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Evaluation of a co-developed digital self-management program to reduce sedentary time and increase adherence to reduced sedentary time in older adults in transition to retirement

Submission date
17/10/2023

Recruitment status
No longer recruiting

Registration date
19/10/2023

Overall study status
Completed

Last Edited
30/01/2024

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
For most people, being aged between 60-75 years of old means entering into a transition stage of life, from working life to retirement. Older adults spend a high amount of time in sedentary behavior. Sedentary behavior can be defined as any waking behavior while in a sitting, lying or reclining position that has a low energy expenditure. Extended time spent in sedentary behavior per day is bad for our health and can lead to lifestyle-related non-communicative diseases and premature death. Transition to retirement could be a favorable time in life to introduce interventions to reduce sedentary time. The aim of the study is to evaluate the effect of a co-developed digital self-management program to reduce sedentary time and increase adherence to reduced sedentary time in older adults in transition to retirement.

Who can participate?
Older healthy volunteers aged 60-75 years old who are going to retire within three years or have been retired for at most five years.

What does the study involve?
Participants in the study will be randomized to intervention or control groups. The intervention group will use a digital self-management program. The control group will start to use the program after three months. Sedentary time will be measured using a thigh-worn accelerometer by Axivity for one week at the start of the study and at three, six and twelve-month follow-ups. Health, self-efficacy, self-assessed sedentary time and physical activity will be measured with relevant questionnaires and study-specific questions.

What are the possible benefits and risks of participating?
All participants get access to the developed digital self-management program to reduce sedentary time which could be considered as a benefit of participating in the study. However,

the effect of the developed digital self-management program is yet unknown and will be evaluated in this study.

There is a risk that participants in the study could experience redness or irritation on the skin due to wearing the accelerometer. To counteract this risk, plasters for sensitive skin are being used.

Where is the study run from?
Mälardalen University (Sweden)

When is the study starting and how long is it expected to run for?
March 2019 to December 2024

Who is funding the study?
Swedish Research Council (Sweden)

Who is the main contact?
Lisa Hultman (Phd Physiotherapy), lisa.hultman@mdu.se (Sweden)

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Grant number: 2018-02928

Study information

Scientific Title
Evaluation of the effect of a co-developed digital self-management program to reduce sedentary time and increase adherence to reduced sedentary time in older adults in transition to retirement.

Study objectives
What is the effect of a digital co-developed self-management program to reduce sedentary time in older adults?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/08/2019, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46 010-475 08 00; registrator@etikprovning.se), ref: 2019-03836

Study design
Interventional randomized controlled trail

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Health promotion in older adults in transition to retirement.

Interventions
A digital internet-based intervention programme was developed using a participatory design where participants were researchers within physiotherapy, behaviour change and e-intervention development, a web developer and older adults in transition to retirement.

The intervention group uses the co-developed self-management digital program to reduce sedentary time. There is not a fixed number of sessions involved. Instead, the participants engage in the intervention program as they require. Participants are recommended to view instructional videos of how to use the program and are asked to look at the feature for finding joyful activities to participate in to reduce sedentary time and a feature for goal setting. The program sends a text message to the participant's phone number to notify time for goal follow-up. No face-to-face sessions are provided. The program has a function for contacting one of the researchers by email if questions arise.

The control group receives no treatment in the first three months and starts to use the program after the three-month follow-up. A computer-generated, permuted-block randomization scheme with a 1:1 ratio between the intervention and control groups is used for randomization.

Intervention Type
Behavioural

Primary outcome(s)
Sedentary time measured using a thigh-worn accelerometer by Axivity at baseline and 3, 6 and 12 months

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline and 3, 6 and 12 months:
1. Sedentary time measured using the Longitudinal Aging Study Amsterdam sedentary behavior questionnaire (LASA)
2. Self-efficacy and motivation to reduce sedentary time measured using study-specific questions
3. Self-assessed ability for physical activities measured using a study-specific questionnaire, since self-efficacy beliefs are situation-specific, and the question is developed in accordance with Albert Bandura’s instructions
4. Self-efficacy for physical exercise using the Self-Efficacy for Exercise (SEE) scale
5. Perceived change in sedentary time using a single rating, ranging from 1 (much less sitting time) to 7 (much less sitting time) [note
there is no assessment at baseline]
6. Perceived health-related quality of life using the EQ-5D-5L questionnaire
7. Subjective well-being using the General Population (GP)-Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE)
8. Anxiety and depression using the Hospital Anxiety and Depression Scale (HADS)
9. Physical activity using the International Physical Activity Questionnaire (IPAQ)
10. Quality of life using the Brunnsviken Brief Quality of Life (BBQ) scale

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Aged 60-75 years of age at inclusion
2. Speak and understand Swedish and be able to understand the study instructions
3. If working, plan to retire within 3 years
4. If retired, have been retired for at most 5 years
5. Spend 6 hours or more a day in sedentary behavior
7. Severe disease

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
75 years

Sex
All

Total final enrolment
43

Key exclusion criteria
1. Sever disease
2. Contraindicated to physical activity due to health conditions
3. Severe visual impairment or impaired communicative ability
4. Inability to walk 500 meters without support
5. Use or have used any other self-management program for behavioral change regarding their physical activity or sedentary behavior during the past year

Date of first enrolment
14/08/2023

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Mälardalen University
Mälardalen Universitet Box 883
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Sponsor information

Organisation
Mälardalen University

ROR
https://ror.org/033vfbz75

Funder(s)

Funder type
Government

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes