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First pill hardest to swallow: An evaluation study of cardiovascular nurse-led follow-up phone calls

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Introduction: Screening for cardiovascular disease (CVD) followed by preventive medication is expected to reduce CVD (2,3,5). However, insufficient medication adherence may affect screening effectiveness (11-12). It remains uncertain which interventions are suitable to support citizens in their decision-making about taking CVD preventive medication.
Objective: We evaluated *if* and *how* three nurse-led telephone follow-up (TFU) calls supported citizens in making informed decisions regarding CVD preventive medication and thereby potentially strengthened their medication adherence.
Methods: Employing a theory-based evaluation design inspired by Dahler-Larsen (39-41), we developed and tested a programme theory describing *if* and *how* the TFU calls supported medical decision-making and potentially improved medication adherence. Data were collected via telephone.
Findings: We analysed 61 TFU calls collected between May 2017 and April 2019 and found that TFU calls supported participants' reflections on preventive medication. TFU calls supported informed decision-making regarding initiating medication, allowing participants to consider personal preferences and values, including both opting for and abstaining from medication. The content of the TFU calls revolved around four crucial themes: I) understanding the purpose of taking the medicine; II) meaningfulness and joint reflection support the decision; III) relation to healthcare professionals; and IV) taking medication for the first time.
Conclusion: TFU calls effectively supported citizens' understanding and addressed their needs. Trusted healthcare professionals' recommendations were preferred for decisional support. Initiating CVD preventive medication was particularly challenging for citizens who had not previously taken such medication. We recommend scheduling TFU calls early: the first after one week, the second after one month and the third after six months.

Introduction

Cardiovascular disease (CVD) is the second leading cause of morbidity and death, accounting for 32% of deaths worldwide.[1] According to international guidelines, preventive medication is crucial in lowering CVD incidence and its consequences.[2,3] This importance is underscored by the expected rise in CVD rates due to aging and the rising prevalence of obesity and diabetes.[4]

Population screening for subclinical and manifest CVD entailed a 7% mortality reduction among 65-74-year-old men[5], and an 11% decrease in 65-69-year-old men.[6,7] Cardiovascular conditions, like abdominal aortic aneurysm (AAA), peripheral arterial disease (PAD) and carotid plaque (CP), often start asymptomatic yet hold a potential for preventive interventions targeting diet, smoking, alcohol and exercise and initiation of preventive medication with antiplatelets and lipid-lowering therapy.[2,3,8–11] However, low medication adherence could diminish the positive screening effect, with only 55-65% of patients adhering to the recommended preventive medication.[11,12] Moreover, research indicates low adherence to prescribed medication, with only 25-30% being taken as

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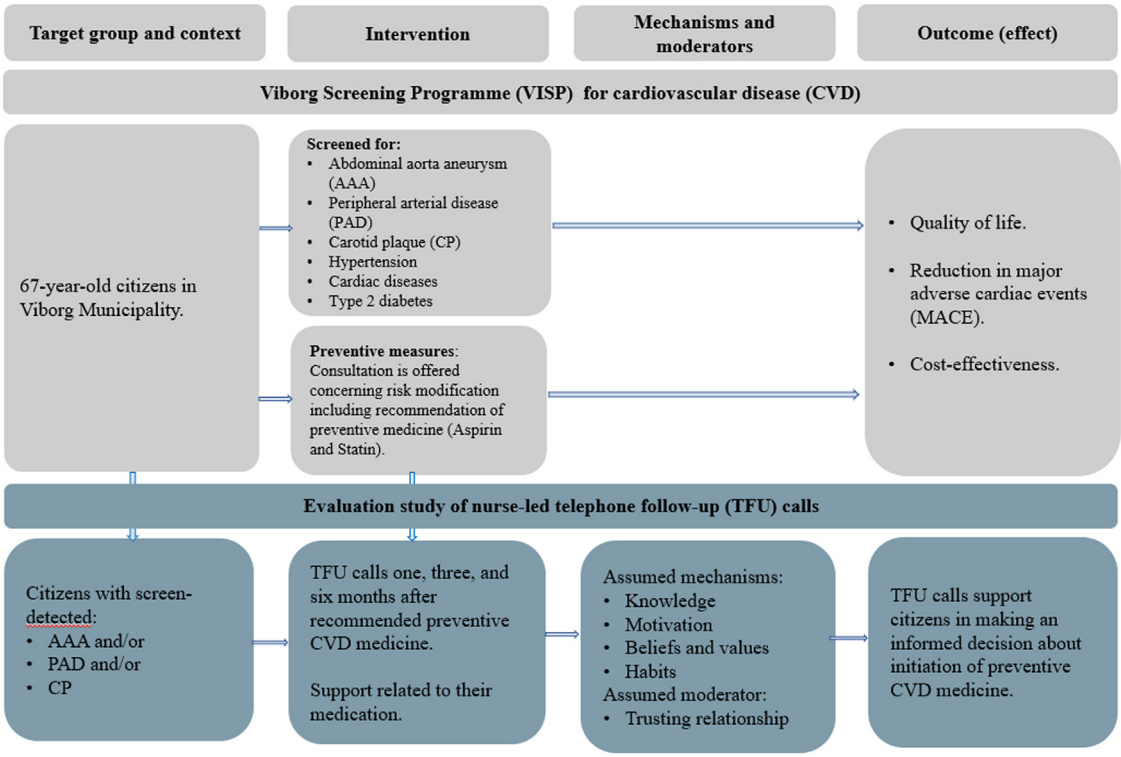


