

The addition of mobile elements to online physical activity programs for adults aged 50 years and older

Submission date 14/04/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/04/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/11/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Although being sufficiently physically active is important for healthy ageing, a large proportion of adults 50 years and older are not meeting the physical activity guidelines of the World Health Organization (WHO). Online computer-based programs can help this population increase their physical activity levels. In recent years, also mobile-based programs are more often used for this purpose. During this study, combined computer- and mobile-based programs were tested. Three mobile elements were developed: an activity tracker, a smartphone program with personal physical activity (PA) tips, and a digital PA coach. These mobile elements were separately integrated with the existing computer-based programs Active Plus and I Move. The aim of this study is to investigate whether the renewed programs could improve physical activity behavior and whether use and ratings differed between the programs.

Who can participate?

Adults aged 50 years and older

What does the study involve?

Participants are equally divided among four research groups. The first group follows an online physical activity program including an activity tracker. The second group follows an online program including a smartphone program with physical activity tips. The third group follows an online program including a mobile-based physical activity coach. The fourth group is a control group which completes only the measurements and followed no online program. Physical activity levels are measured at three timepoints via questionnaires, namely at the start, at 3 months and at 6 months. Physical activity levels are also measured via motion meters (accelerometers) at the start and at 6 months. The results of the research groups following an online program are compared to the results of the control group. Also the usability and satisfaction of the renewed online programs were rated by participants through questionnaires.

What are the possible benefits and risks of participating?

Following the online programs could improve the PA behavior of participants, which is important for improving and/or maintaining their health. There are no risks involved for participants.

Where is the study run from?
Open Universiteit (Netherlands)

When is the study starting and how long is it expected to run for?
June 2019 to April 2022

Who is funding the study?
ZonMW (Netherlands)

Who is the main contact?
Lilian Lechner, Lilian.Lechner@ou.nl

Study website
<https://www.ou.nl/actiefleven>

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

A randomized controlled trial of online physical activity interventions with added mobile elements within adults aged 50 years and over

Acronym

A4L

Study objectives

H1: Higher objectively and subjectively measured physical activity levels are shown at T1 and T2 in the intervention groups compared to the waitlist control group.

H2: Effects regarding physical activity levels at T1 and T2 differ between the intervention groups.

H3: Intervention programs differ regarding appreciation rates on usability and content.

H4: Intervention programs with better appreciation rates lead to better results on physical activity levels.

H5: Participation and drop-out rates differ between research groups and levels of engagement with the intervention differ within the experimental conditions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/07/2020, central ethical review committee of the Open Universiteit of the Netherlands (Valkenburgerweg 177, 6419 AT Heerlen, the Netherlands; +31 (0)45 5762410; ceto@ou.nl), ref: U202004903

Study design

Four-arm randomized controlled trial with repeated measures

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Stimulation of physical activity within adults aged 50 years and over

Interventions

Block randomization is applied, where each participant is randomly assigned to one of the research groups. The randomization procedure takes place automatically via a built-in algorithm within the software of the used online intervention programs after inclusion procedures (inclusion criteria questionnaire and signing informed consent).

Participants are randomly allocated to one of three experimental groups or to a waiting list control group. All participants are instructed to wear an ActiGraph accelerometer for 7 days at baseline (T0) and 6 months post-baseline (T2). Online questionnaires are filled in at T0, three months post-baseline (T1) and T2. Participants in the experimental groups follow the online physical activity stimulating intervention Active Plus or I Move with a duration of 12 weeks including one of the following three mobile elements:

1. Activity tracker
2. Ecological momentary intervention (EMI)
3. Chatbot

Participants in the control group participate in the first 6 months only in the accelerometer and questionnaire measurements. No access is provided to the intervention during this period. Control group participants receive a combined tailored physical activity advice of the Active Plus intervention directly after completion of the T2 questionnaire.

Intervention Type

Mixed

Primary outcome measure

Moderate to vigorous physical activity (MVPA) measured via the self-reported SQUASH questionnaire at T0, T1 and T2 and via ActiGraph accelerometers at T0 and T2

Secondary outcome measures

1. Commitment measured using a scale based on Webb et al. (2005) at T0, T1 and T2
2. Self-efficacy measured based on the self-efficacy for exercise scale at T0, T1 and T2
3. Intention measured based on Sheeran et al. (1999) at T0, T1 and T2
4. Appreciation rates of the mobile elements measured using a self-composed usability and experience questionnaire at T1
5. Appreciation rates of the intervention program including mobile element measured using a self-composed usability and experience questionnaire at T2
6. Participation rates and drop-out rates are measured via questionnaire participation rates (at T0, T1, and T2), accelerometer participation rates (at T0 and T2), Active Plus (at T0, 4 weeks post-

baseline, and at T1) and I Move (at T0, 3 weeks post baseline, 6 weeks post-baseline and at T1) participation rates and process data (continuously)

Overall study start date

01/06/2019

Completion date

30/04/2022

Eligibility

Key inclusion criteria

1. 50 years or older
2. Able to use a computer, laptop or tablet
3. Own a smartphone from 2012 or later

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

800

Total final enrolment

954

Key exclusion criteria

1. Younger than 50 years of age
2. Not able to use a computer, laptop or tablet
3. Not owning a smartphone from 2012 or later

Date of first enrolment

01/04/2021

Date of final enrolment

30/09/2021

Locations

Countries of recruitment

Netherlands

Study participating centre

Recruitment takes place via social media advertisements

Netherlands

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Sponsor information

Organisation

Netherlands Organisation for Health Research and Development

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.zonmw.nl/en/>

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

Research organisation

Funder Name

ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Results and Publications

Publication and dissemination plan

The results of this randomized controlled trial will be described in two papers:

- 1. Effects: effects on physical activity levels measured objectively via accelerometers and subjectively via the SQUASH questionnaire.
- 2. Process evaluation: results regarding usability, satisfaction, intervention use, drop-out and participation rates.

Publication is planned in high-impact, peer-reviewed and open-access journals.

Intention to publish date

01/08/2024

Individual participant data (IPD) sharing plan

The anonymized datasets analysed during the current study will be stored in the Dutch repository Data Archiving and Networked Services (DANS) after the completion of the Active4Life (A4L) project. Access will be possible with the prior consent of the researchers. Preconditions (e.g. by what criteria the data will be shared with whom, for what types of analyses, and by what mechanism) will be determined in consultation with the user that requests permission to access the datasets.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/06/2024	06/08/2024	Yes	No
Results article		16/09/2024	15/11/2024	Yes	No