Title page

Citation

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Table of contents

1.Title

The MIPAM trial: A 12-week intervention with motivational interviewing and physical activity monitoring, to enhance the daily amount of physical activity in community dwelling older adults – a randomized controlled trial

2. Trial registration

ClinicalTrials.gov Identifier: NCT03906162

3. Protocol version

Version 3.0

4. Funding

The content presented within this paper was produced as part of the project REACH: this project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 690425 [1].

5. Roles and responsibilities

Names, affiliations, and roles of protocol contributors

The affiliations of Rasmus Tolstrup Larsen (RTL), Christoffer Bruun Korfitsen (CBK), Carsten Bogh Juhl (CJ), Henning Boje Andersen (HBA), Jan Christensen (JC) and Henning Langberg (HL) is reported on the title page.

All authors did actively contribute to the design of this intervention study. The intervention content was developed by RTL and CBK. The outcome measures were chosen and evaluated by RTL, CBK, CJ, JC and HL. Besides being actively contributing to the design, HBA served as the primary technology expert and CJ served as the methodological expert as well as proving statistical counselling. The study was originally initiated by HL and HBA. RTL was the primary author of this protocol, but all authors contributed to its content.

The funder (Horizon 2020) have not contributed to any work regarding this study protocol.

Fitrockr (https://www.fitrockr.com/#!/welcome), will serve as the data management team responsible for handling the data export from the PAMs and exporting the data to the research and intervention team. Data processor agreement forms have been completed prior to registration and beginning of this RCT, in accordance with approval from the Danish Data Protection Agency.

Introduction

6. Background and rationale

Twenty-seven percent of older adults in Denmark (65-74) and 39-46% of very old adults (75+) do not meet the WHO recommendations for minimum PA [2] and the motivation for increasing PA levels is lowest for these two age groups [3] possibly due to the many barriers known to this age group [4–14]. The identification of reliable predictors of exercise adherence will allow healthcare providers to effectively intervene and change patterns of physical activity in sedentary elderly.

Evidence suggest that behavioral (walking, exercise) and cognitive (counselling and motivational interviews) interventions are effective for short-term physical activity increase in older people [14]. In order to maintain long-term participation in PA, individualized interventions modelled using behavioral theories may be required [14]. Social support may be especially important for increasing PA in older adults as social support, strain, and social networks influence health behaviors and outcomes [15]. Another reason for lack of motivation for exercise in older adults can be by low self-efficacy or outcome expectancy for exercise beliefs, which is often closely related to PA levels in older people [16].

The lack of PA cannot be attributed solely to personal motivation and the complexity of physical activity interventions has been recognized by stakeholders who increasingly are electing to employ multi-component approaches in increasing a population's PA [12, 17, 18]. Multi-component community wide interventions however fail to effectively increase PA in populations however making access to exercise facilities does show to be feasible to increase PA in some studies [12, 19].

To increase long-term participation in PA in older adults interventions should include delivered materials about health recommendations, behavior and cognitive strategies which are theory- and motivational based [20]. The content and positive framing of recommendations and feedback is important to consider when examining the promotion of PA in older adults [21] and a focus on action planning, identifying environmental or contextual barriers may be needed to have an impact and to motivate behavior change in sedentary older adults [15].

Walking programs with elderly are effective in increasing physical activity on a short term, but the programs should be individualized to maintain long term participation [14]. Walking interventions based on activity monitoring are becoming more frequent and hence, an increasing number of scientific results suggest that the monitors can facilitate motivational behavioral change and increase the average number of daily steps in older adults [22].

An intervention strategy including PAMs, facilitating goal setting [23] and using Motivational Interviewing (MI) have shown to promote maintenance of increased physical activity behavior at six months [24]. Incorporating techniques such as MI may increase motivation and self-efficacy [25]. MI addresses the behavioral and psychological aspects of why people maintain current health habits [26] and shows potential for exercise behavior change (23,26,27). When health professionals set out to assist clients with changing a health behavior such as PA, they usually begin by giving their clients advice using a direct communication approach. The expectation is that the client will make a favorable health related decision because the advice is sensible. Advice often has little or no impact on health behaviors because often times the information is too complex for the client, is of no concern to the client, or is too overwhelming in its amount or content and is, therefore, not heard [27]. In using MI, Rollnick and colleagues [27] suggest that health professionals not dispense advice or instructions on how a client should change a behavior because of the natural human behavior to resist being told what to do. This resistance creates ambivalence about the change [27]. Combining resistance with perceived barriers to PA only adds to the problem. The client envisions how one "should exercise", imagines the difficulty in doing it, and eventually quits thinking about it all together [27]. In MI, ambivalence to change is viewed as part of normal human behavior [27]. Health professionals who understand this are better able to help their clients move through a process of change that is consistent with their goals and values [27]. This is accomplished by employing empathy, one of the core principles in MI [27]. The goal of MI is to attain an initiation and commitment for change that is collaborative, evocative, honoring of client autonomy and sought by both the client and the practitioner [26, 27]. The 'objective is to have the client verbally express the reasons to change to a more physically active lifestyle and then in combination with hearing those reasons as they are said, the progress towards improved physically active behavior is strengthened [28]. Future research has been previously recommended to determine if there is a minimum amount and length of MI interventions needed that should be delivered to produce consistent long term results [26].

7. Objectives

The objective of this randomized controlled trial is to investigate if motivational interviewing provided as an add-on intervention to a physical activity intervention will increase the average daily step count in community-dwelling participants above the age of 70.

1. It is hypothesized that motivational interviewing, will enhance the average daily step count among participants.
2. It is hypothesized that motivational interviewing, will affect self-reported physical activity and quality of life.
3. It is hypothesized that self-efficacy and outcome expectancy for exercise, will mediate the effect and explain heterogeneity in the results.

8. Trial design

Study Type:	Interventional
Estimated Enrollment:	154 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
	12-week intervention with two groups in a parallel design
Masking:	Double (Investigator, Outcomes Assessor)
	Primary investigator will be blinded for allocation before making the final analyses. No outcome assessments will be made by an assessor. Only objectively measured steps per day and participant reported outcome measures will be used for this study.
Primary Purpose:	Prevention

The primary hypothesis till be investigated with a superiority analysis.

Methods: Participants, interventions, and outcomes

9. Study setting

Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained'.

This RCT will be conducted in Denmark. Participants eligible for inclusion will receive the content necessary for participation by mail. The participants will only have contact with the research team via phone or e-mail correspondence.

10. Eligibility criteria

Participants will be considered eligible for inclusion if they; 1) are retired and community-dwelling, 2) at least 70 years of age by the day of enrolling the trial, 3) own a smartphone or tablet able to install the *Garmin Connect application,* 4) have an email address and are able to correspond and complete the study survey on a computer and 5) have hearing abilities sufficient to receive a telephone interview.

Participants will not be considered eligible for inclusion, and hence excluded, if; 1) they have cognitive impairment from moderate to severe dementia or Alzheimer's disease, 2) they are undergoing active chemotherapy or palliative care from cancer, 3) have a major mobility impairment (e.g. from paralysis, amputations, severe arthrosis or arthritis, Sclerosis or Parkinson's disease).

11. Interventions

Experimental: Motivational interviewing Experimental content + base intervention	Behavioral: Motivational interviews During the 12-week intervention, the participants will receive seven telephone calls from a physical therapist (PT). Using an intervention schedule inspired by the work of King et al. to facilitate initiation and maintenance of behavior change, calls are delivered in week 1, 2, 3,5,7,9, and 12 [29]. The telephone call will consist of a motivational interview (MI) focused on enhancing the daily level of physical activity in the participants. MI is a form of counselling aiming at prompting increases in self-efficacy, which may leave people more open to and invested in changing their behaviors and shows potential for significant effects for exercise behavior change. In this person-centered intervention model, participants are guided through self-reflective counseling. They receive feedback on these health behaviors in relation to national recommendations; consistent with a MI approach [27], this feedback also highlights the discrepancy between their health goals and their current health behaviors; they set collaborative goals for physical activity change with their PT, with the participant encouraged to begin with the target area in which she/he is most motivated to change; all of this is incorporated into a behaviorally-specific plan that specifies exactly what is to be done and when; barriers and supports are identified; confidence is assessed and problem-solving is discussed as necessary. These steps are repeated during intervention contacts, with goals being adjusted as necessary. During the maintenance face (week 5-12) increasing emphasis is placed on identification of multi-level supports for health behavior change. Participants are encouraged to use a variety of supports including family and friends, as well as neighborhood and community supports. In collaboration with local community partners, a community reference