Figure 1. The programme theory.

directed.[13] While preventive medication is endorsed to effectively prevent CVD, acknowledging potential drawbacks for healthy individuals is vital. Balancing pros and cons, individuals must align decisions with personal values and preferences, underscoring the need to respect and accept informed decisions regarding medication adherence.[14–16]

WHO emphasises the value of continuous communication efforts, e.g. telephone follow-up (TFU) calls, as a simple, cost-effective strategy to enhance medication adherence.[17] Several studies confirm that TFU calls positively impact medication adherence and decision-making[18–24]; conversely, another study documents low-certainty evidence for the effects of mobile phone-based interventions.[25] Furthermore, a meta-analysis revealed 19% higher non-adherence among patients encountering healthcare providers with inadequate communication skills.[26] Enhancing communication improves medication adherence, necessitating effective techniques. Pharmacists are key players in this endeavour. Thus, pharmacy research has demonstrated effective strategies to enhance medication adherence by exploring factors like beliefs, attitudes, knowledge, and successful initiation of new medications. By structured pharmacist-patient conversations addressing competence, adherence, satisfaction, self-management and drug-related problems, patients are given tailored solutions to support their decision-making.[27,28] Semi-structured conversations including, e.g., brief face-to-face and telephone counselling sessions between pharmacists and patients boosted adherence by approximately 10%.[29–32] However, these effects are poorly elucidated in screening contexts. A Danish study showed a single TFU call after three months improved statin adherence, but no sustained effect persisted at 12- and 60-month follow-up visits.[33] For optimal prevention, targeted individual intervention investigating long-term medication adherence effectiveness is needed.[34,35] Future research should prioritize assessing the communication aspects with the greatest impact on patient adherence.[26] Research literature acknowledges that providing individuals with necessary information is an ethical standard in healthcare systems.[36] Thus, the objective is to evaluate *if* and *how* nurse-led TFU calls support citizens with early-detected CVD in making informed decisions about initiating preventive medication, potentially enhancing their adherence to recommended treatment protocols while respecting their individual freedom of choice.

Material and methods

This study was reported in accordance with the consolidated SQUIRE 2.0. guideline criteria.[37]

Theoretical framework

We followed recommendations concerning theory-based evaluation proposed by Dahler-Larsen[38–40], who, in turn, was inspired by realistic evaluation as described by Pawson & Tilley.[41] This approach allowed us to understand and study complex phenomena in depth, supporting participants in their medical decision-making. In short, the focus is on examining what works for whom, why, and under what circumstances.[41] The theory-based evaluation design was based on programme theory[38,39,42–44], as illustrated in Figure 1.

