

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

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<b>Registration date</b> 24/07/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/09/2018	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## 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  
Leez@fudan.edu.cn  
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**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

**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 measure**

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.

**Secondary outcome measures**

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.

**Overall study start date**

01/01/2017

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

230

**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

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**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****Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

30/03/2019

**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?
<a href="#">Results article</a>	results	01/11/2018		Yes	No