	guide is compiled that enabled the counselor to refer participants to specific community resources (e.g., walking groups). In addition to the telephone based motivational interviews, the experimental group will also receive the "base intervention" which is described in detail under the "control intervention paragraph". **Behavioral: Base intervention** The "base intervention" consists of a physical activity monitor (PAM) for everyday use in the intervention period and a pamphlet with information about Danish recommendations on physical activity in aging populations. The PAM will be the Garmin Vivofit 3 monitor linked to a pre-specified Garmin Connect account. The participants will be asked to install the Garmin Connect application on their smartphone and use the given ID/password in the app. The participants will be asked to wear the monitor 24-hours a day for the 12-week intervention period. The participants can use the PAM as they like but they will be asked to try to use the PAM and the application to enhance their daily level of physical activity.
Active Comparator: Control intervention Base intervention	Behavioral: Base intervention The "base intervention" consists of a physical activity monitor (PAM) for everyday use in the intervention period and a pamphlet with information about Danish recommendations on physical activity in aging populations. The PAM will be the Garmin Vivofit 3 monitor linked to a pre-specified Garmin Connect account. The participants will be asked to install the Garmin Connect application on their smartphone and use the given ID/password in the app. The participants will be asked to wear the monitor 24-hours a day for the 12-week intervention period. The participants can use the PAM as they like but they will be asked to try to

	use the PAM and the application to enhance their daily level of physical activity.

11.b, Fidelity

The intervention (and the actual content of the motivational interviews) will be tailored to the individual participant, but the number of calls will not be adjusted.

The project telephone counselor has a masters degree in physiotherapy and additional training in the MI approach to telephone health behavior counseling. Training involved a four-day course, reading study materials, discussions with previous study investigators, viewing of MI recording, and roll plays. Prior to this study the counselor has also conducted more than 200 interviews with older adults and staff in the community to familiarize with the community culture and local resources.

During the study, with participants' verbal consent, telephone MI (and control) sessions is audiotaped on a regular basis to ensure fidelity of intervention delivery and to provide counselor feedback. Based on a review of these recordings the fidelity monitoring is conducted by two experienced independent MI coders who are blinded to treatment assignment using the Motivational Interviewing Treatment Integrity (MITI) Scale, a tool developed to measure MI treatment adherence [30].

12. Outcomes

Primary Outcome Measure:

1. Individual intervention period average steps per day, recorded every day by the PAM. The average number of steps per day throughout the 12 weeks will be the primary outcome for the individual participant.

   Time frame: A daily average of the 12 weeks of intervention

The Garmin Vivofit 3 will serve as the PAM and thus, measure the primary outcome. Garmin Vivofit 3 has to our knowledge only been validated in older adults by our own research group (manuscript being prepared for submission).

Four physical activity monitors were included in the validation study; Misfit Shine, Nokia GO, Jawbone UP and Garmin Vivofit 3. The aim of the study was to compare different PAMs on different body locations. All hip-worn PAMs fulfilled the a priori hypothesized moderate criterion validity, when evaluating all participants. The hip-worn Garmin Vivofit 3 fulfilled the a priori

hypothesized criterion validity evaluating all participants, participants with rollator and participants without rollators and it was evaluated as the best performing device in older adults in general.

The validation study is currently being finalized for submission.

Secondary Outcome Measures:

1. International Physical Activity Questionnaire [Time Frame: Baseline + end point at 12 weeks + follow up at 6 months and 12 months]
2. Nordic Physical Activity Questionnaire [Time Frame: Baseline + end point at 12 weeks + follow up at 6 months and 12 months]
3. EQ5D Quality of life questionnaire [Time Frame: Baseline + end point at 12 weeks + follow up at 6 months and 12 months]
4. UCLA Loneliness Scale [Time Frame: Baseline + end point at 12 weeks + follow up at 6 months and 12 months]
5. Self-Efficacy for Exercise [Time Frame: Baseline + end point at 12 weeks + follow up at 6 months and 12 months]
6. Outcome expectancy for Exercise-2 [Time Frame: Baseline + end point at 12 weeks + follow up at 6 months and 12 months]
7. Copenhagen Social Relations Questionnaire [Time Frame: Baseline + end point at 12 weeks + follow up at 6 months and 12 months]

Secondary outcome measures include participant reported outcomes administered by online questionnaires. The baseline measurement will be undertaken before the intervention group receives the first motivational interview and the end point measurement will be undertaken in the days after the last motivational interview.