Dahler-Larsen's scientific theoretical position aligns with social constructivism. Here, processes and contexts lie at the root of all causality. With a process-based approach to causality, knowledge is gained on how causal mechanisms work, providing an understanding of the underlying mechanisms affecting the intervention.[38,45,46] In Table 1, we illustrate Dahler-Larsen's six steps of theory-based evaluation.[38,45]

The following two questions guided the process of evaluating *if* and *how* TFU calls worked (step one):

Table 1
Six steps of theory-based evaluation.

1. Ask the evaluation question.
2. Find data for a programme theory.
3. Create a programme theory.
4. Prepare the programme theory for evaluation.
5. Select a method and collect data.
6. Analyse and conclude on the most effective mechanisms and moderators contributing to refining the programme theory.

1. What factors influence TFU call in supporting informed decisions on initiating preventive medicine for participants with early-detected CVD?
2. What contents and time should be addressed for the TFU calls to ensure that participants are supported in making informed decisions?

Setting and population

The *context* for this study was the **Vi**borg **S**creening **P**rogramme (VISP) for the municipality's 67-year-old citizens.[47] In brief, VISP participants were screened for AAA, PAD, CP, hypertension, type 2 diabetes and cardiac abnormalities. Those with early-detected AAA, PAD and CP were recommended Aspirin 75 mg and/or Atorvastatin 20 mg at a 30-minute post-screening follow-up appointment concerning risk modification and medical prevention. A prescription was given, if not initiated already and contraindicated. If potential contraindications existed, participants were advised to consult their general practitioner (GP) regarding the initiation.[11,47] VISP participants with early-detected AAA, PAD or CP were invited to participate in a randomized controlled trial (RCT) (control group, n=205 and intervention group, n=204). Participants were excluded if unable to understand Danish or prove informed consent. The first 40 participants randomized to the intervention group participated in the present study.

Intervention: nurse-led TFU calls

We adapted and tested a known intervention (*TFU calls*) in a screening context[48], as described above. The intervention group received TFU calls at one, three- and six-months post-recommendation for preventive medication. The first TFU was scheduled after one month, giving participants time to redeem prescriptions, gain initiation experience, and address any doubts or questions. The second and third TFUs followed times to redeem prescriptions after three and six months. They were supported in enquiring and deciding about the medical recommendation. We drew inspiration from motivational interviewing (MI)[49] to guide supporting screened participants in making informed decisions about initiating preventive CVD medicine. MI addresses health behaviours like medication adherence, aiming to enhance motivation and commitment to change by facilitating patients' understanding of their health. MI respects patients' autonomy builds patient confidence and supports decision-making. The counselling session follows a patient-centred, nonjudgmental and empathetic approach.[13,49] Researchers and screening nurses developed a script for the TFU calls inspired by research concerning medication adherence.[27,50] Inspired by pharmacists, we aimed to streamline TFU calls, offer customised information, bolster decision-making, address concerns and empower patients in medication management.[32,51] A pilot test produced a few changes to the script for the TFU calls, e.g., we added questions regarding preventive medication concerns. The same script was used for all three TFU calls, comprising questions about the participant's knowledge of their medicine, motivation, beliefs and values, and habits (Additional file). Screening nurses, trained and supervised for TFU calls, performed screening exams, follow-up visits and TFU calls.

Mechanisms, moderators and outcomes

Mechanisms are hidden components assumed to impact *outcomes*.[52] Mechanisms assumed to influence whether the participants felt supported in making an informed choice about CVD prevention included medication knowledge, motivation, beliefs and values, and habits. *Moderators* are conditions activating the mechanism between cause and effect.[42] We assumed that a moderator was a trusting relationship between the screening nurse and the participant.

Data collection

Data were collected from May 2017 to April 2019. After analysing TFU calls continuously, data richness and thickness[53] was reached after 61 TFU calls. The distribution of TFU calls is illustrated in Figure 2. Calls, lasting 10-15 minutes, were recorded and transcribed verbatim.

Data analysis

Following Dahler-Larsen's guidelines[38,39], we analysed the data in four steps. First, the first author read and re-read transcripts, noted analytical considerations, and gained an initial overview, identifying "meaning units". Second, we identified mechanisms and moderators by studying the nurse-participant process, as described by Dahler-Larsen, clarifying underlying mechanisms. Third, we identified differences and similarities in the process, observing how mechanisms influenced participants' sense of being supported. Ultimately, four themes emerged. To illustrate transparency and credibility, examples of the analytical process and our interpretation are presented in Table 2.

