observed ADL motor ability measured using AMPS.[38 39] This combination is chosen, as previous studies have shown limited relationship between measures of self-reported and observed ADL ability.[13 14]

The ADL-I (performance and satisfaction)

ADL-I is a standardised evaluation tool, used by OTs, to describe and measure the self-reported ADL ability,[41 45] in terms of physical effort and/or fatigue, efficiency, safety and independence (ADL-I performance), that is, quality of ADL task performance. In the ADL-I, the clients report their perceived ADL ability for each of 47 ADL items using seven response categories ranging from 'I perform the task independently without use of extra time or effort and without risk' to 'the task is performed by others for me—I cannot participate actively'.[41 45] Moreover, ADL-I is used to measure the client's perceived satisfaction with the quality of performance for each of the 47 ADL tasks, using a 4-point ordinal satisfaction scale ranging from 'very satisfied' to 'very dissatisfied' (ADL-I satisfaction).[41]

To measure changes in self-reported quality of ADL task performance and satisfaction, the 47 ordinal quality of performance and satisfaction scores are transformed into overall linear (interval scale) measures of self-reported quality of ADL task performance and satisfaction, adjusted for the difficulty of the ADL tasks, based on Rasch measurement methods.[41] The measures are expressed in logits (log-odds probability units).[14 41]

Previous studies indicate that ADL-I can be used to generate valid and reliable linear measures of self-reported quality of ADL task performance among persons living with chronic conditions,[11 13 41] and furthermore, that the instrument is sensitive to change in older persons receiving a home-based reablement programme.[30 46] According to the ADL-I manual,[45] a difference of ≥0.64 logits indicates a clinically relevant difference in self-reported ADL task performance.

The Assessment of Motor and Process Skills (AMPS)

The AMPS[38 39] is a standardised observation-based evaluation tool used by OTs to measure a person's observed ADL ability in terms of physical effort and/or fatigue, efficiency, safety and independence, that is, quality of ADL task performance. The person evaluated chooses and performs two standardised ADL tasks of personal relevance and appropriate challenge. During an AMPS evaluation, two domains of performance are evaluated: ADL motor (16 items) and ADL process (20 items) skills. Following observation, the quality of each skill is evaluated on a 4-point ordinal scale according to scoring criteria in the AMPS manual.[39] Available AMPS software,[47] based on Many-Faceted Rasch statistics, makes it possible to convert ordinal raw scores into overall linear ADL motor and ADL process ability measures adjusted for task challenge, skill item difficulty and rater severity. Measures are expressed in logits (log-odds probability units).[38] Several studies support that AMPS ability measures are reliable and valid among persons with chronic conditions.[13 14 48–50] Furthermore, several studies reveal that the AMPS demonstrates sensitivity to change.[24 30 50 51] According to the AMPS manual,[38] a difference of ≥0.30 logits on the ADL motor and ADL process scales defines a clinically relevant difference in ADL ability.

Secondary outcomes

Secondary outcomes are assessed at weeks 10 and 26 as changes from baseline in the participant's perceived satisfaction with quality of ADL tasks performance (ADL-I satisfaction)[41]; and observed ADL process ability (AMPS).[38 39] Moreover, participants' self-reported quality of ADL task performance (ADL-I performance)[41 45] and observed ADL motor ability (AMPS) are secondary outcomes assessed at week 26.

Explorative outcomes

At baseline and at weeks 10 and 26, the participants' perceived occupational balance (Occupational Balance Questionnaire (OBQ11),[22] perceived problems (Client-Weighted Problems Questionnaire) and general health (SF36-SF1) are examined.

Occupational Balance Questionnaire

OBQ11 is a generic 11-item instrument assessing aspects necessary for the experience of and satisfaction with occupational balance, defined as 'the experience of having the right amount of occupations and the right variation between occupations in the occupational pattern'.[22] A four-category response scale ranging from 'completely disagree' to 'completely agree' is employed. Scores are summed into a total score ranging from 0 to 33, with 33 representing complete occupational balance. OBQ11 has been examined for internal construct validity in a general population using Rasch measurement theory,[22] but not yet in clinical samples.

Client-Weighted Problems Questionnaire

A 5-item questionnaire addressing participants' identified problems, need for help and hope for the future was constructed. Each item is rated on an 11-point ordinal scale ranging from 'not at all' to 'to a high extent'. The questionnaire was tested for appropriateness in the previous pilot study.[31]

General Health (SF36-SF1)

General health is assessed using the first question (SF1) of the MOS 36-item Short Form Survey Instrument (SF36)[52] as an indicator of general health and well-being based on self-report. Thus, the following question is asked: 'In general, would you say your health is excellent (=1), very good (=2), good (=3), fair (=4) or poor (=5)'. Previous studies indicate that this question is applicable in persons with chronic conditions.[52]

Process evaluation

The process evaluation addresses the delivery of ABLE 2.0 in terms of fidelity, dose, adaptations and reach; and interactions between context, mechanisms and outcomes. Data consist of a combination of quantitative and qualitative data,[53] collected among participants receiving ABLE 2.0 and ABLE OTs.

Investigation of delivery is a replication of what was done in the previous feasibility study,[30 54] that is, determine adjustments made; components implemented;

extent of contribution to goal attainment; perceived value, benefits, harms and unintended consequences; feasibility and acceptability in practice; and adherence to intervention procedures and manual. The framework by O'Cathain *et al*[55] is used.

A realist evaluation approach is applied to investigate under what circumstances, for whom, why and how ABLE 2.0 enhances the ADL ability in persons living with chronic conditions. Accordingly, a programme theory has been developed, illustrating the causal assumptions between ABLE 2.0 and the outcomes. The programme theory is expressed as so-called context+mechanisms=outcomes (CMO) configurations (CMOs), that is, how contexts (C), understood as 'material/social/organisational/economic/technical/individual characteristics'[36] and mechanisms (M), understood as 'the interaction between the resources in the intervention programme and the persons' reasoning'[35 36 56] may produce desired outcomes (O), understood as 'results of the interaction between a mechanism and its triggering context'.[36 57] In short, CMOs describe how particular aspects of the context shapes the mechanisms leading to certain outcomes (C+M=O).[35 36 57] The CMOs were informed by the results of the feasibility study.[30] Table 1 provides an overview of the CMOs to be tested.

Registration forms

Clients' registration forms inform on mechanisms of impact. OTs' registration forms also inform on mechanisms of impact as well as intervention delivery (ie, dose: the quantity delivered; fidelity: whether the intervention is delivered as intended and; adaptations: changes made during delivery)[32]; experienced positive and/or negative side effect; organisational or practical barriers and/or facilitators to delivering the intervention components.[32] Table 2 provides an overview of the questions asked in the

Table 1 CMO configurations to be tested in process evaluation of ABLE 2.0

CMO title	CMO related to ABLE 2.0	Context	Mechanism	Outcome
CMO (a) Relationship and collaboration	Assumed to be active throughout the programme	ABLE is delivered by an OT feeling engaged and prepared to deliver session content to a client motivated for making changes …	… activates a therapeutic relationship and the client finding the programme meaningful and satisfactory …	… leading to: ► Client staying in the programme ► Increased ADL ability
CMO (b) Valid assessment	Assumed to be active during delivery of session 1	OT conducts valid occupation-focused and /or occupational-based assessments in the client's home, taking client's perspectives into account …	… activates client getting a deeper understanding of his/her problems related to ADL task performance and feeling informed and involved …	… leading to: ► Occupation-focused and/or occupation-based starting point ► Client finding participation in session 1 satisfactory ► Client finding the content of session 1 meaningful
CMO (c) Goal setting	Assumed to be active during delivery of session 2	OT and client together define occupation-focused goals and clarify causes for ADL problems …	… activates client feeling involved …	… leading to: ► Client finding participation in session 2 satisfactory ► Client finding the content of session 2 meaningful
CMO (d) Adaptive interventions	Assumed to be active during delivery of session 3–7	Adaptive intervention components delivered in the client's home (including optional homework), delivered by OT familiar with components and acting as facilitator of change …	… activates collaboration between client and OT on finding solutions and client being willing to try solutions during performance of ADL tasks …	… leading to: ► Commencing goal attainment ► Client finding participation in programme purposeful ► Client finding participation in session 3–7 satisfactory ► Client finding the content of session 3–7 meaningful
CMO (e) Reevaluation	Assumed to be active during delivery of the final session	Client gets feedback on goal attainment and obtained changes …	… activates client expecting to carry on using the new solutions …	… leading to: ► Goal attainment ► Measurable changes in perceived and observed ADL task performance ► Satisfaction with obtained ADL ability

ABLE, occupational therapy programme; ADL, activities of daily living; CMO, context+mechanisms=outcomes; OT, occupational therapist.

Table 2 Questions asked in registration forms

Aspect	Timepoint	Questions for clients To what extent …*	Questions for ABLE OTs To what extent …*
Mechanisms of impact	**All sessions**	Did you feel informed? Did you feel involved? Did you find the content meaningful? Did you feel satisfied with the content? Do you feel that participation in the programme has a purpose?	Was the session meaningful to you? Was the session in your opinion meaningful to the client? Was delivery of this session satisfactory to you? Was this session in your opinion satisfactory to the client?
	Session 1	Did the interview and observation of your performance provide you with new knowledge on problems related to your activities of daily living? Did the interview and practical testing contribute to clarification of focus for intervention? Did you and the OT establish a good basis for further cooperation?	Did you gain knowledge about problems related to the client's ADL tasks and skills? Did the session clarify focus for intervention? Did you and the client establish a good basis for further cooperation?
	Session 2	Did you like setting goals for the intervention? Was the conversation about reasons for your problems relevant?	Did the conversation about discrepancies work well? Did the conversation related to goal setting work well? Did the conversation about reasons for ADL task performance problems work well?
	Session 3–7	Did the session contribute to your goal attainment? Have you currently reached your goals?	Did the session contribute to client's goal attainment? Did the client and you have a beneficial collaboration when finding solutions? Was the client willing to practice the suggested solutions?
	Final session	Did the programme overall contribute to your goal attainment? Did the programme overall contribute to improved ability to perform activities of daily living? Will you carry on using the new solutions?	Did the intervention programme overall contribute to client's goal attainment? Did the intervention programme overall contribute to enhancing client's ADL ability? Do you believe the client will continue using the new solutions?
			Register:
Intervention delivery (dose, fidelity, adaptations)	**All sessions**		Minutes delivered What was delivered? Did you deliver according to manual?
Context	**All sessions**		Did you experience organisational barriers and/or facilitators?† Did you experience practical barriers and/or facilitators? † To what extent did you feel prepared to deliver the session/familiar with content?* To what extent did you feel engaged during the session?* To what extent did you Involve the client?*
Other	**All sessions**		Did you perceive positive/negative side effects?†

*A 5-point ordinal scale is applied: 1=to a very low degree; 2=to a low degree; 3=to some degree; 4=to a high degree; 5=to a very high degree.
†Response categories: yes or no.
ABLE, occupational therapy programme; ADL, activities of daily living; OT, occupational therapist.

registration forms. A flow chart will capture information on reach, including number of sessions received (ie, the participants' contact with the intervention).[32]

Goal Attainment Scale

GAS,[42 43] used for goal setting in session 2 and re-evaluation in the final session of ABLE 2.0, informs about goal attainment. Since the collaboration on goal setting is an important part of ABLE 2.0, GAS is chosen as a process outcome. The level of goal attainment is described using an ordinal scale from −2 to +2. The actual level of performance is described at level −1, and the expected level is described at level 0. Levels +1 and +2 are descriptions of what the person will be able to, if he or she achieves more than expected. Level −2 describes the level, where the person achieves less than expected. A study[58] concludes that GAS is applicable among older adults with multiple chronic conditions living at home.

Interviews

Individual interviews are conducted with the ABLE OTs, followed by invidual interviews with a sample of participants in the ABLE group and finally, a focus group interview with the ABLE OTs. This longitudinal structure, allowing insights from completed interviews to inform the interview guide for the subsequent ones, aims to

further develop and validate the programme theory as the investigators get more knowledge along the way.[59] Interview guides are developed and structured to capture in-depth information on the CMOs. The realistic evaluation approach[36 59] is reflected in interview guides as well as during interviews, to help identifying key contextual differences in outcome patterns[59] (see table 1).

In the ABLE OT interviews, the questions relate to their experiences of what (mechanisms), for who and under which circumstances (context) successes and failures (outcomes) occurred.[36] Concerning the participants in the ABLE group, the questions relate to their experiences of whether ABLE 2.0 encouraged them to make changes in relation to ADL task performance (mechanisms).[36] The final focus group interview with the ABLE OTs provides a deeper insight into what was revealed on the CMOs in the individual interviews.[36 59]

The individual interviews with the ABLE OTs are conducted by two experienced investigators both knowledgeable about ABLE 2.0 and the hypothesised CMOs, but otherwise not involved in the evaluation. The individual interviews with participants in the ABLE group are conducted by the primary and the principal investigator, whereas the focus group interview with the ABLE OTs is conducted by one of the interviewers from the first interviews and the primary investigator.

Economic evaluation

As recommended by the MRC guidance on how to develop and evaluate complex interventions,[29] a cost-effectiveness evaluation from a societal perspective is performed.

Cost-utility

EuroQool 5-dimension

The outcome in the cost-utility analysis is quality-adjusted life years (QALYs) assessed by the EuroQool 5-dimension (EQ-5D-5L) and valued by preference.[60] The EQ-5D-5L assesses five different health dimensions; mobility, self-care, usual activities, pain/discomfort and depression/anxiety on 5-point Likert scales.[61] Permission to use the outcome measure has been given by the EuroQol Research Foundation . Currently, there are no value sets available for the Danish Version of the EQ-5D-5L, and therefore the value sets for the UK is used.[62]

Cost-effectiveness

The outcome in the cost-effectiveness analysis is changes in ADL ability measured by the AMPS ADL motor scale[38 39] and the ADL-I performance scale.[41 45]

Costing

The costs of the intervention is estimated using micro-costing. Use of primary healthcare services (including costs to general practitioner, specialised doctor, physiotherapist, etc) is extracted and valued from the Danish National Health Service Register for Primary Care. Use of secondary healthcare services is extracted from the National Patient Registry. This register includes information on hospital departments, dates of admission and discharge, and diagnosis. The valuation is determined by reimbursement rates from the Diagnosis-related grouping and the outpatient-grouping system. A modified version of the Dutch cost diary is used in order to collect costs related to formal and informal care, delivery of food from the municipality and non-prescriptive medication.[63]

Procedures

Effectiveness evaluation

Outcome measures are collected approximately 1 week before session 1 (week 0, baseline), 10 weeks after baseline (week 10, primary endpoint) and 6 months after baseline (week 26, secondary endpoint). Baseline test takes place within 7 weekdays after inclusion. At each timepoint, assessors visit participants in their homes to collect data. Participants receive questionnaires 2–8 days before each visit. Filled-in questionnaires are handed in to the assessor at each visit. Assessors are OTs, who are trained and recalibrated (ie, their testing skills are approved for use in research) AMPS raters and certified to use ADL-I.

Data on usual occupational therapy are extrachted from client records according to a study specific schedule, tested in the pilot study,[31] including information on: dose, methods applied for evaluation of ADL ability, goal setting, content of treatment phase, referral services and programmatic and/or clinical changes during trial (eg, new clinical guidelines).[64] Data extraction is conducted retrospectively by the primary investigator assisted by a physiotherapist from the municipality, familiar with clinical practice and client records. As information on duration of visits in minutes is not extractable from client records, this information is collected in registrations forms filled in by the usual occupational therapy OTs. Description on usual occupational therapy will follow the TiDieR checklist.[34]

Process evaluation

Registration forms are filled in after each session by client and OT separately.

Qualitative interviews are employed after completion of the intervention period of the study (figure 1). The ABLE OTs are the first ones to be invited for individual interviews. Then the individual interviews with participants are carried out, followed by the focus group interview with the ABLE OTs. Knowing that the process of theory testing is unpredictable,[59] and considering the purpose of obtaining knowledge about variations in how ABLE 2.0 works,[59 65] eight participant interviews will be conducted.[65] To focus on mechanisms and minimise recall bias, a sample with a variety in outcome reach (GAS) and process outcomes (see outcomes in table 1) among the last participants allocated to ABLE 2.0 is composed. The following criteria for the sample are sought fulfilled: ≥three males; ≥four participants with baseline AMPS ADL motor ability <1.0 logits; variation in number of sessions received; and in age.

Economic evaluation

The EQ-5D-5L[60–62] and the modified version of the Dutch cost diary[63] used in the economic evaluation are collected in parallel to the effectiveness outcomes (figure 2). The register-based data used in the study are administrated by the Danish Health Data Authority and permission to extract pseudo anonymised data is requested through Scientific Services. The date of randomisation counts as the start of the time frame, ending at week 26 follow-up.

Retention

To promote participant retention and complete follow-up, an appointment for week 10 assessment is made at the baseline home visit. Furthermore, all participants are contacted by telephone, to schedule an appointment for week 26 follow-up.

Data analysis

Sample size for evaluation of effectiveness

Sample size is calculated based on prior studies.[30] The calculation was performed using nQuery Advisor.[66] The portal 'repeated measures for two means' was selected. The number of levels was set to be 3.

For the observation-based primary outcome, AMPS ADL motor ability, an average difference of 0.30 logits (ie, a clinically relevant difference[38]) between the ABLE group and the control group is expected; the SD is assumed to be 0.56.[30] When the sample size in each group is n=25, a two-sided test for the time averaged difference between two means in a repeated measure design with a significance level set to 5% ($p<0.05$) has a statistical power of 90%. Similarly, for the self-reported coprimary outcome, ADL-I ability, a clinically relevant difference of 0.64 logits[45] between the intervention and control group is expected; the SD is assumed to be 1.45.[30] With a sample size of n=34 in each group, a two-sided test for the time averaged difference between two means in a repeated measures design with a 0.05 significance level, has a statistical power of 90%. Account for dropout is taken by recruiting 40 participants in each group.

Data management

Details of data management procedures are described in the registration of the study (J.nr. P-2020-203), approved by the Knowledge Center for Data Registration, in the Capital Region of Denmark

Demographics

Baseline participant characteristics are presented descriptively. Nominal data are reported based on numbers and percentages. Ordinal data are presented in medians, ranges, quartiles, absolute numbers and frequencies. Continuous variables are reported in means (SD), if data are normally distributed. Continuous data with lack of normal distribution are presented based on median (range).

Analysis of effectiveness

Data are analysed using IBM SPSS Statistics, V.25.[67]

Statistical analyses

All confirmatory data analyses are carried out according to the prespecified analysis plan. The coprimary outcomes are analysed on an intention-to-treat (ITT) basis, with the last observation carried forward in case of missing data. The trial is designed as a superiority trial, that is, the group allocated to ABLE 2.0 will improve ≥0.30 logits on the ADL motor scale, and/or ≥0.64 logits on the ADL-I performance scale, compared with the usual occupational therapy group. Following the ITT analysis, a per-protocol analysis is conducted, including participants with baseline and week 10 measures. Moreover, participants in the ABLE group should have received a minimum of three sessions, and participants in the usual occupational therapy group sufficient intervention (based on a professional estimate by usual occupational therapy OTs after the end of intervention period).

Primary (AMPS ADL motor and ADL-I performance) and secondary (AMPS ADL process and ADL-I satisfaction) outcomes are investigated using analyses of covariance with time by programme (ABLE 2.0/usual occupational therapy) as repeated measures, reported at the primary and secondary endpoint and followed by post-hoc testing. The model includes ADL-I performance baseline measures as an additional covariate. Differences in means between groups are statistically significant at $p\leq0.05$ and are investigated for clinical relevance.

Responder analysis

Responders are defined as participants achieving a clinically relevant improvement in AMPS ADL motor ability (≥0.30 logits)[38] and ADL-I ability (≥0.64 logits)[45] measures. The proportions (number and percentages) of responders is calculated and compared by Pearson's χ^2 test, and mean changes in observed and self-reported ADL ability for responders are analysed and compared using paired samples and independent samples t-tests and reported in means and 95% CI.

Analysis of process

Analysis of data related to delivery of ABLE 2.0 is conducted in line with what was done in the previous feasibility study.[30 54] Reach is analysed by investigating the flow chart and characterising who received the ABLE 2.0 at the end of the study, providing a descriptive result on the persons who the intervention reached.

Analysis of data related to CMOs takes shape as an iterative process within and across data sources. That is, core and recurrent patterns of CMOs are identified to inform refinement or further development of the ABLE 2.0 programme theory.[36 68] During the analysis a 'retroductive' approach is applied, referring to the use of a combination of inductive and deductive reasoning, and incorporation of the different data sources.[69] The process of retroduction leads to refinement of the programme theory.[69]

Quantitative data

Analyses of quantitative process data begin with descriptive statistics related to the dimensions investigated.[32] The mechanisms in ABLE 2.0 are tested through intragroup comparison, by investigating if there is a relationship between the mechanisms (eg, the therapeutic relationship) and the process outcomes (eg, client staying in programme) on different contextual factors (eg, OTs feeling engaged and prepared to deliver session content). For this purpose, cross tabulations are applied.[70]

Following the descriptive statistics, it is decided whether regression analyses are possible, given the relatively small sample.[70] Still, it also depends on the strength of the mechanisms that is, regression analysis on CMOs with few, strong mechanisms may be relevant to explore the functioning of the programme.

Qualitative data

Interview data are transcribed verbatim and analysed in the following steps following Realist And Meta-narrative Evidence Syntheses: Evolving Standards(RAMESES) II reporting standards for realist evaluations[57] and inspired by Gilmore *et al*[71]: (1) recordings are listened through and transcripts read to gain overview of each interview; (2) transcripts are separately examined for CMO configurations, by colour coding: context in blue, mechanisms in yellow and outcomes in green; (3) a table is produced for each type of transcript (ie, ABLE OTs (individual), clients, ABLE OTs (focus group)), listing the identified CMOs and registering the exact source of findings.[57] Core citations are extracted to document the findings; (4) the most effective CMOs are identified, marked and extracted. A CMO is determined effective, if it: (a) is found in more than one data source; (b) is expressed which emphasis in one data source; and/or (c) causes particularly positive or negative changes. Each CMO is assessed on its impact on the programme theory (support/refute/refine initial programme theory) including suggestions for future actions, for example, how to improve the manual. A template (online supplemental appendix C) is used to depict the results of this step. Steps 1 and 2 are conducted independently by two investigators, whereas step 3 is conducted by the primary investigator. Step 4 is conducted by two investigators in collaboration and the results discussed in the overall research group.

Synthesis of analysis of quantitative and qualitative data

As a final step of the analysis of CMOs, the results of the analysis of the mechanisms (intragroup comparison) and the most effective CMOs, identifyed from qualitative data, are compared and synthesised. The synthesis will result in evidence to corroborate and/or refine the initial programme theory.[57 71]

Analysis of cost-effectiveness evaluation data

The cost-effectiveness evaluation is performed in accordance with the ITT principle. The incremental cost-effectiveness ratio (ICER) is calculated using the formula: ICER = (CA − CB)/(EA − EB), where C denotes costs and E denotes effects with A and B referring to comparators. Bias corrected and accelerated bootstrapping with 10 000 replications are performed in order to estimate 95% confidence intervals around cost differences and the uncertainty surrounding the ICERs.[72] Uncertainty is shown in cost-effectiveness plans. The cost-effectiveness acceptability curve is drawn in order to show the probability that the ABLE intervention is cost-effective at different thresholds for willingness to pay for a gain in QALY or a clinically relevant improvement in ADL ability (ADL-I performance and/or AMPS motor) as defined earlier.[73] Sensitivity analyses are performed to test the robustness of the study results.

Participants and public involvement

As reported in earlier papers concerning this research programme, persons from the target group were involved during development of the intervention.[21 30] Thus, their values and preferences are integrated in the programme. Furthermore, the results of the feasibility study,[30] including registration forms and qualitative interviews with participants, informed the revision of the ABLE manual and the design of this study.

Trial status

The protocol was prospectively registered at www.ClinicalTrials.gov on 12 December 2019.

Originally, this study was planned to be initiated on 1 January 2020 and to include an internal pilot. Due to the COVID-19 pandemic, the study was truncated on 11 March 2020, and as a consequence the internal pilot was turned into an external pilot. Based on the results of the external pilot, a few adjustments on outcome measurements, inclusion criteria and extraction of information on usual care were applied, before initiation of this full-scale trial. Recruitment was started on 20 July 2020, and the first participant was included on 1 August 2020. No amendments have been made to the protocol (V.1.6 on 15 July 2020) or the registration since recruitment of the first participant. Any future amendments will be communicated together with the results. When this manuscript was submitted for publication (25 March 2020), a total of 66 participants had been included in the trial. The last evaluation of the last participant is expected by October 2021.

ETHICS AND DISSEMINATION

The study is approved by the Danish Data Protection Service Agency: Journal-nr.: P-2020-203. The Ethical Committee confirmed that no approval is needed for this study: Journal-nr.: 19 045 758. Informed consent is obtained from each participant, emphasising the right to withdraw from the study. Participants are given an ID code, with which all data are pseudonymised and only accessed by authorised study personnel obliged to secrecy. After data collection is completed, personalised

information is deleted and all data completely anonymised. Analyses are performed on anonymised data. The results will be disseminated to participants, published in peer-reviewed journals and presented on national and international conferences.

DISCUSSION

This study will contribute to establish evidence for an occupational therapy intervention programme aiming at enhancing ADL ability among persons with chronic conditions and add knowledge to the complexities in delivering such interventions. The study is conducted in a 'real-world context' and will generate new knowledge on the effectiveness of ABLE 2.0 on ADL ability, how the programme functions and the cost-effectiveness of the programme. The evaluation will provide important knowledge in case of recommending implementation in municipal settings.[29]

The strengths of the planned study design include a strategy to reach a relatively high response rate. Hence, all assessor visits are agreed on in a telephone conversation and followed by a letter with information on the agreement. Further, to obtain a more complete data set, the assessors collect the questionnaires during participant visits. Recruitment procedures are developed to ensure recruitment of persons matching the aims of the intervention, that, a less biased sample.[74 75] However, considering the target group of the study, being mostly elderly and frail persons, withdrawel is expected. This, due to the burden of study-related activities or due to development in their condition. To accommodate this, and based on recommendation from the pilot study, the number of questionnaires is low.[31]

While the design of an effectiveness, process and cost-effectiveness study conducted alongside each other is considered a strength, it is also important to recognise inherent limitations. In the intervention group, activities related to the process evaluation are applied, including filling in registration forms after each session and interviews with eight participants post intervention. To balance the attention in the two groups, the same number of interviews is conducted with participants in the control group, as a separate process evaluation of the usual occupational therapy services. Still, to avoid affecting what is delivered in the control group, a replacement for the registration forms is not applied in the control group. In terms of the qualitative interviews conducted as part of the process evaluation, the primary investigator is involved as interviewer in the client interviews and the focus group, to exploit her insight in the ABLE programme theory. As the ABLE OTs cooperate with her during the intervention period, and the participants talk to her on the phone when recruited, their reporting may be affected.

The study is designed to intend blinding of participants, assessors and investigators. However, as the OTs delivering ABLE 2.0 and usual occupational therapy are not blinded to allocation, the blinding of participants may be broken, even though they are instructed not to disclose the allocation. Contamination is minimised as the OTs delivering ABLE 2.0 and usual occupational therapy are recruited from different geographical areas in the municipality. This is supported by delivering all interventions in the clients' homes.

Author affiliations
[1]Copenhagen University, Bispebjerg and Frederiksberg Hospital, The Parker Institute, Copenhagen, Denmark
[2]Department of Public Health, University of Southern Denmark, Odense, Syddanmark, Denmark
[3]Department of Occupational Therapy, VIA University College, Holstebro, Denmark
[4]Department of Occupational Therapy, University College of Northern Denmark (UCN), Aalborg, Denmark
[5]DEFACTUM, Department of Public Health and Rehabilitation, Central Denmark Region, Aarhus, Denmark
[6]Department of Physiotherapy and Occupational Therapy, Aarhus University Hospital, Aarhus, Denmark
[7]Department of Rehabilitation & Scientific Institute for Quality of Care Research, Radboud University Medical Center, Nijmegen, Netherlands

Contributors Study design: VH, KTN, CvB, MG, LGO and EEW. Writing first draft: VH, EEW (evaluation of effectiveness and process) and LGO (evaluation of cost-effectiveness). Critical revision of manuscript: KTN, CvB, MG, LGO and EEW.

Funding This work was supported by: The Oak Foundation (OCAY-13-309); The municipal fund for quality development (A327); VIA University College; Southern Denmark University; Bispebjerg and Frederiksberg Hospital, University of Copenhagen; Research Fund of the Danish Association of Occupational Therapy (FF1/19-R112-A2271 and FF2/19-R132-A2835); and the Lundbeck foundation (A8059).

Competing interests None declared.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Vita Hagelskjær http://orcid.org/0000-0002-0342-8024
Kristina Tomra Nielsen http://orcid.org/0000-0002-4944-9453
Lisa Gregersen Oestergaard http://orcid.org/0000-0003-2255-1391

REFERENCES

1 Steultjens EMJ, Dekker J, Bouter LM, *et al*. Evidence of the efficacy of occupational therapy in different conditions: an overview of systematic reviews. *Clin Rehabil* 2005;19:247–54.
2 Hand C, Law M, McColl MA. Occupational therapy interventions for chronic diseases: a scoping review. *Am J Occup Ther* 2011;65:428–36.
3 Waehrens EE, Fisher AG. Improving quality of ADL performance after rehabilitation among people with acquired brain injury. *Scand J Occup Ther* 2007;14:250–7.