International Physical Activity Questionnaire short form (IPAQ-SF)

The seven-item IPAQ-SF measure assesses the types of intensity of physical activity and sitting time that people has done the past seven days as part of their daily lives are considered to estimate total physical activity in MET-min/week and time spent sitting [31]. The score is categorized to three levels of (categories) of PA; low, moderate and high [32]. In a review of 16 international studies of

the measurement properties IPAQ-SF showed acceptable reliability (Spearman's rho: 0,32-0,88) [31] and low to moderate concurrent validity against accelerometer had a pooled correlation coefficient of 0.30 (Spearman's rho range: 0,09-0,38) [33]. The Danish version have been used in a Danish population of older adults [34].

Nordic Physical Activity Questionnaire short (NPAQ-short)

The two-item NPAQ-short [35] is a short revised version of the original NPAQ, a survey tool based on telephone interviews designed for assessment of Moderate and Vigorous Physical Activity (MVPA). It is developed to monitor compliance with the WHO recommendations on PA [36] and has showed moderate correlation with objectively measured MVPA (Spearman's rho: 0.33) in a Danish population with an average age of 43 (range: 17-85) [35].

The 5-level EuroQol-5 Domain (EQ-5D-5L) Quality of life questionnaire

The EQ-5D-5L is a generic health-related quality of life (HRQoL) measure developed as a non-disease-specific instrument for describing and valuing health states [37] and comprises five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each of which has three levels (no problems, moderate problems and extreme problems) and a visual analogue scale (EQ VAS). The score for the five dimensions can be combined into a five-digit number that describes the patient's health state. The EQ VAS records the patient's self-rated health on a vertical visual analogue scale, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. The EQ-5D-5L has shown general feasibility for measuring HRQoL in a geriatric population sample [38] as well as acceptable reliability and validity [39]. The EQ-5D-5L is adapted to Danish [40] and in the national sample of Danish 70-79 year-olds, the mean EQ-5D-5L index score was 0.83 (SD: 0,19) [41].

UCLA Loneliness Scale

The 20-item UCLA loneliness scale (third version) is a self-report measure of loneliness and social isolation [42]. The scale consists of 11 positive and nine negative items and the total score is calculated by finding the sum of 20 items (0-60), with a higher score indicating more loneliness. Items one, five, six, nine, 10, 15, 19 and 20 are all reverse scored. The scale is adapted to Danish and this version has shown high internal consistency (Cronbach's Alpha: 0.92) and has shown evidence of

convergent validity as a moderate to high correlation with other measures of emotional loneliness (r: 0.69) and social loneliness (r: 0.73). In addition, the scale shows evidence of discriminant validity by its relations to self-esteem (r: -0.58), depression (r: 0,59), extraversion (r: 0.57) and neuroticism (r: 0,58). in a population of Danish 8th grade students that are comparable to the original scale [43]. The scale has showed acceptable model fit as a unidimensional structure [43].

Self-Efficacy for Exercise (SEE-DK)

The nine-item SEE-DK addresses confidence to engage in regular exercise [44], when challenged by known barriers to exercise [4]. The scale was developed initially for sedentary adults in the community who participated in an outpatient exercise program [45] and was revised to older adults [44]. It is designed to be administered using face-to-face interview. Response categories range from 0 (no confidence) to 10 (very confident) [44]. Item scores are used to calculate a total score (0-90), with higher scores indicating higher confidence, or self-efficacy, related to exercise. The SEE-DK is adapted to Danish older adults with acceptable face and content validity, construct validity by acceptable model fit as a unidimensional scale, and test-retest reliability [46].