To strengthen the rigor[54] of our study, the authors continuously discussed their analysis at research team dialogue meetings.[55] NVivo software version 12 was used to structure our findings and facilitate the analysis.[56]

Ethical considerations

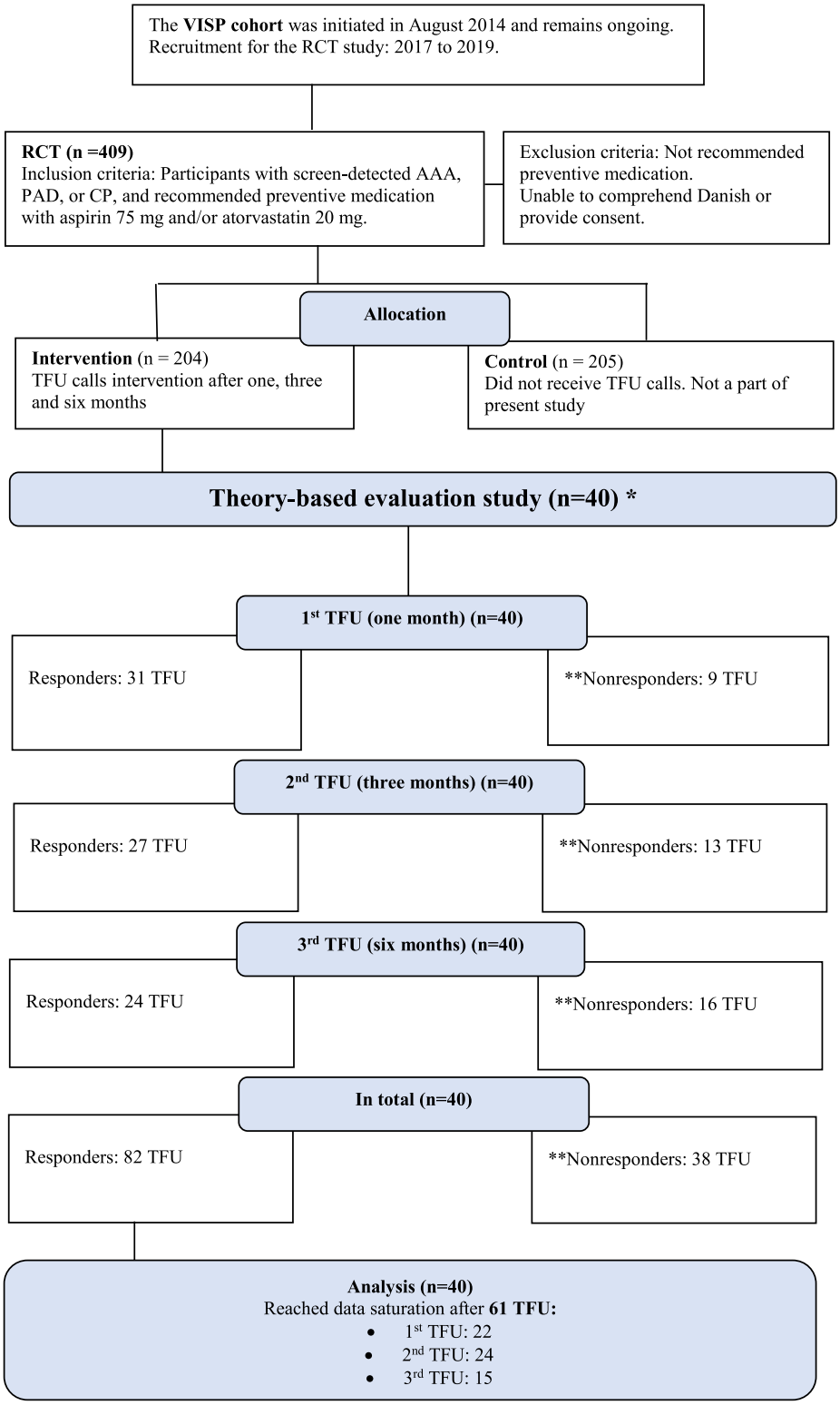
All included participants were informed verbally and in writing about the project and consent was obtained before each interview. All data collected were kept confidential and the study was approved by the Danish Data Protection Agency (Supplement to VISP cohort no.1-16-02-232-15). Furthermore, the study was approved by the Science Ethics Committees for the Central Denmark Region, case number:1-10-72-250-19 and VISP was recorded with ClinicalTrials.gov (NCT03395509).

