Implicit and explicit motor learning during gait rehabilitation and the use of simple technologies to support independent gait training at home in people after stroke.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON45557

Source
ToetsingOnline

Brief title
Implicit motor learning in gait training after stroke

Condition

- Movement disorders (incl parkinsonism)
- Vascular haemorrhagic disorders

Synonym
CVA, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Zuyd Hogeschool
Source(s) of monetary or material Support: Nationaal Regieorgaan Praktijkgericht Onderzoek SIA

Intervention

Keyword: gait, motor learning, rehabilitation, stroke

Outcome measures

Primary outcome

The main outcome parameter in work package A is walking speed measured in

single and dual task conditions.

The main outcome parameter for work package B is the technology acceptance of

the Stappy-system.

Secondary outcome

Secondary outcome measures in work package A include: quality of gait

(Spatiotemporal gait parameters, Dynamic Gait Index), the participants

satisfaction? (Likert-scale), the general level of mobility (Rivermead

Mobility Index) and quality of life (Stroke and Aphasia Quality of Life Scale).

Secondary outcomes in work package B are based on the feasibility and potential

first effects on walking performance.

Study description

Background summary

A significant part of rehabilitation focuses on facilitating motor skills. Gait training is one of the most practiced motor skills within rehabilitation in people after stroke. The use explicit and implicit motor learning strategies may support physiotherapists to structure their gait training sessions. Clients are also often encouraged to practice gait independently at home outside guided therapy sessions. Recently an easy-to-use technology, named the Stappy-system, has been developed to support independent gait training at home-based environments.

Study objective

The objective of this study is twofold. The first objective is to study the effectiveness of implicit motor learning on walking speed in clients after stroke in daily practice. The second objective is to determine the technology acceptance, feasibility, and first effects on walking performance of the Stappy-system.

Study design

This research protocol involves two work packages A (objective 1) and B (objective 2). In work package A, a randomized, controlled, single blinded study design will be adopted. Work package A will be followed by work package B in which a prospective process evaluation of a technology intervention will take place.

Intervention

Work package A consists of a 3-week intervention period that includes 3 training sessions per week. The experimental group receives gait training based on implicit learning principles (analogy Learning) and the control group will receive gait training based on explicit learning principles. In work package B, the participants in de experimental condition will receive an easy-to-use technology (Stappy-system) to support their gait exercises independently at home. The control group will not receive any support.

Study burden and risks

Work package B: Participants will be randomized into the control (explicit motor learning) or the experimental (implicit motor learning) condition. Interventions: Participants are asked to participate in 9 sessions during a 3-week period and to complete 3 measurement sessions. The sessions take place at the client*s home environment. Each training session lasts for 30 minutes. Measurements: All assessment sessions will take place the home environment of the participants. Primary and secondary outcome measures are assessed at baseline (T0), directly after the intervention (T1) and again 1-month after the intervention (T2). The outcome assessments last for approximately 30 to 60

minutes.
Both conditions do not include any invasive interventions, nor any untested measurement instruments, there is no anticipated significant additional risk to the assessment or therapy of the participant. The measurements include standardised tests and questionnaires that are being used within standard clinical practice and/or research settings. Participants may possibly feel a little fatigued after the gait training or measurement sessions.

Working package C: Participants will be randomized into the control (nothing) or the experimental (technology) condition. Both conditions do not include any invasive interventions, nor any untested measurement instruments, there is no anticipated significant additional risk to the assessment or therapy of the participant. Technology group: The technology condition requires some extra proceedings. These involve recharging the batteries of the Stappy-system and setting up the system (e.g. placing sensors on shoes). Control group: People in the control group, even as people in the people in technology group will be asked to train their gait independently at home, however they will not receive the additional support of a technology. In both groups people will be free the o choose when, how often (frequency) and for how long (duration) they would like to practice with the Stappy-system over a 4-week period. If people are allocated to the control condition while they would actually also like to try out the technology, they will be offerend the chance to work with the technology after the end of the study.

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

* has had a stroke and is in the chronic stage of recovery (> 6 months after stroke)
* wants to improve his/her walking performance
* has a walking speed slower than 1.0 m/s (there is limited space for improvement if walking speed would be too high (ceiling effect)

Exclusion criteria

* cannot walk a minimal distance of 10 meters (if necessary with manual assistance or walking aid)
* has additional impairments, not related to stroke, that can influence the gait pattern e.g. severe osteoarthritis or amputation of the lower limb

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2017
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	21-02-2017
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	25-01-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	01-03-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL60338.096.17