Implicit motor learning in gait training after stroke

No registrations found.

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

Summary

ID

NL-OMON20141

Source
NTR

Health condition

The study is targeted at people after stroke who are in the chronic stage of recovery.

Stroke, CVA

Sponsors and support

Primary sponsor: This work was supported by Nationaal Regieorgaan Praktijkgericht Onderzoek SIA (RAAKPRO; grant number 2014-01-49PRO).
Source(s) of monetary or material Support: http://www.regieorgaan-sia.nl/contact

Intervention

Outcome measures

Primary outcome

The main outcome parameter in work package A is walking speed measured using the 10-Meter Walk Test

The central outcome parameter in work package B is the technology acceptance of the Stappy-system

Secondary outcome

Secondary outcome measures include: dual-task performance, quality of gait (modified Dynamic Gait Index), the propensity for conscious processing (Movement Specific Reinvestment Scale), the participants' satisfaction (Likert-scale), and quality of life (Stroke Specific Quality of Life

Secondary outcomes of interest in work package B are the feasibility of the Stappy-system and potential effects on walking performance (walking speed).

Study description

Background summary

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.

Study population: The same participants will take place in both work packages A and B. People will be eligible for participation if they have had a stroke (>6 months after stroke), would like to improve their walking performance, have a slower walking speed than (10 m/s), can communicate in Dutch language (enough to understand the instructions), and can follow a 3-stage command. People will be excluded for participation if they cannot walk a minimum of 10 meters, or have other additional impairments that may influence their gait.

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 and the control group will receive gait training based on explicit learning principles. In work package B, the participants will receive an easy-to-use technology (Stappy-system) to support their gait exercises independently at home.

Main study parameters/endpoints
Demographic data: Age, gender, Length, time post stroke, side of stroke, walking aids, educational level, Montreal Cognitive Assessment, Berg Balance Scale, Rivermead Mobility Index, Fugl-Meyer Assessment, Movement Specific Reinvestment Scale

Work package A: The main outcome parameter is walking speed measured using the 10-Meter Walk Test. Secondary outcome measures include: quality of gait (modified Dynamic Gait Index), dual-task performance, the participants' satisfaction (Global Perceived Effect), the propensity for conscious processing (Movement Specific Reinvestment Scale) and quality of life (Stroke and Aphasia Quality of Life Scale-39).

Work package B: The main outcome parameter for work package B is the technology acceptance of the Stappy-system. Secondary outcomes are based on the feasibility and potential first effects on walking performance.

Study objective

Work package A

The aim of work package A is to examine the effectiveness of analogy learning (based on implicit motor learning principles) compared to explicit motor learning on walking performance in people after stroke.

Work package B

The primary aim of work package B is to evaluate the acceptability of the Stappy-system for independent gait training in daily life in people after stroke. Secondary aims are to assess the feasibility and potential first effects on walking performance of the Stappy-system in people

Study design

T0: 0-weeks (baseline)

T1: 4-weeks

T2: 8-weeks

Intervention

Depending on randomisation, participants will receive a gait training based on implicit motor learning principles (experimental group) or based on explicit motor learning principles (control group).

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria. The person

 has had a stroke and is in the chronic stage of recovery (> 6 months after stroke)

 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)

 is able to communicate in Dutch langue, at least to understand the verbal instructions of the physiotherapist

 has the ability to complete a 3-stage command

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study. The person

 cannot walk a minimal distance of 10 meters (if necessary with manual assistance or walking aid)

 has additional diagnosed impairments, not related to stroke, that can influence the gait pattern e.g. severe osteoarthritis or amputation of the lower limb

 could not ambulate on level surfaces without manual contact of another person (Functional Ambulation Scale (FAC) < 3)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-05-2017
Enrollment:	80
Type:	Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-03-2017
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	NL6133
NTR-old	NTR6272
CCMO	NL.60338.096.16

Study results