4 Guidetti S, Ranner M, Tham K, *et al*. A "client-centred activities of daily living" intervention for persons with stroke: One-year follow-up of a randomized controlled trial. *J Rehabil Med* 2015;47:605–11.
5 World Health Organization. *Worlds health statistics 2020: monitoring health for the SDG, sustainable development goals*. Geneva: WHO, 2020.
6 Hvidberg MF, Johnsen SP, Davidsen M, *et al*. A nationwide study of prevalence rates and characteristics of 199 chronic conditions in Denmark. *Pharmacoecon Open* 2020;4:361–80.
7 Iheanacho I, Zhang S, King D, *et al*. Economic burden of chronic obstructive pulmonary disease (COPD): a systematic literature review. *Int J Chron Obstruct Pulmon Dis* 2020;15:439–60.
8 Hajat C, Stein E. The global burden of multiple chronic conditions: a narrative review. *Prev Med Rep* 2018;12:284–93.
9 Dalsgaard CT, Kjærgaard M, Lemvigh K. Financial management of home care and rehabilitation services - Inspiration for the municipalities. *VIVE* 2020.
10 Goodman RA, Posner SF, Huang ES, *et al*. Defining and measuring chronic conditions: imperatives for research, policy, program, and practice. *Prev Chronic Dis* 2013;10:120239.
11 Bendixen HJ, Wæhrens EE, Wilcke JT, *et al*. Self-Reported quality of ADL task performance among patients with COPD exacerbations. *Scand J Occup Ther* 2014;21:313–20.
12 Lindahl-Jacobsen L, Hansen DG, Wæhrens EE, *et al*. Performance of activities of daily living among hospitalized cancer patients. *Scand J Occup Ther* 2015;22:137–46.
13 Nielsen KT, Wæhrens EE. Occupational therapy evaluation: use of self-report and/or observation? *Scand J Occup Ther* 2015;22:13–23.
14 Wæhrens EE, Bliddal H, Danneskiold-Samsøe B, *et al*. Differences between questionnaire- and Interview-Based measures of activities of daily living (ADL) ability and their association with observed ADL ability in women with rheumatoid arthritis, knee osteoarthritis, and fibromyalgia. *Scand J Rheumatol* 2012;41:95–102.
15 Daving Y, Claesson L, Sunnerhagen KS. Agreement in activities of daily living performance after stroke in a postal questionnaire and interview of community-living persons. *Acta Neurol Scand* 2009;119:390–6.
16 Hariz G-M, Forsgren L. Activities of daily living and quality of life in persons with newly diagnosed Parkinson's disease according to subtype of disease, and in comparison to healthy controls. *Acta Neurol Scand* 2011;123:20–7.
17 Norberg E-B, Boman K, Löfgren B. Activities of daily living for old persons in primary health care with chronic heart failure. *Scand J Caring Sci* 2008;22:203–10.
18 Sturkenboom IHWM, Graff MJL, Hendriks JCM, *et al*. Efficacy of occupational therapy for patients with Parkinson's disease: a randomised controlled trial. *Lancet Neurol* 2014;13:557–66.
19 Wæhrens EE. *Almindelig daglig levevis: ADL*. Munksgaard, 2015.
20 Avlund K, Schultz-Larsen K, Kreiner S. The measurement of instrumental ADL: content validity and construct validity. *Aging* 1993;5:371–83.
21 Nielsen KT, Klokker L, Guidetti S, *et al*. Identifying, organizing and prioritizing ideas on how to enhance ADL ability. *Scand J Occup Ther* 2019;26:382–93.
22 Håkansson C, Wagman P, Hagell P. Construct validity of a revised version of the occupational balance questionnaire. *Scand J Occup Ther* 2020;27:441–9.
23 Nielsen TL, Petersen KS, Nielsen CV, *et al*. What are the short-term and long-term effects of occupation-focused and occupation-based occupational therapy in the home on older adults' occupational performance? A systematic review. *Scand J Occup Ther* 2017;24:235–48.
24 Graff MJL, Vernooij-Dassen MJM, Thijssen M, *et al*. Community based occupational therapy for patients with dementia and their care givers: randomised controlled trial. *BMJ* 2006;333:1196–9.
25 Amris K, Bülow Cvon, Christensen R, *et al*. The benefit of adding a physiotherapy or occupational therapy intervention programme to a standardized group-based interdisciplinary rehabilitation programme for patients with chronic widespread pain: a randomized active-controlled non-blinded trial. *Clin Rehabil* 2019;33:1367–81.
26 Nielsen KT, Klokker L, Wæhrens EE. Self-Reported quality of activities of daily living task performance in four diagnostic groups with chronic conditions. *IJTR* 2021;28:1–10.
27 Nielsen KT. *Occupational therapy for persons living with chronic conditions - Development and feasibility of the ABLE program*. Syddansk Universitet, 2018.
28 Wade D. Rehabilitation - a new approach. Part four: a new paradigm, and its implications. *Clin Rehabil* 2016;30:109–18.
29 Craig P, Dieppe P, Macintyre S, *et al*. Developing and evaluating complex interventions: the new medical Research Council guidance. *BMJ* 2008;337:a1655–83.
30 Nielsen KT, Guidetti S, von Bülow C, *et al*. Feasibility of able 1.0—a program aiming at enhancing the ability to perform activities of daily living in persons with chronic conditions. *Pilot Feasibility Stud* 2021;7:1–15.
31 Hagelskjær V, Nielsen KT, von Bülow C, *et al*. Occupational therapy addressing the ability to perform activities of daily living among persons living with chronic conditions: a randomised controlled pilot study of able 2.0. *Pilot Feasibility Stud* 2021;7:122.
32 Moore GF, Audrey S, Barker M, *et al*. Process evaluation of complex interventions: medical Research Council guidance. *BMJ* 2015;350:h1258.
33 Chan A-W, Tetzlaff JM, Gøtzsche PC, *et al*. Spirit 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346:e7586–42.
34 Hoffmann TC, Glasziou PP, Boutron I, *et al*. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687–12.
35 Kazi MAF, Spurling LJ. *Realist evaluation for evidence-based practice*. Switzerland: Spurling. Realist Evaluation for evidence-based practice, 2000.
36 Pawson R, Tilley N. *Realistic evaluation*. Reprint. London: Sage, 1997: 235.
37 Moore G, Audrey S, Barker M. Guidance on process evaluation of complex interventions. *Br Med J* 2015;350:h1258.
38 Fisher AG, Jones KB. Assessment of motor and process skills. In: Collins F, ed. *Development, standardization, and administration manual*. 1. 7th edn. Fort Collins, Colorado, USA: Three Star Press, 2012.
39 Fisher AG, Jones KB. Assessment of motor and process skills.. In: *User manual*. 2. 7th edn. Fort Collins, Colorado, USA: Three Star Press, 2012.
40 Fisher AG, Marterella A. *Powerful practice : A Model for Authentic Occupational Therapy*. Fort Collins: CIOTS - Center for Innovative OT Solutions, 2019.
41 Wæhrens EE. *Measuring quality of occupational performance based on self-report and observation. development and validation of instruments to evaluate ADL task performance*. Sweden, Umeå: Department of Community Medicine and Rehabilitation, Umeå University, 2010.
42 Kiresuk TJ, Smith A, Cardillo JE. *Goal Attainment Scaling : Applications, theory, and measurement*. Hillsdale, N.J.: L. Erlbaum Associates, 1994.
43 Krasny-Pacini A, Hiebel J, Pauly F, *et al*. Goal attainment scaling in rehabilitation: a literature-based update. *Ann Phys Rehabil Med* 2013;56:212–30.
44 Strong S, Rigby P, Stewart D, *et al*. Application of the Person-Environment-Occupation model: a practical tool. *Can J Occup Ther* 1999;66:122–33.
45 Wæhrens EE, ADL-Interview NKT. *ADL-Interview (ADL-I). Klinisk version 1.0 - Introduktion, ADL-I og administration (Clinical version 1.0 - Introduction, ADL-I, and administration)*. ACE Copenhagen, 2020.
46 Winkel A, Langberg H, Wæhrens EE. Reablement in a community setting. *Disabil Rehabil* 2015;37:1347–52.
47 OTAP. *OT assessment package (OTAP)*. Fort Cloons, Colorado, USA: Center for Innovative OT Solutions, 2016.
48 Moore K, Merritt B, Doble SE. Adl skill profiles across three psychiatric diagnoses. *Scand J Occup Ther* 2010;17:77–85.
49 Von Bülow C, Amris K, La Cour K, *et al*. Ineffective ADL skills in women with fibromyalgia: a cross-sectional study. *Scand J Occup Ther* 2016;23:391–7.
50 Wæhrens EE, Amris K, Fisher AG. Performance-Based assessment of activities of daily living (ADL) ability among women with chronic widespread pain. *Pain* 2010;150:535–41.
51 Ellegaard K, von Bülow C, Røpke A, *et al*. Hand exercise for women with rheumatoid arthritis and decreased hand function: an exploratory randomized controlled trial. *Arthritis Res Ther* 2019;21:1–9.
52 Gill TK, Broderick D, Avery JC. Self reported overall health status: implications for intervention strategies. *Australas Med J* 2009;2:44–57.
53 F. Moore G, Raisanen L, Moore L, *et al*. Mixed-method process evaluation of the Welsh national exercise referral scheme. *Health Educ* 2013;113:476–501.
54 Guidetti S, Nielsen KT, von Bülow C, *et al*. Evaluation of an intervention programme addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a feasibility trial (able). *BMJ Open* 2018;8:e020812.
55 O'Cathain A, Hoddinott P, Lewin S, *et al*. Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. *Pilot Feasibility Stud* 2015;1:O88.

56 Salter KL, Kothari A. Using realist evaluation to open the black box of knowledge translation: a state-of-the-art review. *Implementation Sci* 2014;9:1–14.
57 Wong G, Westhorp G, Manzano A, *et al*. RAMESES II reporting standards for realist evaluations. *BMC Med* 2016;14:1–18.
58 Toto PE, Skidmore ER, Terhorst L, *et al*. Goal attainment scaling (gas) in geriatric primary care: a feasibility study. *Arch Gerontol Geriatr* 2015;60:16–21.
59 Manzano A. The craft of interviewing in realist evaluation. *Evaluation* 2016;22:342–60.
60 Wittrup-Jensen KU, Lauridsen J, Gudex C, *et al*. Generation of a Danish TTO value set for EQ-5D health states. *Scand J Public Health* 2009;37:459–66.
61 The EuroQol Group. EQ-5D [Internet]. [cited 2021 Jan 20]. Available: https://euroqol.org/eq-5d-instruments
62 Devlin NJ, Shah KK, Feng Y, *et al*. Valuing health-related quality of life: an EQ-5D-5L value set for England. *Health Econ* 2018;27:7–22.
63 Goossens ME, Rutten-van Mölken MP, Vlaeyen JW, *et al*. The cost diary: a method to measure direct and indirect costs in cost-effectiveness research. *J Clin Epidemiol* 2000;53:688–95.
64 Erlen JA, Tamres LK, Reynolds N, *et al*. Assessing usual care in clinical trials. *West J Nurs Res* 2015;37:288–98.
65 Emmel N. *Sampling and choosing cases in qualitative research. A realist approach*. London: Sage, 2013.
66 Statistical Solutions, Saugus, MA U. nQuery Advisor®, version 8.5.0.0. computer program [Internet]. [cited 2021 Jan 20]. Available: https://www.statsols.com/
67 IBM Corp. *Ibm SPSS statistics for windows, version 25.0*. Armonk, NY: IBM Corp, 2021.
68 Astbury B, Leeuw FL. Unpacking black boxes: mechanisms and theory building in evaluation. *Am J Eval* 2010;31:363–81.
69 The RAMESES II Project. Retroduction in realist evaluation. *Nihr* 2017;207:1–3.
70 Ravn R. Testing mechanisms in large-N realistic evaluations. *Evaluation* 2019;25:171–88.
71 Gilmore B, McAuliffe E, Power J, *et al*. Data analysis and synthesis within a realist evaluation: toward more transparent methodological approaches. *Int J Qual Methods* 2019;18:1–11.
72 Johnson RW. An introduction to the bootstrap. *Teach Stat* 2001;23:49–54.
73 Fenwick E, Claxton K, Sculpher M. Representing uncertainty: the role of cost-effectiveness acceptability curves. *Health Econ* 2001;10:779–87.
74 Michelet M, Lund A, Sveen U. Strategies to recruit and retain older adults in intervention studies: a quantitative comparative study. *Arch Gerontol Geriatr* 2014;59:25–31.
75 Chatfield MD, Brayne CE, Matthews FE. A systematic literature review of attrition between waves in longitudinal studies in the elderly shows a consistent pattern of dropout between differing studies. *J Clin Epidemiol* 2005;58:13–19.

Paper II

Hagelskjær et al. Pilot and Feasibility Studies (2021) 7:122
https://doi.org/10.1186/s40814-021-00861-9

Pilot and Feasibility Studies

RESEARCH Open Access

Occupational therapy addressing the ability to perform activities of daily living among persons living with chronic conditions: a randomised controlled pilot study of ABLE 2.0

Vita Hagelskjær[1,2,3*], Kristina Tomra Nielsen[1,4], Cecilie von Bülow[1,2], Maud Graff[5] and Eva Ejlersen Wæhrens[1,2]

Abstract

Background: The ABLE intervention was developed to enhance the ability to perform activities of daily living (ADL) tasks among persons living with chronic conditions. ABLE is a generic, home-based, individualised, 8-week occupational therapy intervention program, developed to be delivered in Danish municipalities. In a previous study, the feasibility of ABLE was evaluated in terms of content and delivery. In this pilot study, the remaining feasibility aspects of a randomised controlled trial including (i) trial procedures (recruitment and retention), (ii) randomisation, (iii) adherence to program, (iv) feasibility of additional outcome measurements, and (iv) access to information on usual occupational therapy were evaluated.

Methods: The study was conducted in a Danish municipality, using a two-armed parallel randomised controlled design, planning a recruitment strategy including 20 persons living with one/more chronic conditions and experiencing problems performing ADL. The following progression criteria were used to determine if a future full-scale randomised controlled trial was feasible: (i) recruitment (50% met the eligibility criteria) and retention (80%), (ii) randomisation (80% accepted randomisation, procedure was executed as planned), (iii) adherence to program (100% followed the treatment protocol), (iv) outcome measurements (80% of the participants delivered relevantly and fully answered questionnaires), and (v) usual occupational therapy (extraction of needed information was successful).

Results: Due to the COVID-19 pandemic, the study was truncated resulting in limited but sufficient data to answer most of the study questions. (i) Eighteen of 37 eligible persons (48.6%) were recruited; of those treated ($n = 6$), all remained (100%); (ii) 18 accepted randomisation (100%), and procedure was effective; (iii) ABLE was delivered with adherence (100%); (iv) 92.3–100% of the participants gave relevant and complete answers in two of three questionnaires; and (v) needed information on usual occupational therapy was extractable in seven of nine aspects.

* Correspondence: vita.hagelskjaer@regionh.dk
[1]The Parker Institute, Bispebjerg and Frederiksberg Hospital, University of Copenhagen, Copenhagen, Denmark
[2]Occupational Science & Occupational Therapy, User Perspectives and Community-based Interventions, Department of Public Health, University of Southern Denmark, Odense, Denmark
Full list of author information is available at the end of the article

Conclusions: Proceeding to full-scale trial is recommendable; however, a few adjustments on outcome measurements, inclusion criteria and extraction of information on usual occupational therapy are needed.

Trial registration: The study was registered at ClinicalTrials.gov (Identifier: NCT04295837) on December 5th, 2019. Retrospectively registered.

Keywords: ADL ability, Everyday life, Goal setting, Complex interventions, Occupational Therapy Intervention Process Model (OTIPM), Rehabilitation

Key messages regarding feasibility

- *What uncertainties existed regarding the feasibility*? The development of the ABLE intervention program and feasibility aspects related to content and delivery have been addressed in previous studies. This pilot study addressed remaining uncertainties including evaluation of trial procedures (recruitment and randomisation), adherence, access to information on usual occupational therapy and feasibility of additional outcome measurements.
- *What are the key feasibility findings*? The procedures for recruitment and randomisation were feasible; the ABLE intervention program was adherently delivered; and almost all the desired information on usual occupational therapy was accessible. In terms of the feasibility of outcome measurements, the administration of the ADL-Questionnaire (ADL-Q) in this client population was associated with challenges, whereas the Occupational Balance Questionnaire (OBQ11) and Client Weighted Problems questionnaire (CWP) were appropriate.
- *What are the implications of the feasibility findings for the design of the main study*? The study results implied a need for a few adjustments related to inclusion criteria, extraction of information on usual occupational therapy and to the outcome measurements. A full-scale randomised controlled trial is recommended.

Background

The number of persons living with chronic conditions is increasing worldwide. A recent register-based study [1] has revealed that 65.5% of Danish residents, aged 16 or above, have one or more chronic condition. Several studies provide evidence to support that persons with chronic conditions generally experience problems performing activities of daily living (ADL) tasks [2–9]. This is also reflected in the definition of chronic conditions proposed by Goodman et al.: '*Conditions that last 1 year or more and require ongoing medical attention and/or limit activities of daily living*' [10]. ADL involve tasks that most people need to perform in their everyday lives, including personal and instrumental ADL tasks [11]. Personal ADL involve basic self-care tasks that are necessary to perform for all people across gender, age, culture and interests. Examples are eating, toileting, grooming and dressing. Instrumental ADL tasks involve more complex household chores, necessary for independent living, including shopping, cooking, cleaning and doing laundry [12]. Addressing ADL task performance problems is a core element in occupational therapy and results from studies indicate that occupational therapy interventions in general may improve ADL ability among older persons with various chronic conditions [13–16]. However, rigorous studies, testing the outcomes of occupational therapy for persons living with chronic conditions experiencing ADL task performance problems are limited [13–17]. A scoping review on occupational therapy for chronic conditions [14] suggested that similar interventions addressing ADL may be applicable across a range of diagnoses. In support of this, a study examining self-reported quality of ADL task performance among n = 593 persons living with chronic conditions [18, 19], found similar types of ADL task performance problems across a range of chronic conditions. Hence, there was a need to develop a generic intervention program to address decreased ADL ability across chronic conditions causing disability.

Accordingly, the research program "A better everyday life", launched in 2015, aims to develop and evaluate an occupational therapy intervention program (named ABLE) focusing on enhancing the ADL ability among persons living with chronic conditions experiencing ADL task performance problems. The research program is guided by the British Medical Research Council's (MRC) guidance on how to develop and evaluate complex interventions [20]. The guidance prescribes four stages: (1) Development, (2) Feasibility/piloting, (3) Evaluation, and (4) Implementation [20].

In prior phases, the first version of the ABLE intervention program (ABLE 1.0) was developed [18, 19, 21] incorporating knowledge based on existing evidence, clinical expertise of occupational therapists (OTs) and client needs [18, 19, 21, 22]. Moreover, feasibility was addressed in terms of content and delivery, and the selected outcome measurements were ascertained [23]. However, the feasibility evaluation also revealed a need

to adjust the recruitment procedure, apply minor changes to the intervention manual and further monitor adherence to the intervention program [23]. A pilot randomised controlled trial (RCT) study was recommended before proceeding to a full-scale RCT [23].

Consequently, the ABLE intervention program faced pilot testing involving evaluation of trial procedures (including recruitment and randomisation), adherence, feasibility of additional outcome measurements and access to information on usual occupational therapy. In preparation for this, a new strategy for recruitment was planned, a randomisation procedure was developed, the ABLE intervention program manual was revised (ABLE 2.0), questions related to evaluating the feasibility of additional outcome measurements were developed and decisions regarding needed information on usual occupational therapy were made.

Methods

Aims and objectives

The overall aim of this ABLE pilot study was to inform the decision on whether to proceed to full-scale RCT. The pilot study should strengthen the design and conduct a future RCT, in relation to the remaining feasibility aspects [24, 25]. The specific aims of the ABLE pilot study were to:

(i) Assess effectiveness of the recruitment process and retention in the context of a future trial
(ii) Assess the randomisation procedure and determine the acceptability of randomisation among the participants
(iii) Assess adherence to intervention program in the same context as the future RCT trial
(iv) Assess appropriateness of additional outcome measurements
(v) Determine if needed information on usual occupational therapy can be extracted from the client records in the municipality

Study design

The ABLE pilot was designed as a two-armed parallel randomised controlled study with random and stratified allocation to ABLE 2.0 and usual occupational therapy, respectively (n = 20).

Setting, participants and recruitment

The ABLE pilot study was scheduled to be conducted from January to May 2020 in a Danish municipality, with almost 90,000 inhabitants. The Rehabilitation Unit in the municipality is organised in four comparable geographic areas (North, East, South, and West). Participants were recruited from all four areas. ABLE 2.0 and usual occupational therapy sessions were delivered, and data collection was conducted, in the homes of the participants. Participants in both the ABLE intervention group and the control group (usual occupational therapy) received other health care services as usual.

Eligible participants lived with one or more medically diagnosed chronic condition, were aged ≥ 18 years; lived in own home; experienced ADL task performance problems; communicated independently and relevantly (without severe cognitive deficits); were motivated and ready for making changes in performance of ADL; motivated and ready for cooperating with an occupational therapist (OT) in finding solutions to the experienced problems; and able to understand and relevantly answer a questionnaire. Exclusion criteria were known substance abuse; mental illness and/or other acute illness effecting ADL task performance; or language barriers.

OTs delivering ABLE 2.0 (ABLE OTs) (n = 3) were recruited among OTs in the municipality based on having at least 2 years of experience working with persons living with chronic conditions and ADL task performance problems, and being calibrated as Assessment of Motor and Process Skills (AMPS) [26, 27] raters. In preparation for delivering ABLE 2.0, the ABLE OTs participated in a three-and-a-half-day tailored workshop.

Assessors (n = 2), conducting observation-based outcomes evaluation of ADL ability using the AMPS at baseline and post-intervention, were OTs trained and calibrated as AMPS raters recruited from a nearby Hospital Unit.

Participants were recruited using a two-step model. In the first step, all persons referred to rehabilitation services in the municipality, or persons already receiving any kind of rehabilitation services, were screened for eligibility. A key OT in each Rehabilitation Unit area performed the screening based on a guideline including a checklist on the eligibility criteria. In a telephone conversation, the key OT provided the potential participant with initial information on the ABLE pilot study and asked for permission to forward contact information to the primary investigator. In the second step, and within three weekdays from the forwarded contact information, the primary investigator called to provide more detailed information, determine if the person was interested in participating and finalise screening of eligibility for inclusion. If the person met the inclusion criteria, preliminary oral consent to participate was obtained.

ABLE 2.0 intervention program

The manualised ABLE 2.0 intervention program is a generic, systematic and client-centred 8-week occupational therapy intervention program, addressing ADL task performance problems among persons living with chronic conditions. It is characterised by offering an individualised combination of intervention components

adapted to the single person. Three models underpin the ABLE intervention program, namely the Occupational Therapy Intervention Process Model (OTIPM) [28], describing the problem-solving process (here using an adaptational approach); the Person-Environment-Occupation (PEO) model [29], here explaining performance of daily activities as doing shaped by the interaction between person, environment and occupation; and finally, the Transactional Model of Occupation (TMO) [28], clarifying reasons for ADL task performance problems. ABLE 2.0 consists of five to eight sessions (Fig. 1).

Session 1 involves standardised assessment of perceived and observed ADL ability by means of the ADL-Interview (ADL-I) [30] and the Assessment of Motor and Process Skills (AMPS) [26, 27], respectively. AMPS is an observation-based assessment measuring two aspects of ADL task performance: ADL motor ability (reflecting physical effort) and ADL process ability (reflecting efficiency, safety and independence) [26, 27].

Session 2 concerns setting client-centred goals using Goal Attainment Scaling (GAS) [31, 32] based on ADL task performance problems identified and prioritised using ADL-I in session 1.

Sessions 3–7 are intervention sessions, focusing on adaptation by employing a combination of intervention components to improve ADL task performance, and delivered face-to-face or by telephone, with or without homework (e.g. practicing strategies and trying out new ways of doing) between sessions.

The final session includes re-evaluation of self-reported and observed ADL ability using the ADL-I and AMPS and evaluation of goal attainment using GAS.

Mandatory sessions are 1–2, and at least two intervention sessions and the final session. The program is delivered in the homes or local areas of the participants and is designed to be implemented as part of community-based rehabilitation. Structure and overall content of ABLE 2.0, including a brief case example, is presented in Fig. 1; Table 2 provides information on the intervention components; and Additional file 1 provides description of instruments and tools used in the ABLE 2.0.

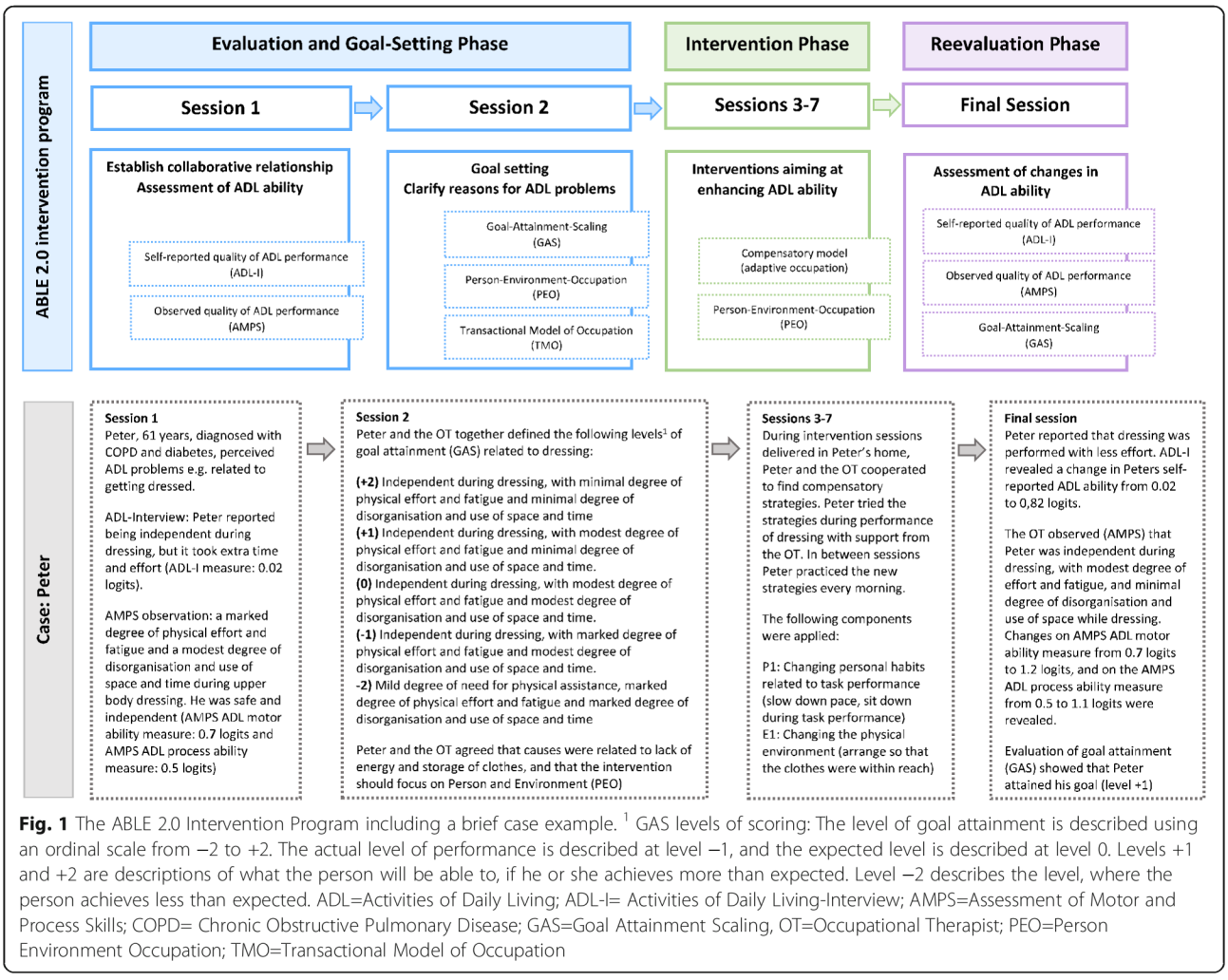


Fig. 1 The ABLE 2.0 Intervention Program including a brief case example. [1] GAS levels of scoring: The level of goal attainment is described using an ordinal scale from −2 to +2. The actual level of performance is described at level −1, and the expected level is described at level 0. Levels +1 and +2 are descriptions of what the person will be able to, if he or she achieves more than expected. Level −2 describes the level, where the person achieves less than expected. ADL=Activities of Daily Living; ADL-I= Activities of Daily Living-Interview; AMPS=Assessment of Motor and Process Skills; COPD= Chronic Obstructive Pulmonary Disease; GAS=Goal Attainment Scaling, OT=Occupational Therapist; PEO=Person Environment Occupation; TMO=Transactional Model of Occupation

Usual occupational therapy

Participants in the control group received standard occupational therapy services provided by the municipality (usual occupational therapy). To gain a preliminary insight into the usual occupational therapy prior to the pilot study, information was extracted from ten records representing people similar to those to be recruited for the pilot study. Those data suggested that the typical dose of usual occupational therapy was 3 x 60 min. Also, the content of usual occupational therapy seemed to vary based on client conditions and needs, but observation of ADL task performance, counselling and evaluation of the use of helping aids were common. Examples of established goals included "ability to bath independently" or "toilet safety".

Data collection

Criteria for progressing to full-scale RCT, based on data derived from this pilot study, were clarified using frameworks by O'Cathain [24], Bowen [33] and Charlesworth [34] and included the following aspects: Recruitment and retention, randomisation procedure, adherence to program, appropriateness of outcome measurements, and information on usual occupational therapy.

Recruitment and retention

The previous feasibility study [23] revealed recruitment and retention challenges. Thus, 33% of the participants dropped out due to lack of motivation or reporting no need of intervention. Consequently, recruitment procedures in this pilot study were specified to recruit participants that actually experienced ADL task performance problems and were ready to make changes, using a two-step model, described above. Moreover, the former inclusion criteria on motivation and readiness for change were specified by splitting it into two criteria: (a) '*motivated and ready for making changes in performance of ADL'* and (b) '*motivated and ready for cooperating with OT in finding solutions to the experienced problems'.*

To monitor recruitment and retention, the flow of participants was registered, capturing information on (1) how many persons were contacted to recruit 20 participants for the pilot study, (2) reasons for accepting/not accepting to participate and (3) number of and reasons for dropouts. Progression criteria on recruitment were that 50% of the persons contacted met the eligibility criteria and accepted participation and that 80% stayed in the program.

Randomisation procedure

To assess the randomisation procedure and determine the acceptability of randomisation among the participants, a randomisation procedure was developed reflecting a procedure to be employed in a future randomised controlled trial. Hence, before inclusion of participants, a randomisation list was generated based on permuted random blocks of variable size (2 to 6 in each block). Participants were allocated in a 1:1 ratio to either ABLE or usual occupational therapy taking into account baseline level of observed ADL ability, using AMPS ADL motor ability (≤ 1.0 vs > 1.0) and ADL process ability (≤ 0.7 vs > 0.7) independence cut-offs [26]. Potential participants were informed about randomisation procedures and given the possibility to withdraw. Monitoring method was to register the randomisation progress including reasons to refuse randomisation. Progression criteria were that 80% accepted randomisation and that procedures were executed as planned.

Adherent delivery of ABLE 2.0

Changes to the ABLE manual

The previous feasibility study [23] revealed some deviations from the manual in delivery (e.g. omission of AMPS in first and/or final sessions, omission of goal setting due to participants having no goals to address, and delivery of less than the minimum of five sessions). Thus, steps were taken to increase adherence to the ABLE manual. The manual was revised, applying results from the feasibility study and also incorporating updates of the theoretical framework OTIPM [28] underpinning the intervention. To examine the revised ABLE manual in terms of any aspect that could lead to confusion or misunderstanding among OTs delivering the program, a cognitive debriefing [35] was conducted. The input and suggestions from the participating OTs (n = 5) were incorporated in the manual, resulting in ABLE 2.0. Further details on the cognitive debriefing process will be published in a separate paper.

Changes in training workshop

The training workshop for the ABLE OTs was extended to three-and-a-half days over a period of a month and providing in-between feedback on e.g. the OTs' use of instruments and delivery of sessions. The workshop consisted of introduction to ABLE 2.0 including underlying intervention theories, practicing the use of instruments, and training delivery of the ABLE intervention components. It was emphasised why both initial AMPS evaluation and goal setting are regarded core mechanisms of change in the program.

Changes in physical environments

The ABLE feasibility study [23] reported limited access to helping aids to try out and practice using. Accordingly, direct access to helping aids was ensured in the pilot study.

To monitor adherence, registration forms were filled in after each session by both participant and OT

informing on perceived engagement; participant involvement, meaningfulness and satisfaction with intervention. Furthermore, OT registration forms informed on number of sessions delivered and time use in each session (dose). Also, what was delivered, including deviations from manual, goal setting and instruments applied for evaluation of ADL ability (fidelity); confidence in delivering the program; unintended side effects; and practical and/or organizational facilitators and barriers. Aspects related to confidence in delivering the program; involvement of participant; OT's and participant's engagement, meaningfulness and satisfaction with the program, were scored using Likert scales from 1 to 5; 1 = very low degree, 2 = low degree, 3 = fair degree, 4 = high degree and 5 = very high degree. Progression criterion on adherence was ABLE 2.0 delivered as intended in terms of dose and fidelity.

Appropriateness of outcome measurements

Several outcome measurements planned for application in the full-scale ABLE RCT were already evaluated for appropriateness in the feasibility study [23], but some remained to be tested: ADL-Questionnaire (ADL-Q) [36], Occupational Balance Questionnaire (OBQ11) [37], and five questions specifically constructed for this study, named Client Weighted Problems questionnaire (CWP) (Additional file 2). Appropriateness was evaluated by counting the number of relevantly and fully answered ADL-Q, OBQ11 and CWP questionnaires at baseline and post-intervention. Progression criterion was 80% of the participants giving relevant and complete answers in questionnaires.

ADL-Questionnaire

ADL-Q is a standardised evaluation tool to describe and measure self-reported quality of ADL task performance [36], in terms of physical effort and/or fatigue, efficiency, safety and independence. The persons report their perceived ADL ability for each of 47 ADL tasks using seven response categories: (a) I perform the task independently without use of extra time or effort and without risk; (b) I perform the task independently, but I use helping aids; (c) I perform the task independently, but it takes me extra time; (d) I perform the task independently, but I use extra effort/get tired; (e) I perform the task independently, but there is a risk that I might injure myself; (f) I need assistance from someone but do participate; and (g) the task is performed by others for me—I cannot participate actively. The person is instructed to use more than one response category, if several apply to their performance of the specific ADL task (e.g. mark both c and d if they spend extra time and get tired). Finally, ratings for personal ADL tasks should be based on ADL task performances within the past 24 h and for instrumental ADL tasks within the past 7 days [36].

To create an overall linear measure of self-reported quality of ADL task performance (reported in log-odds probability units; logits), based on the Rasch measurement methods, the mark given in the lowest response category on each task is re-scored using an ordinal rating scale from 0 to 3: *Competent* (score = 3) covering response categories (a) and (b), *Using extra time/effort* (score = 2) covering response categories (c) and (d), *At risk/need help* (score = 1) covering response categories (e) and (f) and *Unable* (score = 0) covering response category (g) [36]. The present version of the ADL-Q can also be used to measure the person's perceived satisfaction with the quality of performance for each of the 47 ADL tasks, using a four-point ordinal satisfaction scale: 4 = 'very satisfied', 3 = 'satisfied', 2 = 'dissatisfied' and 1 = 'very dissatisfied' [36]. ADL-Q satisfaction measures are also generated based on the Rasch measurement methods [36]. ADL-Q performance measures have demonstrated sensitivity to change, when applied in persons with rheumatoid arthritis [2].

Occupational Balance Questionnaire

OBQ is an 11-item questionnaire evaluating occupational balance of individuals and groups. Occupational balance is defined as *"the experience of having the right amount of occupations and the right variation between occupations, including work, leisure, rest and sleep"* [38]. In OBQ11, the participants report their perceived occupational balance for each of 11 items, using a four-response category scale from 0 = 'completely disagree' to 3 = 'completely agree'. Scores are summed into a total score ranging from 0 to 33, with 33 representing complete occupational balance. OBQ11 has been examined for internal construct validity in a general population using the Rasch measurement theory [37], but not yet in clinical samples.

Client-weighted problems

To complete the investigation on how, from the participants' point of view, engagement in ADL task performance contribute to well-being, and how the participants experienced changes, five questions (CWP) (Additional file 2) were constructed specifically for this study, e.g.: "*How big a problem is it for you, that your chronic condition(s) affects your possibilities to perform and participate in daily tasks in and around your home (e.g. shopping, cleaning, doing laundry, transport)?*". The questions were related to the participant's identified problems and perceived need for help and hopes for the future. The perceived weight was scored on an 11-point numeric scale ranging from '0' representing "*not at all*" to '10' representing "*to a high extent*".

Accessible information on usual occupational therapy

Decisions on needed information on usual occupational therapy was structured by the MRC guidance [39], and inspired by Erlen et al. [40] and Hoffmann et al. [41]. Identification of the specific aspects of information was guided by several hypotheses on mechanisms of action in the ABLE 2.0 intervention program. Aspects included *dose* (duration of intervention, number of visits, length of visits), *evaluation of ADL ability* (use of standardised instruments, self-report and/or observation), *goal setting* (whether goals were formulated, how goals were negotiated), *content of treatment phase* (applied approaches including practicing performance of ADL tasks, counselling, focus on occupation/body functions/environment, involvement of home carer or relative), *referral services* (e.g. social services, group exercises or peer support groups) and *programmatic and/or clinical changes during trial* (changes applied based on e.g. new guidelines or participation in specialised courses) [40].

The monitoring method was the investigation of routinely collected records of participants receiving usual occupational therapy in the ABLE pilot (n = 10). A study-specific schedule for registering data on the predefined aspects of information was developed. Data collection was conducted by the primary investigator and a person from the municipal Rehabilitation Unit, specialised in client records and knowledgeable about rehabilitation practices in the municipality, but not otherwise involved in the study [40]. Progression criterion was access to information on the predefined aspects of usual occupational therapy in 80% of the participants.

Procedures

Following inclusion, a letter was sent to the participants, containing written information on the ABLE pilot study, informed consent form and questionnaires. A baseline home visit by an assessor was scheduled within seven weekdays from the inclusion and oral consent. At the visit, the participant was asked to hand in the signed informed consent form and the filled-in questionnaires. If the participant needed help to fill in any of these, the assessor offered and registered the need of help. Thereafter, observation-based evaluation of ADL ability using the AMPS [26, 27] was performed.

To minimise contamination between interventionists, ABLE 2.0 was delivered by OTs employed in Rehabilitation Unit areas West and East, whereas usual occupational therapy was delivered by OTs employed in Rehabilitation Unit areas South and North. The OTs had rare contact across areas, and ABLE OTs were informed not to share information of any kind on ABLE 2.0 with their colleges. Furthermore, the OTs delivering ABLE 2.0 did not deliver usual occupational therapy. Still, to be able to randomise at an individual level, both the ABLE OTs and the usual occupational therapy OTs delivered interventions in all four geographical areas, depending on the outcome of the randomisation.

External assessors were masked on allocation to intervention at post-intervention and follow-up.

Sample size

Based on the study aims, sample size calculation was not required [42, 43]. Rather, the number of participants was based on representativity related to the target study population, and a sample size large enough to provide useful information about the aspects of the study [43]. Hence, it was decided to include 20 participants.

Data analyses

Data were analysed using IBM SPSS Statistics, version 25. Nominal and ordinal data were reported as number and percentage. Continuous variables were reported as mean and standard deviation (SD), provided that data were normally distributed. Ordinal data and data with lack of normal distribution were presented based on median and range, and nominal data based on percentages. Participant demographic data on age, gender, diagnosis, civic status, job situation, educational level, ADL ability, occupational balance and self-reported general health were presented in a table.

Recruitment, retention and randomisation

Data on recruitment and retention, including number of participants recruited and retention rate, and on randomisation procedures, including flow of participants in relation to randomisation, were presented in flowcharts.

Adherent delivery of ABLE 2.0

Data in registration forms concerning what and how much was delivered, deviations from the intervention manual, work on goal setting, evaluation of ADL ability, unintended side effects and practical and/or organizational facilitators and barriers were summarised and presented in a table, and supported by quotes presented in text.

Appropriateness of outcome measurements

Number of relevantly and fully answered ADL-Q, OBQ11 and CWP questionnaires were reported in numbers and percentages.

Accessible information on usual occupational therapy

Overview on whether information on predefined aspects of usual occupational therapy was accessible or not was provided in a table. Furthermore, it was described if the quality of the information related to goal setting and content of usual occupational therapy was sufficient to

be compared to similar types of information gathered during the ABLE intervention.

Results

The COVID-19 pandemic

Due to the COVID-19 pandemic, the ABLE pilot study was truncated on March 12th, 2020. Consequently, an evaluation was performed to determine the extent to which the collected data was sufficient to address the study aims. Additional actions were launched where possible. Data related to monitoring recruitment and randomisation procedures were judged to be sufficient. Information on retention was limited, and rates could not be determined. Data on adherence to program was limited with no opportunity to gather further data. Thus, results of adherence to intervention program was based on information from registration forms related to two completed and three interrupted ABLE interventions. Data on appropriateness of outcome measurements was limited, based on baseline evaluations of 13 participants. Due to the limited data, a supplementary group interview with assessors on their experiences from baseline assessments was conducted. As the number of baseline ADL-Q data was insufficient for generating ADL-Q measures, they could not be reported. Results of information on usual occupational therapy were based on three completed cases. Therefore, information from client records on another seven clients, representative for the study sample and receiving usual occupational therapy interventions before the pilot study, were included. Despite the truncation of the study, it was concluded that the pilot data were sufficient to answer the majority of the study questions.

Presentation of sample

Participant demographic data are presented in Table 1.

A total of n = 37 persons with chronic conditions were assessed for eligibility, and n = 18 were enrolled. Demographic data indicated variation across diagnoses, age, gender, civic status and educational level. Baseline mean AMPS ADL motor ability measures were below competence cut-off (< 2.0 logits) in both the ABLE and usual occupational therapy group, indicating physical effort, fatigue and/or clumsiness during ADL task performance. Also, baseline mean AMPS ADL process ability measures were below competence cut-off (< 1.0 logit), suggesting

Table 1 Participant baseline characteristics (n = 13)

	Total (n = 13)	ABLE 2.0 (n = 6)	UOT (n = 7)
Gender: Female, n (%)	10 (77)	4 (67)	6 (86)
Age: Median (range)	81 (46–99)	82 (73–93)	81 (46–99)
Diagnosis: n (%)			
Neurological	6 (46)	3 (50)	3 (43)
Medical	2 (15)	0 (0)	2 (33)
Musculoskeletal	5 (38)	3 (50)	2 (33)
Civic status: n (%)			
Living alone	6 (46)	3 (50)	3 (50)
Living with partner	6 (46)	2 (33)	4 (57)
Living with partner and children	1 (8)	1 (17)	0 (0)
Job situation: n (%)			
Senior citizen or early retirement	13 (100)	6 (100)	7 (100)
Educational level: n (%)			
Lower level education [a]	10 (77)	4 (67)	6 (86)
Higher level education [b]	3 (23)	2 (33)	1 (14)
SF-1 of SF-36: Self-reported general heath: median (range)	4 (1–5)	4 (1–4)	4 (3–5)
AMPS ADL motor ability: mean (SD)	0.92 (0.36)	0.83 (0.27)	1.0 (0.42)
AMPS ADL process ability: mean (SD)	0.87 (0.29)	0.93 (0.34)	0.81 (0.26)
Occupational Balance Questionnaire: median (range)	22.5 (7–33)	23.50 (20–33)	19 (7–31)

Neurological: parkinsonism, stroke, multiple sclerosis
Medical: chronic obstructive pulmonary disease, cardiovascular disease
Musculoskeletal: osteoarthritis, back/neck pain, rheumatoid arthritis, shoulder pain
UOT usual occupational therapy
[a] Collapse of three subgroups (primary school, vocational education, short higher education)
[b] Collapse of two subgroups (medium-term higher education, higher education)

ineffective use of time, space and objects, safety risk and potential need for assistance in everyday life [26, 27].

Below, results are presented in relation to the specific aims of the pilot study.

Recruitment and retention

Of 37 potential participants contacted, 18 agreed to participate, resulting in an inclusion of 48.6%. Of these, 13 participants went through baseline evaluations before study was truncated (Fig. 2). Seven of the 13 participants needed help filling out the questionnaires. One participant had a limited use of the scale on ADL-Q performance (a score of 6 in 45 of 47 items). She explained her scores by saying: *"I can perform all tasks, but I tend to not get it done"*. Thus, even though she received daily assistance from spouse to initiate her task performances, she rated her ability to perform the tasks as independent and competent. Furthermore, on the CWP questionnaire she reversed her answers completely, when the assessor gave her further information on the scale.

In relation to retention, no participants dropped out of the study during the active data collection period.

Randomisation procedure

None of the 18 eligible participants refused randomisation. In five cases, further procedures were interrupted due to the COVID-19 pandemic causing lockdown in the municipality. Hence, 13 participants were randomised, with six participants allocated to the ABLE arm and seven to usual occupational therapy arm. All 13 participants stayed in their allocated program until the lockdown (Fig. 2).

Adherent delivery of ABLE 2.0

Sessions delivered, instruments applied, intervention components implemented, and time used

Two participants completed ABLE 2.0 with a minimum of five sessions, and one participant completed ABLE 2.0 except the final session. Another participant completed sessions 1 and 2. In all four cases, evaluation of ADL ability (AMPS and ADL-I) was conducted, and GAS was

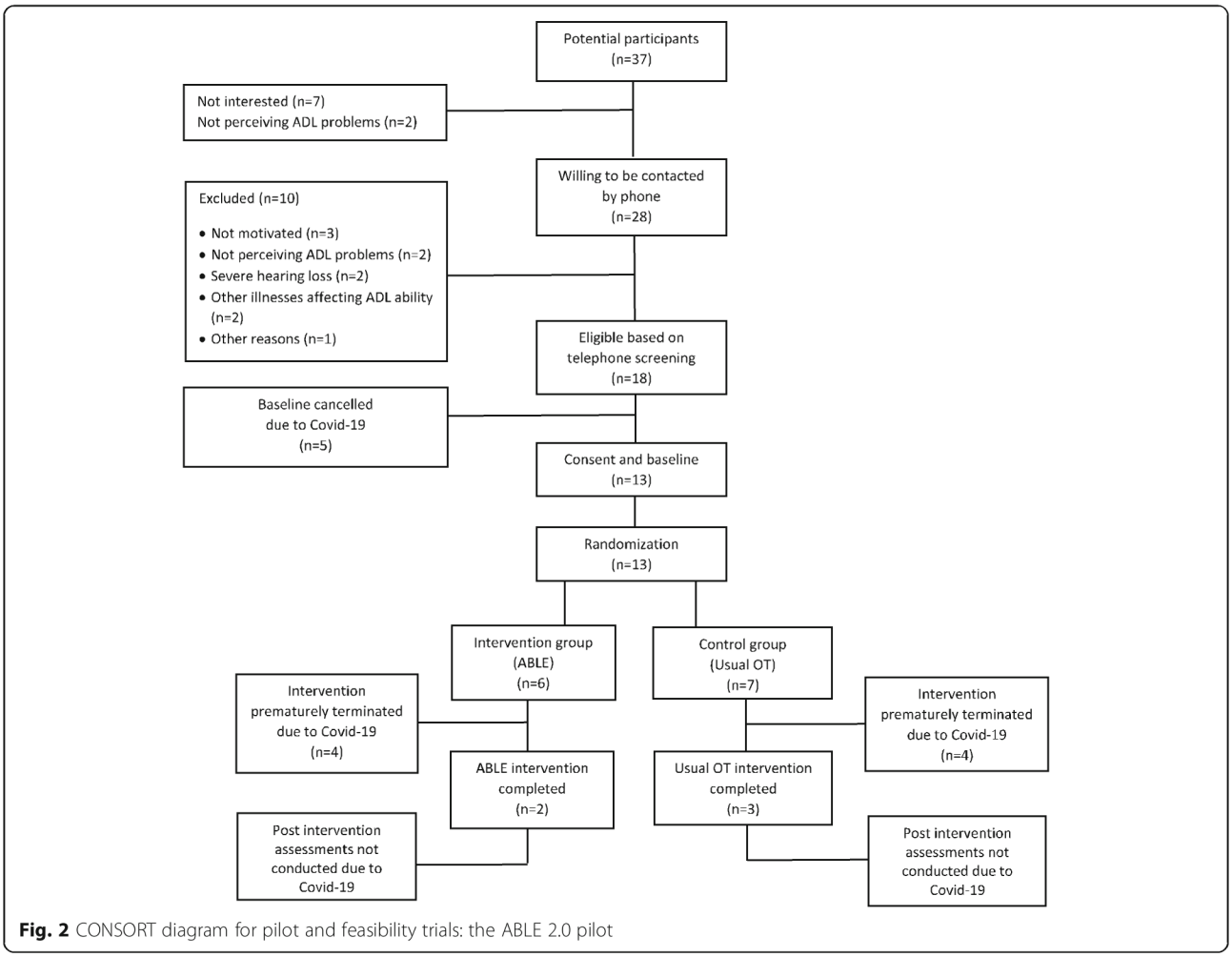


Fig. 2 CONSORT diagram for pilot and feasibility trials: the ABLE 2.0 pilot

used for negotiating and setting goals in accordance with the manual. One more participant completed session 1 and went through ADL evaluations (Fig. 2). Finally, one randomised participant did not receive any sessions, before study ending. The two participants completing ABLE 2.0, also went through ADL re-evaluation (AMPS and ADL-I) in the final session as prescribed in the manual.

Eight of the nine potential intervention components to be applied during sessions 3–7 were applied across participants receiving ABLE 2.0 (Table 2).

The median number of minutes spent at sessions delivered face-to-face varied between 27 and 135 minutes with a tendency to spend more time on the first (median = 93 min) and final sessions (median = 72 min) involving ADL evaluations.

In the usual occupational therapy group, three participants completed their intervention process. Another participant had the intervention process interrupted after one visit, and three participants did not enter the usual occupational therapy intervention.

Deviations from the manual

The OTs reported no deviations from the manual, only adjustments within the inherent flexibility of the program. Instruments and models were applied according to the manual.

Goal setting

Goals were negotiated for all participants completing session 2 (n = 4). Two participants each defined two goals, and two participants each defined one goal. The OTs' satisfaction with delivering session 2 was high (median = 4.5; range: 3 to 5), whereas the OTs experience on how the dialogue on goal setting worked was somewhat lower (median = 3; range: 2 to 5) (Table 3).

The OTs perceived some challenges related to goal setting: "*difficult to guide the participant on grading the goals*"; "*participant found it difficult to understand the scale*"; and "*it was difficult to explain GAS*". Still, the participants all reported that they highly appreciated working with goal setting (median = 4).

Table 2 Frequency of implemented intervention components throughout sessions 3–7 in ABLE 2.0

ABLE 2.0 intervention components[a] organised by PEO[b]	Frequency
P1: Changing habits related to task performance	3
P2: Changing attitude	3
P3: Plan, prioritise and reject	0
E1: Changing the physical environment	1
E2: Changing the social environment	1
E3: Use of tools, technology and/or helping aids	3
E4: Referring to other relevant services and opportunities	2
O1: Dividing the task into minor steps/distributing the task performance over longer time	1
O2: Simplifying the process/simplifying the task	1
Homework between sessions[c]	3

[a] Based on n = 3 participants who completed the minimum of five intervention sessions

[b] *Abbreviations*: *P* Person, *E* Environment, *O* Occupation

[c] Homework between session was applied in all three cases; examples were taking the bus with a friend, practice preparing lunch in smaller parts with rests in between, and practice using cordless vacuum cleaner

Confidence, engagement, involvement of participant, meaningfulness and satisfaction with ABLE 2.0

The OTs' confidence in delivering ABLE 2.0 was high, and they felt highly engaged during the sessions (Table 3). Degree of participant involvement was high, with similar scores from OTs and participants. Participants and OTs found the content of the sessions highly meaningful and satisfactory.

Unintended side effects

OTs registrated a few examples of positive side effects: "*Based on the ADL task performance during the session, the participant was more able to describe the experienced problem related to the task*"; "the *participant seemed more motivated* [at the end of session 2]".

Practical and/or organizational facilitators and barriers

There were no registrations of problems related to access to needed helping aids.

Appropriateness of outcome measurements

At baseline, four participants (30.7%) completed the performance ratings of the ADL-Q. In contrast, only two participants (15.4%) completed the satisfaction ratings of the ADL-Q. The OBQ11 assessments at baseline was completed by twelve participants (92.3%). Finally, all participants (100%) completed the CWP questionnaire at baseline. Thus, the progression criterion of 80% completely answered questionnaires was met in OBQ11 and CWP, but not in ADL-Q.

Seven participants needed assistance to fill in the questionnaires, one due to limited vision, another six for reasons like "*lack of overview*", "*overwhelming*", "*lack of energy*", "*receiving the questionnaires only the day before the meeting [baseline assessment]*" and "*not understanding a term* [occupational balance]". Two of these seven participants needing help filling in the questionnaires, received only minor assistance (less than 10% of the items) to complete.

Information on usual occupational therapy

Table 4 presents information on which of the predefined aspects of usual occupational therapy information was accessible.

Table 3 Pilot aspects related to delivery of the ABLE 2.0 (registrations[a] from OTs (n = 3) and participants (n = 6))

		Session 1	Session 2	Sessions 3–7	Final session
Number of OT registrations: n (%)		5 (83) [b]	4 (100)	6 (100)	2 (67) [b]
Session 1	The session gave me knowledge on which ADL tasks and skills are problematic: median (range)	4.0 (3–5)			
	The session clarified focus (ADL tasks and skills) for intervention: median (range)	4.0 (3–5)			
	The participant and I established a good basis for further cooperation: median (range)	4.0 (3–5)			
Session 2	The dialogue on discrepancy worked well: median (range)		4.0 (3–5)		
	The dialogue on goal setting worked well: median (range)		3.0 (2–5)		
	The dialogue on reasons for ADL problems worked well: median (range)		4.0 (4)		
Sessions 3–7	The session contributed to goal attainment: median (range)			3.0 (2–4)	
	The participant and I had a good cooperation on finding new strategies: median (range)			4.0 (3–5)	
	The participant was willing to try new strategies: median (range)			4.0 (2–5)	
Final session	The intervention overall contributed to goal attainment: (range)				(3)
	The intervention overall contributed to better ADL ability: (range)				(4)
	I believe client will carry on using new strategies: (range)				(3, 4)
Questions asked on all sessions	Confidence in delivering: median (range)	4.0 (4–5)	4.5 (3–5)	4.0 (3–5)	(4, 5)
	OT engagement: median (range)	4.5 (4–5)	5.0 (4–5)	4.0 (3–5)	(5)
	Involvement of client: median (range)	3.5 (3–4)	4.0 (4)	4.0 (3–4)	(4, 5)
	Perceived meaningfulness: median (range)	4.0 (3–4)	4.5 (3–5)	4.0 (2–5)	(4, 5)
	Perceived client meaningfulness: median (range)	3.5 (3–4)	3.5 (3–5)	3.5 (3–4)	(4, 5)
	Perceived satisfaction on delivery: median (range)	3.5 (2–4)	3.5 (3–5)	4.0 (2–5)	(4, 5)
	Perceived client satisfaction: median (range)	4.0 (3–5)	3.5 (3–5)	4.0 (3–5)	(4, 5)
Number of participant registrations: n (%)		5 (83)	4 (100)	6 (100)	2 (67)
Session 1	ADL-I and AMPS gave me new knowledge on my ADL problems: median (range)	2.0 (2–3)			
	ADL-I and AMPS clarified focus for intervention: median (range)	4.0 (2–4)			
	OT and I established a good basis for further cooperation: median (range)	4.0 (3–5)			
	I can see a purpose in participating in program: median (range)	4.0 (2–5)			
Session 2	I liked the work on goal setting: median (range)		4.0 (4)		
	It was relevant to talk about reasons for my ADL problems: median (range)		4.0 (3–4)		
	I can see a purpose in participating in program: median (range)		4.0 (4)		
Sessions 3–7	Session contributed to goal attainment: median (range)			3.5 (3–5)	
	I have at this point attained my goals: median (range)			3.0 (2–3)	
	I can see a purpose in participating in program: median (range)			4.0 (3–5)	
Final session	Intervention overall contributed to goal attainment: (range)				(3, 4)
	Intervention overall contributed to better ADL ability: (range)				(3, 4)
	I will carry on using the new strategies: (range)				(3, 4)
Questions asked on all session	I felt informed: median (range)	4.0 (3–5)	4.0 (4)	3.5 (3–5)	(3, 4)
	I felt involved: median (range)	4.0 (4–5)	4.0 (3–4)	4.0 (3–5)	(4)
	Session was meaningful to me: median (range)	4.0 (3–5)	4.0 (4)	4.0 (3–5)	(4, 5)
	Session was satisfactory to me: median (range)	4.0 (3–5)	4.0 (4)	4.0 (4–5)	(4)

[a] Scored using Likert scales from 1–5; 1 = very low degree, 2 = low degree, 3 = fair degree, 4 = high degree and 5 = very high degree
[b] One registration form was not completed

Table 4 Information on usual occupational therapy, accessible in client records (n = 10)

Aspect	Prespecified information	Access to information
		Yes
Dose	Duration of intervention in days	10
	Number of visits	10
	Duration of visits in minutes	0[a]
Evaluation of ADL ability	Applied methods[b]	9
Goal setting	Whether goals were formulated	9
	How goals were negotiated	9
Content of treatment phase	Applied approaches[c]	10
Referral services		10
Programmatic and/or clinical changes[d]		0

[a]Scheduled time was accessible
[b]Use of standardised instruments; use of observation; use of self-report
[c]Practicing performance of ADL tasks; counselling; focus on occupation/body functions/environment; involvement of home carer or relative
[d]Changes applied based on e.g. new guidelines or participation in specialised courses

The quality of the information related to goal setting and content of usual occupational therapy was assessed to be sufficient for comparison to similar types of information gathered during the ABLE intervention.

Discussion

This pilot study evaluated the remaining feasibility aspects of the ABLE 2.0 intervention program in terms of design, conduct and processes of an outcome trial, including recruitment, randomisation, adherence, appropriateness of outcome measurements and access to information on usual occupational therapy. The results indicated that the procedures for recruitment and randomisation were feasible and that ABLE 2.0 was delivered according to the manual and with engagement. OTs were overall satisfied delivering the ABLE intervention. Moreover, adherence was sufficient since the minimum number of sessions, the mandatory assessments and intervention components for good quality of ABLE 2.0 intervention delivery, were applied by the OTs. Additionally, it was possible to extract almost all the desired information on usual occupational therapy from the client records. Concerning the outcome measurements, the application of ADL-Q in this client population was associated with challenges, whereas the OBQ11 and CWP were eligible.

The revised procedures on recruitment enabled inclusion, as almost half of the persons referred agreed to participate. This differs from the results of the former feasibility study [23], suggesting the revised procedures are recommendable in a future trial. Considering the challenges related to answering the questionnaires, and the inclusion criteria on '*being able to understand and relevantly answer a questionnaire*', we recognise that we are dealing with a population that might be challenged on this criterion. Striving at recruiting persons who seem to match the aims of the intervention and a sample as less biased as possible [44], it is suggested to reduce the amount of questionnaires rather than exclude persons being on the edge of this criteria. Furthermore, we suggest asking potential future participants if they feel confident in answering questionnaires.

In this study, one person, referred for the study, needed help filling in the questionnaires due to limited vision, and another two persons, referred, could not be provided with information on the study due to limited hearing. Hence, their sensory losses introduced a risk to quality of data, preventing them from participation in the study. Accordingly, the exclusion criteria on '*language barriers*' should be adjusted to '*communication barriers*'. Another three persons, referred, were not included due to lack of motivation. The legislation in Denmark prescribes that persons, who apply for home care to assist with household chores, instead as a standard procedure are referred to reablement, a time-limited intervention provided in people's homes to support reacquisition of skills to manage their household chores [45]. Being referred to intervention rather than receiving the requested home care, may have resulted in a higher number of potential participants at entrance of the pilot study, who not all were motivated for participating in the program. Furthermore, research indicate that elderly persons who are frail and have decreased health are more difficult to recruit into research [44, 46], as reflected in the progression criteria of 50% on recruitment in this pilot study. Knowing that differences between participants and non-participants might bias the results of a future RCT and decrease external validity [44], much attention should be paid on recruitment in a future trial.

The challenges on adherent delivery of the first version of ABLE intervention program revealed in the ABLE feasibility study was related to application of AMPS and

goal setting. In the present study involving ABLE 2.0, all instruments were applied according to the manual, and only few adjustments were made delivering the sessions, all within the frame of the program. The results indicate that the revisions of the manual and the tailored course for the OTs overall were efficient. In addition, it is appropriate to emphasise, with reference to the MRC's guidance [47], that some flexibility in the intervention program should be allowed, as interventions may work better if adaptation is acceptable. Thus, the inherent flexibility in ABLE 2.0 is regarded a strength. Results of the present pilot study related to dose (sessions delivered, intervention components implemented and time use) was quite in line with the positive results from the ABLE feasibility study on the same aspects. Hence, the minimum of five sessions should be maintained.

The biggest challenge on outcome measurements in the ABLE 2.0 pilot was related to answering the ADL-Q performance and satisfaction scales, as only 4 of 13 scored the performance scale, and two of 13 scored the satisfaction scale. Fortunately, we learned from the former feasibility study [23] that the interview-based equivalent, ADL-I, is feasible in this population. Hence, the use of ADL-I seems more appropriate to use in this population as it likely provides more complete datasets. Previous research has shown that measures of ADL ability is dependent on the methods applied with questionnaire and interview yielding different but related information about ADL ability [2]. The pattern is a higher self-reported ADL ability based on questionnaire compared with interview [2]. Thus, it is recommended to replace the ADL-Q with the ADL-I, evaluating self-reported ADL ability in terms of performance and satisfaction in a future trial. Furthermore, this will ease the participants´ burden related to answering questionnaires.

Thorough information on usual occupational therapy is critical for investigating effectiveness of the ABLE 2.0 intervention program [20, 41, 48]. Hoffmann et al. [41] suggest describing usual care in a trial with the same level of detail as in the intervention group. But usual care is by nature a dynamic phenomenon. Therefore, it is unlikely that all participants in a control group will receive the same usual care, and furthermore, usual care typically reflects locally adapted practices and may vary at different time points during a trial [40, 49]. Hence, description of usual occupational therapy, based on retrospective investigation on what was delivered to participants receiving usual occupational therapy, should be optimal in a future trial. Information on actual duration of each visit could be requested documented in a future RCT, providing data that are comparable to information gathered during the ABLE intervention. Due to lack of accessibility to information on programmatic and/or clinical changes in the client records in the municipality, it is recommended to conduct short and focused interviews on this aspect, with OTs delivering usual occupational therapy, after the intervention period in a future RCT. Also, it is recommended that data collection on usual occupational therapy is conducted by research staff assisted by a person from the Rehabilitation Unit in the municipality, familiar with clinical practice and client records, to extract information on all possible aspects. Finally, it is recommended to maintain the study-specific schedule developed for this pilot, to collect consistent data on usual occupational therapy interventions.

Conclusions

This pilot study has provided useful information on important aspects related to evaluating the ABLE 2.0 intervention program. Adding the results of this study to the results of the previous feasibility study, and following the recommendations of the MRC guidance on developing and evaluating complex health interventions, progressing to a full-scale RCT including evaluation of effectiveness, processes and economy of the ABLE 2.0 program is recommendable. A limitation of the study is the incomplete dataset, caused by the COVID-19 pandemic prematurely terminating the study and resulting in weaker evidence on some pilot aspects, primarily on adherence to ABLE 2.0 and appropriateness of outcome measurements. There are important findings though, that the procedures on recruitment and randomisation were effective and that it was possible to recruit a sample representing the population being target group of the ABLE intervention. Further, for planning a future trial, it is important to know that the ABLE intervention was delivered according to the manual and that the first five persons included completed the intervention sessions and stayed in the program.

Abbreviations

ADL: Activities of daily living; ABLE: A Better everyday LifE; MRC: Medical Research Council; OT: Occupational therapist; RCT: Randomised controlled trial; AMPS: Assessment of Motor and Process Skills; OTIPM: Occupational Therapy Intervention Process Model; GAS: Goal Attainment Scaling; ADL-Q: Activities of Daily Living Questionnaire; ADL-I: Activities of Daily Living Interview; CWP: Client-Weighted-Problems Questionnaire; OBQ11: Occupational Balance Questionnaire; SF-36: MOS 36-Item Short Form Survey Instrument; SD: Standard deviation

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-021-00861-9.

Additional file 1. Description of instruments integrated in the ABLE 2.0 Intervention Program.

Additional file 2. Client Weighted Problems (CWP).

Additional file 3. CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*.

Acknowledgements
First, we thank all pilot study participants for contributing. We also thank the involved health professionals, in the municipality of Herning for contributing to the study, and the Department of Occupational Therapy and Physiotherapy in the Regional Hospital West Jutland for contributing to the data collection.

Authors' contributions
Study design: VH, KTN, CvB, MG, EW. Acquisition of participants/data: VH, KTN, EW. Analysis and interpretation of data: VH, KTN, MG, EW. Writing manuscript: VH, EW. Critical revision of manuscript: KTN, CvB, MG, EW. The author(s) read and approved the final manuscript.

Funding
This work was funded by: The Oak Foundation [OCAY-13-309]; The municipal fund for quality development [A327]; VIA University College; Southern Denmark University; Bispebjerg and Frederiksberg Hospital, University of Copenhagen; Research Fund of the Danish Association of Occupational Therapy [FF1/19-R112-A2271 and FF2/19-R132-A2835]; and the Lundbeck foundation [A8059].

Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by the Danish Data Protection Service Agency: Journal-nr. P-2020-203. The Ethical Committee confirmed that no approval was needed for this study: Journal-nr.: 19045758. Informed consent was obtained.

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

Author details
[1]The Parker Institute, Bispebjerg and Frederiksberg Hospital, University of Copenhagen, Copenhagen, Denmark. [2]Occupational Science & Occupational Therapy, User Perspectives and Community-based Interventions, Department of Public Health, University of Southern Denmark, Odense, Denmark. [3]Department of Occupational Therapy, VIA University College, Holstebro, Denmark. [4]Department of Occupational Therapy, University College of Northern Denmark, Aalborg, Denmark. [5]Department of Rehabilitation & Scientific Institute for Quality of Care Research, Radboud University Medical Center, Nijmegen, The Netherlands.

