Home-based exergaming for enhancing resistance to falls after stroke (HEROES): Proof-of-principle evaluation.

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This proof-of-principle evaluation aims to investigate whether a home-based balance training using an exergame (HEROES), following a single session of perturbation-based training improves reactive step quality in people with chronic stroke.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON56779

Source
ToetsingOnline

Brief title
HEROES Proof-of-principle evaluation

Condition

- Structural brain disorders

Synonym
Cerebro vascular accident (CVA), Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: DCVA-IMDI-UA grant (n. 104021002 project HEROES)

Intervention

Keyword: Balance, Recovery, Stroke, Training

Outcome measures

Primary outcome

The primary outcome is the quality of the reactive stepping response following perturbations from standstill. The quality will be expressed as the angle of the stepping leg relative to the vertical at foot contact.

Secondary outcome

- Multiple stepping threshold in the forward and backward direction.

- Spatiotemporal step characteristic (step onset, step duration, step length and step velocity) and anticipatory step characteristics (forward lean and weight-bearing assymetry) at the multiple stepping threshold in the forward and backward direction, as these parameters have the potential to explain the presence or absence of differences in the primary outcome.

- Clinical outcome measures (Fugl-Meyer Motor Assessment lower extremity subscale, Trunk Impairment Scale, Mini-BESTest, Functional Ambulation Category, 10-meter Walk Test, Dynamic Gait Index). This standardized core set of post stroke balance and mobility assessments will be performed according to the consensus-based recommendations from the Stroke Recovery and Rehabilitation Roundtable.

Study description

Background summary

In people with stroke, reactive stepping responses to recover from a loss of balance are often impaired, which increases their risk of falling. Adequate reactive stepping is critical for preventing falls following external balance perturbations. Perturbation-based training (PBT) has a great potential to improve reactive stepping performance. However, PBT requires expensive equipment and supervision, which limits its clinical uptake. Also, it is not yet possible to perform this type of training in a safe way at home. A promising solution to fill this gap is training based on action observation and motor simulation (AOMS) of reactive stepping. Therefore, we developed the HEROES exergaming intervention based on the principle of AOMS. This approach sets our intervention clearly apart from any currently available home-based exergames, which aims at healthy persons and lacks the required personalization. The ultimate goal is fall reduction in people with stroke (PwS), but with this evaluation we first aim to proof the principle of the HEROES (Home-based exergaming for enhancing resistance to falls after Stroke) intervention in PwS.

Study objective

This proof-of-principle evaluation aims to investigate whether a home-based balance training using an exergame (HEROES), following a single session of perturbation-based training improves reactive step quality in people with chronic stroke.

Study design

Three-arm proof-of-principle evaluation with a randomized design.

Intervention

Participants will randomly be assigned to;
• experimental group A - single training session with real perturbations, immediately followed by 5 weeks of home-based HEROES exergame training
• experimental group B - single session with real perturbations, followed by 5 weeks of home-based HEROES exergame training after a waiting period of 5-6 weeks
• a control group - no perturbation-based training session and home-based training with a commercially available game (which is not expected to improve reactive stepping)

Study burden and risks

BENEFITS
• Experimental groups: Participants in the experimental groups will receive a single perturbation-based training session followed by home-based training with virtual balance perturbations with the HEROES exergame. The single PBT session is expected to improve resilience to postural disturbances and thus possibly

reduce risk of falls. Furthermore, the home-based exergaming period is expected to result in improved reactive balance control.
• Control group:The control participants will be provided with a commercially available step game for voluntary instead of reactive step training. Voluntary step training is expected to not improve reactive stepping performance, but control participants may benefit from improvements in a variety of physical and cognitive functions associated with falls, as other studies evaluating technology-based stepping interventions delivered at home demonstrated.

BURDEN
• Experimental groups: The participants will complete four lab visits (intake session and pre-intervention, mid-term and post-intervention balance assessments) over the course of about 12 week, each lasting about 2-3 hours. The second lab visit contains an additional hour of PBT. In between lab visit 2 and 3 (experimental group A) or lab visit 3 and 4 (experimental group B), the participants will perform home-based reactive step training 3 times per week for 30 minutes for 5 weeks in total.
• Control: Similarly to the experimental group, the control participants will complete four 2-3 hour lab visits (intake session and pre-intervention, mid-term and post-intervention balance assessments) over the course of about 12 weeks, with no additional hour of PBT. In between lab visit 2 and 3, they will perform home-based voluntary step training 3 times per week for 30 minutes for the duration of 5 weeks.

RISKS
• Balance assessments and the additional PBT session: The risks associated with the balance assessments and the additional PBT session are deemed negligible. Firstly, these sessions are performed on a CE-certified instrumented treadmill (GRAIL). Similar use of this treadmill is standard healthcare practice at the clinical centers involved. Secondly, actual falls and fall-related injuries are prevented by the safety harness that participants will wear at all time on the instrumented treadmill. This safety harness which will catch participants when they lose their balance.
• Home-based training: The risks of falls and fall-related injuries associated with the home-based step training are deemed negligible as well. Rehabilitation physicians and physical therapists have concluded at expert panel meetings that the stepping movements evoked by the game are no more dangerous than normal steps in everyday life. Furthermore, previous research has shown that step training at home in elderly and in balance impaired clinical populations occurred with no adverse events such as falls. Moreover, the risks of the home-based training were thoroughly discussed with a technical and medical expert panel and with patients, and these risks were further minimalized accordingly.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age between 18 and 75 years old.
- Have sustained a unilateral stroke in the cerebrum more than 6 months ago.
- Have completed inpatient rehabilitation within the past two years.
- Experiencing mild to moderate impairments in balance and walking.
- Physically able to stand and walk independently (Functional Ambulation Categories score >=4).
- Living in the community.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Conditions in which physical activity is contra-indicated.
- Conditions in which reactive step training on the GRAIL is contra-indicated.
- Any other neurological or musculoskeletal conditions affecting balance or gait abilities.
- Impaired vision that is not corrected by glasses or lenses.
- Severe cognitive problems based on the Montreal Cognitive Assessment.
- Persistent visuo-spatial neglect based on the Star-Cancellation Test.
- Use of psychotropic drugs or other medication negatively affecting balance.
- Behavioural problems interfering with compliance to the study protocol.
- Unable to use the intervention system independently.
- Unable to give a personal informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-09-2024
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	HEROES software
Registration:	No

Ethics review

Approved WMO Date:	23-04-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL85745.091.23