hoMEcare aRm rehabiLItatioN

Gepubliceerd: 18-02-2019 Laatst bijgewerkt: 18-08-2022

We hypothesize that patients will recover more from training with the ArmAssist than from conventional treatment.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28842

Bron
NTR

Verkorte titel
MERLIN

Aandoening

Stroke (single) with resulting unilateral paresis.

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: EIT Health (Nr. 19094) and Stichting Beatrixoord Noord-Nederland (Nr. 210.183)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Wolf Motor Function Test (WMFT)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Some stroke survivors are able to (partially) recover if proper rehabilitation therapy is followed regularly. The key principle in rehabilitation training is repeating task-specific movements to stimulate motor learning. More training has shown to be associated with better motor recovery. Since the number of patients with chronic stroke is increasing and the resources to treat all these patients are limited, the focus of rehabilitation shifts from rehabilitation centers to training at home using robotic tools. The effectiveness of robotic therapy has been proven. The upper extremity (UE) is rarely tackled. In this project we will evaluate hoMEcare aRm rehabiLItatioN (MERLIN). MERLIN will provide an easy to use and affordable device to assist and stimulate arm function (ArmAssist) which is coupled to the Antari Homecare platform ("GMV"). The home training with ArmAssist provides the possibility for patients to train daily with the (remote) supervision of the therapist via the Antari Homecare platform, which is often not possible in rehabilitation centers. We hypothesize that patients will recover more from training with the ArmAssist than from conventional treatment.

The goal of this study is to test the effectiveness of using the ArmAssist and Antari Homecare platform at home on upper extremity function in chronic stroke patients. We will use a repeated measures (within subject) design.
12 Chronic (single) stroke patients of 18 years or older will take part in this intervention study. The intervention consists of training for six weeks with Merlin for minimal 3 hours per week divided over minimal 4 to maximal 7 sessions. The time between training sessions should be at least 24 hours.

The main study outcome is the Wolf Motor Function Test (WMFT). Secondary outcomes are the Action Research Arm Test (ARAT), Fugl-Meyer Assessment-Upper Extremity (FMA-UE), EuroQol-5D (EQ-5D), Intrinsic Motivation Inventory (IMI), System Usability Scale (SUS), Dutch Quebec User Evaluation of Satisfaction with Assistive Technology (D-QUEST) and biomechanical data using the ArmAssist Assessment (AAA) and Inertial Measurement Units (IMUs). Subjective opinion will be assessed during in-depth interviews. Patients will perform the WMFT, ARAT, FMA-UE and EQ-5D tests six weeks before the intervention (T0), just before the start of the intervention (T1) and after six weeks of intervention (T2). To examine the retention, these tests will be performed again six weeks after the end of the intervention (T3) and after 6 months (T4). AAA will be done at T1, T2 and once every 2 weeks in the intervention period. IMI, SUS, D-QUEST and in-depth interviews will be done at T2.

Doel van het onderzoek

We hypothesize that patients will recover more from training with the ArmAssist than from conventional treatment.

Onderzoeksopzet

We want to start in September with the measurements. Due to the availability of the devices, we start with 3 patients at the same time. In december we will receive 3 extra devices, this makes it possible to measure 6 patients at the same time. The measurements with the ArmAssist should be completed at the end of June.

Measurements will take place six weeks before the intervention (T0), just before the start of the intervention (T1) and after six weeks of intervention (T2). To examine the retention, these tests will be performed again six weeks after the end of the intervention (T3) and after 6 months (T4).
The period between T0 and T1 will function as the control, to examine the natural recover of patients.

Onderzoeksproduct en/of interventie

The intervention consists of training for six weeks with Merlin for minimal 3 hours per week divided over minimally 4 to maximal 7 sessions. The time between training sessions should be at least 24 hours.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18 years or older
- Unilateral paresis with at least some proximal voluntary movement capability (max FMA-UE

= 50)
- First incidence of single stroke or stuttering stroke
- Minimal 6 months and maximal 3 years post-stroke
- Able to perform finger extension 3 times
- Ability to give informed consent, understand and execute simple instructions
- Visual, mental and cognitive ability to assimilate and actively participate in the protocol
- Being able to speak and understand Dutch/English
- Know how to operate a computer (or have someone to help) and have the possibility to train at home.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Multiple strokes or bilateral impairment
- Inability to give informed consent
- Moderate or severe cognitive impairment
- Depression
- Other medical disorders which could have effect on the results of the intervention such as rheumatic disorders or shoulder pain
- Following occupational or physiotherapy specifically focussed on the arm/hand
- Patients who have a positive predictor within 24 hours, such as wrist movement

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	15
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	18-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7535
Ander register	METC Groningen : 69064.042.19

Resultaten

Samenvatting resultaten

Rozevink, S. G., Sluis, C. K. van der, Garzo, A., Keller, T., & Hijmans, J. M. (2021). hoMEcare aRm rehabiLItatioN (MERLIN): Telerehabilitation using an unactuated device based on serious games improves the upper limb function in chronic stroke. Journal of NeuroEngineering and Rehabilitation (InPress), 18(48), 1–12. https://doi.org/10.1186/s12984-021-00841-3

Rozevink, S. G., van der Sluis, C. K., & Hijmans, J. M. (2021). HoMEcare aRm rehabiLItatioN (MERLIN): preliminary evidence of long term effects of telerehabilitation using an unactuated training device on upper limb function after stroke. Journal of NeuroEngineering and

Rehabilitation, 18(141), 1–9. https://doi.org/https://doi.org/10.1186/s12984-021-00934-z