The PreventIT Feasibility RCT comparing two lifestyle-integrated exercise interventions delivered by use of ICT or an instructor with a control group in young older adults.

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To evaluate the feasibility and usability of the adapted Lifestyle-integrated Functional Exercise Programme (aLiFE) and the enhanced LiFE (eLiFE) intervention, versus a control group, in a population of young old adults (61-70 years) at three sites...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45652

Source
ToetsingOnline

Brief title
Protocol The PreventIT Feasibility RCT

Condition

- Other condition

Synonym
gerontology, old age

Health condition

Geriatrische aandoening, functieverlies

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Elderly, Exercise, Physical activity, Risk prevention

Outcome measures

Primary outcome

We will use two primary outcome measures: 1. Late-Life Function and Disability Instrument (LLFDI), to measure function and disability in the young older adults. 2. Complexity Metric, to assess behavioural complexity in the domains of physical activity, sleep, and social participation.

Secondary outcome

Various secundary parameters will be collected during the RCT.

Study description

Background summary

There is an urgent need for innovative solutions to prevent functional decline and inactivity at older age. The PreventIT project focuses on a new behavioural change activity approach for young older adults (61-70 years of age) with an overall aim to shift focus from treatment of conditions and diseases to early prevention and to empower people to take care of their own health. For enhancement of these aims, an unobtrusive mobile health system is developed and tested.

Study objective

To evaluate the feasibility and usability of the adapted Lifestyle-integrated Functional Exercise Programme (aLiFE) and the enhanced LiFE (eLiFE)

intervention, versus a control group, in a population of young old adults (61-70 years) at three sites: Stuttgart, Amsterdam, and Trondheim.

Study design

12-months randomized controlled trial.

Intervention

The aLiFE intervention is a lifestyle-integrated functional exercise program adapted to young older adults. The eLiFE intervention is a lifestyle-integrated functional exercise programme to young older adults delivered as an ICT-based intervention (smartphone and smartwatch).

Study burden and risks

The risk during the aLiFE and eLiFE training is estimated to be small, particularly given the young old population. Participants of our RCT may benefit from the intervention in terms of improving their functional performance and increasing their physical activity, although this is not the primary aim of this feasibility study.

Contacts

Public
Vrije Universiteit

van der Boechorstraat 7
Amsterdam 1081 BT
NL
Scientific
Vrije Universiteit

van der Boechorstraat 7
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

We will include community-dwelling adults aged 61-70 years, who have been retired for more than 6 months, are able to speak Dutch, are able to walk for 500 metres without walking aid and are available for home visits in the first 6 weeks following inclusion.

Exclusion criteria

we exclude people that are too active (participating in exercise class > 1 time per week, or on their own * 150 minutes per week), that have travels planned for > 2 months during the intervention period, with cognitive impairment (MOCA <24 points) and are suffering from various medical comorbidities where exercise is contraindicated.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2017

Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Application (iPAS system) called PreventIT;delivered via smartphones and smartwatches
Registration:	No

Ethics review

Approved WMO Date:	22-12-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL59977.029.16