Symptom experience and burden of patients within 1 year following their first stroke

Submission date	Recruitment status No longer recruiting	Prospectively registered		
07/07/2018		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
24/07/2018		[X] Results		
Last Edited	Condition category	Individual participant data		
21/09/2018	Nervous System Diseases			

Plain English summary of protocol

Background and study aims

Stroke is one of the most common chronic diseases. It is one of the leading causes of adult disability and mortality. After the onset of stroke, the patients will have a lot of symptoms. These symptoms have adverse impacts on the patients' mood, rehabilitation and mortality. We need pay more attention to these symptoms. But most attention of doctors, nurses and researchers have been put into disfunctions and complications these years. Although they are also very important, we need to understand stroke patients from their perspective. This study aims to recruit about 190 stroke patients to investigate the symptom experience and burden. The goals are to find the most prevalent and burdensome symptoms and to find the impact factors of symptom burden. The study's findings will improve the understanding of stroke patients and help to provide information for symptom management.

Who can participate?

Stroke patients over the age of 18 who take a rehabilitation in Shanghai, China.

What does the study involve?

Participants are asked to join this study when they take a rehabilitation in hospitals and rehabilitation centers. After a written informed consent is got, the patient will be investigated by a structured questionnaire. The questionnaire involves the demographic and clinical characteristics, the symptom experience scale for stroke patients and the stroke impact scale.

What are the possible benefits and risks of participating?

Because the investigators are very professional, the patients may correct their misunderstandings and know more about stroke rehabilitation by the communication with the investigators. There will be no risks of participating.

Where is the study run from?

The study takes place in rehabilitation departments of Xuhui District Center Hospital of Shanghai and the Shanghai Sunshine Rehabilitation Center, Shanghai, China.

When is the study starting and how long is it expected to run for? March 2017 to September 2019

Who is funding the study? Fuxing Nursing Research Foundation, Fudan University (FNF201611).

Who is the main contact?
1. Prof. Zheng Li
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2. MS. Dan Shi
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Updated PES as of 19/07/2018:

Background and study aims

Stroke is one of the most common chronic diseases, and is one of the leading causes of adult disability and mortality. After having a stroke, patients have various symptoms that can have effects on patient's mood, rehabilitation process and mortality. These include weakness, paralysis, pain, numbness, fatigue and speech problems, amongst many others. Too little attention has been paid to these symptoms, especially from the perspective of stroke patients themselves.

This study aims to investigate the experience and burden of stroke symptoms in patients, and understand which are the most prevalent, with the aim of furthering understanding of stroke patients and providing information for symptom management.

Who can participate?

Adult stroke patients undergoing rehabilitation in Shanghai, China

What does the study involved?

Participants will be asked to take a structured questionnaire, where they will be asked questions about their symptom experience and burden.

What are the possible benefits and risks of participating?

A possible benefit of participating is that participants may gain a better understanding of stroke rehabilitation through communicating with the investigators. There are no known risks to participants taking part in this study.

Where is the study run from?

- 1. Xuhui District Center Hospital, Shanghai, China
- 2. Shanghai Sunshine Rehabilitation Center, Shanghai, China

When is the study starting and how long is it expected to run for? January 2017 to September 2019

Who is funding the study? Fuxing Nursing Research Foundation, Fudan University (China)

Who is the main contact?

- 1. Prof Zheng Li (leez@fudan.edu.cn)
- 2. Dr Dan Shi (15211170003@fudan.edu.cn)

Contact information

Type(s)Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

1.0

Study information

Scientific Title

Symptom experience and symptom burden of patients following first-ever stroke within 1 year: a cross-sectional study

Study objectives

Stroke patients have a heavy symptom burden within 1 year. This study aimed to describe the multidimensional symptoms and concurrent symptoms within 1 year after stroke. This is a part of a wider cross-sectional study with the purpose of developing a symptom experience scale for stroke patients and describing symptom experience among stable stroke patients within 1 year.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Nursing School of Fudan University, China, 18/04/2017, IRB#2017-4-3

Study design

Observational study (part of a wider cross-sectional study)

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Stroke

Interventions

Participants were asked to complete a structure questionnaire, designed using the Symptom Experience Model with two sections - demographic and clinical characteristics, and the symptom

experience scale. Symptom experience and symptom burden were assessed using the self-made Symptom Experience Scale for Stroke Survivors.

Intervention Type

Other

Primary outcome(s)

Symptom experience during the preceding week, assessed using a self-made and patient-completed symptom questionnaire (Symptom Experience Scale for Stroke Survivors) at the baseline.

Key secondary outcome(s))

Symptom burden during the preceding week, assessed using nineteen symptoms in the Symptom Experience Scale, at the baseline. The mean score of symptom burden of these represents the total symptom burden of the patient.

Completion date

01/09/2018

Eligibility

Key inclusion criteria

- 1. Diagnosed with stroke within one year of study enrolment
- 2. Aged 18 years or older
- 3. Attacked by stroke for the first time
- 4. Accurately communicate by oral expression or writing
- 5. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

Key exclusion criteria

- 1. Unstable stage (undergoing medical and surgical treatments, rather than rehabilitation)
- 2. Dementia or severe cognitive impairment
- 3. Complications in the rehabilitation process (e.g. gastrointestinal bleeding, fracture, tumor, recurrent infections)
- 4. Cured of malignant tumor within the last 5 years

Date of first enrolment

01/03/2017

Date of final enrolment

01/09/2017

Locations

Countries of recruitment

China

Study participating centre

Rehabilitation Departments of Xuhui District Center Hospital of Shanghai

No. 966, Huaihai Middle Road, Xuhui District Shanghai China 200030

Study participating centre

Shanghai Sunshine Rehabilitation Center in China

No.2209, Guangxing Road, Songjiang District, Shanghai Shanghai China 201600

Sponsor information

Organisation

School of Nursing, Fudan University

ROR

https://ror.org/013q1eq08

Funder(s)

Funder type

Not defined

Funder Name

Fuxing Nursing Research Foundation of Fudan University of China, No. FNF201611.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from SHI Dan, 15211170003@fudan.edu.cn. This cross-sectional data will become available in 01/01/2021 for two years. Data will be shared with people who are interested in symptom management of stroke patients and want to compare the symptom burden between different groups of patients.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created Date	added Peer reviewed?	Patient-facing?
Results article	results	01/11/2018	Yes	No
Participant information shee	Participant information sheet	11/11/2025 11/11	/2025 No	Yes