ISRCTN08913646 https://doi.org/10.1186/ISRCTN08913646

Study to determine whether the empowered stroke patients demonstrate better self-management behaviour and health outcomes

Submission date
02/05/2012

Recruitment status
No longer recruiting

Registration date
06/06/2012

Overall study status
Completed

Last Edited
23/06/2017

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 is a serious condition that occurs when the blood supply to part of the brain is cut off. People who survive a stroke are often left with long-term problems caused by injury to their brain, and some need a long period of rehabilitation before they can recover their former independence. The aim of this study is to assess the effects of a Health Empowerment Intervention for Stroke Self-management (HEISS) on the self-management behaviour and health outcomes of stroke rehabilitation patients.

Who can participate?
Stroke patients aged over 18 who are experiencing functional difficulties

What does the study involve?
Participants are randomly allocated to either the control group receiving usual care or the treatment group receiving HEISS. Usual care is the current stroke rehabilitation programme. HEISS, in addition to the usual care, is designed to empower patients with the knowledge and skills to practice self-management in the stroke rehabilitation journey. The emphasis is on patients' perspective, taking into account their available resources, needs and preference, to set behavioural goals and an action plan for the highest possible self-care independence. The control group and the treatment group are compared in terms self-efficacy, engagement in self-management behaviours, ability to do daily activities, quality of life, unplanned hospital re-admissions and stroke recurrence. Data is collected at the start of the study and after 1 week, 3 months and 6 months.

What are the possible benefit and risks of participating?
Participants should benefit from HEISS by acquiring essential knowledge and skills, building self-efficacy in self-care performance after stroke, and establishing a supportive relationship with their significant others in the stroke recovery process. The study's findings should provide directions for bridging hospital and community care for stroke rehabilitation patients. There should be no direct risk or harm from participating in the study except participants may experience tiredness or reduced concentration from prolonged small group interactions.

Therefore, the study runs at a short duration (around 20 minutes per session per week) with a short break scheduled according to participants' needs.

Where is the study run from?
The Chinese University of Hong Kong

When is the study starting and how long is it expected to run for?
May 2012 to May 2014

Who is funding the study?
Health Service Research Fund of the Food and Health Bureau, Hong Kong Government

Who is the main contact?
Dr Janet W.H. Sit

Contact information

Type(s)
Scientific

Contact name
Dr Janet Sit

Contact details
The Nethersole School of Nursing
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The Chinese University of Hong Kong
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Hong Kong
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09100551

Study information

Scientific Title
The effect of a Health Empowerment Intervention for Stroke Self-management (HEISS) on the self-management behaviour and health outcomes of stroke rehabilitation patients

Acronym
HEISS

Study objectives
Compared with the control group, participants in HEISS will have a significant improvement in:
1. Self-efficacy
2. Self-management behaviour
3. Functional ability in activities of daily living

Null hypothesis:
There will be no difference between control group and treatment group in the above three outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Hong Kong East Cluster, Hospital Authority, ref: HKEC-2011-038

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Stroke post-acute stage

Interventions
Participants will be randomised to either the control group receiving usual care or the treatment group receiving HEISS

HEISS is based on the Theory of Health Empowerment. It consists of:
Part I: Six weekly small group sessions (20 mins per session and 4-6 participants per group). On completion of the 6 sessions, an individualized mutually agreed action plan and Stroke Self-management Work Book will be made for individual home-based implementation.
Part II: Home-based implementation of the action plan with two nurse reinforcement telephone follow-ups.

Part III: A small group re-union session after the individual home-based implementation (20 mins with the same group composition as in Part I). The purpose is to facilitate personal reflection and experience sharing.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Self-efficacy
2. Engagement in self-management behaviour
3. Functional ability in activities of daily living (ADLs)
Measured pre-test, 1-week, 3-month and 6-month post-test

Secondary outcome measures
1. Quality of life
2. Unplanned hospital re-admission rate
3. Stroke recurrent rate

Overall study start date
10/05/2012

Completion date
09/05/2014

Eligibility

Key inclusion criteria
1. Patients who experience stroke (haemorrhagic or ischaemic) as diagnosed by medical doctors, currently admitted to the ambulatory stroke rehabilitation programme with no pre-morbid disability
2. Experiencing post-stroke functional difficulties that limit participation in self-care activities
3. Aged over 18, with Chinese ethnicity and Cantonese dialect communicability

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
210

Key exclusion criteria
1. Patients with aphasia and/or cognitive decline [minimental state examination (MMSE)<18] that are severe enough to affect participation in the intervention
2. Patients who are currently diagnosed to have depression

Date of first enrolment
10/05/2012

Date of final enrolment
09/05/2014

Locations

Countries of recruitment
Hong Kong

Study participating centre
The Chinese University of Hong Kong
-
Hong Kong
-

Sponsor information

Organisation
Hong Kong SAR Government (Hong Kong)

Sponsor details
Health and Health Service Research Fund
Food and Health Bureau
-
Hong Kong
-

Sponsor type
Government

Website
http://www.gov.hk/en/

ROR
https://ror.org/034179816

Funder(s)

Funder type
Government

Funder Name
Health Service Research Fund - Hong Kong SAR Government (Hong Kong) ref: 09100551

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration