

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

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<b>Registration date</b> 06/06/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/06/2017	<b>Condition category</b> 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 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

Faculty of Medicine

The Chinese University of Hong Kong

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Hong Kong

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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  
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Hong Kong  
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## Sponsor information

**Organisation**  
Hong Kong SAR Government (Hong Kong)

**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

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration