

Rehabilitation monitoring device to improve quality of life in stroke patients

Submission date 27/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/07/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/06/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Peru

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Sponsor information

Organisation

Unidad de Conocimiento y Evidencia, Universidad Peruana Cayetano Heredia

Sponsor details

Av. Honorio Delgado 430

Distrito de Lima

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Peru

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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