The effectiveness and cost-effectiveness of Occupational Therapy at Home E-Rehabilitation (OTHER) for persons post-stroke

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To determine the (cost)effectiveness of OTHER (Occupational Therapy at Home E-Rehabilitation), as compared to usual OT, on improving the self-perceived performance in daily activities of community-dwelling older persons post-stroke over a 24-week...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53807

Source
ToetsingOnline

Brief title
OTHER

Condition

- Other condition

Synonym
CVA, stroke

Health condition

Stroke/CVA

Research involving

Human

Sponsors and support

Primary sponsor: Hogeschool van Amsterdam
Source(s) of monetary or material Support: Subsidie is verstrekt via ZonMW

Intervention

Keyword: Activity monitoring, coaching by videoconferencing, CVA, home-based geriatric rehabilitation

Outcome measures

Primary outcome

The primary outcome measure is the between group difference in *perceived daily performance* 4 weeks, 13 weeks and 26 weeks after the start of the intervention. This is measured by the Canadian Occupational Performance Measure.

Secondary outcome

Secondary outcomes are patients satisfaction with their daily performance, self-management, activity level and mobility, patients quality of life, satisfaction with occupational therapy, and cost-effectiveness. Process evaluation outcomes focus on how participants experienced OTHER in the transition from a geriatric rehabilitation centre to home, treatment fidelity and adherence to OTHER, and the facilitators and barriers persons post-stroke and OTs experience.

Study description

Background summary

In the Netherlands, every year 40.000 people suffer from stroke, constituting the third-largest burden of disease and responsible for 2.5% of total healthcare costs. The exact stroke consequences depend on the location of the stroke, e.g. limitations in sensory-motor, speech, cognitive and social-emotional functioning . Also, stroke may affect partners, if any, often in their role as caregiver they too may suffer from emotional and physical burden. 23 % of persons who suffer from a stroke in the Netherlands went for rehabilitation to a geriatric rehabilitation centre (GRC) after hospitalization. During transition from GRC to home or transition fom hospital to home, persons are confronted with reality and realize that they are often not ready to take up daily activities and to self-manage. The majority of persons post-stroke at home are inactive and sedentary. Breaking up sedentary time with light activities of daily living is associated with health indicators. Performance of daily activities is an important arena in which persons post-stroke also develop self-management and being in charge. Recognizing the demand on healthcare services, e-rehabilitation interventions are a promising cost-effective solution to support GR at home for persons post-stroke and e-rehabilitation can be applied to increase the performance of daily activities, support self-management and be(com)ing in charge. Therefore, persons post-stroke at home could benefit from Occupational Therapy (OT) at Home E-Rehabilitation (OTHER), a program to support persons to increase performance in daily activities and to support their post-stroke self-management.

Study objective

To determine the (cost)effectiveness of OTHER (Occupational Therapy at Home E-Rehabilitation), as compared to usual OT, on improving the self-perceived performance in daily activities of community-dwelling older persons post-stroke over a 24-week period after initiation of OTHER or CAU, as measured longitudinally (at week 4, 12 and 24).

Study design

The (cost)effectiveness of OTHER will be evaluated in a 2-armed stepped-wedge randomized trial in eight geriatric rehabilitation centres and two area's from hospital to home in the Netherlands. Alongside the (cost-)effectiveness study, we will conduct a process evaluation using mixed methods, to investigate treatment fidelity and adherence to the intervention protocol. Moreover, we will qualitatively evaluate patient and care personnel*s experiences, barriers and facilitators and satisfaction with the intervention content and its delivery.

Intervention

All participants receive home-based OT care as usual. Participants included

during intervention periods will additionally receive activity monitoring and (online)coaching. The intervention starts during clinical geriatric rehabilitation as soon as if it is clear that a participant is going home, at least three weeks before discharge and ends 12 weeks after discharge or within four weeks from discharg from hospital to home. The intervention from hospital preferably starts within 4 weeks after discharge from hospital to home and lasts 12 weeks.The intervention consists of a validated platform for activity monitoring supported by face-to-face coaching and videoconferencing. Participants receive a wearable sensor worn on the hip which measures the amount of physical activity. Via a web-based application, participants can see the visualization of their data. The therapist and participant monitor the activities via a secure website and the daily and weekly reports of the sensor data are used as feedback for coaching; patterns of daily activities are discussed and related to experiences during the day. Accordingly, new goals for daily activities can be set. The intervention will comprise a weekly coaching session during inpatient rehabilitation and 6 physical sessions and 4 online videoconference follow up sessions at home in 12 weeks.

Study burden and risks

The burden for participants is low, during baseline, at 4 weeks, 13 weeks follow-up moments and 26 weeks follow up, study measurements will cost the participant about one hour. The burden for professionals is low, filling in a questionnaire for participants (5 minutes). A small group of participants (and if involved during OTHER, also their informal caregiver) (max N= 20) will also be approached for interviews which will last an hour and a small sample (N=8-10) professionals will be asked to participate in a focus group (2 hours).

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

To be eligible to participate in this study, the persons post-stroke must meet all the following criteria:
• be able to walk a few steps with or without a walking device
• 60 years or older
• An assessment score of at least 16 on the Montreal Cognitive Assessment (MoCA).
• An indication for follow up (GR) Rehabilitation at home.

Exclusion criteria

Persons post-stroke who meets any of the following criteria will be excluded from participation in this study:
• Who are terminally ill.
• Who have severe aphasia; problems with understanding
• Who has been assessed legally incapable by a (geriatric) doctor or neurologist.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-04-2023
Enrollment:	170
Type:	Actual

Medical products/devices used

Generic name:	Hipper
Registration:	No

Ethics review

Approved WMO Date:	14-02-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2024
Application type:	Amendment
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
ClinicalTrials.gov	NCT05855226
CCMO	NL81848.029.22