Perturbation-based gait training: Evaluation of a tool to improve balance and gait in older people at risk of falling.

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In this study we want to investigate how a perturbation-based treadmill training with cognitive dual-task improves daily life gait stability in older adults compared to conventional treadmill training with cognitive dual-task.The results of this...

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

Summary

ID

NL-OMON45859

Source
ToetsingOnline

Brief title
Perturbation-based gait training

Condition

- Other condition

Synonym
gerontology, old age

Health condition

age-related functional decline and fall risk

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: European Committee

Intervention

Keyword: fall prevention, older adults, perturbation, treadmill

Outcome measures

Primary outcome

daily life gait stability (accelerometer data)

Secondary outcome

- Physical activity in daily life (accelerometer data)

- clinical balance and gait assessment scores (FSST, SPPB, MiniBESTest)

- measurement for balance recovery derived from force plate data from treadmill

Study description

Background summary

Falls are the leading cause of injuries in older adults (65+) that affects their quality of life and raises health care costs. There is an urgent need for innovative solutions to reduce fall risk in older adults. Despite our knowledge that balance and strength training can improve balance, the (long-term) effectiveness of conventional training programs to decrease fall risk and improve (daily life) gait function appear to be limited. Promising approaches are the use of perturbation-based training tools to improve reactive balance responses.

Study objective

In this study we want to investigate how a perturbation-based treadmill training with cognitive dual-task improves daily life gait stability in older adults compared to conventional treadmill training with cognitive dual-task. The results of this study lead to further development of balance training that is easy to apply and therefore accessible to a wider population. With the development of this step we want to reduce annual fall incidents in older

adults.

Study design

randomized controlled trial

Intervention

4 weeks:

Intervention 1: Perturbation-based gait training on a treadmill
Intervention 2: Conventional treadmill walking

Study burden and risks

The risks of the perturbation-based gait training and conventional treadmill training are estimated low. Participants of our RCT may benefit from the intervention in terms of improving their functional performance, balance and physical activity.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age 65 years or older
- Potential fall risk, as assessed by a short questionnaire (G. Peeters (20 12), VeiligheidNL)

Exclusion criteria

- MoCa < 24 points
- Body weight over 135 kg
- Body height over 2.0 m
- Open skin lesion or bandage in the area of the harness contact
- Lower extremity fractures or torn ligaments in the past 6 months
- Hip or knee joint replacement in the past 6 months
- Not able to walk without a walking aid at self-preferred speed
- Neurological comorbidities, e.g. Parkinson*s disease, multiple sclerosis, diabetic neuropathy, stroke, polyneuropathy
- Cardiovascular or pulmonary comorbidities, e.g. heart or lung/breathing diseases where physical activity at medium intensity is discommended

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2020
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	REACT module for C-Mill VR+
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	21-01-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	15-07-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21354
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66322.028.18
OMON	NL-OMON21354

Study results

Date completed:	29-05-2020
Actual enrolment:	70