Findings

We identified four themes playing an essential role in the intervention outcome. Two themes related to *mechanisms* were found: (I) understanding the purpose of taking the medicine and (II) meaningfulness and joint reflection support the decision. Furthermore, two themes related to *moderators* were identified: (III) relation to the healthcare professionals and (IV) taking medication for the first time.

Understanding the purpose of taking the medicine

We found participants' understanding of the purpose of preventive medication to be an important mechanism underpinning



* The first 40 citizens who were randomized to the intervention group participated in the present study
**Nonresponders: Contact was not achieved.

Figure 2. CONSORT flowchart of participants and telephone follow-up (TFU) calls in the study.

Table 2
Examples of the analytical process.

Meaning units	Mechanisms and moderators	Differences and similarities in mechanisms and moderators	Developing main themes to refine our programme theory
"Well, I take the medication because the calcification has been diagnosed. I must take the medication to prevent further atherosclerosis" (Participant 2778, 3 months).	Understanding the purpose	Comprehending the intended use of the medication enhances decision-making, whereas a lack of understanding generates uncertainty regarding the decision.	(I) Understanding the purpose of taking the medicine
"What do you think about the medication you have been recommended?" (Screening nurse and participant 3368, 1 month).	Reflection	Supporting participants' reflections promoted meaningfulness, whereas neglecting their thoughts and concerns made decision-making more difficult.	(II) Meaningfulness and joint reflection support the decision
"After visiting the GP…it was pleasant to talk about the status of my medication and ensure everything was in order" (Participant 2698, 3 months).	Trusting relationship	A trusting relationship became decisive for participants' decision-making, whereas a lack of relationship hindered the feeling of being supported in the decision-making.	(III) Relation to the healthcare professionals
"I received a diagnosis of rheumatoid arthritis approximately 10-15 years ago, and I have been taking medication for it since then. Considering the alternatives, I perceive this medication in a similar way. Therefore, if it is necessary, I have no doubts whatever that I should continue taking it" (Participant 6654, 3 months).	Experience with medicine	No experience with medicine creates insecurity, whereas experience with medicine reduces uncertainty.	(IV) Taking medication for the first time

informed decision-making. If the screening nurse facilitated understanding effects, side effects and contraindications of the medicine, participants felt supported.

> *"When I get an explanation of how it works (statin), and it makes sense, then there is really no need to worry about it anymore" (Participant 5111, 3 months)*

We interpret that understanding the purpose of the preventive treatment also reduced worries as the TFU calls were essential in clarifying any misunderstandings related to the medicine. Understanding was further facilitated by the visual image of the carotid calcification, which the participant was shown at the post-screening follow-up appointment.

> *"I saw it myself on the ultrasound scan; I saw that white thing on the inside of the arteria" (Participant 6510, 1 month)*

These images aided participants' discussions in TFU calls, enhancing comprehension of abstract concepts. In the TFU call, the nurse also facilitated comprehensibility. This strengthened participants' understanding of the medication's effect.

> *"That cholesterol-lowering tablet, it puts a little layer of varnish on top of the atherosclerosis, so that the blood can more easily pass through despite a slight narrowing in my carotid artery" (Participant 2592, 1 month)*

Using metaphors, nurses were able to establish a shared understanding with their participants, thereby facilitating a person-centred approach.

Meaningfulness and joint reflection support the decision

Jointly reflecting on an individual's perception of the meaningfulness of preventive medication emerged as a crucial mechanism influencing decisions. This process facilitated meaningfulness by weighing treatment pros and cons, fostering informed decision-making. Particularly, meaningfulness correlated with participants' motivation to avert disease and prolong their lifespan.

