

VITAMINE: VITal AMsterdam older adults IN thE city (Dutch: VITale AMsterdamse ouderen IN dE stad)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24204

Source

NTR

Brief title

VITAMINE

Health condition

Physical Functioning, Older adults, Exercise intervention, Protein.

Physical Performance, Body Composition, Executive functioning, Quality of life, Dietary intake, Motivation, Compliance and Sustainability.

Sponsors and support

Primary sponsor: Amsterdam University of Applied Sciences
(Dutch: Hogeschool van Amsterdam)

Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Change in physical functioning measured with the Modified Physical Performance Test (M-PPT) between baseline and at 6 months.

Secondary outcome

- Short Physical Performance Battery (SPPB)
- Timed Up and Go test (TUG)
- 6 minute walking test (6 MWT)
- Physical Activity Level
- Muscle strength: handgrip strength (HGS)
- Executive functioning (Trail Making, Stroop Color Word test, Letter Fluency)
- Quality of life (RAND-36)
- Geriatric Depression Scale (GDS)
- Motivation for exercise (BREQ-2)
- Dietary intake (3-day food record)
- Waist circumference, hip circumference and waist/hip ratio
- Mid upper arm muscle area (Mid upper arm circumference and triceps skinfold)
- Appendicular skeletal muscle mass, regional fat mass, visceral fat mass (DXA)
- Fat mass and fat free mass (Air Displacement Plethysmography)
- Body weight (kg)
- Height (m)
- Body Mass Index
- Total Body Water (bioelectrical impedance analysis)
- Compliance

Study description

Background summary

Our society is ageing rapidly. Ageing is associated with poor physical performance and activities of daily functioning.

Physical activity and optimal protein intake are shown beneficial interventions to prevent and/or treat the decline in daily functioning in the older adults.

More Physical Activity for Older Adults (Meer Bewegen voor Ouderen (MBvO) in Dutch) is a program that promotes physical activity by organizing community-based group exercises. An evaluation of the program, however, revealed ineffective on physical performance, daily functioning and quality of life. A tablet computer might help to improve the training program and thus improve physical performance. In addition, optimal protein intake during exercise training may further improve physical functioning in older adults.

Objective: We aim to evaluate the effectiveness of 1) home-based exercise training program supported by tablet computer and coaching on physical function and 2) increased dietary protein intake during home-based exercise training program supported by tablet computer and coaching on physical function in community dwelling older adults.

Study design: A randomised controlled trial with 3 parallel arms.

Study population: 240 community dwelling older adults (55 and older) who are already participating in weekly group exercise.

Intervention:

1. Control group (regular MBvO group, or other comparable weekly exercise program, n=80)
2. Home-based training program group supported by a tablet computer (VITA group, n=80)
3. Home-based training program group supported by tablet computer + Dietary protein counselling (VITA-Pro group, n=80)

Main study parameters/endpoints:

Change in physical functioning using the Modified Physical Performance Test (M-PPT) between groups after 6 months of intervention.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The risks associated with participation are minimal. Although muscle injury might occur due to exercise, the risks are limited due 1) contra-indication to un-supervised physical exercise will be excluded, 2) instructions via tablet computer and practice of the exercises by the group and personal coaches.

Possible benefits, all participants gained insight in their overall health status. Specific benefits for the intervention is six months personalized training and possibly improvements in physical functioning.

Study objective

A blended home-based exercise program and/or a blended home-based exercise program with dietary protein counseling is effective in changing physical functioning in older adults.

Study design

- baseline
- 6 months (End of coaching)
- 12 months (End of Study)

Intervention

The full study comprises a screening, a 6 month intervention period and a 6 month follow-up (so a total duration of 12 months) After screening, Clusters of participants (i.e. training groups) will be randomly assigned to one of the following groups:

1. Control group (regular MBvO, or other comparable weekly exercise program, group, n=80)
2. Home-based training program group supported by a tablet computer (VITA group, n=80)
3. Home-based training program supported by tablet computer + Dietary protein counseling group (VITA-Pro group, n=80)

Baseline, 6 months and 12 month follow-up measurements will be scheduled.

Contacts

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Eligibility criteria

Inclusion criteria

- 55 years of age or older
- Willingness that general practitioner will be notified on study participation
- Written informed consent
- Willingness to comply with the protocol
- Ability to comply with the protocol in the opinion of the study physician(s)

(screening especially for any condition, medication, or circumstance that might interfere with the study protocol, to ensure safety for the participants)

Exclusion criteria

- Inability to understand the Dutch language

- Current alcohol or drug abuse in the opinion of the investigator
- Cognitive impairment (MMSE <15)
- Knee or hip surgery in the last 6 months

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	24-03-2016
Enrollment:	240
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description

Participants did not sign consent on sharing IPD outside the work of the institution.

Ethics review

Positive opinion	
Date:	03-06-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47088

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5472
NTR-old	NTR5888
CCMO	NL56094.029.16
OMON	NL-OMON47088

Study results

Summary results

- 10.3389/fpsyg.2016.01827
- 10.1186/s12877-018-0863-7
- 10.2196/resprot.9244
- 10.2196/11598