Received: 23 November 2020 Accepted: 24 May 2021
Published online: 11 June 2021

References

1. Hvidberg MF, Johnsen SP, Davidsen M, Ehlers L. A nationwide study of prevalence rates and characteristics of 199 chronic conditions in Denmark. PharmacoEconomics - Open. 2019;4:361–80.
2. Wæhrens EE, Bliddal H, Danneskiold-Samsøe B, Lund H, Fisher AG. Differences between questionnaire-and interview-based measures of activities of daily living (ADL) ability and their association with observed ADL ability in women with rheumatoid arthritis, knee osteoarthritis, and fibromyalgia. Scand J Rheumatol. 2012;41(2):95–102. https://doi.org/10.3109/03009742.2011.632380.
3. Nielsen KT, Wæhrens EE. Occupational therapy evaluation: use of self-report and/or observation? Scand J Occup Ther. 2015;22(1):13–23. https://doi.org/10.3109/11038128.2014.961547.
4. Bendixen HJ, Wæhrens EE, Wilcke JT, Sørensen LV. Self-reported quality of ADL task performance among patients with COPD exacerbations. Scand J Occup Ther. 2014 Jul 21;21(4):313–20. https://doi.org/10.3109/11038128.2014.899621.
5. Lindahl-Jacobsen L, Hansen DG, Wæhrens EE, la Cour K, Søndergaard J. Performance of activities of daily living among hospitalized cancer patients. Scand J Occup Ther. 2015 Mar 1;22(2):137–46. https://doi.org/10.3109/11038128.2014.985253.
6. Daving Y, Claesson L, Sunnerhagen KS. Agreement in activities of daily living performance after stroke in a postal questionnaire and interview of community-living persons. Acta Neurol Scand. 2009;119(6):390–6. https://doi.org/10.1111/j.1600-0404.2008.01113.x.
7. Hariz GM, Forsgren L. Activities of daily living and quality of life in persons with newly diagnosed Parkinson's disease according to subtype of disease, and in comparison to healthy controls. Acta Neurol Scand. 2011;123(1):20–7. https://doi.org/10.1111/j.1600-0404.2010.01344.x.
8. Norberg EB, Boman K, Löfgren B. Activities of daily living for old persons in primary health care with chronic heart failure. Scand J Caring Sci. 2008;22(2):203–10. https://doi.org/10.1111/j.1471-6712.2007.00514.x.
9. Månsson Lexell E, Iwarsson S, Lexell J. The complexity of daily occupations in multiple sclerosis. Scand J Occup Ther. 2006;13(4):241–8. https://doi.org/10.1080/11038120600840200.
10. Goodman RA, Posner SF, Huang ES, Parekh AK, Koh HK. Defining and measuring chronic conditions: imperatives for research, policy, program, and practice. Prev Chronic Dis. 2013 Apr 25;10:120239. https://doi.org/10.5888/pcd10.120239.
11. Wæhrens EE. Almindelig daglig levevis. Munksgaard, København: ADL; 2015.
12. Avlund K, Schultz Larsen K, Kreiner S. The measurement of instrumental ADL: Content validity and construct validity. Aging Clin Exp Res. 1993;5(5):371–83. https://doi.org/10.1007/BF03324192.
13. Steultjens E, Dekker J, Bouter L, Leemrijse C, van den Ende C. Evidence of the efficacy of occupational therapy in different conditions: an overview of systematic reviews. Clin Rehabil. 2005;19(3):247–54. https://doi.org/10.1191/0269215505cr870oa.
14. Hand C, Law M, McColl MA. Occupational therapy interventions for chronic diseases: a scoping review. Am J Occup Ther. 2011;65(4):428–36. https://doi.org/10.5014/ajot.2011.002071.
15. Guidetti S, Ranner M, Tham K, Andersson M, Ytterberg C, Von Koch L. A "client-centred activities of daily living" intervention for persons with stroke: one-year follow-up of a randomized controlled trial. J Rehabil Med. 2015;47(7):605–11. https://doi.org/10.2340/16501977-1981.
16. Nielsen TL, Petersen KS, Nielsen CV, Strøm J, Ehlers MM, Bjerrum M. What are the short-term and long-term effects of occupation-focused and occupation-based occupational therapy in the home on older adults' occupational performance? A systematic review. Scand J Occup Ther. 2017 Jul 4;24(4):235–48. https://doi.org/10.1080/11038128.2016.1245357.
17. Sturkenboom IHWM, Graff MJL, Hendriks JCM, Veenhuizen Y, Munneke M, Bloem BR, et al. Efficacy of occupational therapy for patients with Parkinson's disease: a randomised controlled trial. Lancet Neurol. 2014 Jun 1;13(6):557–66. https://doi.org/10.1016/S1474-4422(14)70055-9.
18. Nielsen KT, Klokker L, Wæhrens EE. Self-reported quality of activities of daily living (ADL) task performance in four diagnostic groups with chronic conditions. International Journal of Therapy and Rehabilitation 2021;28(4):1–10. https://doi.org/10.12968/ijtr.2020.0025.
19. Nielsen KT. Occupational therapy for persons living with chronic conditions - development and feasibility of the ABLE program. Odense: University of Southern Denmark; 2018.
20. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337(7676):979–83.
21. Nielsen KT, Klokker L, Guidetti S, Wæhrens EE. Identifying, organizing and prioritizing ideas on how to enhance ADL ability. Scand J Occup Ther. 2019;26(5):382–293. https://doi.org/10.1080/11038128.2018.1424235.
22. Hoffmann T, Bennett S, Del Mar C. Evidence-based practice across the health professions. Sydney: Churchill Livingstone/Elsevier; 2010. p. xiv. 349 s
23. Nielsen KT, Guidetti S, von Bülow C, Klokker L, Wæhrens EE. Feasibility of ABLE 1.0 – a program aiming at enhancing the ability to perform activities of daily living in persons with chronic conditions. Pilot Feasibility Stud. 2021;7(1):1–15.
24. O'Cathain A, Hoddinott P, Lewin S, Thomas KJ, Young B, Adamson J, et al. Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. Pilot Feasibility Stud. 2015;1(1):O88.

25. Fletcher A, Jamal F, Moore G, Evans RE, Murphy S, Bonell C. Realist complex intervention science: applying realist principles across all phases of the Medical Research Council framework for developing and evaluating complex interventions. Evaluation. 2016;22(3):286–303. https://doi.org/10.1177/1356389016652743.
26. Fisher AG, Jones KB. Assessment of motor and process skills. Volume 1: development, standardization, and administration manual. 7th ed. Fort Collins: Three Star Press; 2012.
27. Fisher AG, Jones KB. Assessment of motor and process skills. Volume 2: user manual. 7th ed. Fort Collins: Three Star Press; 2012.
28. Fisher AG, Marterella A. Powerful practice: a model for authentic occupational therapy. Fort Collins: CIOTS - Center for Innovative OT Solutions; 2019.
29. Strong S, Rigby P, Stewart D, Law M, Letts L, Cooper B. Application of the Person-Environment-Occupation Model: a practical tool. Can J Occup Ther. 1999;66(3):122–33. https://doi.org/10.1177/000841749906600304.
30. Wæhrens EE, Nielsen KT. ADL-Interview (ADL-I). Klinisk version 1.0 - Introduktion, ADL-I og administration. Copenhagen: ACE; 2020.
31. Kiresuk TJ, Smith A, Cardillo JE. Goal Attainment Scaling: applications, theory, and measurement. Hillsdale: L. Erlbaum Associates; 1994.
32. Krasny-Pacini A, Hiebel J, Pauly F, Godon S, Chevignard M. Goal Attainment Scaling in rehabilitation: a literature-based update. Ann Phys Rehabil Med. 2013;56(3):212–30. https://doi.org/10.1016/j.rehab.2013.02.002.
33. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How we design feasibility studies. Am J Prev Med. 2009;36(5):452–7. https://doi.org/10.1016/j.amepre.2009.02.002.
34. Charlesworth G, Burnell K, Hoe J, Orrell M, Russell I. Acceptance checklist for clinical effectiveness pilot trials: a systematic approach. BMC Med Res Methodol. 2013;13(78):1–7.
35. Wild D, Alyson G, Mona M, Sonya E, Sandra M, Verjee-Lorenz A, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures. Value Health. 2005;8(2):95–104.
36. Wæhrens EE. Measuring quality of occupational performance based on self-report and observation. Development and validation of instruments to evaluate ADL task performance. Umeå: Department of Community Medicine and Rehabilitation, Umeå University; 2010.
37. Håkansson C, Wagman P, Hagell P. Construct validity of a revised version of the Occupational Balance Questionnaire. Scand J Occup Ther. 2019;0(0):1–9.
38. Wagman P, Håkansson C, Björklund A. Occupational balance as used in occupational therapy: a concept analysis. Scand J Occup Ther. 2012;19(4):322–7. https://doi.org/10.3109/11038128.2011.596219.
39. Moore G, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions. UK Med Res Counc Guid. 2014;19–45:64–75.
40. Erlen JA, Tamres LK, Reynolds N, Golin CE, Rosen MI, Remien RH, et al. Assessing usual care in clinical trials. West J Nurs Res. 2015;37(3):288–98. https://doi.org/10.1177/0193945914526001.
41. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348(March):1–12.
42. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. BMC Med Res Methodol. 2013;13(1):2–7.
43. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010;10(1):1–10. https://doi.org/10.1186/1471-2288-10-1.
44. Michelet M, Lund A, Sveen U. Strategies to recruit and retain older adults in intervention studies: a quantitative comparative study. Arch Gerontol Geriatr. 2014;59(1):25–31. https://doi.org/10.1016/j.archger.2014.03.002.
45. Aspinal F, Glasby J, Rostgaard T, Tuntland H, Westendorp RGJ. New horizons: reablement - supporting older people towards independence. Age Ageing. 2016;45(5):574–8. https://doi.org/10.1093/ageing/afw094.
46. Chatfield MD, Brayne CE, Matthews FE. A systematic literature review of attrition between waves in longitudinal studies in the elderly shows a consistent pattern of dropout between differing studies. J Clin Epidemiol. 2005;58(1):13–9. https://doi.org/10.1016/j.jclinepi.2004.05.006.
47. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337(7676).
48. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med. 2008;148(4):295–310. https://doi.org/10.7326/0003-4819-148-4-200802190-00008.
49. Yorganci E, Evans CJ, Johnson H, Barclay S, Murtagh FEM, Yi D, et al. Understanding usual care in randomised controlled trials of complex interventions: a multi-method approach. Palliat Med. 2020;34(5):667–79. https://doi.org/10.1177/0269216320905064.

Publisher's Note

Paper III

TITLE:

Effectiveness of a systematic problem-solving individualised occupational therapy intervention programme using adaptational strategies on the ability to perform activities of daily living among persons with chronic conditions: a double-blinded randomised controlled trial of the ABLE programme

Authors:

Vita Hagelskjær, OT, MSc, PhD student[1,2,3]

Cecilie von Bülow, OT, PhD[1,2]

Kristina Tomra Nielsen, OT, PhD[1,4]

Marius Henriksen, PT, PhD[1]

Eva Ejlersen Wæhrens, OT, PhD[1,2]

Corresponding author: Vita Hagelskjær, Liljekonvallen 44, 7500 Holstebro, Denmark

e-mail: viha@via.dk

Telephone: +45 8755 2462

Affiliations

1. The Parker Institute, Bispebjerg and Frederiksberg Hospital, University of Copenhagen, Copenhagen, Denmark
2. User Perspectives and Community-based Interventions, Department of Public Health, University of Southern Denmark, Odense, Denmark
3. Department of Occupational Therapy, VIA University College, Holstebro, Denmark
4. Department of Occupational Therapy, University College of Northern Denmark, Aalborg, Denmark

Keywords: ADL; rehabilitation research; complex interventions; Assessment of Motor and Process Skills, AMPS, ADL interview, ADL-I, goal setting, Goal Attainment Scaling, GAS, Occupational Therapy Intervention Process Model, OTIPM

INTRODUCTION

Persons with chronic conditions often report problems performing Activities of Daily Living (ADL) tasks (1–8), which is also reflected in this definition of chronic conditions: "*conditions that last a year or more and require ongoing medical attention and/or limit activities of daily living*" (9). Since an increasing number of persons live with such conditions worldwide (10), resulting in a potentially decreased quality of life for the persons concerned and an increasing financial burden for community-based rehabilitation services (11–13), there is a need for effective interventions addressing decreased ADL task performance.

ADL, including Personal ADL (PADL) and Instrumental ADL (IADL), is a term capturing tasks that most people need to perform in their everyday lives. PADL tasks include self-care tasks such as eating, toileting, grooming and dressing, while IADL tasks include domestic tasks necessary for independent living such as shopping, cooking, cleaning and doing laundry (14,15). Persons with chronic conditions often report ADL task performance problems, reflected as increased effort/fatigue, increased use of time, safety risk and need for assistance when performing specific tasks (2–4,16), such as "*increase in time spent on showering*" or "*increased effort and/or fatigue when cooking a meal*" (2).

The Danish law on social services prescribes that the municipal council must offer rehabilitation to remedy decreased level of functioning, caused by diseases not treated under hospitalisation (17). Further, they must offer short-lived and time-limited rehabilitation for persons with decreased level of functioning, if such services is expected to increase the person's level of functioning and thereby decrease the need for support (18). Usually these rehabilitation services are delivered by interdisciplinary teams including individually delivered occupational therapy. Evidence support occupational therapy interventions to improve ADL ability in persons with various chronic conditions (19–23) and a structured and individualised problem-solving process applied as a part of the occupational therapy process (19). However, rigorous effectiveness studies are limited (19–22,24).

Studies within occupational therapy, addressing ADL ability, have generally been conducted within specific diagnostic groups (21,23–29). But in some studies occupational therapy interventions were applied across diagnostic groups (30–32) or in persons with multi morbidity (33,34). This is in line with Wade (35) suggesting to focus on disabilities in relation to activities rather than interventions based on diagnosis in rehabilitation. Application across diagnostic groups is further supported by a study documenting that persons across diagnostic groups, age, and sex report similar types of problems related to ADL task performance in terms of types of tasks (especially within the IADL domain), and in general experience a decreased quality of ADL task performance in terms of using extra time and/or increased physical effort (especially within the PADL domain) (16). Hence, it is relevant to develop programmes applicable across diagnoses, age, and sex

(16,20) and apply the same type of intervention to address ADL task performance problems across a range of diagnoses. Accordingly, the research programme "A Better Everyday Life" was established to develop and evaluate a new intervention programme to address decreased quality of performance related to ADL tasks (16) among persons with various chronic conditions.

By following the British Medical Research Council's (MRC) guidance (36) on how to develop and evaluate complex interventions, the first version of the ABLE intervention programme (ABLE 1.0) was developed (37–39) and evaluated for its feasibility in terms of content and delivery (39,40). The feasibility evaluation suggested minor programme adjustments resulting in the second version of the ABLE intervention programme (ABLE 2.0) (37,41). ABLE 2.0 is a systematic; individualised; problem-solving; occupational therapy intervention programme based on an adaptational approach, applicable across sex, age, and diagnoses; addressing ADL task performance problems in persons with chronic conditions. Further, a pilot randomised controlled study was conducted (41), suggesting few adjustments related to the design of a future full-scale trial and justifying to evaluate its effectiveness in a full-scale trial (40,41). Information gathered in the pilot study indicated that ABLE 2.0 differs from usual occupational therapy in its systematic (i.e. a logic order in the content of the programme sessions including evaluation of ADL ability, followed by goal setting prior to intervention sessions) and problem solving approach, in actively involving the client in setting goals, and finding solutions building on an adaptational approach (41). Therefore, it was hypothesised that clients receiving ABLE 2.0 would achieve a significantly higher increase in ADL ability compared to clients receiving usual occupational therapy.

Accordingly, the aim of this study was to determine the effectiveness of ABLE 2.0, compared to usual occupational therapy, in persons with chronic conditions, on ADL ability, evaluated at 10 and 26 weeks from baseline.

METHODS

The Danish Data Protection Service Agency approved the trial (Journal-nr. P-2020-203) and the Ethical Committee confirmed that no ethical approval was needed (Journal-nr.: 19045758). The trial was registered with ClinicalTrials.gov (identifier: NCT04295837) before data collection occurred between August 2020 and October 2021. The study was performed in accordance with the ethical standards laid down by the Helsinki declaration. It was reported according to the consolidated Standards of Reporting Trials (CONSORT) 2010 Statement (42). All enrolled participants provided written informed consent to participate. Details of design and methodology were published previously (41).

Design

This was a single-centre, randomised controlled, outcome-assessor and investigator blinded superiority trial with two parallel groups. The study was designed to compare ABLE 2.0 with usual occupational therapy with primary endpoint at 10 weeks from baseline (i.e. end of ABLE 2.0 programme), and a further follow-up 26 weeks from baseline.

Setting

The study was conducted in a Danish municipality. Delivery of interventions and data collection took place in the homes of the participants. As recommended for complex interventions (43), the evaluation included process and cost-effectiveness evaluations conducted alongside this trial. All interventions were delivered by occupational therapists (OTs) employed in the municipality with rehabilitation services organised in four interdisciplinary rehabilitation teams representing four demographically comparable geographic areas (North, East, South, and West). ABLE 2.0 was delivered by three OTs (ABLE OTs) from teams in East or West, whereas usual occupational therapy was delivered by any OT from teams in North or South.

Participants: inclusion, recruitment, and informed consent

Participants were eligible if they had one or more medically diagnosed chronic conditions, were aged ≥ 18 years, lived in own home in the municipality, experienced ADL task performance problems, were motivated and ready for making changes in performance of ADL tasks, were motivated and ready to participate in occupational therapy, communicated independently and relevantly, and were able to understand and relevantly answer a questionnaire. They were excluded if they had personal ADL problems causing acute unmet need for help, known substance abuse, mental illness, and/or other acute illness (< three months) affecting ADL task performance, communication barriers (e.g., severe cognitive deficits or other barriers preventing receiving information on study), and/or received other occupational therapy services addressing decreased ADL ability during the intervention period (weeks 0-9).

Participants were recruited from all four areas of the municipality among persons referred to or already receiving rehabilitation services. One OT from each of the four interdisciplinary rehabilitation teams assessed participants for eligibility using guidelines including a checklist on eligibility criteria (41). The OT provided initial information on the trial and asked for permission to forward contact information to the primary investigator. Within three weekdays, the primary investigator called the potential participant to provide additional trial information and finalise screening of eligibility for inclusion. If a person met the eligibility criteria, preliminary oral consent to participate was obtained. Following recruitment, a letter was sent to the participant containing written information, consent form, and baseline questionnaires. Before baseline assessments, the participants were asked if they understood the written information, including the right to withdraw from the study, and if they had any related questions. Finally, they were asked to sign and hand over the consent form.

The ABLE OTs were recruited provided they had ≥two years of experience working with the study target group and were calibrated as Assessment of Motor and Process Skills (AMPS) raters.

Randomisation, allocation, blinding

Randomisation and stratification were conducted with 1:1 allocation to either ABLE 2.0 or usual occupational therapy in random blocks of variable sizes (2 to 6 in a block), considering their baseline level of observed ADL ability measured with the AMPS (27,28). A randomisation list with four mutually independent randomised sequences was generated by a statistician applying AMPS independence cut offs. AMPS independence cut offs indicate the need of moderate to maximal assistance to live in the community (motor ADL ability (≤1.0 vs >1.0 logits) and process ADL ability (≤0.7 vs >0.7) (27,28)). Allocation concealment was ensured as the primary investigator (blinded to randomisation and unable to foresee group assignment) forwarded ID and baseline AMPS measurements to the principal investigator, who (blinded to coding of group allocation) allocated each participant to either '0' or '1' using the randomisation list. Allocation information was returned to the primary investigator, who told the ABLE or usual occupational therapy OT to initiate the ABLE 2.0 or usual occupational therapy intervention, respectively. The previous pilot RCT showed that this randomisation procedure was acceptable (41).

Intending to blind the participants on allocation, only general information on differences between ABLE 2.0 and usual occupational therapy was provided, e.g., different ways to initiate and/or finalise the intervention. Contamination between ABLE OTs and usual occupational therapy OTs were minimised by recruiting ABLE OTs and usual occupational therapy OTs from different geographic areas. The ABLE OTs only rarely had contact with the usual occupational therapy OTs, and they were informed not to share information of any kind on ABLE 2.0 with their colleges. To make randomisation at an individual level possible, both the

ABLE OTs and the usual occupational therapy OTs delivered interventions in all four geographical areas in the study period.

Blinding of outcome assessors was achieved by not informing them on the content of interventions or the participants' group allocation. To avoid breaking the assessor-blinding at week 10 and 26 assessments, participants were reminded not to disclose information on their intervention to the outcome assessor. Furthermore, assessors were prompted not to discuss the intervention with the participants. Finally, to blind the investigators on the participants' group allocations, participants were re-coded by an independent statistician before data analysis and a statistician not involved in the study conducted the statistical analyses.

Interventions

ABLE 2.0 (experimental group)

Full details on the ABLE intervention programme has been provided in previous publications (39–41,44). In short, the present version, ABLE 2.0 is a home-based; individualised; 8-week occupational therapy intervention programme; applicable across sex, age, and diagnosis; to be delivered as part of community-based rehabilitation services. Based on an occupational therapy intervention process model (45), it addresses ADL task performance problems among persons with chronic conditions by offering standardised evaluation of perceived and observed ADL ability using the ADL Interview (ADL-I) (46) and AMPS (47,48), respectively; client-centred goal setting using Goal Attainment Scaling (GAS) (49,50) and clarification of reasons for ADL tasks performance problems; an individualised combination of nine intervention components (40), building on an adaptational approach (e.g., changes in physical or social environments, use of assistive devices, and adjusting daily routines and habits); and finally re-evaluation of perceived and observed ADL ability (ADL-I and AMPS) (46–48) and re-evaluation of goal attainment (GAS) (49,50).

Training ABLE OTs in delivering ABLE 2.0

The ABLE OTs were trained in delivering ABLE 2.0 as described in the manual (51), by attending a three-and-a-half-day course including introduction to ABLE 2.0 and the underpinning theories and models, practicing the use of instruments in the programme (ADL-I, AMPS and GAS) and training delivery of ABLE sessions. Furthermore, feedback activities were employed in the course. The course was conducted by the researchers who developed the programme.

Usual occupational therapy (control group)

Participants in the control group received standard occupational therapy services delivered in the municipality. The occupational therapy services were framed by local "professional standards" related to interventions addressing ADL task performance problems within personal hygiene, dressing, cleaning, toilet

visits, cooking, and transportation. The professional standards offered descriptions of how to assess the client's resources and level of functioning, pamphlets for delivery, competency requirements, resources (e.g., assistive devices), procedures, intervention components, how to finalise the intervention, and collaboration with colleagues. As described in the protocol (52), and argued for in the pilot paper (41), information on usual occupational therapy was collected retrospectively and hence presented in the results section.

Data collection

Data collection was conducted according to the protocol (41) (Figure 1). Data on age, sex, job situation, civic status, level of education, and whether the participants lived alone or with others, were collected in a questionnaire at baseline. Data on participants' types of chronic conditions were collected from client records.

Figure 1 Schedule of enrolment, interventions, and outcomes assessments

		Allocation	Post group allocation		
	Screening	Baseline	Interventions	Primary endpoint	Secondary endpoint
TIMEPOINT week	**-3 to -1**	**0**	**1-9**	**10**	**26**
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
ABLE			⟷		
UOT			⟷		
ASSESSMENTS:					
ADL-I		X		X	X
AMPS		X		X	X
OBQ11		X		X	X
CWP-Q		X		X	X
SF1 of SF-36		X		X	X

ABLE=a better everyday life (experimental group); ADL-I=activities of daily Living-interview; AMPS=assessment of motor and process skills; CWP-Q=client weighted problems questionnaire; OBQ11=occupational balance questionnaire; SF1 of SF36=first question of the MOS 36-item short form survey instrument; UOT=usual occupational therapy (control group)

Outcomes

Co-primary outcomes were participants' self-reported quality of ADL task performance, measured by the ADL-I (35) and observed ADL motor ability measured by the AMPS (30,31) assessed at baseline and week 10 (52). Secondary outcomes were participants' perceived satisfaction with quality of ADL task performance (ADL-I Satisfaction) (53) and observed ADL process ability (AMPS) (47,48) assessed at baseline, week 10 and week 26. Moreover, participants' self-reported quality of ADL task performance (ADL-I Performance) (46,53) and observed ADL motor ability (AMPS) were secondary outcomes assessed at week 26.

Explorative outcomes were participants' perceived occupational balance (Occupational Balance Questionnaire (OBQ11)) (54), perceived change (Client-Weighted Problems Questionnaire (CWP-Q), created for this study), and general health (the first question (SF1) of the MOS 36-item Short Form Survey Instrument (SF36) (SF36-SF1)) (55), assessed at baseline, and at weeks 10 and 26. Outcome measures are briefly described here. Details can be found in the protocol paper (41).

ADL Interview (ADL-I) (Performance and Satisfaction) is a standardised evaluation tool, used by OTs, to describe and measure self-reported ADL ability (46,53), in terms of physical effort and/or fatigue, efficiency, safety and independence (ADL-I Performance), i.e. quality of ADL task performance. The client report perceived ADL ability for each of 47 ADL items using seven response categories ranging from '*I perform the task independently without use of extra time or effort and without risk*' to '*the task is performed by others for me – I cannot participate actively*' (46,53). Moreover, ADL-I is used to measure the client's perceived satisfaction with quality of performance for each of the 47 ADL tasks, using a four-point ordinal scale ranging from '*very satisfied*' to '*very dissatisfied*' (ADL-I Satisfaction) (53). Based on Rasch measurement methods (53), the raw ordinal data are converted into overall linear (interval scale) measures of self-reported quality of ADL task performance and satisfaction, adjusted for the difficulty of the ADL tasks. The measures are expressed in logits (log-odds probability units) (1,53). The ADL-I Performance has demonstrated sensitivity to change when applied in older persons receiving a home-based reablement programme (40,56) and can generate valid and reliable linear measures of self-reported quality of ADL task performance among persons living with chronic conditions (2,3,53). A clinically relevant difference/change on the ADL-I Performance is >0.64 logits (46).

The Assessment of Motor and Process Skills (AMPS) (47,48) is a standardised observation-based evaluation tool used by OTs to measure a person's observed ADL ability in terms of physical effort and/or fatigue, efficiency, safety and independence i.e. quality of ADL task performance. The client chooses and performs two standardised ADL tasks of personal relevance and appropriate challenge. During an AMPS evaluation, two domains of performance are evaluated: ADL motor (16 items) and ADL process (20 items)

skills. Following observation, the quality of each ADL skill is evaluated on a four-point ordinal scale according to scoring criteria in the AMPS manual (48). Available software (57), based on Many-Faceted Rasch statistics, converts ordinal raw scores into two overall linear measures of ADL motor and ADL process ability, expressed in logits (log-odds probability units), adjusted for rater severity as well as ADL task and skill item difficulty (47). Measures below the AMPS ADL motor scale competence cut off (2.0 logits) indicate increased physical effort, fatigue, and/or clumsiness, whereas measures below the AMPS ADL process scale competence cut off (1.0 logits) indicate ineffective use of time, space and objects, safety risk, and potential need for assistance in everyday life. Further, measures below the AMPS ADL motor scale independence cut off on (1.5 logits) AMPS ADL process scale independence cut off on (1.0 logits) combined also indicate a need for assistance for safe community living (47,48). AMPS has demonstrated sensitivity to change (40,58–60) and can generate reliable and valid measures among persons with chronic conditions (1,2,58,61,62). A clinically relevant difference has been determined as ≥ 0.3 logits on the ADL motor and ADL process skill scales (47).

Occupational Balance Questionnaire (OBQ11) is a generic 11 item instrument designed to assess the experience of and satisfaction with occupational balance, defined as '*the experience of having the right amount of occupations and the right variation between occupations in the occupational pattern'* (54). Occupation refers to being engaged in performance of purposeful and meaningful activities (45). A four-category response scale ranging from '*completely disagree*' to '*completely agree*' is employed. Scores are summed into a total score ranging from zero to 33, with 33 representing complete occupational balance. OBQ11 has been examined for internal construct validity in a general population using Rasch measurement theory (54), but not yet in clinical samples.

Client-Weighted Problems Questionnaire (CWP-Q) is a five-item questionnaire constructed for this study to investigate changes in the participants' perceived problems, acceptance, need for help, and hopes for the future. Each item is rated on an 11-point ordinal scale ranging from '*not at all*' to '*to a high extent*'. The questionnaire was tested for appropriateness in the pilot study (41).

The first question (SF1) of the MOS 36-item Short Form Survey Instrument (SF36) (*SF36-SF1)* (55) is used to assess the client's self-reported general health and well-being. The client is asked: "*In general, would you say your health is excellent* (=1), *very good* (=2), *good* (=3), *fair* (=4) or *poor* (=5)". Previous studies indicate that this question is applicable in persons with chronic conditions (55).

Data on usual occupational therapy

Data on what was delivered in the control group included information on dose, applied approaches for evaluation of ADL ability, goal setting, content of treatment phase, referrals to other services, and programmatic and/or clinical changes during trial (e.g. new clinical guidelines) (63). Data was based on

information from the client records extracted after the intervention period. However, data related to dose in terms of duration of visits in minutes was based on registration forms and data related to programmatic changes and/or clinical changes was based on interviews with OTs delivering the interventions conducted after the intervention period.

Procedures

Outcomes assessors were OTs certified in ADL-I and trained as AMPS raters, recalibrated prior to data collection. Assessors visited participants in their homes at the three timepoints to conduct ADL-I and AMPS evaluations (figure 1). The participants received questionnaires to be filled in 2-8 days prior to the visits. Participants that were assessed at baseline but withdrew from the study did not receive further questionnaires nor test visits. Steps were taken to promote participant retention by making appointment for week 10 assessment at baseline home visit and by contacting participants by telephone to schedule appointment for week 26 follow-up. Registration forms concerning dose in the control group were filled in by the usual occupational therapy OTs during the intervention period.

Sample size

The sample size calculations was based on the co-primary outcomes: change in observed ADL motor ability (AMPS) and self-reported ADL ability (ADL-I Performance) using data reported in the feasibility study (40) and nQuery Advisor® (64). The portal "repeated measures for two means" was selected. The number of levels was set to be 3. Based on AMPS ADL motor ability, an average difference of 0.3 logits (i.e. a clinically relevant difference (47)) between the experimental and control groups was expected; the standard deviation (SD) was assumed to be 0.56 (40). With a sample size of n=25 in each group, a two-sided test for the time averaged difference between two means in a repeated measures design with a significance level set to 5% ($p<0.05$) would have a statistical power of 90%. Similarly, for ADL-I Performance, a clinically relevant difference of ≥0.64 logits (46) between the experimental and control groups was expected; the SD was assumed to be 1.45 (40). Thus, with a sample size of n=34 in each group, a two-sided test for the time averaged difference between two means in a repeated measures design with a 5% significance level, would also have a statistical power of 90%. To account for potential dropouts a total of 40 participants were recruited in each group

Statistical analysis

Minor adjustments were made to the prespecified analysis plan (41) by employing repeated measures mixed linear models handling missing data implicitly, i.e. more conservative principles were applied.

Baseline participant characteristics were reported descriptively. Nominal data were reported based on numbers and percentages. Ordinal data were reported in medians, ranges, quartiles, absolute

numbers, and frequencies. Continuous variables were reported as means and SD when normally distributed. Continuous data with lack of normal distribution were reported based on medians and ranges.

The primary analysis was performed using the intention-to-treat (ITT) population; participants were assessed and analysed as members of their allocated groups, irrespective of adherence to interventions. Continuous outcomes (including the co-primary outcomes) were analysed as change from baseline at week 10 and/or 26 using repeated measures mixed linear models, including participants as random effects, with fixed effect factors for group and week (including all timepoints to respect the ITT principle) and the corresponding interaction, while adjusting for baseline values (to increase precision) and the stratification factors (as part of the design). Results are reported as least squares means and Standard Errors (SEs), and differences between least squares means are reported with two-sided 95% Confidence Intervals (95% CI) and associated p-values. Missing data were handled implicitly in the ITT analysis by the mixed linear models (65). Sensitivity analyses (66) were performed for all outcomes by repeating the primary analyses on the per-protocol (PP) population predefined as participants who attended assessments at primary endpoint (week 10) and received a minimum of three sessions of the ABLE 2.0 (participants in the experimental group), or received sufficient intervention based on a professional estimate by usual occupational therapy OTs after end of intervention (participants in the control group) (52). If the primary analysis and the sensitivity analysis confirm each other, confidence in the results is increased.

The explorative binary outcomes (OBQ11, CWP-Q, SF36-SF1) were analysed using logistic regression with the same factors as the primary analysis. Missing data in binary outcomes were handled using an extreme-set multiple imputation technique followed by applying Rubin's rule to both the observed and four extreme case scenarios (i: Data as observed; ii; Worst-Worst case; iii: Worst-Best case; iv: Best-Worst case, and v: Best-Best case scenario).

Responder analysis

Responders were identified in the PP population as participants achieving a clinically relevant improvement in AMPS ADL motor ability (≥ 0.3 logits) (47) and/or ADL-I Performance (≥ 0.64 logits) (46) measures. The proportions (number and percentages) of responders were calculated and compared by Pearson's chi2 test, and mean changes in observed and self-reported ADL ability for responders were analysed and compared between groups using independent samples t-tests and reported in means and 95 % CI.

Data were analysed using IBM SPSS Statistics, version 25 (67) and SAS (version 9.4).

Results

Baseline demographic and clinical characteristics for participants included in the study are presented in Table 1. A total of n=149 persons with chronic conditions were assessed for eligibility, and n=78 were enrolled and allocated to ABLE 2.0 (n=38) or usual occupational therapy (n=40). Figure 2 illustrates the flow of participants throughout the study, including time-points and reasons for not completing the interventions.

Demographic data indicated variation within the groups in diagnoses, age, sex, civic status, and educational level. More than half of the participants were diagnoses with more than one chronic condition (64.1 %) and most (89.7 %) were senior citizens. Median age among the participants was 76 years and most of them lived alone (65.4 %). At baseline, mean AMPS ADL motor and AMPS ADL process ability measures were below the scale specific competence cut-offs indicating decreased quality of performance in both groups i.e., increased physical effort, clumsiness and/or fatigue, ineffective use of time, space and objects, safety risk, and potential need for assistance in everyday life during ADL task performance (47,48). Also, baseline mean AMPS ADL motor and ADL process ability measures were below the scale specific independence cut-offs in both groups suggesting a need of assistance during ADL task performance.

Table 1: Baseline characteristics for the total sample grouped into ABLE and Usual occupational therapy (UOT)

Variable	ABLE (n=38)	UOT (n=40)
Age: median (range)	75.0 (34-88)	76.5 (29-92)
Sex: female, n (%)	29 (76.3)	27 (67.5)
Diagnosis[a]: n (%)		
Orthopaedic/musculosceletal[b]	18 (47.4)	24 (60.0)
Neurological[c]	6 (15.8)	9 (22.5)
Medical[d]	14 (36.8)	7 (17.5)
Multi morbidity	24 (63.2)	26 (65.0)
Civic status: n (%)		
Living alone	26 (68.4)	26 (65.0)
Living with a partner	12 (31.6)	14 (35.0)
Living with children	2 (5.3)	3 (7.5)
Job situation: n (%)[e]		
Working	0 (0.0)	2 (5.0)
Sick leave	1 (2.6)	4 (10.0)
Senior citizen	36 (94.7)	34 (85.0)
Highest level of education: n (%)[ef]		
Low	28 (73.9)	28 (70.0)
Middle	8 (21.1)	12 (30.0)
High	1 (2.6)	0 (0.0)
SF1 of SF36: median (range)	4.0 (2-5)	4.0 (2-5)
ADL ability: mean (SD)		
AMPS ADL motor	0.9 (0.6)	0.9 (0.6)
AMPS ADL process	1.0 (0.5)	0.9 (0.5)
ADL-I Performance	1.12 (1.10)	0.96 (0.80)
ADL-I Satisfaction	0.97 (1.26)	0.77 (0.96)
OBQ11: median (range)	23 (0-33)	23 (4-33)
CWP-Q: median (range)		
CC affects ADL	8.0 (0-10)	8.0 (2-10)
CC affects social life	7.0 (0-10)	6.0 (0-10)

Need help to accept CC	4.0 (0-10)	4.0 (0-10)
Need assistance in ADL	8.0 (0-10)	8.0 (0-10)
CC affects hope for future	8.0 (0-10)	9.0 (0-10)

ABLE: Experimental group; UOT: control group (e.g., usual occupational therapy); SF1 of SF36: the first question (SF1) of The MOS 36-item Short Form Survey Instrument (SF36); ADL: activities of daily living; ADL-I: activities of daily living interview; AMPS: Assessment of Motor and Process Skills; OBQ: occupational balance questionnaire; CWP-Q: client weighted problems questionnaire; CC: chronic condition

[a] The diagnosis (orthopaedic/musculoskeletal, neurological and medical) that the assessor determined to affect the ADL ability most at baseline
[b] defined as arthritis, chronic/long-term pain, and fracture/replacement
[c] defined as stroke (i.e. right-/left-sided stroke, subarachnoid haemorrhage, cerebral aneurism) and non-stroke (i.e. cerebral palsy, traumatic brain injury, multiple sclerosis, parkinsonism)
[d] defined as cardiovascular disease, respiratory disease, diabetes, cancer, and obesity
[e] Data missing for one participant
[f] Based on the Danish educational system; low: primary education or low-level professional education; middle: secondary education or medium-level professional education; and high: tertiary education (bachelor's degree or higher)

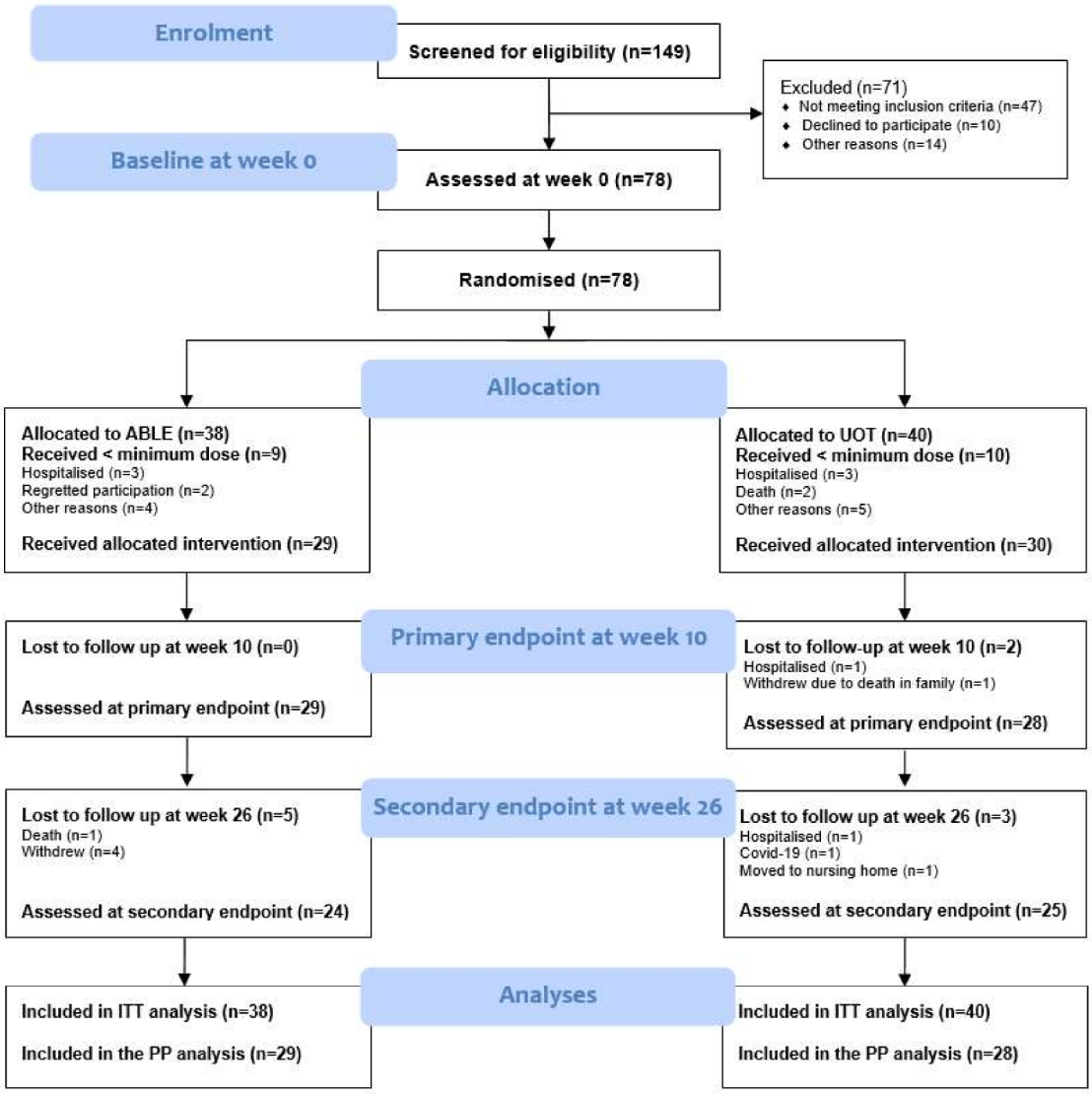


Figure 2 CONSORT 2010 Flow Diagram of the ABLE 2.0 trial

Usual occupational therapy

Thirty (n=30; 75%) of the participants in the usual occupational therapy group completed the intervention. The median number of visits were 2 (range: 1 to 12) and the median duration of each visit was 60 minutes (range: 15 to 90). The median duration of interventions were 14.5 days (range: 1 to 118). Six occupational therapists delivered usual occupational therapy. Five of them had >2 years of experience working with the target group. One usual occupational OT, delivering occupational therapy for one client, had <1 year of experience with the target group. Overall, n=95 sessions were delivered. Of those, n=90 sessions (94.7 %) were delivered in the home of the client, whereas n=5 sessions (5.3 %) were delivered by telephone.

Client records overall indicated a non-standardised approach to evaluation of ADL ability that included dialogue and trying out tasks. Moreover, the client records indicated that evaluation of ADL ability and intervention planning was conducted in a parallel order rather than employing evaluation as a basis for planning intervention. In n=12 cases (40.0 %) client records showed that focus/goals for the intervention was negotiated in collaboration between the OT and the client. Examples of areas of focus/goals were: *"Vacuuming", "preparing coffee", "cleaning the floor", "cooking", "dressing", "safer bathing", "independent bathing"*. In n=17 cases (56.7 %) goals were identified by the referral services, defining focus for the intervention. In a single case (3.3 %) there was no accessible information on goal setting. Concerning content of intervention sessions information in the client records indicated that in n=18 cases (60.0 %) the OTs employed practicing performance of ADL tasks and/or counselling on ADL task performance, whereas in remaining n=12 cases (40.0 %) there was no information on performance of ADL tasks or application of counselling during the intervention. Furthermore, the client records indicated that interventions had various focus on the client's body functions, occupation and/or contextual factors (68). Moreover, involvement of home caregivers and/or relatives were occasionally described. According to the client records, n=9 (30.0%) clients were introduced to and/or referred to assistive devices and n=8 (26.7 %) clients were referred to receive assistance in the home. The interventions were finalised in various ways, including re-evaluation in n=7 (23.3%) cases using non-standardised methods.

Outcomes

Differences in mean changes between the ABLE 2.0 and the usual occupational therapy group on primary, secondary, and explorative outcomes at primary and secondary endpoints are provided in table 2.

The primary analysis of the co-primary outcomes identified no statistically significant difference in mean changes between groups at primary endpoint (week 10) on AMPS ADL motor ability (LS mean change = -0.1; 95%CI = -0.3 to 0.1) or ADL-I performance (LS mean change = -0.16; 95%CI = -0.38 to 0.06). Still, while both groups improved in AMPS ADL motor ability from baseline to week 10, only the ABLE

group obtained a clinically relevant change (LS mean change = 0.3; SE = 0.7). In contrast, in the primary analysis of AMPS ADL motor ability as a secondary outcome at the secondary endpoint (week 26), a statistically significant and clinically relevant difference in mean change between groups was found (LS mean change = -0.3; 95% CI = -0.5 to -0.1).

Table 2. Changes in primary, secondary, and explorative outcomes at primary and secondary endpoints in the intention-to treat (ITT) and per-protocol (PP) populations

	ITT				PP			
Variables	**ABLE (n=38)**	**UOT (n=40)**	**Estimated treatment difference**		**ABLE (n=29)**	**UOT (n=28)**	**Estimated treatment difference**	
	LSMean (SE)	LSMean (SE)	ΔLSMean (95% CI)	P value	LSMean(SE)	LSMean(SE)	ΔLSMean (95% CI)	P value
Primary outcomes at primary endpoint, week 10								
AMPS ADL motor ability	0.3 (0.1)	0.2 (0.1)	-0.1 (-0.3 to 0.1)	0.3430	0.4 (0.1)	0.1 (0.1)	-0.2 (-0.5 to 0.0)	0.0622
ADL-I Performance	0.17 (0.08)	0.01 (0.08)	-0.16 (-0.38 to 0.06)	0.1635	0.19 (0.09)	0.03 (0.09)	-0.15 (-0.41 to 0.10)	0.2384
Secondary outcomes at primary endpoint, week 10								
AMPS ADL process ability	0.1 (0.1)	0.1 (0.1)	-0.1 (-0.2 to 0.1)	0.4036	0.1 (0.1)	0.1 (0.1)	-0.1 (-0.2 to 0.1)	0.4350
ADL-I Satisfaction	-0.10 (0.13)	-0.20 (0.13)	-0.10 (-0.46 to 0.27)	0.6012	0.05 (0.10)	-0.16 (0.11)	-0.21 (-0.51 to 0.08)	0.1553
Secondary outcomes at secondary endpoint, week 26								
AMPS ADL motor ability	0.4 (0.1)	0.1 (0.1)	**-0.3 (-0.5 to -0.1)**	**0.0178**	0.5 (0.1)	0.1 (0.1)	**-0.4 (-0.7 to -0.1)**	**0.0027**
AMPS ADL process ability	0.1 (0.1)	0.1 (0.1)	0.0 (-0.2 to 0.1)	0.6062	0.2 (0.1)	0.0 (0.1)	-0.1 (-0.3 to 0.1)	0.2113
ADL-I Performance	0.19 (0.09)	0.28 (0.09)	0.09 (-0.15 to 0.34)	0.4381	0.14 (0.10)	0.31 (0.10)	0.18 (-0.10 to 0.46)	0.2050
ADL-I Satisfaction	0.22 (0.14)	-0.09 (0.14)	-0.31 (-0.71 to 0.08)	0.1204	0.17 (0.11)	-0.08 (0.11)	-0.25 (-0.57 to 0.07)	0.1245
Explorative outcomes at primary endpoint, week 10*								
OBQ11	1.62 (0.87)	1.01 (0.87)	-0.61 (-3.05 to 1.83)	0.6225	1.91 (1.00)	1.39 (1.00)	-0.52 (-3.31 to 2.28)	0.7140
CWP-Q1 - affects ADL	-0.80 (0.31)	-1.35 (0.32)	-0.56 (-1.44 to 0.33)	0.2182	-0.54 (0.35)	-1.37 (0.36)	-0.83 (-1.82 to 0.16)	0.0999
CWP-Q2 - affects social life	-0.09 (0.32)	-0.34 (0.32)	-0.26 (-1.16 to 0.65)	0.5763	0.10 (0.38)	-0.19 (0.38)	-0.29 (-1.35 to 0.77)	0.5903
CWP-Q3 - need help to accept	-1.44 (0.44)	-0.25 (0.43)	1.19 (-0.03 to 2.41)	0.0551	-1.34 (0.53)	-0.11 (0.50)	1.22 (-0.22 to 2.66)	0.0960
CWP-Q4 - need assistance in ADL	-2.16 (0.44)	-1.20 (0.44)	0.96 (-0.28 to 2.19)	0.1284	-2.41 (0.51)	-1.15 (0.50)	1.26 (-0.15 to 2.67)	0.0803
CWP-Q5 - affects hope for future	-0.29 (0.36)	-0.13 (0.35)	0.16 (-0.84 to 1.15)	0.7524	-0.47 (0.42)	-0.13 (0.42)	0.34 (-0.83 to 1.52)	0.5663
Explorative outcomes at secondary endpoint, week 26*								
OBQ11	1.14 (1.00)	0.97 (0.95)	-0.17 (-2.89 to 2.54)	0.9005	1.30 (1.10)	0.64 (1.08)	0.66 (-3.71 to 2.39)	0.6701
CWP-Q1 - affects ADL	-0.60 (0.36)	-1.19 (0.34)	-0.59 (-1.57 to 0.39)	0.2352	-0.37 (0.39)	-1.10 (0.38)	-0.73 (-1.81 to 0.35)	0.1834
CWP-Q2 - affects social life	-0.15 (0.41)	-0.25 (0.35)	-0.09 (-1.15 to 0.97)	0.8654	-0.06 (0.46)	-0.32 (0.41)	-0.27 (-1.48 to 0.95)	0.6657
CWP-Q3 - need help to accept	-1.05 (0.54)	-0.54 (0.46)	0.51 (-0.89 to 1.91)	0.4710	-0.88 (0.61)	-0.47 (0.54)	0.40 (-1.22 to 2.02)	0.6225
CWP-Q4 - need assistance in ADL	-2.08 (0.50)	-1.78 (0.46)	0.30 (-1.04 to 1.64)	0.6583	-1.81(0.55)	-2.20 (0.52)	-0.40 (-1.90 to 1.10)	0.6000
CWP-Q5 - affects hope for future	-0.48 (0.41)	-0.59 (0.38)	-0.12 (-1.2 to 0.99)	0.8355	-0.36 (0.47)	-0.74 (0.45)	-0.38 (-1.66 to 0.90)	0.5559

ABLE, a better everyday life (experimental group); ADL, activities of daily living; ADL-I, activities of daily living interview; AMPS, assessment of motor and process skills; CI, confidence interval; CWP-Q, client weighted problems questionnaire; OBQ, occupational balance questionnaire; ITT, intention to treat; PP, per protocol; SE, standard error; UOT, usual occupational therapy (control group)

* Data missing at baseline. OBQ: ABLE n=1, CWP-Q1: ABLE n=1, CWP-Q2: ABLE n=2, CW-Q3: ABLE n=4, UOT n=1, CWP-Q4: ABLE n=2, CWP-Q5: ABLE n=1.

This was confirmed in the sensitivity analysis (LS mean change = -0.4; 95% CI = -0.7 to -0.1), where the ABLE 2.0 group obtained a clinically relevant improvement from baseline to week 26 (LS mean change = 0.5; SE = 0.1). The trajectories for the AMPS ADL motor ability and ADL-I performance are illustrated in figures 3 and 4, respectively.

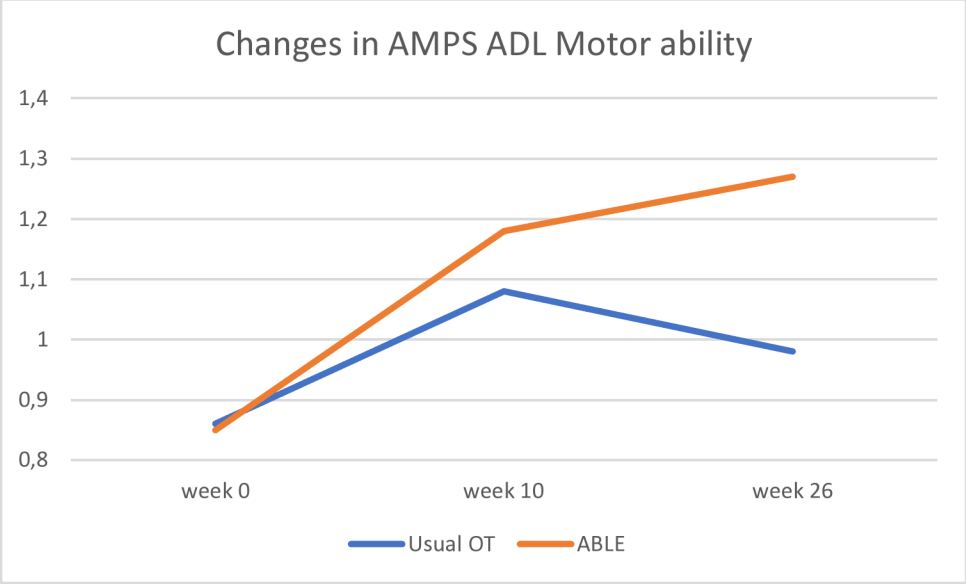


Figure 3 Trajectories of the AMPS ADL motor ability. Higher values represent more ADL ability

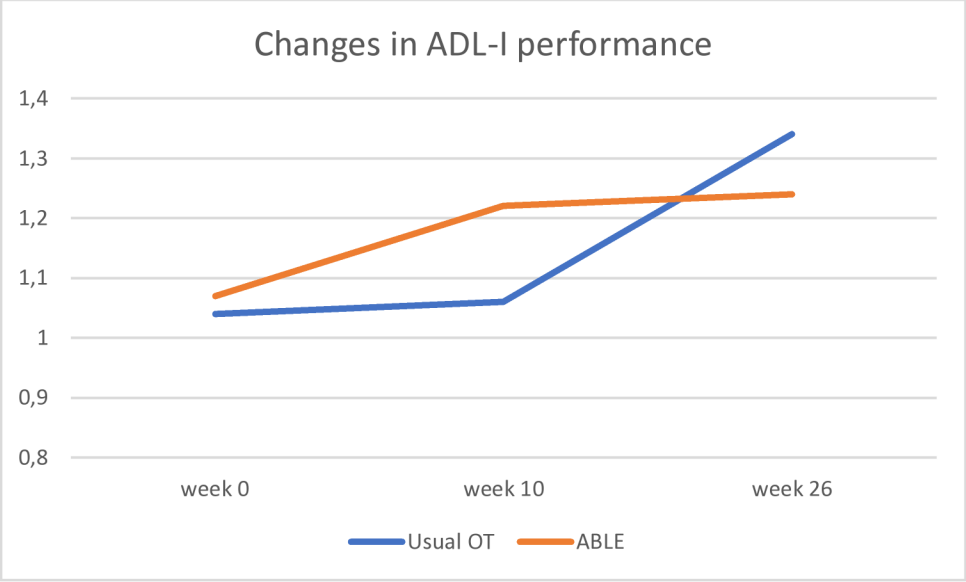


Figure 4 Trajectories of the ADL-I Performance ability. Higher values represent more ADL ability

In terms of self-reported ADL ability (ADL-I Performance and Satisfaction), observed ADL process ability (AMPS process), occupational balance (OBQ11), client weighted changes (CWP-Q) no statistically significant nor clinically relevant changes were revealed between groups at primary or secondary endpoints. Further, logistic regression analysis on overall health, assessed by the SF36-SF1, showed no association between allocation to the ABLE 2.0 intervention (vs. usual occupational therapy) and self-reported improvement in health (odds ratio = 1.3; 95% CI = 0.09 to 22.66; p = 0.8249).

The per protocol analyses confirmed the primary analyses.

Responder analysis

In total n=57 participants received ≥ minimum doses and attended assessments at week 10, i.e. the PP population. Baseline demographics on responders and non-responders at primary endpoint in the two groups are presented in table 3 and an overview of the proportion of responders and mean changes in ADL ability at primary and secondary endpoints is provided in table 4.

Table 3 Baseline demographics on responders and non-responders at primary endpoint in the ABLE and usual occupational therapy (UOT) groups

Variable	ABLE		UOT	
	Responders n=16	Non-responders n=13	Responders n=14	Non-responders n=14
Age: median (range)	76.0 (66-86)	76.0 (51-88)	77.5 (36-92)	75.5 (57-89)
Sex: female, n (%)	12 (75.0)	9 (69.2)	8 (57.1)	12 (85.7)
Diagnosis[a]: n (%)				
Orthopaedic/musculosceletal[b]	7 (43.8)	7 (53.8)	6 (42.9)	10 (71.4)
Neurological[c]	2 (12.5)	2 (15.9)	4 (28.6)	3 (21.4)
Medical[d]	7 (43.8)	4 (30.8)	4 (28.6)	1 (7.1)
Multi morbidity	11 (68.8)	8 (61.5)	9 (64.3)	10 (71.4)
Civic status: n (%)				
Living alone	11 (68.8)	9 (69.2)	9 (64.3)	8 (57.1)
Living with a partner	5 (31.3)	4 (30.8)	5 (35.7)	6 (42.9)
Living with children	0 (0.0)	1 (7.7)	1 (7.1)	0 (0.0)
Job situation: n (%)				
Working	0 (0.0)	0 (0.0)	0 (0.0)	2 (14.3)
Sick leave	0 (0.0)	1 (7.7)	1 (7.1)	1 (7.1)
Senior citizen	16 (100.0)	12 (92.3)	13 (92.9)	11 (78.6)
Highest level of education: n (%)[e]				
Low	11 (68.8)	9 (69.2)	10 (71.4)	8 (57.1)
Middle	4 (25.0)	4 (30.8)	4 (28.6)	6 (42.9)
High	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)
SF1 of SF36: median (range)	4.0 (4-5)	4.0 (3-5)	4.5 (2-5)	4.0 (3-5)
ADL ability: mean (SD)				
AMPS ADL motor	0.6 (0.6)	1.1 (0.4)	0.6 (0.7)	1.2 (0.4)
AMPS ADL process	0.8 (0.5)	1.1 (0.4)	0.9 (0.5)	1.0 (0.5)
ADL-I Performance	0.91 (1.23)	1.32 (1.08)	0.88 (0.76)	1.31 (0.91)
ADL-I Satisfaction	0.73 (0.93)	0.95 (1.02)	0.66 (0.77)	1.13 (0.88)
OBQ11: median (range)	22 (0-33)	25 (12-33)	23 (10-30)	26 (4-32)
CWP-Q: median (range)				
CC affects ADL	8.0 (5-10)	8.0 (0-10)	8.0 (5-10)	8.0 (2-10)
CC affects social life	8.0 (0-10)	6.0 (0-10)	6.0 (0-10)	4.0 (0-10)

Need help to accept CC	5.0 (0-10)	5.0 (0-9)	4.0 (0-10)	1.0 (0-10)
Need assistance in ADL	9.0 (4-10)	6.0 (1-10)	6.5 (0-10)	8.0 (3-10)
CC affects hope for future	8.0 (2-10)	8.0 (1-10)	9.0 (2-10)	6.0 (1-10)

ABLE: experimental group; UOT: control group (e.g., usual occupational therapy); SF1 of SF36: the first question (SF1) of The MOS 36-item Short Form Survey Instrument (SF36); ADL: activities of daily living; ADL-I: activities of daily living interview; AMPS: Assessment of Motor and Process Skills: OBQ: occupational balance questionnaire; CWP-Q: client weighted problems questionnaire; CC: chronic condition

[a] the diagnosis (orthopaedic/musculoskeletal, neurological and medical) that the assessor determined to affect the ADL ability most at baseline
[b] defined as arthritis, chronic/long-term pain, and fracture/replacement
[c] defined as stroke (i.e. right-/left-sided stroke, subarachnoid haemorrhage, cerebral aneurism) and non-stroke (i.e. cerebral palsy, traumatic brain injury, multiple sclerosis, parkinsonism)
[d] defined as cardiovascular disease, respiratory disease, diabetes, cancer, and obesity
[e] based on the Danish educational system; low: primary education or low-level professional education; middle: secondary education or medium-level professional education; and high: tertiary education (bachelor's degree or higher)

Table 4. Proportion of responders and mean changes in ADL ability at primary and secondary endpoints

	ABLE n=29	**UOT** n=28	**Group differences**
Responders on primary outcomes at primary endpoint (week 0-10)			
AMPS ADL motor ability			
n (%)	14 (48.3)	10 (35.7)	Chi^2=0.92; df=1; p=0.34
Mean change (95 % CI)	0.8 (0.5-1.1)	0.8 (0.5-1.1)	0.0 (-0.4 to 0.4)
ADL-I performance			
n (%)	6 (20.7)	4 (13.8)	Chi^2=0.40; df=1; p=0.34
Mean change (95 % CI)	1.15 (0.41-1.88)	1.04 (0.82-1.26)	-0.10 (-0.94 to 0.73)
AMPS ADL motor ability and/or ADL-I performance			
n (%)	16 (55.2)	14 (50.0)	Chi^2=0.19; df=1; p=0.89
Responders on primary outcomes at secondary endpoint (week 0-26)			
AMPS ADL motor ability			
n (%)	13 (44.8)	10 (35.7)	Chi^2=0.50; df=1; p=0.48
Mean change (95 % CI)	1.0 (0.7-1.3)	0.8 (0.4-1.1)	-0.2 (-0.7 to 0.2)
ADL-I performance			
n (%)	6 (20.7)	9 (32.1)	Chi^2=0.96; df=1; p=0.33
Mean change (95 % CI)	1.06 (0.08-1.33)	1.05 (0.82-1.27)	00.02 (-0.34 to 0.30)
AMPS ADL motor ability and/or ADL-I performance			
n (%)	14 (48.3)	17 (60.7)	Chi^2=0.89; df=1; p=0.35

ABLE: experimental group; UOT: control group (e.g., usual occupational therapy); ADL: activities of daily living; ADL-I: activities of daily living interview; AMPS: Assessment of Motor and Process Skills

Sixteen (55.2 %) of the clients completing the ABLE 2.0 intervention obtained a clinically relevant improvement in ADL ability, i.e. were responders, based on self-report (ADL-I Performance) and/or observation (AMPS ADL motor) measured as change from baseline to primary endpoint at week 10. Of these, 4 (25.0 %) achieved a clinically relevant improvement based on both measures. In comparison, in the group receiving usual occupational therapy, n=14 (50.0 %) of the clients completing their intervention obtained a clinically relevant improvement in ADL ability at week 10. None of these achieved a clinically relevant improvement based on both measures. Differences in number of responders between groups were not statistically significant.

At the secondary endpoint, n=14 (48.3 %) of the clients completing the ABLE 2.0 intervention obtained a clinically relevant improvement in ADL ability based on self-report (ADL-I Performance) and/or observation (AMPS ADL motor). Of these, n=5 (17.2 %) achieved a clinically relevant improvement based on both measures. In comparison, n=17 (60.7 %) of the participants in the control group obtained a clinically relevant improvement in ADL ability. Of these, n=2 (7.1 %) achieved a clinically relevant improvement based on both measures. Again, the differences in number of responders between groups were not statistically significant. Finally, at primary and secondary endpoints, mean changes in AMPS ADL motor ability and ADL-I Performance measures were not significantly different between groups of responders.

In the ABLE 2.0 group all the responders were senior citizens, whereas participants with other job situations represented either non-responders or responders in the usual occupational therapy group. The baseline mean AMPS ADL motor ability among responders in the ABLE 2.0 group was 0.5 logits lower compared to non-responders, representing a clinically relevant difference (i.e. ≥ 0.3 logits) (47). In the usual occupational therapy group similar differences (0.6 logits) were seen between responders and non-responders at baseline. Likewise, a clinically relevant difference in baseline mean AMPS ADL process ability (0.3 logits) was seen between responders and non-responders in the ABLE 2.0 group (47), whereas in the usual occupational therapy group the mean difference was 0.1 logits in favour of non-responders, but not clinically relevant.

Baseline mean ADL-I Performance measures among the responders in the ABLE 2.0 group was 0.41 logits lower than among the non-responders. In contrast, in the usual occupational therapy group the mean difference was 0.43 logits in favour of non-responders. Still, none of them represented a clinically relevant difference (i.e. ≥ 0.64 logits).

The results of the CWP-Q showed that responders in both groups at baseline perceived that their chronic conditions affected their ADL ability, social life, and hope for the future more than among non-responders; and that perceived need for assistance was highest among responders in the ABLE 2.0 group.

Discussion

To our knowledge this was the first study to evaluate the effectiveness of a systematic problem-solving individualised occupational therapy intervention programme applicable across diagnoses, sex, and age, and using adaptational strategies aiming to enhance ADL ability among persons with chronic conditions. The outcomes of the ABLE 2.0 intervention was compared those of usual occupational therapy in a Danish municipality. The hypothesis that the ABLE 2.0 intervention programme would be significantly more effective than usual occupational therapy already at end of intervention, was not confirmed. Instead, participants in

both groups obtained an increase in observed ADL motor ability immediately after intervention, reflecting decreased effort, clumsiness, and fatigue during ADL task performance. Consequently, differences between groups at end of intervention were small and statistically non-significant, suggesting that both types of occupational therapy had some impact on observed ADL ability. Still, in the ABLE 2.0 group mean change in observed ADL motor ability reached the level of clinical relevance among participants, while the mean changes among participants in the usual occupational therapy group never reached clinical relevance. Further, the observed ADL motor ability continued to increase in the ABLE 2.0 group from end of intervention to 26 weeks from baseline, whereas observed ADL motor ability in the usual occupational therapy group decreased again to a level close to baseline. Therefore, mean differences between groups in ADL motor ability were statistically significant and clinically relevant at week 26, suggesting that sustainable changes were only obtained in the ABLE 2.0 group. Regarding changes in self-reported ADL ability, a pattern similar to changes in observed ADL ability was seen in the ABLE 2.0 group, with an increase at the primary endpoint, that slightly increased at week 26. Still, mean change in self-reported ADL ability did not reach clinical relevance. A contrasting pattern was seen in the usual occupational therapy group with no change from baseline to primary endpoint followed by an increase at week 26, still not reaching a level of clinical relevance. Between group differences in self-reported ADL ability on the ADL-I performance, and in the remaining secondary and explorative outcomes based on self-report, were all statistically insignificant.

Evaluating the outcomes of a new intervention by comparing it with usual care or another new active intervention generally represents a challenge, as some improvements may be expected from both interventions. This was for example the case in a study, where the outcomes of an 11-week intensive client-centred occupational therapy intervention (the ICC-OT study) was compared with usual brief (maximum three sessions) occupational therapy in a sample of home-dwelling older adults (69). In line with our findings, they found no significant differences in observed change in ADL motor ability between groups post intervention, but in contrast to our results both groups obtained clinically relevant changes in AMPS ADL motor ability immediately after the intervention period (69).

Similarly, in a study comparing the outcomes of a two-week, group-based interdisciplinary rehabilitation programme followed by either 16 weeks of occupational therapy or physiotherapy (the IMPROvE phase-two study) (23), among women with fibromyalgia, they also identified a clinically relevant difference in observed change in ADL motor ability in both groups immediately after the intervention period, with no significant differences between groups (23). The occupational therapy intervention (ADAPT) in the IMPROvE phase-two study (64,128) was structured by the OTIPM (51) and aimed to improve ADL ability by means of adaptation, which is in line with ABLE 2.0, suggesting that the structured approach provided by the OTIPM and the

application of adaptational strategies to resolve ADL task performance problems, as represented in the individual home-based ABLE intervention and the group-based ADAPT intervention, may improve ADL motor ability immediately after the intervention period in people with chronic conditions.

With regard to the further increase in ADL motor ability at week 26, the ICC-OT study (69) found similar result. The ICC-OT intervention is comparable to the ABLE intervention in delivering a home-based, client-centred individualised occupational therapy intervention programme, and in emphasising collaboration with the client on goal setting and practising performance. Hence, such elements may support sustainable changes. However, studies evaluating long-term effectiveness of interventions for people with chronic conditions, often report that achieved improvements are not sustainable. This was the case in the follow-up study on the IMPROvE trial (23,70), reporting that a clinically relevant and statistically significant increase in ADL motor ability immediately after the intervention period (23), decreased to a level close to baseline at week 88 from baseline (70). The ADAPT intervention differs from ABLE 2.0 in being group-based and delivered in a clinical rehabilitation setting. Hence, differences in long-term outcomes between the ADAPT on one hand and the ICC-OT and ABLE 2.0 on the other hand may be explained by the ICC-OT and ABLE 2.0 being individualised interventions delivered in the home of the client.

A reason for not reaching statistically significant changes in the ADL-I might be loss of power. Our sample size calculation suggested 68 participants to reach a power of 90 % in the ADL-I Performance. By planning to include 80 participants a 15% drop-out rate was allowed. However, only n=57 participants were assessed at primary endpoint resulting in loss of statistical power in terms of ADL-I Performance, decreasing the chance of detecting a true difference between groups. Moreover, the challenge of verifying changes based on self-report has been highlighted in studies documenting changes based on observation (23,60,69,71). In both phases of the IMPROvE trial (23,71) and in a study comparing hand-exercise as an add on to usual occupational therapy with usual occupational therapy alone in women with rheumatoid arthritis (60), statistically significant changes over time between groups was found in observation-based ADL ability, whereas no differences were seen in self-reported outcomes. In the ICC-OT study, the Canadian Occupational Performance Measure (COPM), a self-report instrument based on interview, was employed as primary outcome (69). Results indicated a statistically significant difference between groups, but neither differences between groups nor changes over time reached the recommended minimal important change of 3.5 points (72). Considering that any of these studies had omitted observation-based outcomes, the risk would have been that the interventions had been deemed ineffective.

Poor relationships between self-reported and observation-based outcomes has previously been found in comparable samples, e.g., persons with chronic widespread pain (23,71), persons with

inflammatory rheumatoid diseases (1,73), and persons with chronic low back pain (74,75). An explanation for the limited relation may be the different perspectives represented in the two methods. While the self-reported evaluation represents the client's image of the ability over time and across places, potentially influenced by a range of factors such as memory, coping ability, and mood, the observation-based evaluation represents a single example of ability as observed by the assessor, potentially influenced by factors such as the observer's mood and the environment. Further, if self-report is based on interview rather than questionnaire, the interviewer may influence the person in various ways. Acknowledging that information about ADL ability based on self-report and observation are distinct but related, information on ADL ability should be gathered using both methods, confirming the relevance of employing the AMPS and the ADL-I as co-primary outcomes in this trial.

Post hoc sub-group analysis in the ABLE 2.0 group revealed clinically relevant lower AMPS ADL motor ability at baseline among responders compared to non-responders, suggesting room for improvement. Similar results were found in the ABLE 1.0 feasibility study (40), supporting that persons with low observed ADL motor ability may benefit from the ABLE 2.0 intervention. In fact, the responders in the ABLE group represented a baseline level of AMPS ADL ability below the independence cut off (1.5 logits) indicating increased effort, fatigue, inappropriate use of time, space, or objects, and decreased ability to adapt actions efficiently during performance of ADL tasks. Further the level of ADL ability indicated a need for assistance to live in the community (47). That is the responders had an overall lower level of ADL ability, i.e. they used more effort, were less efficient and more dependent during ADL task performance at baseline, compared to non-responders. To explain the positive results the IMPROvE phase-two study (23), evaluating the group-based occupational therapy programme ADAPT applying adaptational strategies, found that the ability measures were clinically and statistically significantly lower among responders compared to non-responders at baseline, overall increasing the confidence in the systematic approach by means of the OTIPM and application of the principles of the compensatory intervention model using adaptational strategies (45).

Clinical messages

- Improvement in ADL motor ability may be obtained by applying a structured approach including standardised evaluation of ADL ability, collaborative goal setting, and application of adaptational strategies to resolve ADL task performance problems
- Involvement of the client in an individualised home-based problem-solving occupational therapy process may lead to sustainable changes

Acknowledgements

First, we thank all study participants for contributing. We also like to extend our sincere thanks to Herning municipality for contributing to this study. Further we would like to thank the Department of Occupational Therapy and Physiotherapy in the Regional Hospital West Jutland, and Ms. Mette Mondrup and Ms. Linda Trier Hald for contributing to the data collection. The authors thank consultant Christian Cato Holm for support regarding the database.

Author contributions

VH, CvB, KTN, and EEW contributed to designing the study. VH and EEW were major contributors in collecting clinical data. MH conducted the statistical analysis of primary and secondary outcomes data. VH, CvB, KTN and EEW contributed to analysis. All authors contributed to interpretation of results. VH drafted the manuscript, CvB, KTN, MH, and EEW contributed significantly in preparing the manuscript and provided critical revision. All authors approved the final version.

Declaration of conflicting interests

None declared

Funding

The trial was funded by the Oak Foundation [OCAY-13-309]; the municipal fund for quality development [A327]; VIA University College; Southern Denmark University; Bispebjerg and Frederiksberg Hospital, University of Copenhagen; Research Fund of the Danish Association of Occupational Therapy [FF1/19-R112-A2271 and FF2/19-R132-A2835]; and the Lundbeck foundation [A8059].

REFERENCES

1. Wæhrens EE, Bliddal H, Danneskiold-Samsøe B, Lund H, Fisher AG. Differences between questionnaire-and interview-based measures of activities of daily living (ADL) ability and their association with observed ADL ability in women with rheumatoid arthritis, knee osteoarthritis, and fibromyalgia. Scand J Rheumatol. 2012;41(2):95–102.

2. Nielsen KT, Wæhrens EE. Occupational therapy evaluation: Use of self-report and/or observation? Scand J Occup Ther. 2015;22(1):13–23.

3. Bendixen HJ, Wæhrens EE, Wilcke JT, Sørensen LV. Self-reported quality of ADL task performance among patients with COPD exacerbations. Scand J Occup Ther. 2014 Jul 21;21(4):313–20.

4. Lindahl-Jacobsen L, Hansen DG, Wæhrens EE, la Cour K, Søndergaard J. Performance of activities of

daily living among hospitalized cancer patients. Scand J Occup Ther. 2015 Mar 1;22(2):137–46.

5. Daving Y, Claesson L, Sunnerhagen KS. Agreement in activities of daily living performance after stroke in a postal questionnaire and interview of community-living persons. Acta Neurol Scand. 2009;119(6):390–6.

6. Hariz GM, Forsgren L. Activities of daily living and quality of life in persons with newly diagnosed Parkinson's disease according to subtype of disease, and in comparison to healthy controls. Acta Neurol Scand. 2011;123(1):20–7.

7. Norberg EB, Boman K, Löfgren B. Activities of daily living for old persons in primary health care with chronic heart failure. Scand J Caring Sci. 2008;22(2):203–10.

8. Månsson Lexell E, Iwarsson S, Lexell J. The complexity of daily occupations in multiple sclerosis. Scand J Occup Ther. 2006;13(4):241–8.

9. Goodman RA, Posner SF, Huang ES, Parekh A, Koh HK. Defining and Measuring Chronic Conditions : Imperatives for Research , Policy , Program , and Practice Conceptual Model for Standardizing the Analysis of Health Data Sets for Selected Chronic Conditions. Prev Chronic Dis. 2013;10(Mcc):1–16.

10. World Health Organization. Worlds Health Statistics 2020: Monitoring health for the SDG, sustainable development goals. Geneva; 2020.

11. Iheanacho I, Zhang S, King D, Rizzo M, Ismaila AS. Economic burden of chronic obstructive pulmonary disease (COPD): A systematic literature review. Int J COPD. 2020;15:439–60.

12. Hajat C, Stein E. The global burden of multiple chronic conditions: A narrative review. Prev Med Reports. 2018;12(September):284–93.

13. Dalsgaard CT. Økonomisk Styring af Hjemmepleje og Rehabiliteringsforløb [Financial Management of Home Care and Rehabilitation Services]. VIVE DK. 2020.

14. Wæhrens EE. Almindelig daglig levevis: ADL [Activities of daily living: ADL]. Munksgaard; 2015.

15. Avlund K. Disability in old age. Longitudinal population-based studies of the disablement process. Dan Med Bull. 2004;51(4):315–49.

16. Nielsen KT, Klokker L, Wæhrens EE. Self-reported quality of activities of daily living task performance in four diagnostic groups with chronic conditions. IJTR. 2021;28(4):1–10.

17. Serviceloven [Law on Social Services] § 86. (SEL) [Internet]. [cited 2021 Dec 14]. Available from:

https://danskelove.dk/serviceloven/86

18. Serviceloven [Law on Social Services] § 83a. (SEL) [Internet]. [cited 2021 Dec 14]. Available from: https://danskelove.dk/serviceloven/83a

19. Steultjens E, Dekker J, Bouter L, Leemrijse C, Ende C van den. Evidence of the efficacy of occupational therapy in different conditions: an overview of systematic reviews. Clin Rehabil. 2005;19(3):247–54.

20. Hand C, Law M, McColl MA. Occupational therapy interventions for chronic diseases: A scoping review. Am J Occup Ther. 2011;65(4):428–36.

21. Guidetti S, Ranner M, Tham K, Andersson M, Ytterberg C, Von Koch L. A 'client-centred activities of daily living' intervention for persons with stroke: One-year follow-up of a randomized controlled trial. J Rehabil Med. 2015;47(7):605–11.

22. Nielsen TL, Petersen KS, Nielsen CV, Strøm J, Ehlers MM, Bjerrum M. What are the short-term and long-term effects of occupation-focused and occupation-based occupational therapy in the home on older adults' occupational performance? A systematic review. Scand J Occup Ther. 2017 Jul 4;24(4):235–48.

23. Von Bülow C, Amris K, Bandak E, Danneskiold-Samsøe B, Wæhrens EE. Improving activities of daily living ability in women with fibromyalgia: An exploratory, quasi-randomized, phase-two study, improve trial. J Rehabil Med. 2017;49(3):241–50.

24. Sturkenboom IHWM, Graff MJL, Hendriks JCM, Veenhuizen Y, Munneke M, Bloem BR, et al. Efficacy of occupational therapy for patients with Parkinson's disease: a randomised controlled trial. Lancet Neurol. 2014 Jun 1;13(6):557–66.

25. Norberg E-B, Löfgren B, Boman K, Wennberg P, Brännström M. A client-centred programme focusing energy conservation for people with heart failure. Scand J Occup Ther. 2017 Nov;24(6):455–67.

26. Waehrens EE, Fisher A. Improving quality of ADL performance after rehabilitation among people with acquired brain injury. Scand J Occup Ther. 2007;14(4):250–7.

27. Pilegaard MS, la Cour K, Gregersen Oestergaard L, Johnsen AT, Lindahl-Jacobsen L, Højris I, et al. The 'Cancer Home-Life Intervention': A randomised controlled trial evaluating the efficacy of an occupational therapy–based intervention in people with advanced cancer. Palliat Med. 2018;32(4):744–56.

28. Martinsen U, Bentzen H, Holter MK, Nilsen T, Skullerud H, Mowinckel P, et al. The effect of occupational therapy in patients with chronic obstructive pulmonary disease: A randomized controlled trial. Scand J Occup Ther. 2017;24(2):89–97.

29. Sturkenboom IH, Graff MJ, Borm GF, Veenhuizen Y, Bloem BR, Munneke M, et al. The impact of occupational therapy in Parkinson's disease: A randomized controlled feasibility study. Clin Rehabil. 2013;27(2):99–112.

30. Gitlin LN, Winter L, Dennis MP, Corcoran M, Schinfeld S, Hauck WW. A randomized trial of a multicomponent home intervention to reduce functional difficulties in older adults. J Am Geriatr Soc. 2006;54(5):809–16.

31. Ciro CA, Smith P. Improving personal characterization of meaningful activity in adults with chronic conditions living in a low-income housing community. Int J Environ Res Public Health. 2015;12(9):11379–95.

32. Mirza M, Gecht-Silver M, Keating E, Krischer A, Kim H, Kottorp A. Feasibility and preliminary efficacy of an occupational therapy intervention for older adults with chronic conditions in a primary care clinic. Am J Occup Ther. 2020;74(5):1–13.

33. Garvey J, Connolly D, Boland F, Smith SM. OPTIMAL, an occupational therapy led self-management support programme for people with multimorbidity in primary care: A randomized controlled trial. BMC Fam Pract. 2015;16(1):1–12.

34. O'Toole L, Connolly D, Boland F, Smith SM. Effect of the OPTIMAL programme on self-management of multimorbidity in primary care: A randomised controlled trial. Br J Gen Pract. 2021;71(705):E303–11.

35. Wade D. Rehabilitation-a new approach. Part four: A new paradigm, and its implications. Clin Rehabil. 2016;30(2):109–18.

36. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions : new guidance. 2008;(January):4–5.

37. Nielsen KT, Hagelskjær V, Pilegaard MS, von Bülow C, Wæhrens EE. The development of the A better Everyday LifE (ABLE) intervention program. Unpubl Work.

38. Nielsen KT, Klokker L, Guidetti S, Wæhrens EE. Identifying, organizing and prioritizing ideas on how to enhance ADL ability. Scand J Occup Ther. 2018;26(5):382–93.

39. Guidetti S, Nielsen KT, von Bülow C, Pilegaard MS, Klokker L, Wæhrens EE. Evaluation of an intervention programme addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a feasibility trial (ABLE). BMJ Open. 2018;8(5):e020812.

40. Nielsen KT, Guidetti S, von Bülow C, Klokker L, Wæhrens EE. Feasibility of ABLE 1.0—a program aiming at enhancing the ability to perform activities of daily living in persons with chronic conditions. Pilot Feasibility Stud. 2021;7(1):1–15.

41. Hagelskjær V, Nielsen KT, von Bülow C, Graff M, Wæhrens EE. Occupational therapy addressing the ability to perform activities of daily living among persons living with chronic conditions: a randomised controlled pilot study of ABLE 2.0. Pilot Feasibility Stud. 2021;7(1):122.

42. Charlesworth G, Burnell K, Hoe J, Orrell M, Russell I. Acceptance checklist for clinical effectiveness pilot trials: A systematic approach. BMC Med Res Methodol. 2013;13(1).

43. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337(7676):979–83.

44. Nielsen KT. Occupational therapy for persons living with chronic conditions - Development and feasibility of the ABLE program. Thesis. Southern Denmark University; 2018.

45. Fisher AG, Marterella A. Powerful practice : A Model for Authentic Occupational Therapy. Fort Collins: CIOTS - Center for Innovative OT Solutions; 2019.

46. Wæhrens EE, Nielsen KT. ADL-Interview (ADL-I). Klinisk version 1.0 - Introduktion, ADL-I og administration [Clinical version 1.0 - Introduction, ADL-I, and administration]. ACE Copenhagen. 2020.

47. Fisher AG, Jones KB. Assessment of motor and process skills. Volume 1: Development, standardization, and administration manual. 7th ed. Fort Collins, Colorado, USA: Three Star Press; 2012.

48. Fisher AG, Jones KB. Assessment of motor and process skills. Volume 2: User manual. 7th ed. Fort Collins, Colorado, USA: Three Star Press; 2012.

49. Krasny-Pacini A, Hiebel J, Pauly F, Godon S, Chevignard M. Goal Attainment Scaling in rehabilitation: A literature-based update. Ann Phys Rehabil Med. 2013;56(3):212–30.

50. Kiresuk TJ, Smith A, Cardillo JE. Goal Attainment Scaling : Applications, theory, and measurement. Hillsdale, N.J.: L. Erlbaum Associates; 1994.

51. Nielsen KT, Hagelskjær V, Wæhrens EE. Manual: ABLE 2.0 - et ergoterapeutisk interventionsprogram for personer med kroniske tilstande [ABLE 2.0 - an occupational therapy intervention programme for persons with chronic conditions]. Unpubl Work. 2020;

52. Hagelskjær V, Nielsen KT, von Bulow C, Oestergaard LG, Graff M, Wæhrens EE. Evaluating a complex intervention addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a randomised controlled trial (ABLE). BMJ Open. 2021;11(11):e051722.

53. Wæhrens EE. Measuring quality of occupational performance based on self-report and observation. Development and validation of instruments to evaluate ADL task performance [Internet]. Thesis. Department of Community Medicine and Rehabilitation, Umeå University; 2010. Available from: http://umu.diva-portal.org/smash/record.jsf?pid=diva2%3A318271&dswid=3508

54. Håkansson C, Wagman P, Hagell P. Construct validity of a revised version of the Occupational Balance Questionnaire. Scand J Occup Ther. 2019;0(0):1–9.

55. Gill TK, Broderick D, Avery JC, Dal Grande E, Taylor AW. Self reported overall health status: Implications for intervention strategies. Australas Med J. 2009;2(8):44–57.

56. Winkel A, Langberg H, Wæhrens EE. Reablement in a community setting. Disabil Rehabil. 2015;37(15):1347–52.

57. OT Assessment Package (OTAP). Fort Cloons, Colorado, USA: Center for Innovative OT Solutions; 2016.

58. Wæhrens EE, Amris K, Fisher AG. Performance-based assessment of activities of daily living (ADL) ability among women with chronic widespread pain. Pain. 2010;150(3):535–41.

59. Graff MJL, Vernooij-Dassen MJM, Thijssen M, Dekker J, Hoefnagels WHL, Rikkert MGMO. Community based occupational therapy for patients with dementia and their care givers: Randomised controlled trial. Br Med J. 2006;333(7580):1196–9.

60. Ellegaard K, von Bülow C, Røpke A, Bartholdy C, Hansen IS, Rifbjerg-Madsen S, et al. Hand exercise for women with rheumatoid arthritis and decreased hand function: An exploratory randomized controlled trial. Arthritis Res Ther. 2019;21(1):1–9.

61. Moore K, Merritt B, Doble SE. ADL skill profiles across three psychiatric diagnoses. Scand J Occup Ther. 2010;17(1):77–85.

62. Von Bülow C, Amris K, La Cour K, Danneskiold-Samsøe B, Wæhrens EE. Ineffective ADL skills in women with fibromyalgia: a cross-sectional study. Scand J Occup Ther. 2016;23(5):391–7.

63. Erlen JA, Tamres LK, Reynolds N, Golin CE, Rosen MI, Remien RH, et al. Assessing Usual Care in Clinical Trials. West J Nurs Res. 2015;37(3):288–98.

64. Statistical Solutions, Saugus, MA U. nQuery Advisor®, version 8.5.0.0. computer program [Internet]. [cited 2021 Jan 20]. Available from: https://www.statsols.com/

65. Detry MA, Ma Y. Analyzing repeated measurements using mixed models. JAMA - J Am Med Assoc. 2016;315(4):407–8.

66. Little RJ, Ph D, Agostino RD, Ph D, Cohen ML, Ph D, et al. The Prevention and Treatment of Missing Data in Clinical Trials. 2012;367:1355–60.

67. IBM Corp. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.;

68. World Health Organization (WHO). International Classification of Functioning, Disability and Health (ICF) [Internet]. World Health Organization; [cited 2022 Jan 26]. Available from: https://www.who.int/standards/classifications/international-classification-of-functioning-disability-and-health

69. Nielsen TL, Andersen NT, Petersen KS, Polatajko H, Nielsen CV. Intensive client-centred occupational therapy in the home improves older adults' occupational performance. Results from a Danish randomized controlled trial. Scand J Occup Ther. 2018;0(0):1–17.

70. Amris K, Bülow C von, Christensen R, Bandak E, Rasmussen MU, Danneskiold-Samsøe B, et al. The benefit of adding a physiotherapy or occupational therapy intervention programme to a standardized group-based interdisciplinary rehabilitation programme for patients with chronic widespread pain: a randomized active-controlled non-blinded trial. Clin Rehabil. 2019;33(8):1367–81.

71. Amris K, Wæhrens EE, Christensen R, Bliddal H, Danneskiold-Samsøe B. Interdisciplinary rehabilitation of patients with chronic widespread pain: Primary endpoint of the randomized, nonblinded, parallel-group IMPROvE trial. Pain. 2014;155(7):1356–64.

72. Larsen AE, Christensen JR, Wehberg S. The responsiveness of the Danish version of the Canadian Occupational Performance Measure. Br J Occup Ther. 2022;

73. Poole JL, Atanasoff G, Pelsor JC, Sibbitt WL. Comparison of a self-report and performance-based test

of disability in people with systemic lupus erythematosus. Disabil Rehabil. 2006;28(10):653–8.

74. Reneman MF, Jorritsma W, Schellekens JMH, Göeken LNH. Concurrent validity of questionnaire and performance-based disability measurements in patients with chronic nonspecific low back pain. J Occup Rehabil. 2002;12(3):119–29.

75. Wittink H, Rogers W, Sukiennik A, Carr DB. Physical functioning: Self-report and performance measures are related but distinct. Spine (Phila Pa 1976). 2003;28(20):2407–13.

Paper IV

TITLE:

Realist evaluation of an occupational therapy intervention program (ABLE), addressing ability to perform activities of daily living among persons with chronic conditions

Authors:

Vita Hagelskjær, OT, MSc, PhD student[1,2,3]

Kristina Tomra Nielsen, OT, PhD[1,4]

Cecilie von Bülow, OT, PhD[1,2]

Eva Ejlersen Wæhrens, OT, PhD[1,2]

Corresponding author: Vita Hagelskjær, Liljekonvallen 44, 7500 Holstebro, Denmark

e-mail: vita.hagelskjaer@regionh.dk

Telephone: +45 8755 2462

Affiliations

1. The ADL unit, The Parker Institute, Bispebjerg and Frederiksberg Hospital, University of Copenhagen, Copenhagen, Denmark
2. Occupational Science, User Perspectives and Community-based Interventions, Department of Public Health, University of Southern Denmark, Odense, Denmark
3. Department of Occupational Therapy, VIA University College, Holstebro, Denmark
4. Department of Occupational Therapy, University College of Northern Denmark, Aalborg, Denmark

BACKGROUND

Problems related to performance of activities of daily living (ADL) is associated with chronic conditions (1–9). Accordingly, chronic conditions has been defined as "*conditions that last a year or more and require ongoing medical attention and/or limit activities of daily living*" (10). ADL involves tasks that most people need to perform in their everyday lives. Personal ADL tasks include self-care tasks such as eating, toileting, grooming and dressing, while instrumental ADL tasks include domestic tasks necessary for independent living such as shopping, cooking, cleaning and doing laundry (11,12). A recent study revealed that more than 65% of the Danish population, aged 16 or above, live with one or more chronic condition (13). As the probability of dying from one of these diseases is decreasing (14), an increasing number of persons is living with diseases often causing problems with ADL task performance. Limitations in ADL associated with chronic conditions may result in decreased quality of life, and reduced energy and time for participation and engagement in other types of wanted or needed activities at home and in the community (15–17). Besides affecting these persons' everyday lives, this also entails an increasing financial burden in community-based rehabilitation and caregiver services (18–20). Hence, the need for developing effective interventions is urgent. The ABLE intervention programme was developed to enhance the ability to perform ADL tasks among persons with chronic conditions.

Attempting to change the everyday lives of persons with chronic conditions into the better, the 'A Better Everyday Life' research programme was established in 2015. The focal point in 'A Better Everyday Life' is development of a complex occupational therapy intervention programme, named ABLE. By following the United Kingdom Medical Research Council's (MRC) guidance (21) on how to develop and evaluate complex interventions, the ABLE intervention programme was developed (22–24), feasibility evaluated in terms of content and delivery (24,25) and pilot tested to prepare a full scale trial (26). This resulted in the ABLE intervention programme version 2.0 (ABLE 2.0) (22) and justification for proceeding to evaluation of effectiveness, process and cost-effectiveness of the intervention programme (25,26). This paper concerns parts of the process evaluation, conducted alongside effectiveness and cost-effectiveness evaluations, as recommended for complex interventions (21).

The ABLE 2.0 has been described in detail in previous studies (22,24–27). In short, the manualised ABLE 2.0 is a home-based, individualised, 8-week occupational therapy intervention programme, applicable across diagnoses, age, and sex. It was developed to be delivered as part of community-based rehabilitation services. In a maximum of eight sessions, it addresses ADL task performance problems among persons with chronic conditions by offering standardised ADL evaluation, client-centred goal setting, individualised intervention sessions building on an adaptational approach, and finally, re-evaluation of ADL ability and assessment of goal attainment.

When initiating the evaluation phase (21), the ABLE intervention programme was well described, tested, accompanied by a manual, and continuously revised. However, considering the nature of complex interventions, our knowledge on how the intervention worked in different contexts was still preliminary. The value of process evaluation of a complex intervention, within a trial, was recognised in the MRC's guidance (21), stating that such an evaluation could *"be used to assess fidelity and quality of implementation, clarify causal mechanisms, and identify contextual factors associated with variation in outcomes"* (28). However, guidance on how to conduct process evaluations was not provided. Later, in 2015, the MRC in a guidance by Moore et al (28) highly recommend a theory-driven approach to process evaluation to understand the causal assumptions underpinning an intervention and when building an evidence base to inform policy and/or practice on how the intervention works (28). Still, examples on how to conduct process evaluations within a trial are limited. The realist evaluation approach is increasingly used in health service research (29), being a form of theory-driven evaluation, addressing the question "*what works, for whom, in what circumstances, and how*?" (30). Realist approaches assume that nothing works everywhere for everyone and that context affects programme outcomes (30,31). In a realist evaluation the question is not only "*what works*?" but *"how or why does this work, for whom, in what circumstances?"*, and it provides a way of gaining a deeper insight into the nature of a complex intervention and in the implementation context (29). Programme theory is central to realist evaluation forming the means to providing plausible explanations of why a certain intervention works or not in certain circumstances (30).

The overall purpose of conducting a realist evaluation of the ABLE 2.0 was to investigate in what circumstances, for whom, how and why the intervention programme functions (29). Thus, the aim of the present study was to identify how mechanisms, in terms of changes in reasoning and behaviour of the participants, were triggered by particular contexts leading to certain outcomes, based on an initial program theory. More specifically, it was intended to confirm, refine, or reject aspects of the initial program theory, and identify prominent interactions between context, mechanisms, and outcomes.

METHODS

Design and setting

The study was designed as a process evaluation with a theory-driven realist evaluation approach (28,30,32,33) applied during data-collection and analysis. Realist evaluation, first described by Pawson and Tilley (30), is based on the assumption that complex intervention programmes work under certain conditions, i.e. contextual factors, and are influenced by the way different stakeholders respond to them (30,31). Hence, introducing the term 'mechanism', i.e. the underlying changes in the reasoning and behaviour of persons triggered by the particular contexts (34), ABLE 2.0 is considered to works (or not) because deliverers and receivers of the intervention programme make particular decisions in response to the resources and

opportunities provided by the intervention programme, causing certain outcomes. Contextual factors are defined as material/ social/ organisational/ economic/ technical/ individual characteristics and outcomes are defined as the results of the interaction between a mechanism and its triggering context (29,30). Contextual factors at different levels (i.e. infrastructural, institutional, interpersonal, and individual) (35) may enable or prevent mechanisms from being triggered, which is expressed as context-mechanism-outcome configurations (CMOCs) (29).

The process evaluation was nested in a randomised controlled trial (RCT) (36) evaluating the effectiveness and cost-effectiveness of ABLE 2.0. Details of the design and methods were provided in the published protocol (36). The reporting of this study follows the RAMESES (Realist And Meta-narrative Evidence Syntheses: Evolving Standards) II reporting standards for realist evaluations (29).

The study was conducted from August 2020 to October 2021 in a Danish municipality, counting about 90,000 people. Around 50,000 live in the main town, and the rest live in villages or rural areas. Rehabilitation services in the municipality were organised in four demographically comparable geographic areas (North, East, South, and West). The process evaluation took place in East and West areas. Delivery of the ABLE 2.0 and data collection took place in the homes of the clients.

Participants and recruitment

Clients were recruited to the ABLE 2.0 RCT provided they lived with one or more medically diagnosed chronic conditions; were aged ≥ 18 years; lived in own home; experienced ADL task performance problems; were motivated and ready for making changes in performance of ADL tasks; were motivated and ready to participate in an occupational therapy intervention; communicated independently and relevantly; and were able to understand and relevantly answer a questionnaire. Exclusion criteria were: personal ADL problems with acute, unmet need for help, known substance abuse, mental illness, and/or other acute illness (< three months) effecting ADL task performance, communication barriers (e.g. severe cognitive deficits; barriers that prevented receiving study information), receiving other occupational therapy services addressing decreased ADL ability during the intervention period. Participants in the present study were a sub-sample of the last included clients randomised to receive the ABLE 2.0 . For composition of the sub-sample the following criteria were applied: ≥three males; ≥four clients with Assessment of Motor and Process Skills (AMPS) (37,38) ADL motor ability <1.0 logits, assessed at baseline in the RCT, indicating the need of moderate to maximal assistance to live in the community; variation in number of sessions received; and variation in age. Further, they should demonstrate variation in outcomes (assessed at the final session of the intervention and measured by Goal Attainment Scaling (GAS) (39,40)). The AMPS and the GAS will be described in further details in the following paragraph on the ABLE 2.0 intervention programme.

Occupational therapists (OTs) delivering ABLE 2.0 (ABLE OTs) (n=3) were recruited among OTs in the municipality, provided they had ≥two years of experience working with the study target group, were calibrated AMPS raters, and also delivered ABLE 2.0 in the pilot study (26). The ABLE OTs were trained in delivering ABLE 2.0 by attending a three-and-a-half-day course. The course consisted of introduction to ABLE 2.0 and the underlying theories and models, practicing the use of instruments in the programme, and training delivery of ABLE sessions. To further support delivery of the programme, feedback activities were offered in addition to the course, and a folder containing the material needed for each session in ABLE 2.0 were provided for each client.

ABLE 2.0 intervention programme

The manualised ABLE 2.0 is a systematic, client-centred, eight-week intervention programme, applicable across sex, age, and chronic conditions, delivered by an OT in the client's home as part of community-based rehabilitation. Standardised instruments and theoretical models are incorporated in ABLE 2.0. The overall structure of ABLE 2.0 is informed by the Occupational Therapy Intervention Process Model (OTIPM) (41), prescribing a problem-solving process. The problem-solving process informed by OTIPM (41) includes evaluating ADL ability based on both self-report and observation; involving the client in setting goals and clarifying reasons for the identified ADL task performance problems, and in finding solutions (41). The conceptual model 'the Transactional Model of Occupation' (TMO) (41) describes how the client's occupations (i.e. meaningful and purposeful doings) has three interwoven elements; occupational performance (i.e. observable aspects), occupational experience (i.e. how the doing is experienced), and participation (i.e. occupational engagement). Further, the TMO frames occupation as a response to several situational elements, including environmental, sociocultural, task, and temporal elements (41,42). The Person-Environment-Occupation Model (PEO) (43) explains the complex relationship between person, environment, and occupation supporting the analysis of the ADL task performance, the planning of the intervention, and the communication and collaboration with the client. Hence, TMO and PEO support the client-centred reasoning during delivery of the programme. The ADL-Interview (ADL-I) (44–46) is used for evaluating the client's self-reported ADL ability. ADL-I is a standardised evaluation tool, used by OTs, to describe and measure self-reported ADL ability (44–46), in terms of physical effort and/or fatigue, efficiency, safety, and independence (ADL-I Performance), i.e. quality of ADL task performance. The Assessment of Motor and Process Skills (AMPS) (37,38) is a standardised observation-based evaluation tool used by OTs to measure a person's observed ADL ability in terms of physical effort and/or fatigue, efficiency, safety and independence i.e. quality of ADL task performance. ADL-I and AMPS are generic instruments to be applied across diagnoses. GAS (39,40) is a tool for defining and monitoring individual goals. The client is actively involved in defining the goals and describing levels of goal attainment.

ABLE 2.0 consists of a maximum of eight sessions. Session 1 includes ADL evaluations, using a combination of the ADL-I (44–46) and the AMPS (37,38). Session 2 includes goal setting, using GAS (39,40), and clarification of reasons for the identified ADL task performance problems, using PEO (43) and/or TMO (41). Sessions 3-7 consist of individually tailored intervention sessions combining nine potential intervention components (27), organised based on PEO (43), and building on an adaptational approach (27,41). An adaptational approach includes collaboration between the client and the ABLE OT in finding compensatory solutions to the ADL problems, and engagement of the client in consultation and education (i.e. collaborative decision-making and strategies on how the client can learn to use the chosen compensatory solutions) (41). The adaptational approach reflects the problem-solving process. Adaptational strategies may include e.g., changes in habits, in the physical environments, or modification to task performance (27). Use of adaptational strategies aims to reduce effort and/or increase efficiency, safety, and independence in ADL task performance. The final session includes re-evaluation of the perceived and observed ADL ability (ADL-I and AMPS) (37,38,46) and evaluation of goal attainment using GAS (39,40).

Realist evaluation procedures

Following the realistic evaluation cycle (30), the first step was to develop the ABLE 2.0 initial programme theory (IPT), capturing the assumptions of ABLE 2.0 in terms of 'what works, for whom, in what circumstances, and how?' (29).

The IPT, illustrated in figure 1, was informed by the theory-of change-logic model (27), constructed during development of the first version of the ABLE intervention programme (23,27,47) and the results of the feasibility study (24,25,27). The overarching IPT was, that ABLE 2.0 would improve clinical outcomes in terms of observed and/or self-reported ADL ability, based on a structured and individualised problem-solving process and by applying adaptational strategies in the client's home.

