Auditory-paced walking following stroke: Effects on hemiplegic gait

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Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON30123

Source
ToetsingOnline

Brief title
Auditory paced walking

Condition

- Central nervous system vascular disorders
- Vascular haemorrhagic disorders

Synonym
Stroke; Brain attack

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cueing, Rehabilitation, Stroke, Walking

Outcome measures

Primary outcome

- Mean and variability of the discrete relative phase between instants of heel strike and auditory stimuli;

- Adjustment time to the sudden change in auditory pacing stimuli as an index of flexibility (i.e., an inverse measure of gait flexibility);

- largest Lyapunov exponent of the continuous relative Hilbert phase between the feet (a measure of gait stability);

- gait parameters (e.g., steplength, steptime, temporal and spatial asymmetry) based on kinematics of the feet;

Secondary outcome

Standard clinical measurement scales

Study description

Background summary

In gait rehabilitation following stroke, the use of external auditory rhythms is a particular expedient means to improve the speed and appearance of hemiplegic walking. However, hemiplegic gait patterns still remain asymmetric with auditory pacing. Consequently, a perfect bilateral synchronization between auditory stimuli and footfalls is inherently impossible. Previous studies observed that stroke patients synchronized or timed the footfalls of their non-paretic limb to the auditory stimuli. However, it remains open how the auditory stimuli should be applied in order to obtain the best results, that is, auditory stimuli can be provided according to the step or stride frequency. For example, instructing hemiplegics to time or synchronize the heel strikes of their paretic instead of their non-paretic leg to the pacing signal might tentatively lead to a reduced gait asymmetry by increasing step length of the

paretic limb. Gait stability and flexibility might also be affected by auditory pacing. With respect to the latter, it entails that the gait pattern can be adjusted quick and adequately to sudden changes in the environment, such as avoiding an obstacle on the side walk. Paced treadmill walking is ideally suited to study (and practice) gait flexibility by suddenly changing the consecutive interbeat interval of the pacing stimuli. The stroke patient is instructed to adjust his gait to the altered pacing signal, for example, by elongating step lengths or step intervals

Study objective

The purpose of this study is to gain insight into the effects of auditory pacing on the stability and flexibility of hemiplegic gait coordination. It will be examined how auditory pacing can be best administered to improve the quality of hemiplegic gait. We expect that the results will contribute to a better understanding of auditory-paced walking which might ultimately lead to both evidence- and theory-based rehabilitation goals.

Study design

Hemiplegic gait patterns in treadmill walking with and without auditory stimuli will be assessed in three sessions. The first session is used to accommodate to treadmill walking and auditory-paced walking. The preferred walking speed and the corresponding stride frequency will be determined. In addition, a physician will assess standard clinical measurements. In the second session, gait coordination will be studied in four experimental conditions: 1) bilateral auditory pacing, 2) unilateral auditory pacing on the paretic side, 3) unilateral auditory pacing on the non-paretic side and 4) no auditory pacing, under the instruction to synchronize footfalls with pacing stimuli on the same side. Besides these four conditions, the third session will also assess gait flexibility in trials in which the temporal ordering of auditory stimuli is suddenly changed. Participants are instructed to adjust to the altered rhythm as soon as possible. All sessions take place at the Duyvensz-Nagel Research Laboratory at the Rehabilitation Centre Amsterdam. The three sessions are planned within three weeks.

Intervention

External auditory pacing during treadmill walking

Study burden and risks

The risks associated with participation are limited and comparable to normal every-day walking. Participants will be allowed sufficient time and help to practice and become acquainted with treadmill walking and auditory-paced walking. For safety purposes, participants will wear a safety belt and are

accompanied by two persons alongside the treadmill (at least one physician). Furthermore, an emergency button can be used by both the investigator and the participant to immediately stop the treadmill. There are three sessions to limit physical stress. During each session as many breaks are allowed as desired by the participants. The total session time is about 1.5h, including breaks.

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

- Age 18+
- Ischemic or hemorage stroke (established by means of CT or MRI);
- Hemiplegic gait pattern
- Able to walk independently without aids; Functional Ambulation Score * 3. (FAC 3 <=

supervision: patients requires for safety reasons verbal assitance of one person but can walk without physical assistance
- Able to walk for 3 minutes without walking aid such as a cane. However, ankle-foot ortheses are allowed.

Exclusion criteria

- Orthodpedic impairments of the lower extremity or other neurological impairments (not related to the Stroke) that may influence walking.
- Cognitive or mental impairments that undermine the understanding of the task instructions. Note that (light) neglect and afasia are not perse exclusion criteria as long as the patient is able to fully understand the instructions.
- Hearing deficit

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL13293.029.06