> *"You don't have any symptoms, so you don't think you're sick, and then it's nice that you get such an "inspection", just like the car also gets checked" (Participant 6608, 3 months)*

For others, medication was meaningful because it allowed them to follow self-selected recommendations, particularly with respect to dietary recommendations.

> *"So, I can eat little extra cheese snacks for a few days and then say 'never mind' because I take the pills" (Participant 6569, 6 months)*

Reflections on meaningfulness were based on an individual negotiation process. Some established meaningfulness by perceiving the intervention as a warning to take good care of themselves, combined with a fear of having a CVD event.

> *"It would be stupid not to take it and then something happened, you would never forgive yourself" (Participant 4054, 3 months)*

As such, TFU calls served as a platform allowing joint reflection on individual meaningfulness elements, addressing decisional ambivalence and fear. In summary, we found joint reflection to be predominately useful at the first and second TFU call. The main themes were the rationale for taking preventive measures and remedying decisional ambivalence and fear. Decisional ambivalence was thus still present in several participants three months after the recommendation.

Relation to the healthcare professionals

Trust and relationships with screening nurses decisively supported participants in matters of preventive medication. A trusting relationship emerged as the contextual element with the greatest impact on the effectiveness of TFU calls. Our findings revealed that participants followed the advice of healthcare professionals they held the highest confidence in.

> *When you (the screening nurse) say it helps me, I trust it (Participant 3219, 1 month).*

Thus, establishing trust between participants and screening nurses during the examination was crucial. This trust provided a sense of safety, enabling open discussion of preventive medication concerns during subsequent TFU calls. We also found that within the first week after the screening examination, participants sought advice on preventive medication from friends, family and their GP. Participants sought the GP's advice for a second opinion and to address doubts regarding the recommended medicine. They valued the GP's comprehensive assessment due to their familiarity.

"Yes, so I have had him (GP) for many years, and he knows me inside and out…and just when I was told that there was some calcification, I got a bit nervous, but (GP) says, there's no need… calm down now…." (Participant 6510, 1 month)

These doubts typically arose when participants returned home and had time to reflect on the preventive medication recommendations. This underscores the need of rescheduling the first TFU to an earlier time point.

Taking medication for the first time

Experience with medications was of great importance for participants' decision concerning CVD preventive medication initiation. Those already using prescription medication simply considered the new preventive medication recommendation an "extra pill" added to their pillbox.

"I don't have much trouble with that, it's because I need to take something else, too. I need to take some asthma medication, so yes then it's hitting two birds with one stone" (Participant 6689, 1 month)

Correspondingly, participants with additional symptomatic diseases, alongside asymptomatic CVD, were often less worried about initiating recommended preventive medication because other illnesses occupied more a significant portion of their focus.

"I would actually say that my back takes up a lot more attention, because I feel it. The second (early detected CVD) I do not feel" (Participant 2962, 6 months)

Conversely, the decision was more difficult for those who had not previously taken prescribed medications.

"I think it was frustrating, you go from not having to take any medication to suddenly having to take some medicine all the time. It was quite a shock to be told that now you must start taking this medicine. I don't take medicines, no one in my family does" (Participant 6569, 3 months)

Taking the first pill was overwhelming, impacting participants' well-being. These participants discussed doubts and questioned the recommendation during TFU calls. Addressing their concerns provided a sense of "peace of mind". Furthermore, participants felt empowered to make informed decisions aligned with their values. TFU call content varied based on whether the participant were new to medication or had prior experience.

Contents and timing for the nurse-led TFU calls

The identified mechanisms and moderators revealed a need to refine the programme theory in terms of 1) contents of the script for the TFU calls and 2) schedule of the TFU calls. Regarding the TFU call contents, we found variation between what participants needed to talk about at the first, second and third calls. Notably, a greater focus was required on participants' perspective regarding preventive medication recommendations. Using a script of the TFU calls (Additional material) as originally suggested in our programme theory was not optimal. Nevertheless, common themes emerged across the three TFU calls, guiding the creation of a refined, tailored and dialogue-based script for the TFU calls (Figure 3).