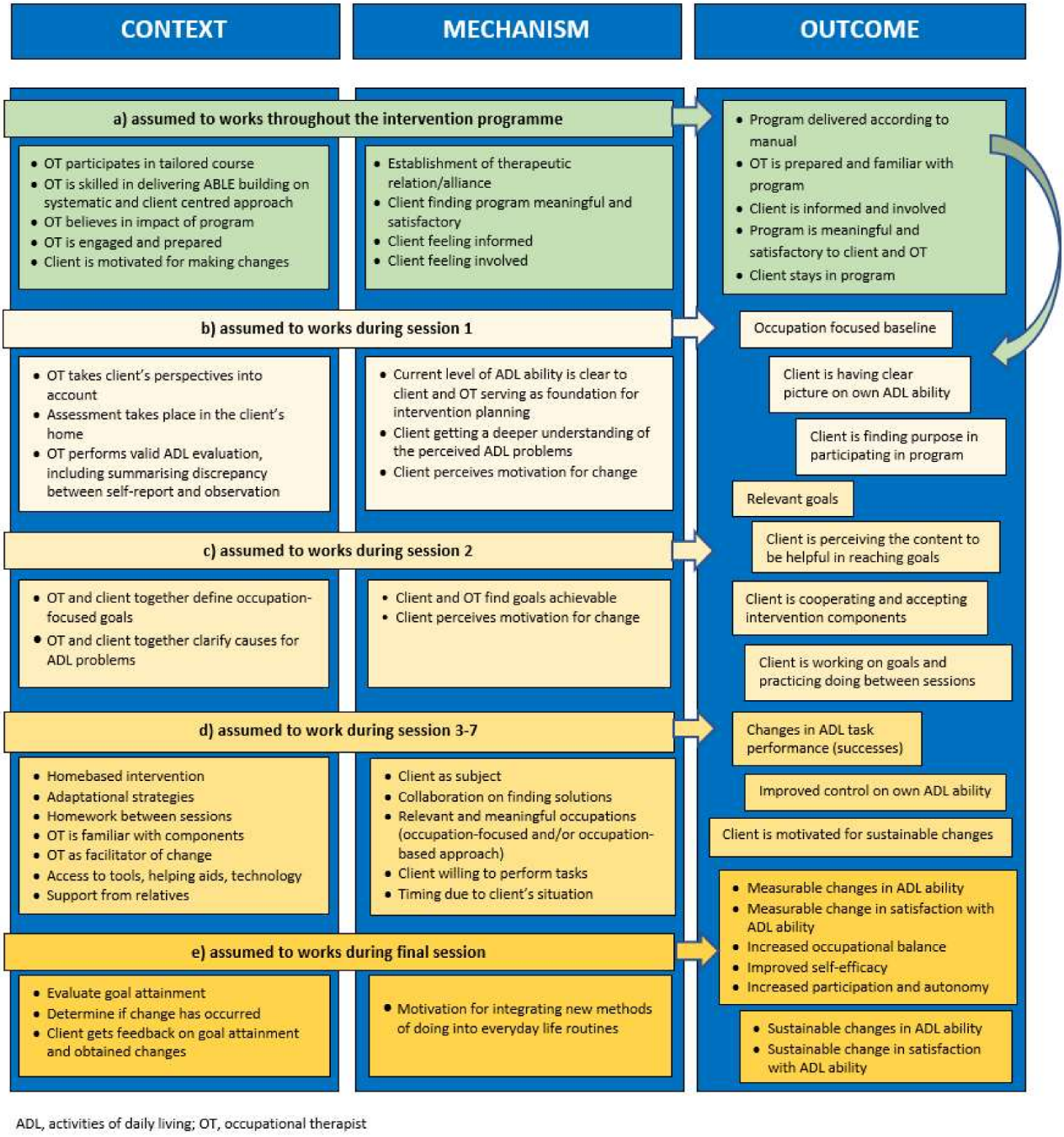


Figure 1 ABLE 2.0 initial programme theory

Data collection

To evaluate the interactions between context, mechanisms, and outcomes qualitative data based on realist interviews (30,32) was collected among clients who received, and OTs who delivered, ABLE 2.0. The interviews were conducted to confirm, refine, or reject aspects of the IPT and identify emerging CMOCs.

Realist interviews

According to the realist approach, the purpose of an interview is to present the programme theory for the interviewees, for confirmation, refinement or rejection (30,48). To reveal nuances on how the mechanisms were turned up and down in different circumstances, both positive and less positive examples were revealed and investigated.

First, individual interviews were conducted with the ABLE OTs, followed by individual interviews with the sub-sample of clients. Finally, a focus group interview with the ABLE OTs was conducted. In the individual OT interviews, questions related to their experiences of what (mechanisms), for who and in which circumstances (context) successes and failures (outcomes) occurred (30). In interviews with the clients, the questions primarily related to their experiences of whether ABLE 2.0 encouraged them to make changes in reasoning and/or behaviour in relation to ADL task performance (mechanisms) (30). The final focus group interview with the ABLE OTs provided a deeper insight into what was already revealed about the IPT in the individual interviews with ABLE OTs and clients (30,48).

The interviews were conducted in a longitudinal structure, allowing insights from completed interviews to inform the interview guide for the subsequent ones, aiming to further develop and validate the programme theory, as the investigators gained more knowledge (48). Interview guides were developed and structured to capture in-depth information on programme theory, by using the teacher-learner function (30). For example when interviewing the clients on the goal setting process, first the IPT was presented to the client by saying: *"A purpose of defining goals in the way it was done was to encourage you to make a change in your daily life, in order to reduce the problems".* Where after the interviewer asked the client: "*Do you think it worked that way? If so, can you say something about what it was that particularly worked for you? If not, will you try to explain why? How did you perceive that the OT listened to your perspective?"* And further the client would be asked: "*How did you experience the OT's ability to explain the goal setting procedure to you?"* Furthermore, to prompt the participants in remembering details from their sessions, we brought up examples from their intervention e.g., their specific goals in focus, or if the client only received few sessions, a question could be: *"What happened since you chose to end the programme?"* In this way, the realist evaluation approach (30,48) was reflected in the interview guides as well as during the interviews, to help identifying key contextual differences in outcome patterns (48).

Each of the interviews were conducted by two of the authors. The primary investigator, who was involved in the individual client interviews and the focus group interview with the ABLE OTs, was the only one known by the clients and the ABLE OTs.

Data analysis

According to realistic evaluation, the analysis took shape as an iterative process (30,33,48) and insights were pursued along the way modelling the understanding of the functioning of ABLE 2.0. Data analysis took a 'retroductive' approach i.e. "*identification of hidden causal forces that lie behind identified patterns or changes in those patterns*" (49), using a combination of inductive and deductive reasoning seeking evidence to confirm or refine the IPT (49). Using the standards by Wong et al (29) and inspired by Gilmore et al (50), several steps were conducted. First each interview recording was listened through and the transcript read for an overview. Second, each interview was examined and coded in terms of contextual factors, activated mechanisms, and perceived outcomes, and paragraphs reflecting emerging CMOCs were extracted. Third, a table on each type of interview, e.g., the individual client interviews, was produced including quotes. Fourth, the content of the tables was examined across the three tables to group the data into contiguous units (themes) including emerging CMOCs, i.e. found in more than one data source, expressed with emphasis, or perceived to cause particularly positive or negative changes. Finally, the results of the initial steps of the analysis were held up against the content of the IPT for confirmation, refinement, or rejection determining which CMOCs offered the most robust explanations of the observed patterns of outcomes.

Each theme included descriptions of how ABLE 2.0 functioned including determination of whether aspects of the IPT (i.e. a-e) was confirmed, refined, or rejected. In addition, each theme included descriptions of interactions between context, mechanisms, and outcomes as derived from data. Results were documented with quotes as follows: ABLE OT interviews, numbered OT1-3; client interviews, numbered C1-8; and the focus group, FG. Finally, the prominent CMOCs, derived across data sources were presented in a table.

RESULTS

Participants

Overall, eight clients and three OTs were included in this process evaluation. Characteristics on the interviewed clients are presented in table 2. In summary three men and five women aged between 69 and 85 years, with a variety of chronic conditions, and seven of them with multimorbidity, were included. Four of the participants had an AMPS ADL motor score <1.0 logits assessed at baseline, indicating the need of moderate to maximal assistance to live in the community (37,38). In total n=22 goals were defined by the eight clients (median n=3, range 1-5) during their ABLE 2.0 interventions. In n=20 (90.9 %) goals the client reached the expected, more, or much more than expected level of goal attainment. In n=1 (4.5 %) goal the client remained at the baseline level. The ABLE OTs were women, aged between 35 to 43 years, and having 7 to 11 years of experience working as occupational therapists with ADL ability among persons with chronic conditions.

Table 2 Characteristics on clients who participated in interview

Client number	Sex	Age	Diagnosis	AMPS ADL motor ability at baseline	Number of sessions received
1	Female	84	Medical[c], orthopaedic/musculosceletal[a]	0.8	3
2	Male	74	Medical[c], 0rthopaedic/musculosceletal[a]	0.7	4
3	Female	69	Orthopaedic/musculosceletal[a]	1.1	5
4	Female	74	Medical[c], neurological[b]	0.7	5
5	Female	75	Neurological[b]	1.1	4
6	Male	70	Medical[c]	0.8	4
7	Male	75	Medical[c], orthopaedic/musculosceletal[a]	1.3	4
8	Female	85	Medical[d], orthopaedic/musculosceletal[a]	1.4	4

ADL: activities of daily living; AMPS: assessment of motor and process skills
[a] 'orthopaedic/musculoskeletal' covers arthritis, chronic/long-term pain, and fracture/replacement
[b] 'neurological' covers stroke (i.e. right-/left-sided stroke, subarachnoid haemorrhage, cerebral aneurism) and non-stroke (i.e. cerebral palsy, traumatic brain injury, multiple sclerosis, parkinsonism)
[c] 'medical' covers cardiovascular disease, respiratory disease, diabetes, cancer, and obesity

The results are presented within four themes derived from data: building a foundation for the entire intervention; establishing the focus for further intervention; identifying and implementing relevant compensatory solutions; and re-evaluating ADL ability to finalise intervention. The prominent CMOCs are presented in table 3.

Building a foundation for the entire intervention

Data reflected that during sessions 1 and 2 contextual factors at different levels facilitated or constrained the process of building a solid foundation for the entire intervention. This was framed and structured by the thorough evaluation of the client's ADL ability, by actively involving the client in this process, and by taking the client's perspective into account.

At the infrastructural level, the client's pathway to rehabilitation service played a role in building a foundation for the entire intervention. The following paragraph describes how this refines the IPT. The clients' pathways affected their motivation for participating in the intervention programme and readiness for making changes. In the municipality a client could be referred from the referral services (e.g., when applying for support in the home), or from the rehabilitation team (e.g., if a physiotherapist discovered that a client experienced ADL task performance problems). It was common practice in the municipality, that the referral service defined goals for the granted intervention. This tended to prevent building a foundation for the entire intervention, by counteracting the certain order of the content of ABLE 2.0, prescribing evaluation of ADL ability prior to goal setting. An ABLE OT said: "*If the client was referred from the referral service, for example 'needing help bathing', this is what they expect us to take care of … but sometimes some completely different problems appeared … then we must return to the referral service with other needs … how do we solve that? Who is the authority? There is something in relation to the way we are organised …*" (OT3). Another ABLE OT agreed: "*It is confusing for the clients, they expect us to work on* [goals related to] *bathing* [as defined by the referral service], *and then we also ask about dressing and cooking* [as prescribed in the

ADL-I] *… the order of things in ABLE involves the client a lot more"* (FG). Hence, when a client was referred from the referral services, and goals were defined prior to initiating the occupational therapy intervention process, and prior to evaluating the client's ADL ability, building a foundation for the entire intervention was obstructed.

At the institutional level, the support from the management in prioritising time for training ABLE OTs in delivering ABLE 2.0 in accordance with the manual, and in legitimising deviations from usual practice, facilitated the OTs feeling obliged and responsible. This refines the IPT and led to increased effort and engagement related to delivering what the ABLE OTs called '*quality occupational therapy'*, and a sense of being skilled among the ABLE OTs. Furthermore, the supportive management resulted in important support from colleagues in terms of accepting new ways of working, and in referring relevant clients to occupational therapy. Sometimes the ABLE OTs perceived lack of understanding of the new way of working among their colleagues, especially related to delivery of session 1, taking more time than a usual start-up. An ABLE OT said: " … *of course the manager's attitude* [matters]*, the fact that you have an employer who thinks it's important to deliver these interventions, and that we get enough time for it"* (OT2). Another ABLE OT said: "S*ome of our colleagues said, well it was good you finished it* [participating in the research] *… they thought it took a lot of time and that we were less available* …" (FG). Another contextual factor at the institutional level, confirming the IPT (a), was related to training and support in delivering the intervention, i.e. the three-and-a-half-day course, the exchange of questions and experiences between the ABLE OTs, and the access to supervision on delivery from the research group in relation to occurring challenges. This activated the ABLE OTs feeling confident in delivering the programme, leading to ABLE OTs feeling satisfied and engaged. An ABLE OT said: "*I have used her* [the primary investigator] *very much, to make sure I was on the right track. It has just meant a lot … I have also had two colleagues who have been involved in it* [delivering ABLE], *and we have shared many things …*" (OT1).

At the interpersonal level, ABLE 2.0 provided a frame for building confidence and collaborative relationships between the client and the OT, overall confirming the IPT (a, b) in terms of triggering the therapeutic relationship as a mechanism. Such relationships were found core in building the foundation for the intervention process and led to satisfaction and engagement among both clients and ABLE OTs. A client said: *"She was nice and straightforward, she listened to me, and I was straightforward too, and then we just got started … we were on wavelength right away, yes, we were, and that has helped a lot"* (C2). Administration of evaluations based on both self-report and observation of ADL ability at session 1 was found to be a prerequisite for initiating the problem-solving process. This systematic approach framing the first meeting between the client and the OT, activated involvement of the client. A client said: "*I think it was really good, especially because of those schemes* [AMPS and ADL-I] *we used*. *I got something out of it. I think it made*

a lot of sense. I even got an insight – thinking in a different way. We put it into words, whether I needed help, or it was hard or easy for me, whether I felt pain, - I could see it. And I saw that yes, it is actually true that I need help" (C7). Data also showed, that when the ABLE OT was feeling skilled and engaged in delivering what they termed '*true*' occupational therapy, e.g., using the instruments for evaluating the ADL ability, it led to the client feeling satisfied, engaged, listened to, seen and understood. Further, this led to revealing the client's perspective on his/her ADL ability. An ABLE OT said: "*You feel well informed* [after having conducted ADL-I and AMPS] *to move forward, and you really feel you have established a common starting point to move forward, because we got in depth with* [understanding] *the client's everyday life …"* (OT2). Also, the ABLE 2.0 manual provided guidelines for identifying potential discrepancies between the client's and the OT's perspectives on the ADL ability. This dialogue was found to activate the client feeling confident in the collaborative relationship, leading to a common foundation for further intervention. This dialogue was especially important in cases where discrepancy occurred. An OT said: "*Having both the client's perspective and the therapeutic perspective, has a huge impact … it shows a very clear picture of the situation. If we only see one perspective, then the assessment of the need for intervention will be completely different*" (OT2). Relatives may have facilitated or constrained the intervention process, refining the IPT. In one case a spouse was ill and needed special care from the client, causing lack of energy to actively participate in ABLE 2.0, limiting the establishment of a foundation for the entire intervention. On the other hand, when a relative actively supported the process of a client by e.g., helping to describe how certain ADL problems occurred in the home, the intervention process was facilitated.

At the individual level the most influential contextual factors confirming the IPT (a, b) were the ABLE OTs being skilled and professional, activating a feeling among the OTs of delivering what they called '*true*' occupational therapy, and a sense of believing in the impact of the programme. The skills also involved being able to communicate about the programme and thereby actively involve the client. The skills that the ABLE OTs built during the three-and-a-half day course and the practising in delivering the programme, simultaneously improved their ability to communicate with the client about the different parts of the intervention, e.g., the instruments used for evaluation of ADL ability, refining the IPT. Hence, when the OT felt confident in explaining how and why the models or instruments were used, it activated a fruitful communication and the client perceiving that the ABLE OT was professional, leading to the client finding content meaningful and to establishing a foundation and agreement on focus for further intervention. An ABLE OT said: "*…being forced to professionally stick to the manual, to use those tools, and have to use some professional terms when communicating with the client …"* (OT1). Furthermore, the clients' motivation and readiness for making changes, and his/her positive expectations, seemed to have activated mechanisms in terms of the ABLE OT being more engaged in the assessment of the ADL ability, leading to establishing therapeutic relationship as basis for further collaboration.

Establishing the focus for further intervention

Data reflected that contextual factors at different levels facilitated or constrained the process of establishing the focus for further intervention, provided that the previously described foundation was built during the first sessions. A strength in ABLE 2.0 was perceived to be the coherence between the different parts, the logic order of the sessions and the way each step led to the next step. All together involving the client in the problem-solving process and establishing the focus for further intervention. The focus for the further process was primarily established during session 2, framed by using GAS for goal setting and PEO and/or TMO in clarifying causes for the ADL problems, including an active involvement of the client and taking the client's perspectives into account.

At the institutional level, delivery of the intervention in the home of the client was important for establishing the focus for further intervention, promoting the ABLE OT's knowledge of the client's ADL ability, everyday life, and preferences; and affecting the client's engagement and experience of meaningfulness. A client said: "*She saw how I did things in my bedroom, in my own bed. That was good because I know how it works for me here"* (C3). This confirmed the IPT (b, c), regarding the impact of delivering ABLE 2.0 in the client's home. Delivery in the home of the client was the ideal context to facilitate a dialogue focusing on ADL task performance (i.e. occupation-focused dialogue), involving the client in an analytic approach, and in setting occupation-focused goals based on the client's priorities. An OT said: "*They were more relaxed in their own surroundings; it was the most natural setup and it was always an advantage to be in the client's home*" (OT3). Discussing and determining the focus for the further process in the home of the client led to more knowledge on the ADL task performance problems and served as an eyeopener for new ideas for possible solutions. Hence, it pointed towards content in the future occupation-based (i.e. engaging the client in performing ADL tasks), intervention sessions. Further, delivering the interventions in the homes of the clients, supported the inherent element of flexibility in terms of how the OT planned and timed the intervention, facilitating the ABLE OTs feeling obliged and responsible, and the client being more relaxed, leading to client empowerment, fruitful dialogues, and relevant goals.

At the interpersonal level the ABLE 2.0 provided a frame for focusing the further intervention by facilitating a collaborative and occupation-focused dialogue between the OT and the client, in defining goals and discussing causes for the ADL problems. This refined the IPT on the functioning of session 2. In most cases the clients were actively involved in defining goals and levels of goal attainment, which activated the ABLE OT's and the client's reasoning and served as a starting point for focusing the process. The ABLE OTs agreed: "*You cannot conduct an ABLE intervention if you don't use GAS or the other tools. It just wouldn't work … you cannot get from A to Z if you do not use K or F. You must practice and practice and become proficient in using them"* (FG). Further they said: "*GAS is a good tool. It is complicated to use though. And*

some clients are difficult to involve, especially those with cognitive deficits" (FG). When applied as intended, the goal setting process activated a dialogue on both parties' notions of expected outcomes. This led to relevant and clear goals framing and targeting the intervention and establishing the basis for monitoring the progress. An OT said: *"The levels* [in GAS] *helped me to think in steps and made it* [the focus] *clear to the clients. So, GAS helped to set the frame for the intervention and to align expectations"* (OT2). Another OT said: *"Most of my clients were really involved in defining the different levels … it became concrete … and at the end of the intervention it was easy to monitor"* (OT2). In the context of discussing causes for the ADL problems, data showed that the use of models (i.e. PEO and TMO) offered an opportunity to move from a disease-oriented to a more transactional perspective on the clients ADL problems. An OT said: *"Many of the elderly tend to point to themselves* [when talking about causes for ADL problems] saying "*It's because I'm an old one". Using the PEO model was a way of opening the dialogue on this. We could talk about other causes than those pointing at themselves".* Another OT said: *"If you find it hard to explain to the client, then the model* [PEO] *helps you. Some clients never thought about other reasons than their disease. It becomes clear, how we can find resources in the environment and they can find opportunities to be able to do the things they want to be able to do … this talk just means everything for the further focus*". Hence, the dialogue based on a transactional perspective led to involving the client in the problem-solving process. This was an eye opener and of great importance for establishing a focus for the intervention in terms of relevant and clear goals pointing towards potential compensatory solutions.

At the individual level the most influential contextual factors in establishing the focus for further intervention were the OTs' skills in facilitating dialogue on goal setting and causes for ADL task performance problems, refining the IPT. Moreover, client characteristics were influential, also refining the IPT. The ABLE 2.0 offered models that supported the ABLE OT in communicating about GAS, PEO and/or TMO. By applying GAS for goal setting, the OT was provided with a vocabulary to communicate with the client about setting goals. Hence, in the context of being a skilled OT, mastering the use of GAS and involvement of the client, having words to facilitate a dialogue on causes, the collaborative relationship between client and OT was activated, establishing the focus for further intervention. However, there was also cases where involving the client in defining goals and levels of goal attainment failed, i.e. implementation failure. An OT said: "*The main goal is fairly easy to define in collaboration with the client, but those sub-goals … it is something I usually do by myself, you know, the client says his or her main goal, and then I formulate the sub-goals, in relation to time, energy, risk of falling and those things* [quality of performance]. *I* [sometimes] *found it difficult to define in detail* [the levels in GAS] *with the client"* (OT1). The OTs described that they sometimes perceived lack of skills in using GAS. This was amplified by the usual workflow in the municipality, implying that the OTs followed the goals defined by the referral service, and hence did not involve the clients in goal setting and/or in a dialogue on causes for ADL problems. When the implementation failure on goal setting

occurred there was a tendency that the intended problem-solving process was interrupted, as goals were formulated as concrete solutions (e.g., be able to vacuum the kitchen floor with a cordless vacuum cleaner) rather than as quality of functioning (e.g., be able to vacuum the kitchen floor without risk of falling) as prescribed in the ABLE 2.0 manual.

The interviewed clients only rarely recalled the dialogue on goal setting. They recalled the focus for the intervention, but not the intended dialogue and formulation of levels in goal attainment. This might be due to examples of implementation failure in goal setting (e.g., the ABLE OTs sometimes did not include the clients in the goal setting process and formulated goals including the solution rather than the functional level to be attained).

Identifying and implementing relevant compensatory solutions

Data revealed that contextual factors at different levels facilitated or constrained the process of identifying and implementing relevant compensatory solutions to enhance the clients' ADL ability, provided that the previously described foundation for the entire intervention was built and the focus for further intervention was established. Identification and implementation of relevant compensatory solutions was done during the intervention sessions (sessions 3-7). This was framed by the ABLE 2.0 intervention components and conducted in collaboration and dialogue between the client and the ABLE OT by actively involving the client in the problem-solving process, and by trying out possible solutions in the client's home.

At the institutional level, the use of the environment (here the client's home) facilitated the process of finding and trying out solutions, confirming IPT (d). When the intervention sessions were delivered in the client's home, it supported how the client could both explain and demonstrate issues related to his/her ADL task performance in the actual environment. Thus, the consultative process of finding effective and sustainable solutions was facilitated. Further, the ABLE OTs perceived that clients were less likely to cancel appointments, as they did not have to leave the home. An ABLE OTs said: "*I think it* [finding solutions in the home] *gives them peace and makes them feel confident, that it is exactly in their everyday duties and their environment ... I do not find it possible to do it* [practice solutions] *in other ways … and when we come to them, there is a greater chance that they will accept it … if they have to come to us, we sometimes experience dropouts*" (OT2). In addition, which refined the IPT, when the collaboration across the community-based organisation (i.e. rehabilitation service, referral service, assistive device service, home care service) was timed on the client's premises and was experienced to be smooth and effective, the clients and the ABLE OTs felt that it was worth their effort, that solutions could be adjusted to the client and client's context, and that they were successful. This was satisfying and motivating for the client. For example, it was important to have access to a suggested assistive device. A client said: *"It happened pretty fast. They came and lined them up* [assistive devices], *I was completely surprised it happened so fast, … I thought there was a wait for something*

like that. A lot of things happened … I am very happy about it" (C1). On the other hand, when ABLE 2.0 was carried out on the system's premises, with delay in delivery of sessions due to a wait for assistive devices, it had consequences for the problem-solving process, for consultation of the client in using the assistive device, and for the clients confidence with the system, potentially resulting in decreased benefit of the intervention. An ABLE OT said: *"… the client may lose function and loose ability to use the assistive device or lose confidence in our help. Or maybe they will need more home care. I had a case that was completely interrupted. I was not able to introduce it* [the assistive device]. *Maybe she thought 'what does she* [the OT] *do good for at all?'"* (FG).

At the interpersonal level, data revealed that collaboration, dialogue and discussion between client and OT were crucial and facilitated the process of finding and implementing solutions. Hence, several solutions were discussed and tried out to determine which to apply. Further, when the ABLE OT had a non-directive approach suggesting different solutions, it led to the client feeling actively involved in the problem-solving process and having the power to accept or reject suggested solutions, and was associated with the experience that the content was meaningful. A client said: *"We discussed it, whether it was the right solution"* (C5). This refined the IPT. Several clients also highlighted the fact that the OT observed their ADL task performance during the problem-solving process, confirming the IPT (d). As the ABLE OT observed the client being engaged in e.g., watering flowers or cleaning the floor, she had the opportunity to suggest and guide in new ways of doing. One of the clients described this as an *"eye-opener"* (C7). Another client expressed the value of being observed during engagement in ADL task performance like this: *"I think it was good. Because as I said, talking does not help it all. I prefer some action too, and it was good"* (C1). When the ABLE OT observed the client's performance, the clients sometimes considered it a validation of their needs which to some extend legitimised e.g., applications for assistive devices. One of the clients said: *"I feel that there was really someone who could see that I needed it, that it was not just something I asked for. But she could really see that I needed it too"* (C7).

At the individual level, the most influential contextual factors in identifying and implementing relevant compensatory solutions were related to the characteristics of the ABLE OTs and the clients. For example, that the OT was empathetic, kind, skilled and competent, refining the IPT. The skills and competencies were primarily related to communication and collaboration on relevant solutions. One client said*: "She was nice, kind, and straightforward, and we could just get to the point"* (C5). Another client said: *"She was nice and understanding, and she was on the marks when I claimed about the toilet and the sheets, … I felt she heard me … and it was fixed right away"* (C8). Further, based on the initial sessions in ABLE 2.0 the ABLE OT had a solid foundation for planning and implementing interventions in a competent way. A client said: *"It was the same scheme* [ADL-I] *we used every time, and then when she saw me do it* [water my flowers],

using my new chair, she could guide me. It was an eye opener … Now I can just do it, I can just roll over to my flowers here and fix it, and it does not hurt, when I do it anymore" (C7). Client characteristics in terms of motivation, readiness for making changes, and his/her expectations to the programme, were expressed to have an impact when finding solutions. A client said: *"I was not expecting certain things* [prior to the intervention]*, I was just waiting for what was going to happen … positive thinking you know … I am sure that meant a lot* [for the benefit of the intervention]*"* (C5). And an ABLE OT said: "*The clients' motivation mattered to finding goals and solutions, to how I could help them make changes … and their engagement mattered a lot to the benefits"* (OT2). These individual level contextual factors seemed to activate professionalism both experienced by the ABLE OTs and the clients and a sense of joint commitment, refining the IPT. Further, these factors lead to the ABLE OT being engaged in suggesting targeted and sustainable solutions adjusted to the specific client and his/her environment. Thus, potentially leading to improved ADL ability. On the other hand, when a client specifically had applied for help with, for example cleaning, the client's motivation for finding other compensatory solutions, e.g., using assistive devices or changing the physical environment, was sometimes lacking, which was perceived to impede the collaboration on trying out different solutions. Further, when a client lacked insight, due to age or cognitive deficits, involving the client in the problem-solving process was a challenge. An ABLE OT said: *"In a few clients, if they had decreased insight in their own situation … sometimes they had difficulties seeing the problems. Even though they had reported it in the ADL-I, still they did not remember it in the next sessions and when trying to find solutions. They kind of carried it along during the whole intervention"* (OT3).

Re-evaluating ADL ability to finalise intervention

The ABLE 2.0 IPT included assumptions concerning the functioning of the final session confirmed (a, e) and refined by data. Due to the study design, with evaluation of effectiveness conducted alongside this process evaluation, the re-evaluation session was conducted somewhat different than originally intended in ABLE 2.0. Because AMPS was performed by blinded assessors as part of collecting primary outcome data for the RCT, the AMPS was optional at the final session, resulting in primarily performing re-evaluation based on the ADL-I and the GAS. Hence data on the final session was limited. However, data reflected that contextual factors at different contextual levels facilitated or constrained the process of re-evaluation to finalise the intervention. According to the ABLE OTs, the three instruments applied during the final session seemed to serve different purposes which refined the IPT; for the clients, the most important purpose seemed to be feedback contributing to insight and motivation for aiming at sustainable changes; for the rehabilitation service, the most important purpose seemed to be to provide the client with useful feedback and to document the impact of the occupational therapy intervention in the client records; for the referral services, the most important purpose seemed to be to receive documentation for the level of functioning at the end

of the intervention, which was necessary in case of the client applying for home care or assistive devises at the end of the intervention.

At the institutional level ABLE 2.0 provided a frame for documenting occurred changes and obtained ADL ability refining the IPT (e). The documentation based on the AMPS was especially useful when the clients applied for e.g., home care services and/or assistive devices. An ABLE OT expressed it this way: "*The ADL-I … sometimes it can easily stand completely alone … and I can document without the AMPS. But it depends a lot on what the client is applying for … when I used AMPS* [at the final session] *it was because the referral service should make a decision on the client's need for assistance in tasks related to cleaning …"* (OT1). Further one of the ABLE OTs expressed it like this: *"Using the AMPS for re-evaluation is especially relevant when you need to document to the referral service or to the general practitioner or the nurse, and where I as OT can see, that even though we worked on this for eight weeks, nothing changed, and we need to apply for some assistance in the home"* (FG). Moreover, the AMPS was found useful as documentation in the client records, in the case of future referral to rehabilitation services, which was expressed like this: *"I will absolutely use it in the future* [AMPS to document]. *It might be a client we will hear more about later …* (OT1).

At the interpersonal level ABLE 2.0 provided a frame for re-evaluation of the client's ADL ability by facilitating a dialogue between the client and the ABLE OT on goal attainment, obtained changes and ADL ability at the final session, confirming the IPT (e). Finalising ABLE 2.0, applying the prescribed instruments, had an impact on how to provide feedback to the client. The ABLE OTs agreed that GAS was the preferred instrument for providing feedback to the client on obtained changes, because it assessed the attainment of the specific goals in focus. In comparison, the ADL-I was found less relevant in terms of providing feedback, focusing on the ADL ability at the end of the intervention, but without comparison to the ADL ability at session 1. An OT said: "*My experiences of using GAS* [for monitoring attainment of goals] *are good … it provided an awareness for the client on the current level and what was achieved*" (OT2). Further she said: "*I have had a little bit of a harder time seeing the meaning of using it* [ADL-I] *in the final session … GAS is kind of a better summary for the client. In the ADL-I, I think, the clients are not asked if they felt they improved. We did not compare the scores* [at the beginning of the intervention with scores and at the final session]*. I also think the ADL-I was a little too comprehensive for the clients"* (OT2). An ABLE OT explained how she experienced that ADL-I was less useful for providing feedback to clients: *"Even though the intervention ran over several weeks, they still saw themselves as they functioned before the intervention. As if they had too little time to understand the implementation of their new habits"* (OT3).

At the individual level the ABLE 2.0 provided a frame for the ABLE OT to perform valid re-evaluation to finalise the intervention, confirming the IPT (a, e). When the final session was delivered in the context of an ABLE OT being skilled in interpreting the results, and when the ABLE OT supported the

dissemination of the results with visual material (e.g., the graph in the AMPS report) to the client, it activated the client's insight in occurred changes and motivation for carrying on using the new strategies, potentially contributing to sustainable changes. An ABLE OT said: "*The ADL-I is good, and in a few cases I also performed AMPS, using it to show them, how they did during these eight weeks. I prefer to use the graph from AMPS* [from session 1]*, to compare with where they are now … it makes a huge difference*" (OT1).

Table 3 Prominent context-mechanism-outcome configurations (CMOCs)

CMOC no	Context	Mechanism	Outcome
Building a foundation for the entire intervention			
1	If ABLE 2.0 is delivered in the context of a supportive collaboration between the departments in the municipality in terms of the municipal guidelines for referring to rehabilitation services (i.e., the client's pathway to intervention), allowing the logic order of the intervention (i.e. assessment prior to goal setting and dialogue on causes) …	… it may activate the client being actively involved in the problem-solving process …	… contributing to client being motivated for participating in the intervention programme and being ready for making changes
2	If ABLE 2.0 is delivered in a context of goals defined by the referral service …	… it may activate limited involvement of the client …	… contributing to obstruction of building a foundation for the entire intervention
3	If ABLE 2.0 is delivered in a context of supportive management …	… it may activate the ABLE OT feeling obliged and responsible, and supportive colleagues …	… contributing to the ABLE OT feeling skilled and professional when delivering the programme …
4	If ABLE 2.0 is delivered in a context of training and support, i.e. supervision and exchanging experiences among ABLE OTs …	… it may activate the ABLE OT feeling confident in delivering the programme …	… leading to ABLE OT feeling satisfied and engaged
5	If ABLE 2.0 is delivered in a context of the client and the OT initially perceiving to be 'on wavelength', share thoughts, and the client finds that the ABLE OT is professional …	… it may activate mutual confidence and openness …	… contributing to the ABLE OT being vigorous and client feeling his/her problems are being acknowledged
6	If a systematic approach is applied in the initial sessions, including a mandatory structured dialogue on eventual discrepancy …	… it may activate the client feeling confident and involved, perceiving to gain insight, and a collaborative relationship between the client and the ABLE OT …	… contributing to building a foundation for the intervention, initiating a problem-solving process, and client and ABLE OT gaining a common understanding of the client's ADL ability
7	If ABLE 2.0 is delivered in the context of involved relatives …	… it may activate the client being more/less engaged …	… contributing to a facilitated/limited process
8	If ABLE 2.0 is delivered in the context of a skilled ABLE OT …	… it may activate a sense of believing in the programme and in the ABLE OT …	… contributing to the client finding content of programme meaningful
9	If ABLE 2.0 is delivered in the context of an ABLE OT feeling confident in explaining how and why the models were used …	… it may activate a fruitful communication and the client perceiving that the ABLE OT was professional …	… contributing to the client finding content of the programme meaningful and to establishing a foundation and agreement on focus for further intervention
10	If ABLE 2.0 is delivered in the context of a client with positive/less expectations …	… it may activate the ABLE OT being more/less engaged …	… contributing to easier/constrained establishment of a therapeutic relationship
Establishing the focus for further intervention			
11	If ABLE 2.0 is delivered in the home of the client ...	… it may activate an increased knowledge of the client's everyday life and preferences,	… contributing to client empowerment, defining relevant and occupation-

		client feeling relaxed, flexible planning and timing, ABLE OT feeling obliged and responsible …	focused goals, and future occupation-based intervention
12	If ABLE 2.0 is delivered in the context of an ABLE OT being skilled in communicating and administrating GAS …	… it may activate a collaborative relationship, goal setting primarily based on the client's priorities (including that the client has the power to define and formulate goals and levels of goal attainment) …	… contributing to establishment of basis for monitoring progress, and relevant and clear goals
13	If ABLE 2.0 is delivered in the context of an ABLE OT perceiving to lack skills administrating GAS or goals being defined by the referral service …	… it may activate limited involvement of the client in defining goals and levels of goal attainment and in dialogue on causes for ADL problems …	… contributing to interruption of the logic order in the intervention, interruption of the coherence and the problem-solving process
14	If ABLE 2.0 is delivered in the context of collaboration and dialogue between client and OT, when clarifying causes for the ADL problems using a transactional perspective …	… it may activate involvement of the client in the analytic approach to understanding the ADL problems from a more transactional perspective (e.g., taking other perspectives than diagnosis into account) …	… contributing to more perspectives and new insights on the ADL problems, and to revealing new, other, and more ideas for solutions
15	If ABLE 2.0 is delivered in a context of a client with cognitive deficits …	… it may activate limited involvement of the client in dialogues related to goal setting, causes for ADL problems and in the overall problem-solving process	… contributing to less relevant and clear goals, lack of framing of the further intervention
Identifying and implementing relevant compensatory solutions			
16	If ABLE 2.0 is delivered in the context of the client's home when finding solutions …	… it may activate the consultative process …	… contributing to finding effective and sustainable solutions
17	If ABLE 2.0 is delivered in the context of a system working on the client's premises, including effective coordination between services and access to assistive devices …	… it may activate the client's confidence with the system, and client and ABLE OT feeling successful …	… contributing to client feeling motivated for changes and feeling satisfied with the content of the sessions; and to solutions adjusted to the client's context
18	If ABLE 2.0 is delivered in the context of delivery in the terms of the system …	… it may activate decreased confidence with the system's ability to help and ABLE OT feeling powerless …	… contributing to interruption of the problem-solving process, decreased ADL ability, and decreased benefit of assistive devise
19	If ABLE 2.0 is delivered in the context of dialogue between client and ABLE OT; and the ABLE OT has a non-directive approach to this collaboration …	… it may activate the client feeling involved and having the power to accept or reject suggestions …	… contributing to client finding content of sessions meaningful
20	If ABLE 2.0 is delivered in the context of the ABLE OT observing the client trying out solutions during performance of ADL tasks …	… it may activate the ABLE OT acting as facilitator of change using an adaptational approach and the client feeling that his/her needs are legitimised …	…contributing to client feeling satisfied with content of sessions
21	If ABLE 2.0 is delivered in a context of a client with insight in own ADL ability, and who is able to understand, remember and maintain knowledge on his/her ADL ability and the causes for the ADL problems in focus (revealed during the first sessions) …	… it may activate the client being actively involved in the problem-solving process …	… contributing to finding relevant solutions and goal attainment
22	If ABLE 2.0 is delivered in the context of a client being openminded to finding other solutions than he/she expected in advance …	… it may activate an occupation-based approach where the client is willing to try out solutions and the client and OT discuss and exchange ideas primarily based on the clients priorities, and the	… contributing to client finding the programme content meaningful; motivation for staying in the programme; and finding focused, targeted, and potentially sustainable solutions

		client having the power to accept or reject solutions …	
23	If ABLE 2.0 is delivered in the context of a client having applied for specific practical assistance, e.g., for cleaning …	… it may activate limited motivation for making other types of changes …	… contributing to challenges in finding relevant solutions
24	If ABLE 2.0 is delivered in the context of a client with cognitive deficits …	… it may activate limited involvement in the problem-solving process …	… contributing to limited benefit of intervention
25	If the ABLE 2.0 is delivered in the context of an ABLE OT being empathetic, kind, skilled and competent …	… it may activate focused communication and collaboration between client and ABLE OT …	… contributing to finding relevant solutions and improved ADL ability
Re-evaluating ADL ability to finalise intervention			
26	If ABLE 2.0 is delivered in the context of giving concrete feedback in terms of comparing level of obtained goals with level at session 1 …	… it may activate the client perceiving that the intervention made a difference and feeling motivated for integrating the new methods into everyday life routines …	… contributing to sustainable changes
27	If ABLE 2.0 is delivered in the context of an ABLE OT being skilled in interpreting and explaining the results …	… it may activate the client getting insight in occurred changes and motivation for carrying on using the new strategies …	… contributing to sustainable changes
28	If ABLE 2.0 is delivered in the context of an OT conducting systematic re-evaluation using standardised instruments …	… it may activate clarity on obtained changes …	… contributing to demanded documentation

ABLE, A Better Everyday Life (intervention programme); ADL, Activities of daily living; CMO, context mechanism outcome; GAS, goal attainment scaling; OT, occupational therapist

DISCUSSION

This process evaluation, using a realist evaluation approach, aimed to explain in what circumstances, for whom, why and how ABLE 2.0 may or may not contribute to changes in ADL ability in persons living with chronic conditions. A total of 28 CMOCs were identified within four interrelated themes; building a foundation for the entire intervention; establishing the focus for further intervention; identifying and implementing relevant compensatory solutions; and re-evaluating ADL ability to finalise intervention. The following is a summary of the findings compared with existing research/literature, overall providing valuable information in case of future implementation of the ABLE intervention programme in other contexts.

What works?

Several contextual factors, emerged from data, enabled that the ABLE 2.0 provided a frame for enhancing the ADL ability among the participating clients, and hence are suggested to be prerequisites for successful implementation of the ABLE intervention programme. It is therefore recommended that ABLE 2.0 is delivered in a municipal structure that supports delivery of a problem-solving process involving the client throughout the intervention, and including initial evaluation of the client's ADL ability, goal setting, clarification of causes for the ADL task performance problems, and identification of relevant solutions. Further, delivery should be supported by the management; OTs should be skilled in administrating the

prescribed instruments and in collaboration with their clients; and the clients should be prepared for and ready to make changes in performance of ADL tasks.

The structure and content of the ABLE 2.0 intervention programme is composed of standardised instruments and conceptual practise models. In that respect ABLE 2.0 does not differ from what can be implemented in any clinical occupational therapy practice and does not imply special knowledge or skills. However, ABLE 2.0 is unique in outlining *how* the underpinning theories, conceptual practice models and instruments are applied and *how* the content interdependently work together to provide a coherent client-centred individualised occupational therapy process.

Based on the compensatory model of the OTIPM (41), specific methods such as teaching new strategies in performance of ADL tasks, implementing assistive devices, and modifying the physical and/or social environment are implemented. Due to ineffective performance skills, the client may need to perform the task in a way that is different from what is usually considered typical. However, regarding persons with chronic conditions, performance that is beyond what is typical, may be a way of preventing decline in ADL ability, e.g., as is the case when applying energy conservation principles to help the client manage fatigue during task performance (51). A compensatory intervention approach (41), embraces introduction of adaptational strategies, consultation, and education (41), and emphasises that the OT engages the client to *"try out, practice, and learn to use their chosen adaptation strategies and ensure that they will be able to incorporate them into their daily life routines"* (41). Hence, a compensatory approach involves some kind of habit change, and when aiming for sustainable changes even habit formation. In the previous feasibility and pilot studies (25,26), changing habits was a frequently implemented intervention component, including to introduce the client to such new ways of doing, e.g., using pauses before, during, or after task performance; or adjusting the pace during task performance (27), supporting the impact of applying adaptational strategies. Modifying habits by making changes in the physical or social contexts have previously been suggested to be the most effective and straightforward way of disrupting, developing, or changing habits (52,53). In the ABLE 2.0 this is extended to also include adapting the task itself, reflected in the prominent CMOCs no 22, including to discuss ways of doing the task differently. This may lead to more efficient performance in terms of reducing physical effort during tasks performance, contributing to finding potentially sustainable solutions. Further, the fact that persons vary in the capacity to make contextual changes themselves (54) and that many persons need assistance identifying deficits and potential solutions (52,53) adds to the complexity (55) in interventions aiming to enhance the ADL ability among persons with chronic conditions.

For whom does it work?

The study indicated that the ABLE 2.0 primarily worked for clients with positive expectations, who were openminded towards and perceived to be ready for making changes. Clients who had applied for specific assistance, e.g., assistance cleaning, and in cases where goals were set by the referral service, were perceived to be less openminded for implementing other solutions in relation to ADL task performance. Further, it was revealed that clients with severe cognitive deficits were less able to be involved the problem-solving process and in finding relevant solutions. Finally, it was found that clients who could maintain what was found and discussed during the initial sessions were more likely to benefit. Recognising the challenge of proper involvement of some clients in a collaborative problem-solving process, this study stresses the importance of OTs possessing effective collaborative and communication skills when delivering the ABLE 2.0, especially, when collaborating and communicating about goalsetting and clarification of causes for the ADL problems.

In what circumstances does it work?

According to the IPT, ABLE 2.0 would improve the ADL ability based on a structured, individualised problem-solving process in the client's home. This was overall confirmed. Specifically we found that the administration of initial evaluations, based on both self-report and observation of ADL ability at session 1, was a prerequisite for initiating the problem-solving process and that supportive management, a system working on the client's premises, and the OTs' skills in facilitating a dialogue on goal setting and clarification of causes for ADL task performance problems were core contextual factors. Data revealed that the logical order of the coherent steps in ABLE 2.0, including systematic evaluation of ADL ability, involving the client in the problem-solving process, and facilitating adaptive occupation in the client's home was of prominent importance. Reflected in the implementation failure on goal setting it was clear, that if one part was left out e.g., not involving the client in defining goals and defining levels of goal attainment at session 2, the problem-solving process was obstructed.

Emphasised by both clients and OTs the evaluation of ADL ability, using the AMPS and the ADL-I was crucial in building a solid foundation for the entire intervention, also reflected in the prominent CMOC no 6 (table 3). The previous feasibility study found supportive results (25), that clients and OTs found the formal and standardised evaluations highly meaningful and supportive of client involvement in the process; and the pilot study (26) confirmed the findings with overall high scores on the impact of session 1 in clarifying focus for intervention and establishment of a good basis for further cooperation. Further, this process evaluation revealed that the mandatory dialogue on discrepancy was a core step in the coherent process in terms of both parties becoming aware of the other person's perspective. Overall, the findings provide evidence to support the initial evaluation phase outlined in the OTIPM (41) and reflected in ABLE 2.0 session 1, including evaluation of ADL ability based on both self-reported and observation as basis for goal setting and intervention planning. Further, CMOC no 8 expressed the importance of the OT's skills in administering

the instruments, which was supported by the results of the feasibility study (25) as well as the pilot study (26) that the OTs felt highly confident in delivering the initial session. Hence, the priority of this subject in the three-and-a-half-day training course is suggested important in case of future implementation in other contexts. The assumptions on the impact of the systematic approach in ABLE 2.0 was overall confirmed and stands out as a particularly important contextual factor, provided it was delivered by a trained, skilled, and engaged OT, who was capable of explaining the purpose and use of tools and of actively involving the client in the problem-solving process.

The use of GAS for goal setting and PEO and/or TMO in clarifying causes for the ADL problems was found core in establishing the focus for the further process, as reflected in the prominent CMOC no 12 and 14. However, an implementation failure was identified (CMOC no 13). Several explanations for the challenges related to goal setting are considered. One explanation could be lack of experience among the OTs in collaborative goal setting, because goals typically were defined by the referral service in the municipality. Another could be lack of communication and collaboration skills among OTs, to involve the client in using GAS. And finally, the challenges could be related to lack of ability to involve clients with cognitive deficits in setting goals. The complexity in goal setting among persons with chronic conditions is recognised (56–59). Still, based on this process evaluation, and in agreement with Wade (60), claiming that goal setting is and should be a central feature in rehabilitation and should be a core competence of members of rehabilitation teams, the importance of collaborative goal setting is beyond doubt. Moreover, based on a systematic review by Vermunt et al (56), it is specifically recommended to apply collaborative goal setting with elderly persons with chronic conditions. The present study, however, revealed that the ABLE OTs were sometimes challenged communicating and collaborating with different clients, which may call for a variety of different skills among OTs delivering the programme. Delivering ABLE 2.0 is not simply applying the tools, instruments, and models prescribed in the ABLE 2.0 manual (61). The impact is found in *the way* OTs deliver the ABLE 2.0. Recognising the challenges in goal setting, future research activities related to the ABLE intervention programme should address the OTs' skills in communicating around goal setting, and how to intentionally develop a fruitful therapeutic relationship during delivery of the ABLE 2.0. The OTIPM (41) also emphasises that the collaborative working relationship between the client and the OT is a critical component of the therapeutic process. Moreover, the Intentional Relationship Model (IRM) provides six distinct ways, i.e. therapeutic modes (i.e. advocating, collaborating, emphasising, encouraging, instructing, and problem-solving mode) of relating (62). For example by utilising the *advocating mode*, reflecting that the OT speaks for the client's rights and help to secure resources (62) may be appropriate in case of inappropriate wait for assistive devises or home care; or when involving the client in finding relevant solutions the *collaborating mode,* reflecting that the OT works on an egalitarian level with the client, entrusting that the client lead the

decision-making process (62) may be particularly appropriate. Hence, the IRM may be useful in supporting establishment and obtaining full benefit of the collaborative working relationship.

How does it work?

The ABLE 2.0 showed potential to trigger clients' motivation for making changes in their daily lives. Further, the ABLE 2.0 showed potential to provide the OTs with the demanded skills to deliver the programme as prescribed in the manual, and support the ABLE OTs in being vigorous, responsible, and confident during delivery. The ABLE 2.0 was perceived to contribute to establishing therapeutic relationship and empowerment of the client. The present evaluation revealed that the dialogue between the client and the ABLE OT on clarification of causes for the ADL problems, by using the PEO (43) and/or the TMO (41) (during session 2) triggered a core mechanism of change. Using these models offered an opportunity to move from a disease-oriented to a more transactional perspective on the clients' ADL problems, facilitating the use of e.g., environmental opportunities or adaptive occupations to compensate for ineffective occupational skills. The ABLE OTs found that focusing on the chronic conditions did not explain the client's ADL task performance. As prescribed in the OTIPM (41), we need to understand why the ADL task performance problems occur to help the client improve in ADL ability. In the transactional perspective on occupation, *"occupation is a response to situational elements that naturally shape each other"* (41). Thus, by considering how situational elements affect the person's ADL task performance, and by moving beyond understanding ADL task performance problems as solely individual problems, more efficient, and potentially sustainable, solutions can be identified. Hence the transactional perspective (41) is suggested important in supporting the process of finding relevant and effective solutions.

Strengths and limitations

Several limitations are to be considered. The study was conducted in a single centre, limiting the evidence of how the ABLE 2.0 functions in various contexts. Another limitation occurred due to the parallel conduction of an RCT, preventing interviews to be conducted immediately after delivery of sessions. Instead data were collected several weeks after the inclusion of the client. Hence, the interviewed clients were generally challenged recalling details on the content of their interventions and on mechanisms, specifically concerning goal setting and clarification of causes for ADL task performance problems.

The sample of clients was constructed to represent the heterogeneous group targeted by the ABLE 2.0. This was achieved in terms of diagnoses, sex, age, and level of ADL motor ability at baseline. However, in terms of variation in outcomes the persons interviewed overall reached the expected level of goals, which may represent a problem in gaining nuanced information on participants' experiences of whether ABLE 2.0 encouraged them to make changes in reasoning and/or behaviour in relation to ADL task performance, i.e. mechanisms. However, the clients delivered valuable information on how they perceived

the focus of their intervention, how they felt about the OT, and how they perceived the process and the solutions identified during the intervention. In future studies it would be relevant to conduct client interviews immediately after a session, or alternatively to conduct focus group interviews with a client group selected for the purpose of gaining information on mechanisms of change.

It was considered a strength that both clients having received, and OTs having delivered the ABLE 2.0 was interviewed. Further the use of programme theory, the longitudinal design, and the application of realist principles in terms of the teacher-learner function applied in the interviews, strengthened the study in providing valuable information on the functioning of the ABLE 2.0. The previous studies conducted within the 'A Better Everyday Life' research programme (25,27), informed the development of the IPT, serving as structure for data collection and analysis. The IPT included very limited assumptions regarding infrastructural and institutional level contextual factors of impact, limiting the opportunity to investigate these contextual factors. However, the present study revealed comprehensive evidence on the impact of the infrastructural and institutional level contextual factors, considered to be of great importance in case of future implementation. Based on the IPT, expressing the ideas of how the intervention was assumed to work, we established conversation with the persons receiving and delivering the intervention during collection of qualitative data, and compared the results with existing evidence. This reflects triangulation and resulted in comprehensive knowledge about the functioning of the ABLE intervention programme.

Conclusion

This study investigated in what circumstances, for whom, how and why the ABLE 2.0 intervention programme functioned in a Danish community-based rehabilitation setting. Based on the study it is concluded, that when ABLE 2.0 is delivered within supportive municipal frames by skilled and engaged occupational therapists in the home of the client, and when adaptational strategies to resolve the ADL task performance problems are applied, sustainable changes in the clients ADL ability may be ensured. Further, when ABLE 2.0 was delivered to a client feeling ready for making changes and having room for improvement, a collaborative working relationship between the client and the OT could be established. With that respect, the ABLE 2.0 represents a coherent problem-solving occupational therapy process, applicable across sex, age, and diagnoses, that has the potential to enhance the ADL ability among persons with chronic conditions, when delivered as part of community-based rehabilitation services.

Finally, the study serves as an example of how to conduct a process evaluation using the principles of realistic evaluation, for the purpose of investigating the functioning of a complex intervention.

Abbreviations

ABLE, a better everyday life; ADL, activities of daily living; ADL-I, activities of daily living interview; AMPS, assessment of motor and process skills; C, client; CMOC, context-mechanism-outcome configuration; FG, focus group; GAS, goal attainment scaling; IPT, initial programme theory; IRM, intentional relationship model; OT, occupational therapist; OTIPM, occupational therapy intervention process model; PEO, person-environment-occupation; RCT, randomised controlled trial; TMO, transactional model of occupation

Acknowledgements

First, we thank all study participants for contributing. We also extend our sincere thanks to Herning municipality for contributing to this study and specifically the occupational therapists at the rehabilitation units for contributing to recruitment and data collection.

Author contributions

Study design: VH, KTN, CvB, and EEW. Data collection: VH, KTN, CvB, and EEW. Data analysis: VH and KTN. VH drafted the manuscript and KTN, CvB and EEW provided critical revision. All authors have read and agreed the final content of this manuscript.

Funding

This work was supported by: The Oak Foundation (OCAY-13-309); The municipal fund for quality development (A327); VIA University College; Southern Denmark University; Bispebjerg and Frederiksberg Hospital, University of Copenhagen; Research Fund of the Danish Association of Occupational Therapy (FF1/19-R112-A2271 and FF2/19-R132-A2835); and the Lundbeck foundation (A8059).

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The study was approved by the Danish Data Protection Service Agency: Journal-nr. P-2020-203. The Ethical Committee confirmed that no approval was needed for this study: Journal-nr.: 19045758. Informed consent was obtained.

Consent for publication

Not applicable.

Competing interests

The authors have no competing interests to declare.

REFERENCES

1. Bendixen HJ, Wæhrens EE, Wilcke JT, Sørensen LV. Self-reported quality of ADL task performance among patients with COPD exacerbations. Scand J Occup Ther. 2014 Jul 21;21(4):313–20.

2. Lindahl-Jacobsen L, Hansen DG, Wæhrens EE, la Cour K, Søndergaard J. Performance of activities of daily living among hospitalized cancer patients. Scand J Occup Ther. 2015 Mar 1;22(2):137–46.

3. Nielsen KT, Wæhrens EE. Occupational therapy evaluation: Use of self-report and/or observation? Scand J Occup Ther. 2015;22(1):13–23.

4. Wæhrens EE, Bliddal H, Danneskiold-Samsøe B, Lund H, Fisher AG. Differences between questionnaire-and interview-based measures of activities of daily living (ADL) ability and their association with observed ADL ability in women with rheumatoid arthritis, knee osteoarthritis, and fibromyalgia. Scand J Rheumatol. 2012;41(2):95–102.

5. Daving Y, Claesson L, Sunnerhagen KS. Agreement in activities of daily living performance after stroke in a postal questionnaire and interview of community-living persons. Acta Neurol Scand. 2009;119(6):390–6.

6. Hariz GM, Forsgren L. Activities of daily living and quality of life in persons with newly diagnosed Parkinson's disease according to subtype of disease, and in comparison to healthy controls. Acta Neurol Scand. 2011;123(1):20–7.

7. Norberg EB, Boman K, Löfgren B. Activities of daily living for old persons in primary health care with chronic heart failure. Scand J Caring Sci. 2008;22(2):203–10.

8. Sturkenboom IHWM, Graff MJL, Hendriks JCM, Veenhuizen Y, Munneke M, Bloem BR, et al. Efficacy of occupational therapy for patients with Parkinson's disease: a randomised controlled trial. Lancet Neurol. 2014 Jun 1;13(6):557–66.

9. Storeng SH, Vinjerui KH, Sund ER, Krokstad S. Associations between complex multimorbidity, activities of daily living and mortality among older Norwegians. A prospective cohort study: The HUNT Study, Norway. BMC Geriatr. 2020;20(1):1–8.

10. Goodman RA, Posner SF, Huang ES, Parekh AK, Koh HK. Defining and Measuring Chronic Conditions: Imperatives for Research, Policy, Program, and Practice. Prev Chronic Dis. 2013 Apr 25;10:120239.

11. Wæhrens EE. Almindelig daglig levevis: ADL [Activities of daily living: ADL]. Munksgaard; 2015.

12. Avlund K. Disability in old age. Longitudinal population-based studies of the disablement process. Dan Med Bull. 2004;51(4):315–49.

13. Hvidberg MF, Johnsen SP, Davidsen M, Ehlers L. A Nationwide Study of Prevalence Rates and Characteristics of 199 Chronic Conditions in Denmark. PharmacoEconomics - Open. 2019;4:361–380.

14. World Health Organization. Worlds Health Statistics 2020: Monitoring health for the SDG, sustainable development goals. Geneva; 2020.

15. Ryan A, Wallace E, O'Hara P, Smith SM. Multimorbidity and functional decline in community-dwelling adults: A systematic review. Health Qual Life Outcomes. 2015;13(1).

16. Calderón-Larrañaga A, Vetrano DL, Ferrucci L, Mercer SW, Marengoni A, Onder G, et al. Multimorbidity and functional impairment–bidirectional interplay, synergistic effects and common pathways. J Intern Med. 2019;285(3):255–71.

17. Makovski TT, Schmitz S, Zeegers MP, Stranges S, van den Akker M. Multimorbidity and quality of life: Systematic literature review and meta-analysis. Ageing Res Rev. 2019;53(January):100903.

18. Iheanacho I, Zhang S, King D, Rizzo M, Ismaila AS. Economic burden of chronic obstructive pulmonary disease (COPD): A systematic literature review. Int J COPD. 2020;15:439–60.

19. Hajat C, Stein E. The global burden of multiple chronic conditions: A narrative review. Prev Med Reports. 2018;12(September):284–93.

20. Dalsgaard CT. Økonomisk Styring af Hjemmepleje og Rehabiliteringsforløb [Financial Management of Home Care and Rehabilitation Services]. VIVE DK. 2020.

21. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337(7676):979–83.

22. Nielsen KT, Hagelskjær V, Pilegaard MS, von Bülow C, Wæhrens EE. The development of the A better Everyday LifE (ABLE) intervention program. Unpubl Work.

23. Nielsen KT, Klokker L, Guidetti S, Wæhrens EE. Identifying, organizing and prioritizing ideas on how to enhance ADL ability. Scand J Occup Ther. 2018;26(5):382–93.

24. Guidetti S, Nielsen KT, von Bülow C, Pilegaard MS, Klokker L, Wæhrens EE. Evaluation of an intervention programme addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a feasibility trial (ABLE). BMJ Open. 2018;8(5):e020812.

25. Nielsen KT, Guidetti S, von Bülow C, Klokker L, Wæhrens EE. Feasibility of ABLE 1.0—a program aiming at enhancing the ability to perform activities of daily living in persons with chronic conditions. Pilot Feasibility Stud. 2021;7(1):1–15.

26. Hagelskjær V, Nielsen KT, von Bülow C, Graff M, Wæhrens EE. Occupational therapy addressing the ability to perform activities of daily living among persons living with chronic conditions: a randomised controlled pilot study of ABLE 2.0. Pilot Feasibility Stud. 2021;7(1):122.

27. Nielsen KT. Occupational therapy for persons living with chronic conditions - Development and feasibility of the ABLE program. Thesis. Southern Denmark University; 2018.

28. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. Bmj. 2015;350(mar19 6):h1258–h1258.

29. Wong G, Westhorp G, Manzano A, Greenhalgh J, Jagosh J, Greenhalgh T. RAMESES II reporting standards for realist evaluations. BMC Med. 2016;14(1):1–18.

30. Pawson R, Tilley N. Realistic evaluation. Reprint. London: Sage; 1997. xvii, 235 s., illustreret.

31. Westhorp G. Realist Impact Evaluation. Res Policy Dev. 2014;(September):1–12.

32. Mansoor A. F. Kazi & Lucy J. Spurling. Realist Evaluation for evidence-based practice. Pap Present Eur Eval Soc Fourth Conf Lausanne, Switzerland, Oct 2000.

33. Pawson R. The Science of Evalation. A realist manifesto. SAGE Publications; 2013.

34. Greenhalgh T, Wong G, Jagosh J, Greenhalgh J, Manzano A, Westhorp G, et al. Protocol-the RAMESES II study: Developing guidance and reporting standards for realist evaluation. BMJ Open. 2015;5(8).

35. The RAMESES II Project. RAMESES II Context Report. 2017;1–4.

36. Hagelskjær V, Nielsen KT, von Bulow C, Oestergaard LG, Graff M, Wæhrens EE. Evaluating a complex intervention addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a randomised controlled trial (ABLE). BMJ Open. 2021;11(11):e051722.

37. Fisher AG, Jones KB. Assessment of motor and process skills. Volume 1: Development, standardization, and administration manual. 7th ed. Fort Collins, Colorado, USA: Three Star Press; 2012.

38. Fisher AG, Jones KB. Assessment of motor and process skills. Volume 2: User manual. 7th ed. Fort

Collins, Colorado, USA: Three Star Press; 2012.

39. Krasny-Pacini A, Hiebel J, Pauly F, Godon S, Chevignard M. Goal Attainment Scaling in rehabilitation: A literature-based update. Ann Phys Rehabil Med. 2013;56(3):212–30.

40. Kiresuk TJ, Smith A, Cardillo JE. Goal Attainment Scaling : Applications, theory, and measurement. Hillsdale, N.J.: L. Erlbaum Associates; 1994.

41. Fisher AG, Marterella A. Powerful practice : A Model for Authentic Occupational Therapy. Fort Collins: CIOTS - Center for Innovative OT Solutions; 2019.

42. Dickie V, Cutchin MP, Humphry R. Occupation as transactional experience: A critique of individualism in occupational science. J Occup Sci. 2006;13(1):83–93.

43. Strong, S.; Rigby, P.; Stewart, D.; Law, M.; Letts, L.; Cooper B. Application of the Person-Environment-Occupation Model: A practical tool. Can J Occup Ther. 1999;

44. Wæhrens EE, Kottorp A, Nielsen KT. Measuring self-reported ability to perform activities of daily living: a Rasch analysis. Health Qual Life Outcomes. 2021;19(1):1–17.

45. Wæhrens EE. Measuring quality of occupational performance based on self-report and observation. Development and validation of instruments to evaluate ADL task performance [Internet]. Thesis. Department of Community Medicine and Rehabilitation, Umeå University; 2010. Available from: http://umu.diva-portal.org/smash/record.jsf?pid=diva2%3A318271&dswid=3508

46. Wæhrens EE, Nielsen KT. ADL-Interview (ADL-I). Klinisk version 1.0 - Introduktion, ADL-I og administration [Clinical version 1.0 - Introduction, ADL-I, and administration]. ACE Copenhagen. 2020.

47. Nielsen KT, Klokker L, Wæhrens EE. Self-reported quality of activities of daily living task performance in four diagnostic groups with chronic conditions. IJTR. 2021;28(4):1–10.

48. Manzano A. The craft of interviewing in realist evaluation. Evaluation. 2016;22(3):342–60.

49. The RAMESES II Project. Retroduction in realist evaluation. Nihr. 2017;(p 207):1–3.

50. Gilmore B, McAuliffe E, Power J, Vallières F. Data Analysis and Synthesis Within a Realist Evaluation: Toward More Transparent Methodological Approaches. Int J Qual Methods. 2019;18:1–11.

51. Dreiling D. Energy Conservation. Home Heal Care Manag Pract. 2009;26–33.

52. Fritz H, Cutchin M. Integrating the science of habit: Opportunities for occupational therapy. OTJR Occup Particip Heal. 2016;36(2):92–8.

53. Neal DT, Wood W, Drolet A. How do people adhere to goals when willpower is low? The profits (and pitfalls) of strong habits. J Pers Soc Psychol. 2013;104(6):959–75.

54. Fritz HA. Learning to do Better: The Transactional Model of Diabetes Self-Management Integration. Qual Health Res. 2015;25(7):875–86.

55. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. BMJ. 2021;374(2018):1–11.

56. Vermunt NPCA, Harmsen M, Westert GP, Olde Rikkert MGM, Faber MJ. Collaborative goal setting with elderly patients with chronic disease or multimorbidity: A systematic review. BMC Geriatr. 2017;17(1):1–12.

57. Ranner M, Von Koch L, Guidetti S, Tham K. Client-centred ADL intervention after stroke: Occupational therapists experiences. Scand J Occup Ther. 2016;23(2):81–90.

58. Cameron LJ, Somerville LM, Naismith CE, Watterson D, Maric V, Lannin NA. A qualitative investigation into the patient-centered goal-setting practices of allied health clinicians working in rehabilitation. Clin Rehabil. 2018;32(6):827–40.

59. Kessler D, Walker I, Sauvé-Schenk K, Egan M. Goal setting dynamics that facilitate or impede a client-centered approach. Scand J Occup Ther. 2019;26(5):315–24.

60. Wade DT. Goal setting in rehabilitation: An overview of what, why and how. Clin Rehabil. 2009;23(4):291–5.

61. Nielsen KT, Hagelskjær V, Wæhrens EE. Manual: ABLE 2.0 - et ergoterapeutisk interventionsprogram for personer med kroniske tilstande [ABLE 2.0 - an occupational therapy intervention programme for persons with chronic conditions]. Unpubl Work. 2020;

62. Taylor RR. The intentional relationship: occupational therapy and the use of self. Philadelphia (PA): F.A. Davis Co.; 2008.