Outcome Expectancy for Exercise-2 (OEE2-DK)

The 13-item OEE-2 scale was developed from the original 9-item Outcome Expectations for Exercise scale (OEE) that specifically focused on measuring the positive outcome expectations for exercise (POEE). Based 1n qualitative findings [4, 47], the original OEE was revised to include four items that focused on negative outcome expectations for exercise (NOEE) [48]. It was initially developed for older adults [49, 50]. To complete the OEE2-DK scale the participants are asked, using a Likert scale, to *strongly agree*, *agree*, *neither agree nor disagree*, *disagree*, or *strongly disagree* with the stated outcomes to each statement of exercising. The POEE and NOEE subscales are scored by calculating the average score on each scale (1-5) and the items three, six, nine and 12 (NOEE subscale) are reverse-scored [48]. The OEE2-DK is adapted to Danish older adults with acceptable face and content validity, construct validity by acceptable model fit as a two-dimensional scale, and test-retest reliability [46].

Copenhagen Social Relations Questionnaire (CSRQ)

The 42-items questionnaire was developed originally in Danish in 1999 [51] and measures the structural aspect of social relations, with focus on contact frequency and diversity, and functional aspects with focus on perceived social support. CSRQ has been used in several Danish population-based surveys including in the Copenhagen Aging and Midlife Biobank (CAMB) [52]. In a sample of 38-69 old adults the CSRQ showed acceptable face and content validity and good test-retest reliability by 41% of the items had substantial to almost perfect agreement (kappa: 0.65-0.97) and the rest showed moderate agreement (kappa: 0.41-0.60) [53].

The secondary outcomes will also serve as follow up measurements six and 12 months after ending the intervention. They will also be conducted with online surveys.

13. Participant timeline

Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure).