The script contains four new themes that should be addressed in TFU calls. A: The individual's perspective on medication, needs and wishes for support. B: The individual's questions and concerns related to preventive medication. C: The individual's experiences with initiating preventive medication by exploring personalised motivation, satisfaction and reasons for taking preventive medication and experience with other medications. D: How to establish daily routines for taking preventive medication.

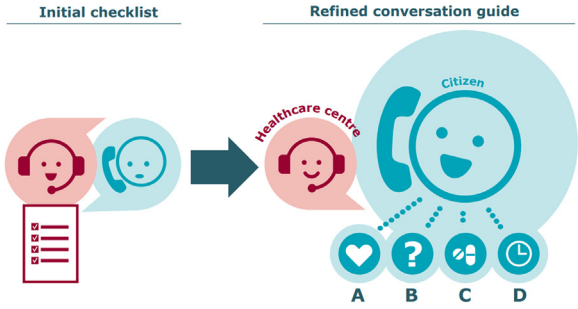


Figure 3. Tailored script for the TFU calls.

In relation to TFU call timing, we found TFU call scheduled at one, three and six months was ineffectual for addressing our participants' needs. Instead, we recommend scheduling the first TFU call *one week* recommending preventive medication as participants' questions and doubts related mainly to the preventive medication when returning home. Furthermore, we recommend the second call to be made after *one month*. By this time, many had gained experience with preventive medication and therefore had other questions, e.g., relating to side effects. In addition, some participants still needed to discuss their choice or were experiencing continued decisional ambivalence. Finally, we recommend the third conversation to be made after *six months* but only upon request or when deemed meaningful. The six-month TFU call should focus on supporting decision-making and underpinning good routines to adherence if the participant has initiated medication. The main findings are summarised in Figure 4.

Discussion

To our knowledge, this is the first study evaluating *if* and *how* three TFU calls support citizens with early-detected CVD in their decision-making about initiating preventive medication. Overall, TFU calls worked, especially for citizens without previously prescribed medication. To be supportive, information had to be *tailored to the citizen's individual needs.* Additionally, health professionals had to possess the necessary *communication skills* to facilitate tailored conversations about preventive medication. Similarly, Woods et al. indicated that TFU calls harboured potential to shape information and care to patients' requirements.[57] Moreover, González de León et al. reported a tailored intervention to be a feasible strategy for working with individuals' resources and ability to promote and maintain health.[34] Furthermore, Pedretti et al. highlighted the importance of educational materials employing plain language and delivering a clear and concise message. This person-centred approach empowers citizens to maintain control over their health issues.[12] Thus, we argue that our refined programme theory with the refined script for the TFU calls provides a person-centred approach facilitating citizens' decision-making process while respecting their right to make informed choices, which may include opting in and out of CVD preventive medication.

Having established that a tailored TFU worked, we also found the nurses' communication skills essential for preventive measures to appear meaningful. Through clear and concise communication, screening nurses supported citizens in considering their motivation and thereby individualized the meaningfulness of prophylaxis. We found communication skills fostered a trusting dialogue, allowing citizens to confidently reflect on their perspectives and express their support needs. Given its impact, development and

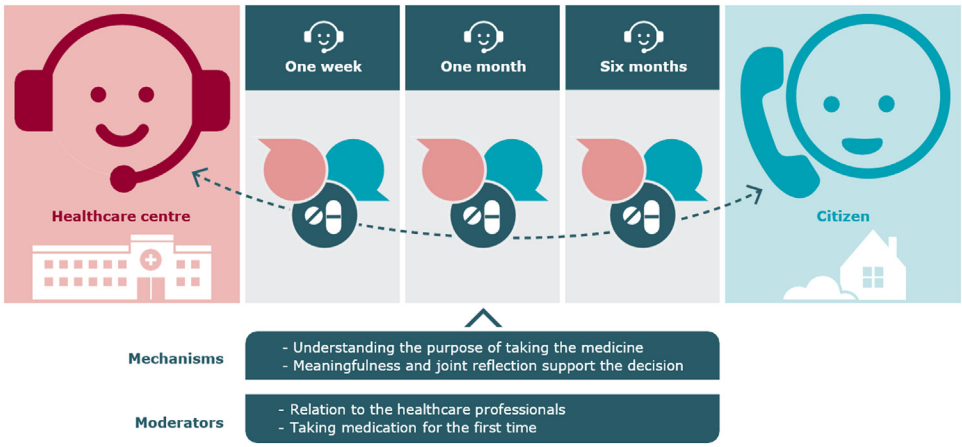


Figure 4. Findings of how TFU calls support participants' decision concerning CVD preventive medication.

