BALANSEAT
RCT study on seated balance training with the Balanseat device in older people

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52787

Source
ToetsingOnline

Brief title
Balanseat

Condition

- Other condition

Synonym
balance and gait

Health condition

Gerontologie, ouderdoms gerelateerde mobiliteits/balans problemen

Research involving
Human

Sponsors and support

Primary sponsor: Hanzehogeschool
Source(s) of monetary or material Support: Ministerie van OC&W,Mopair Technologies, Ltd., Givat Nili, Israel,Philips

Intervention

Keyword: Balance, Falls, Older people, RCT

Outcome measures

Primary outcome

- Therapy adherence; Adherence to the intervention will be assessed based on adherence to the balanseat program during the study. Adherence to the balanseat program will be calculated based on completion of exercise bouts.

- Gait and balance parameters to be measured before, during (after 6 sessions) and after the intervention (post 12 sessions) include; timed up and go (TUG), 10 meter walk test (10MWT), short physical performance battery (SPPB), functional reach test (FRT) and Falls efficacy scale (FES).

Secondary outcome

General mobility, quality and quantity of walking and quality and quantity of chair rises measured with the GoSafe device. One week before the Balanseat intervention, participants from the intervention group will start wearing the GoSafe device to enable a reliable measure of the pre-intervention phase. Participants will continue wearing the GoSafe device throughout the intervention period, and until one week after the intervention period, to enable a reliable measure of the post-intervention phase. The control group will undergo the same assessments and wear the GoSafe device the same amount of

time compared to the intervention group.

Study description

Background summary

The fall incidence in the elderly increases with increasing age and can lead to harmful consequences and even premature death. Reduced motor control while walking, such as reduced trunk and pelvic rotation is a common gait impairment among the elderly and is considered a risk-factor for falls. Exercise regimens that target pelvis and trunk rotation are effective in reducing falls among seniors. However, adherence to exercise therapy is often insufficient, because elderly people often find the exercises too difficult, they feel insecure or the usefulness of doing exercises is not recognized. Moreover, elderly people with mobility problems may find it difficult to visit a therapist and also depend on when the therapist is available. Exercise in a relaxed, seated position such as with Balanseat may enhance adherence, especially among individuals with balance disorders. In settings with limited resources, the use of such technology may also provide a cost-effective approach for training.
The Balanseat (Mopair Technologies, Ltd., Givat Nili, Israel) is a thoraco-pelvic assisted exercise device (CE certified) in which the participant is seated comfortably and safely. The advantage of the Balanseat is that previous experiences indicated that participants found exercising with the Balanseat pleasant, secure and of no burden. The Balanseat scientific background on improving balance and gait is based on two concepts; The mechanical concept reflects exertion of a passive movement in a specific plane that may increase the ability of relevant joints to pass through a predetermined range of motion. Additionally, the motor control concept assumes that the device increases the sensory feedback from the mechano-sensory afferents to improve the dynamic control of the movement.
The earlier study on the Balanseat did not study therapy adherence and used a pre-post-test design without a control group in a small sample size. Hence, we propose this controlled intervention study to evaluate the true effects of the Balanseat on therapy adherence, gait and balance compared to usual daily activity in an elderly population in the Netherlands.

Study objective

The main objective of the proposed study is to evaluate if the Balanseat (used as intended) is feasible when only minor involvement from a therapist is required, contributes to therapy adherence and improves gait and balance compared to usual daily activity.
The second objectives are;
- evaluate the effect of the Balanseat intervention on mobility as assessed in

daily life by using mobility features derived from data collected with the GoSafe device activity tracker (Philips Lifeline, Framingham MA, USA) that reflect (general mobility, quality and quantity of walking and of chair rises) to obtain insights in the daily life mobility of the study population.

Study design

Randomized controlled study

Intervention

one group receives 15 minutes of exercise with the Balanseat (used as intended), twice a week, over 6 weeks (total of 12 sessions) and are given regular advice on healthy lifestyle (eg. staying active and eating healthy), the control group are given regular advice on healthy lifestyle. Both groups will be wearing the GoSafe and will receive information on the purpose and wearing instructions.

Study burden and risks

No burden en no risks.
Sessions with the Balanseat take 15 minutes, twice a week, for 6 weeks within the participants own living facility, no extra traveling is required and will be supervised by a physiotherapist. The movements exerted by the Balanseat are very small and of no risk for the participants. Balanseat is CE certified and will be used as intended. Earlier experience gained from Balanseat, based on a case-series test in elderly in an assisted living facility in Israel, showed that the exercise with the Balanseat was of no burden at all. The Go-Safe activity tracker is worn as a small necklace and is also of no burden or discomfort. The physical activity tests (TUG, 10MWT, SPPB, FRT) are part of regular measurements by physiotherapists, are validated for elderly people and of no risk. All physical test take approximately 30 minutes and take place at baseline, after 3 and 6 weeks within the participants own living facility, so no extra traveling is required.
According to the national guidelines on prevention of fall incidents (richtlijn preventie van valincidenten bij ouderen, Nederlandse Vereniging voor Klinische Geriatrie 2017) all mobile institutionalized elderly are at risk of mobility problems. This makes this population suitable for doing this research. All participants benefit from participating because they gain insight of their physical status and are given advise and information about gaining/remaining a healthy lifestyle and are motived to be active.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

• Age 65+ years
• Ability to walk at least 10 meters on a *at surface, with or without an assistive device
• Decreased walking speed; gait speed < 0.8 m/sec, during walk test
• An informed consent was signed by the participant

Exclusion criteria

• Individuals with a major disease or unstable health that prevents their participation
• Individuals with amputees or who had surgery in the past three months
• Individuals following physical therapy related to back, walking and/or

balance problems
• Individuals with MCI or dementia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-05-2021
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-03-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL72348.042.20