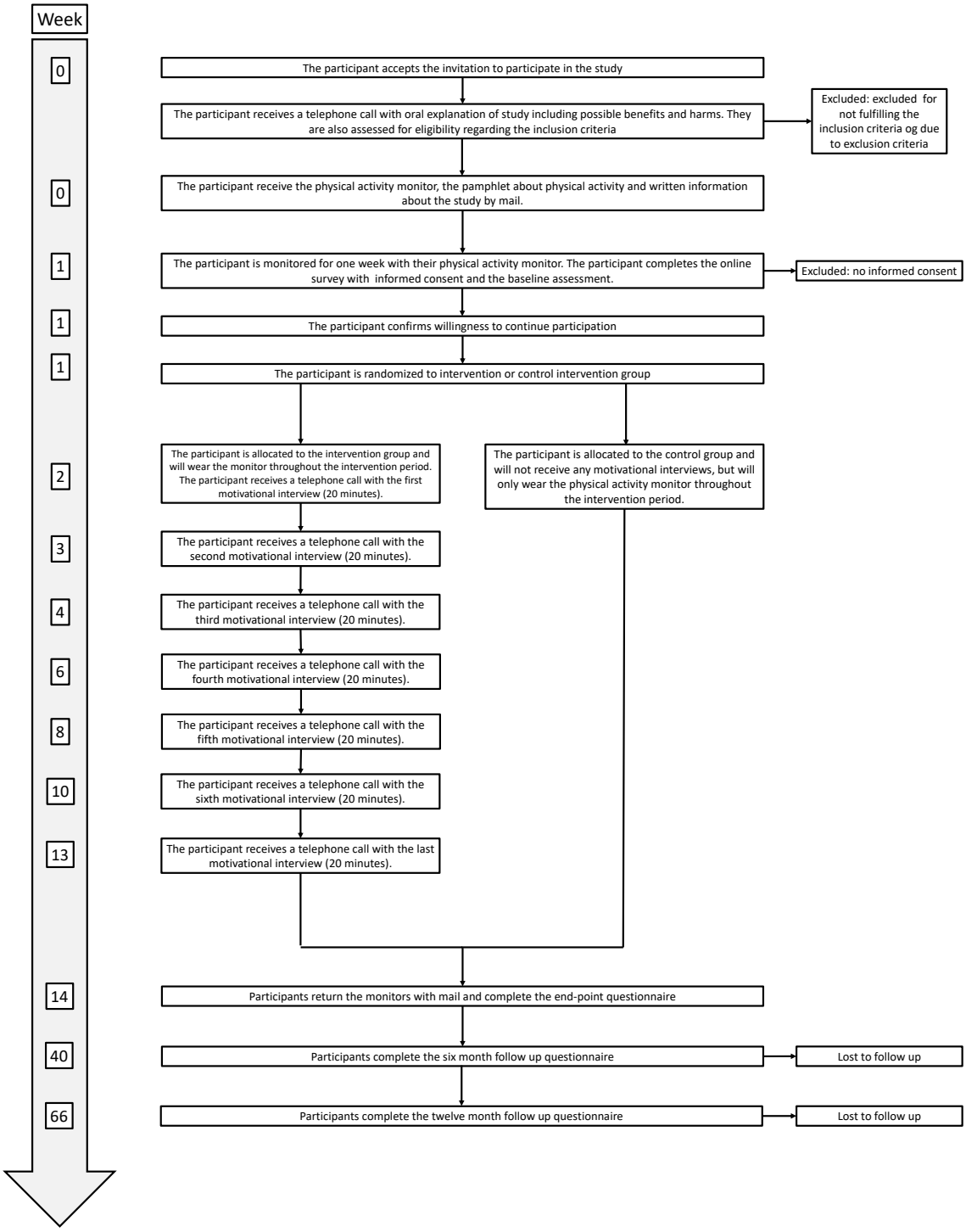

Figure 1. SPIRIT participant timeline.

14. Sample size

Estimated number of participants needed to achieve study objectives is 128 participants. The number will be enough to show a 0.5 standard deviation difference between groups, equal to a moderate effect size. The number of participants will yield a power on 80% with a significance level on 0.05. To account for attrition this study will include 20% more participants than the above mentioned, and hence terminate the inclusion of participants when 154 participants in total and 77 in each group have been enrolled.

15. Recruitment

We will recruit participants through online advertisements on social media and in non-profit organizations working with older adults. We will also try to recruit participants at activity centers and other communities of older adults.

Methods: Assignment of interventions

16. Allocation

16.a. Sequence generation

Participants will be randomly assigned to either the intervention or the control group, with a 1:1 allocation. Eligible participants who have completed the baseline step count, will be randomized in blocks of four participants or more, stratified on sex (M/F) and average baseline step count for the extracted days prior to the allocation. Randomization of participants will happen every week, except weeks with less than four new participants.

16.b Allocation concealment mechanism

Participants will be randomized using STATA, which is a statistical software package. Allocation concealment will be ensured, as the allocation will not be available until the patient has been recruited into the trial, which takes place after the baseline step count measurements have been completed.

16.c Implementation

One investigator will be in charge of the randomization. That investigator will receive a list of participant IDs every week and randomize the participants according to the above. That one investigator will not have anything do to with recruitment nor statistical analyses.

17. Blinding (masking)

17. a

Outcome assessors and data-analysists will be blinded for participant allocation.

17b.

Due to the nature of the intervention neither participants nor staff conducting the motivational interview in the intervention group can be blinded to allocation but are strongly inculcated not to disclose the allocation status of the participants with the principal investigator who will conduct the analyses. The group names of the intervention and the control group will be anonymized before the data will be analyzed to ensure blinding of the principal investigator.

Methods: Data collection, management, and analysis

18. Data collection methods

18a. Plans for assessment and collection of outcomes

Primary outcome

The primary outcome (average steps per day in the 12-week intervention period) will be extracted from the data management software Fitrockr. Participants will be asked to synchronize their PAMs and their Garmin Connect application daily, ensuring daily storage of the step counts. The PAMs have a 30-day storage for daily totals so data will not be lost, even if the participants forget to synchronize their PAMs for longer periods of time. Fitrockr will extract the data from Garmin Connect and make daily step counts available for export through their service. When the participant has completed the 12-week intervention, the daily totals will be extracted as 84 variables (12*7). After the data extraction, the average daily step count will be calculated.

Secondary outcomes

The secondary outcomes are all participant reported and administered through SurveyXact. All participants will receive an email with an electronic SurveyXact invitation on the day of randomization. On the last day of intervention (day 84), the participants will receive a similar SurveyXact invitation with the end-point questionnaire. The six and 12-month follow up assessments will be administered in similar ways to the end-point assessment.

Demographic and other baseline items

Non-outcome variables will be included in the baseline questionnaire.

18b. Plans to promote participant retention and complete follow-up.