enhancement of communication skills should be a focal point in programme theory. Understanding of and insights into their own medical treatment strengthened citizens' confidence in making informed choices about preventive medication. Our findings are underpinned by Sandbæk et al.[58] who developed five items patients discuss with their GP concerning their experiences with adverse drug reactions, excess medication, unnecessary medication, medication satisfaction and medication-related topics. They concluded patient-GP dialogues empowered patients, allowing them to voice their perspectives, and increased their sense of security, satisfaction and insights into their medical treatment. However, they also noted that not all patients wanted to reflect on their medication and stated - for some - reflection triggered worries about the medicine.[58] We found citizens needed to reflect on whether they wanted preventive medication or not. However, we also argue that the diversity in citizen preferences with respect to involvement and reflection must be kept in mind. Likewise, citizens had individual needs concerning the number of TFU calls. Our findings also showed that using MI skills in the TFU calls supported screened citizens in making informed decisions about medication. MI skills are represented by the acronym OARS and include the following components: Open-ended questions, encouraging citizens to think, reflect and provide their opinions and feelings. Affirmations are a way to support patients' self-efficacy. Reflective listening involved paraphrasing and displaying an empathetic understanding of patients' situation. Summaries is a powerful method health professionals may utilise to express interest in and care for a patient, highlighting significant issues raised during the conversation, and, if necessary, redirect attention and focus.[13,49] These communication skills were essential for effective communication respecting citizens' autonomy and supported their decision-making concerning CVD preventive medication in an unbiased and non-judgmental way.

Our recommendation of at least two TFU calls, possibly a third, is underpinned a Danish study showing that a single TFU call three months after a screening was insufficient to support long-term medication adherence to preventive CVD medication.[33] Thus, three TFU calls scheduled within six months seem justified by the fact that citizens need time to reflect on the recommendation, gain experience with preventive CVD medicine and discuss any questions with a healthcare professional.

Strengths and limitations

This study systematically followed Dahler-Larsen's six-step evaluation.[38,39] With 61 TFU calls, we achieved data saturation for our evaluation. By focusing on understanding the underlying mechanisms and moderators we provided a nuanced perspective on *if* and *how* three TFU calls supported medical decision-making. This process-based approach allowed a deeper understanding of how programme theory can be refined and optimized to underpin recommendations for contents and scheduling of TFU calls. A limitation was the lack of measures for assessing the impact of the three follow-up (TFU) calls on medication adherence for CVD. For instance, quantitative follow-up data regarding medication adherence, such as adherence rates upon self-reported or registry-based adherence. More research is therefore warranted to determine whether TFU calls are effective in ensuring long-term adherence to CVD medication.

Conclusion

We propose recommendations for future practice emphasising effective communication acknowledging citizens' needs and choices. TFU calls were effective in supporting understanding and meaningfulness, addressing citizens' needs and preferences, answering questions and doubts, exploring experiences and motivations. No medication adherence information was researched. Trusted healthcare professionals' recommendations were a valued support resource. Initiation of CVD preventive medication proved particularly challenging for citizens without prior medication experience, making the first pill the most difficult to take. Two, potentially three, TFU calls supported medical decision-making. We recommend scheduling the first TFU call after one week, the second call after one month, and the third call after six months to reduce the period in decisional ambivalence.

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Declaration of Competing Interest

None.

CRediT authorship contribution statement

Kirsten Frederiksen: Conceptualization, Formal analysis, Methodology, Project administration, Supervision, Validation, Writing – review & editing. **Annette Langager Høgh:** Conceptualization, Methodology, Project administration, Supervision, Validation, Writing – review & editing. **Marie Dahl:** Conceptualization, Formal analysis, Methodology, Project administration, Supervision, Validation, Visualization, Writing – review & editing.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jvn.2023.11.007.

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