Does virtual reality gait training improve participation in patients after stroke?

No registrations found.

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

Summary

ID

NL-OMON26087

Source
NTR

Brief title
ViRTAS

Health condition

Stroke, Gait

Sponsors and support

Primary sponsor: Revant medisch specialistische revalidatie
Source(s) of monetary or material Support: Revant Innovatie

Intervention

Outcome measures

Primary outcome

Participation assessed with the Utrecht Scale for Evaluation of Rehabilitation Participation (USER-P)

Secondary outcome

- Subjective physical functioning with the Stroke Impact Scale-16 (SIS-16)

- Activity level measured with an accelerometer

- Functional gait ability with the Timed-Up & Go Test (TUG) and the 6 minute walking test

- Fatigue with the Fatigue Severity Scale (FSS)

- Anxiety and depression with the Hospital Anxiety and Depression Scale (HADS)

- Falls efficacy with the Falls Efficacy Scale International (FES-I)

- Quality of life with the Stroke Specific Quality of Life Scale (SS-QOL)

- Intensity of the training sessions with a pedometer

- Perceived exertion at the end of a training session with the Borg RPE Scale

Study description

Background summary

Rationale:

Many patients after stroke experience limitations in walking and physical functioning in daily life,

mainly because of difficulties with performing dual tasks and walking on unlevel surfaces, walking up-

or downhill and walking on stairs. These limitations in walking provoke a reduced activity and

participation level. While using virtual reality training patients can be challenged more when compared

to other forms of gait training, for example by adding visual input and feedback, perturbations and dual

tasks during walking. It has been demonstrated that virtual reality training improves functional outcome

measures in people after stroke. However, there is a lack of measuring follow-up and research on the

effect of virtual reality training on activity and participation level is missing. Therefore, it is

unclear

whether the effects of virtual training are translated in improved daily life activity and participation in

the home environment.

Objectives:

The primary objective of this study is to investigate the effect of virtual reality training, given between 2

weeks and 6 months after stroke, on participation and subjective physical functioning in independently

living patients. Secondary research questions are: What is the effect of virtual gait training on walking

ability in patients between 2 weeks and 6 months after stroke? What is the difference in intensity

between virtual treadmill training and conventional functional gait training? Does gait training on a

treadmill in a virtual environment lead to improved quality of life?

Study design:

A randomized controlled trial will be conducted to compare virtual gait training (experimental group)

with functional gait training (control group).

Study population:

Patients with stroke between 2 weeks and 6 months after stroke who are living independently.

Participants are experiencing constraints with walking and are minimally able to walk without manual

support (FAC 3).

Intervention:

Patients in the experimental group will receive virtual gait training on the Gait Real-time Analysis

Interactive Lab (GRAIL). Training in the control group will take place on a conventional treadmill for

half of the training. The other half of a training session functional gait exercises are performed.

Participants will train 2 times per week for 6 weeks.

Outcome measures:

The primary outcome measure is participation assessed with the Utrecht Scale for Evaluation of

Rehabilitation Participation (USER-P). Secondary outcome measures are: subjective physical

functioning (SIS-16), functional gait ability (TUG, 6 minutes walking test), fatigue (FSS), anxiety and

depression (HADS), falls efficacy (FES-I), quality of life (SS-QOL) and daily life activity level measured

with an accelerometer.

Study objective

The objective of the study is to investigate the effect of virtual reality training, given between 2 weeks and 6 months after stroke, on participation and subjective physical functioning in independently living patients.

Study design

Baseline, after the 6-week training intervention and after 3 months of follow-up

Intervention

The intervention group (28 persons) receives 2 virtual reality training sessions of 30 minutes per week for 6 weeks. The virtual reality training is performed on the Gait Real-time Analysis Interactive Lab (GRAIL). The GRAIL comprises a dual-belt treadmill with force platform, a motion-capture system (Vicon) and speed-matched virtual environments projected on a 180 degrees semi-cylindrical screen. Participants can practice walking ability in combination with extra cognitive tasks or tasks using the upper extremity within the virtual environment of the

GRAIL.

Patients assigned to the control group (28 persons) receive functional gait training of 30 minutes 2 times per week for 6 weeks. The functional gait training will take place on a conventional treadmill for half of the training. The other half of a training session functional gait exercises are performed.

Contacts

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Eligibility criteria

Inclusion criteria

Participants should comply to the following inclusion criteria:

- Diagnosed with stroke according to the definition of the WHO

- Time since stroke between 2 weeks and 6 months

- Independently living

- Minimal Functional Ambulation Category score of 3

- Experiencing constrains with walking

- Age older than 18 and younger than 80

Exclusion criteria

Potential participants who meet one of the following exclusion criteria are excluded:

- Insufficient cognitive skills or understanding of the Dutch language to reliably answer simple questions, based on the clinical impression of the researcher

- Severe visual deficits

- Severe forms of ataxia

- Orthopedic disorders and other co-morbidities that may limit walking ability

- Epileptic seizures

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):	01-03-2017
Enrollment:	56
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	03-02-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47315
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6068
NTR-old	NTR6215
CCMO	NL59737.048.16
OMON	NL-OMON47315

Study results