If possible, reasons for drop out will be collected from each discontinued participant. The available data on the primary outcome will be used to calculate the intervention period average steps per day. If the participant fails to synchronize the PAM and a possible drop out is suspected, a person from the research team will call the participant to either remind them to synchronize the PAM or try to motivate the participant to continue the intervention.

Lost to follow up with the end-point or follow up questionnaires will be reminded via email 7, 14 and 21 days after the deadline.

19. Data management

All outcomes will be handled and stored electronically.
Steps per day will be stored every time the participant synchronizes the PAM. The data handling responsible Fitrockr will extract data from the Garmin applications and store it according to the agreements. Every time a participant completes the intervention period, their data will be exported from the Fitrockr database and stored securely at the University of Copenhagen server.

During the study, with participants' verbal consent, telephone MI (and control) sessions is audiotaped on a regular basis to ensure fidelity of intervention delivery and to provide counselor feedback.

The participant reported outcomes for the secondary outcomes will be administered using SurveyXact, securing data every time a survey has been completed. Every time a participant completes the intervention period, their data will be exported from the Fitrockr database and stored securely at the University of Copenhagen server.

No personal data will be exported from Fitrockr or SurveyXact without pseudonymization. Complete anonymization of all data will be done after the last follow up period. Data protection agency approval Reference number: 514-0268/18-3000

20. Statistical methods

The primary outcome will be analyzed as a mixed effects model, where intervention group are analyzed fixed and participants are random effects. The analysis will investigate the group difference in average daily step count, adjusted for baseline step count and gender. Same analysis will be performed on secondary outcomes.

Drop outs with data on the primary outcome for at least one week will have their average daily step count based on the available days. All analysis will be performed following the Intention to Treat (ITT) principle imputing missing data using a multiple imputation based on age, gender, baseline step counts and average daily step count (for missing data on the secondary outcomes). In

calculating the average daily step count, days with less than 100 steps will be handled as “days of non-wear” and excluded assessing the mean step count.

Methods: Monitoring

21. Data monitoring

Not applicable/relevant

22. Harms

In our study an adverse event will be defined as any untoward medical occurrence in a participant without regard to the possibility of a causal relationship with the intervention. Adverse events will be collected after the subject has provided consent and enrolled in the study. If a participant experiences an adverse event after the electronically administered informed consent has been signed (entry) but the subject has not started to receive study intervention, the event will be reported as not related to the intervention. All adverse events occurring after entry into the study will be recorded. The participants will be asked at the end-point questionnaire if they experienced any adverse events in terms of using the PAMs or trying to enhance their daily amount of physical activity.

23. Auditing

No auditing has been protocolled.

Ethics and dissemination

24. Research ethics approval

According to a written correspondence with the Danish Ethics Committee in the Capital Region of Denmark, this trial was not subject to the current laws on research ethics in Denmark due to the non-invasive behavioral change intervention. The study can be conducted without further approval from the Danish Ethics Committee in the Capital Region of Denmark (Journal-nr.:18004960).

25. Protocol amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the participants or may affect safety, including changes of study objectives, study design, sample population, sample size, study procedures, or significant administrative aspects will require a formal amendment to the protocol that will be revised and re-uploaded to Clinicaltrials.gov.

26. Consent or assent

Informed consent will be collected electronically via SurveyXact. Prior to agreeing and signing the consent survey, the participant will receive written information about the study on email and if the participant has any questions the participant might answer or call the study responsible researcher (RTL).

27. Confidentiality

All study-related information and collected data on participants will be stored securely at a server at University of Copenhagen. The only possible way to extract any personal information is by having access to the secure server.

Any data that will leave the secure server will be anonymized.

28. Declaration of interests

The content presented within this protocol and the study was produced as part of the project REACH: this project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 690425.

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Declare to have no financial ties or non-financial competing interests.

29. Access to data

To ensure validity of the results, all investigators will have access to the anonymized and cleaned data set.

30. Ancillary and post-trial care

No ancillary and post-trial care have been protocolled.

31. Dissemination policy

Upon request, every participant can get access to their own results and the summarized study results. We plan to publish all results in scientific peer-reviewed journals within the area of physical activity, public health, behavioral research or health technology. Furthermore, we plan to communicate important knowledge and experiences from the study to healthcare professionals, municipalities and other relevant parties.

Authorship of all scientific papers will be submitted to the Vancouver recommendations for defining the role of authors and contributors from the International Committee of Medical Journal Editors

Upon reasonable request (to reproduce results or analyses), researchers or other interested external persons will be able to access the anonymized and cleaned participant level dataset including the analysis code for the statistical software.

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Appendix

32. Informed consent materials

Participant information on participation in a research project

***Project title**: The MIPAM trial: A 12-week intervention with motivational interviewing and physical activity monitoring, to enhance the daily amount of physical activity in community dwelling older adults – a randomized controlled trial*

This consent form is part of the informed consent process. It is designed to give you an idea of what this research study is about and what will happen to you if you choose to be in the study. The research project is conducted by the primary investigator and PhD fellow Rasmus Tolstrup Larsen, from University of Copenhagen. You must understand what the content and aim of the research project is, before you decide whether you would like to participate in the project. It is important that you do a thorough read of this document.

It is possible to receive a telephone call with an oral elaboration of this document. It is also possible to include another person (relative or friend) in the telephone call. If you decide to participate, you have to declare it in an electronic consent form (the link is available in the email you received with this document). Remember that you have the right to consider your decision before you agree to participate. It is completely voluntary to participate in the study and you can by any time chose to withdraw from the study.

Aim of the study

The aim of this randomized controlled trial is to find new and effective ways to enhance the daily amount of physical activity in older adults. The study will investigate if motivational interviewing as an add-on intervention will enhance the expected effect from physical activity monitors worn daily. All participants will receive a Garmin Vivofit 3 physical activity monitor to wear every day in 13 weeks. Half of the participants will be randomized to receive seven telephone calls with motivational interviewing.

We aim to include 154 participants for this project.

Trial plan

You will receive the physical activity monitor by mail. In the second week you will receive the baseline questionnaire via e-mail. If you are allocated to receive the motivational interviewing, you will receive seven telephone calls (week 2,3,4,6,8,10 and 13).

After wearing the physical activity monitor for 13 weeks, you will need to answer the end-point questionnaire and return the physical activity monitor via mail.

You will also receive a follow up questionnaire after six and 12 months.

As this study only contains a physical activity monitor and motivational interviewing, we do not expect any side effects from the intervention. However, if you suddenly enhance your daily level of physical activity a lot, you may have days where you feel more tired and if you have degenerative changes (e.g. arthritis) you may also have some days where you feel a bit more pain than you are used to.

After the project, we may ask you to participate in a qualitative interview with one of the investigators. This is also completely voluntary.

To be eligible for inclusion in this study:

- *You must be retired and above 70 years of age*
- *You must be able to walk independently without other people assisting you (rollators and canes are allowed)*
- *You are community dwelling*
- *You have a Windows- or Google smartphone, an iPhone or an iPad to install the Garmin Connect application on.*
  Apple: iOS 10.0 or newer. Windows: Windows 10 Mobile version 10586.0 or newer, Windows 10 version 10586.0 or newer.
- *You have access to an email account.*

To be eligible for inclusion in this study you cannot:

- *Have dementia or Alzheimer's disease*
- *Receive active cancer treatment (e.g. chemotherapy)*
- *Be disabled due to severe diseases or conditions such as Parkinson's disease, post-stroke paralysis, amputations and others.*

Financial compensation

Your participation in this trial is voluntary and you will not be compensated financially.

Personal data management

All information about you will be handled according to current Danish data rules and regulations.
Personal information such as name, address, email and telephone number will only be stored in closed servers at University of Copenhagen. The Data Protection board approval number for this trial is 514-0268/18-3000.
Your data will be anonymized after your participation to use for data analysis in this project and possibly also other research projects investigating other related questions. At any time, you will be able to get your own results from this study.
This research project will be published in a scientific peer reviewed journal. Besides the publication, we will disseminate our findings to health professionals, municipalities, at health conferences and to other interested bodies.

By reading this document, we hope that you now are adequately informed about the study to make an informed decision on whether you would like to participate. We have also included the standard document "the rights of participants in health research projects".

If you would like to know more about the study before deciding, please contact,

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Best regards, Rasmus Tolstrup Larsen

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