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Rehabilitation monitoring device to improve quality of life in stroke patients

Submission date
27/06/2017

Recruitment status
No longer recruiting

Registration date
03/07/2017

Overall study status
Completed

Last Edited
28/06/2017

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A stroke occurs when the blood supply to part of the brain is cut off. Almost half of stroke survivors experience moderate functional disability requiring rehabilitation. However, the amount of therapy these patients receive is below recommended levels. The aim of this study is to test the impact of a rehabilitation monitoring device (HealthRecover) on the quality of life of patients who have had a stroke.

Who can participate?
Patients over 18 years of age who have had stroke and their caregivers

What does the study involve?
Participants are randomly allocated into one of two groups: a control group and an intervention group. Both groups receive the standard care rehabilitation sessions two or three times a week. The intervention group also use a non-invasive rehabilitation monitoring device to monitor rehabilitation. This device counts the number of repetitions performed in each rehabilitation exercise, and evaluates how well these have been performed. Data is collected on the patients' use of the device at three times: immediately after joining the study, and after 15 and 30 days. Data is also collected regarding quality of life, depression, functionality, upper limb motor function, and dependency immediately after joining the study and after 30 days.

What are the possible benefits and risks of participating?
Participants in the intervention group are provided with a rehabilitation monitoring device. There are no potential risks.

Where is the study run from?
Hospital Nacional Cayetano Heredia (Peru)

When is the study starting and how long is it expected to run for?
March 2017 to July 2017

Who is funding the study?
CONCYTEC: Fondo Nacional de Desarrollo Científico y Tecnológico, Fondecyt (Peru)

Who is the main contact?
Dr Alvaro Taype-Rondan

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HealthRecover

Study information

Scientific Title
Use of a rehabilitation monitoring device to improve quality of life in patients with recent stroke: a randomised controlled trial

Study objectives
Post-stroke participants who receive an innovative upper limb device will have better quality of life than participants in usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board from the Hospital Nacional Cayetano Heredia, 27/04/2017, ref: 042-017

Study design
Evaluator-blinded 1-month randomised pilot clinical trial with two parallel groups and a 1:1 allocation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Post-stroke subjects

Interventions
Simple randomization will be performed using the tool in http://www.randomization.com/. Subjects will be randomized to one of the two arms (control or intervention) via opaque, sealed envelopes, each bearing on the outside only the code (from 1 to 20).

Both groups receive the usual care rehabilitation two or three times a week. The intervention group also receive the HealthRecover device, which is a non-invasive device that consists of two straps that fit around the arm and the wrist, along with a mobile phone application. This device monitors the home rehabilitation exercises that the therapist has assigned to each patient (the therapist is able to assign a series of exercise routines). This device collects information from the movement of the participant and the app counts the number of repetitions performed in each rehabilitation exercise, and evaluates how well these exercises have been performed.

An evaluation to collect data on adequate use, frequency of use, and usability, is performed at three time points: immediately after enrollment, at 15 days after enrolling the patient in the study, and at 30 days after the patient has been enrolled in the study. Additionally, an evaluation is carried out in order to collect data on quality of life, depression, functionality, upper limb motor function, and dependency. This is performed immediately after enrollment and at 30 days after enrolling the patient to study.

Intervention Type
Device

Primary outcome measure
Quality of life, evaluated with the Short Form-36 (SF-36) immediately after enrollment and at 30 days

Secondary outcome measures

1. Depression, evaluated using the PHQ-9 immediately after enrollment and at 30 days
2. Functionality, evaluated through the Barthel Index immediately after enrollment and at 30 days
3. Upper limb motor function, assessed through the Wolf Motor Function Test immediately after enrollment and at 30 days
4. Dependency, evaluated using the Katz Index immediately after enrollment and at 30 days

Intervention group only:
1. Adequate use: patients' use of the device, evaluated with direct observation and a checklist immediately after enrollment, at 15 days and at 30 days
2. Usability: defined as the opinion of the participant regarding the use (usefulness?) of the device immediately after enrollment, at 15 days and at 30 days
3. Frequency of use: number of times the participants used the device, as registered in the device software immediately after enrollment, at 15 days and at 30 days

Overall study start date
20/03/2017

Completion date
30/07/2017

Eligibility

Key inclusion criteria
Patients:
1. Have suffered an ischemic stroke at least 6 months ago/in the last 6 months, according to their clinical record
2. Be over 18 years of age
3. Dependency level from A to D according to the Katz Index
4. Have verbal permission from their rehabilitation physician to use the device
5. Have access to an Android phone during their rehabilitation
6. Have a caregiver or a person responsible for attending their basic care
7. Give written informed consent to participate in the study

Caregivers:
1. Be responsible for assisting the post-stroke patient
2. Be over 18 years of age
3. Give written informed consent to participate in the study
4. Be able to use mobile phone applications and understand instructions
5. Do not have/suffer from moderate or severe cognitive, visual or auditory impairment

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
20 patients: 10 in the intervention group and 10 in the control group

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
29/06/2017

Date of final enrolment
30/07/2017

Locations

Countries of recruitment
Peru

Study participating centre
Hospital Nacional Cayetano Heredia.
Av. Honorio Delgado 262
San Martín de Porres de Lima-Perú
Lima
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Sponsor information

Organisation
Unidad de Conocimiento y Evidencia, Universidad Peruana Cayetano Heredia

Sponsor details
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Sponsor type
Government

ROR
https://ror.org/03yczjf25

Funder(s)

Funder type
Government

Funder Name
CONCYTEC: Fondo Nacional de Desarrollo Científico y Tecnológico, Fondecyt (Project number: 259-2015).

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Alvaro Taype-Rondan.

IPD sharing plan summary
Data sharing statement to be made available at a later date