Balanseat

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25419

Source
NTR

Brief title
TBA

Health condition

Elderly with walking and balance problems.

Sponsors and support

Primary sponsor: Research group; Healthy Ageing, Allied Health Care and Nursing, Hanze University of Applied Sciences Groningen
Source(s) of monetary or material Support: Regular source Hanze University of Applied Sciences

Intervention

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

N/A

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

We hypothesize that a six-week exercise program with the Balanseat according to the protocol contributes to therapy adherence and improves balance and gait in an elderly population.

Study design

Baseline, 3 weeks, 6 weeks

Intervention

One group receives 20 minutes of exercise with the Balanseat, twice a week, over 6 weeks (total of 12 sessions), the control group their usual care.

Contacts

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Eligibility criteria

Inclusion criteria

• Age 65+ years • Ability to walk at least 10 meters on a flat 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)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-03-2021
Enrollment:	88
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	10-03-2021
Application type:	First submission

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
NTR-new	NL9330
Other	METC UMC Groningen : METc 2020/184

Study results

Summary results
N/A