# The effective of a combined intervention in stroke survivors with vascular cognitive impairment

Submission date 17/04/2018	<b>Recruitment status</b> No longer recruiting	<pre>[] Prospec</pre>
<b>Registration date</b> 24/07/2018	<b>Overall study status</b> Completed	<ul> <li>Statistic</li> <li>Results</li> </ul>
Last Edited 02/07/2018	<b>Condition category</b> Circulatory System	Individu     Individu     Record

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- updated in last year

#### Plain English summary of protocol

#### Background and study aims

Cognitive deficits are a common problem after a stroke. There is a high risk of patients developing vascular cognitive impairment - a decline in thinking abilities caused by damage to the brain's blood vessels. If intervention is not undertaken as early as possible, this can develop into dementia. Physical exercise and cognitive training may reduce cognitive impairment in older adults. The aim of this study is to investigate the effect of a combined intervention of physical exercise and cognitive training on the cognitive function of stroke survivors with vascular cognitive impairment.

Who can participate?

Patients aged over 18 who have had a stroke within the last 6 months and have vascular cognitive impairment

#### What does the study involve?

Participants are randomly allocated to one of four groups to receive either physical exercise, cognitive training, both, or usual treatment. They receive training for about 50-60 minutes per day, 3 days per week for 12 weeks. At the start, 8 weeks and 6 months, participants undergo four cognitive tasks that assess their cognitive function. The participants from the usual treatment group also receive the intervention when the study is completed.

What are the possible benefits and risks of participating?

All participants have an opportunity to receive the training, and they may benefit from decreased cognitive impairment. There are no risks of physical injury or harm. Increased anxiety and pain may be experienced during the training sessions but this will be comparable to what is encountered in real life crisis situations in the medical profession.

Where is the study run from? Medical Rehabilitation Center of Shanghai General Hospital (China) When is the study starting and how long is it expected to run for? February 2017 to January 2018

Who is funding the study? Department of neurology of Baoshan branch of Shanghai First People's Hospital (China)

Who is the main contact? Dr Wang Ping

# **Contact information**

**Type(s)** Scientific

**Contact name** Dr Wang Ping

**Contact details** Haining Road Hongkou district Shanghai China 200080

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers B2017-020-06

# Study information

#### Scientific Title

The effective of combined physical exercise and cognitive training on cognitive function in stroke survivors with vascular cognitive impairment: a randomised controlled trial

#### **Study objectives**

The purpose of the present study was to investigate the effect of combined physical exercise and cognitive training on cognitive function in stroke survivors with vascular cognitive impairments, and to explore an alternative strategy for preventing cognitive decline in stroke patients.

Ethics approval required

Old ethics approval format

#### **Ethics approval(s)** Ethics and Research Committee of Nanjing Medical University

**Study design** Single-blind randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Prevention

#### 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

#### Interventions

The trialists used the online Research Randomizer (http://www.randomizer.org) to generate the allocation sequence, applying block randomization to achieve four groups with a ratio of 1:1:1:1. A progressive number was assigned to each of the participants in alphabetical order in terms of their surname, an independent research assistant not involved in the study held this random lists of number. After the competition of consents and baseline measurements, the research assistant contacted the participants to determine the next allocation.

Participants were randomly assigned to physical exercise, cognitive training, combined intervention or usual treatment (control group). They received training for approximately 50-60 minutes per day, 3 days per week for 12 weeks.

#### Intervention Type

Behavioural

#### Primary outcome measure

Measured at baseline, 8 weeks and 6 months:

Cognitive flexibility of participants assessed with Trail Making Part B, where participants traced a line alternating between encircled numbers and letters (e.g., 1-A-2-B-3-C). The test is time-limited (maximum 300 s), where shorter times denote better cognitive flexibility.
 Selective attention and conflict resolution assessed with Stroop test, whereby the participant judges the presenting color words (e.g., RED) displayed in either congruent (e.g., red) or incongruent (e.g., green) colors. The participants required to judge the ink color of the word as accurately and as soon as possible. The time to complete the task was record for each condition.
 Capacity to hold numbers in working memory and the ability to operate with them assessed with forward digit span, where random number sequences of increasing length were presented

verbally to the participants (e.g., "3, 8, 5"), who then repeated the numbers back to the examiner in forward order immediately. One point was scored for each correct sequence repeat (maximum score 14).

4. Spatial imagination measured using mental rotation test. The participants were presented with sheets of paper that had a standard object in the left and four comparison objects in the right site. Two of the comparison items were the same and two were mirror rotated. Participants had to decide which of the two comparison items the same as the standard item were. There were a total of 12 tasks presented in the test. The participants were given three minutes to solve the test. One point was given only if both correct sample stimuli of a cube figure were identified correctly. Participants could achieve a maximum of 12 points.

#### Secondary outcome measures

No secondary outcome measures

#### Overall study start date

16/02/2017

Completion date 30/01/2018

# Eligibility

#### Key inclusion criteria

- 1. Aged over 18 years
- 2. Medically stable
- 3. Less than six months post stroke
- 4. Able to understand and follow verbal instructions
- 5. Without severe somatic diseases and mental disorders including anxiety and depression
- 6. Without visual or auditory disturbances in a recent month
- 7. Met the diagnostic criteria of vascular cognitive impairment

Participant type(s)

Patient

**Age group** Adult

**Lower age limit** 18 Years

**Sex** Both

**Target number of participants** 260

#### Key exclusion criteria

- 1. Motor deficits
- 2. Non-stroke related neurological impairments
- 3. Clinically determined to be unsafe to perform physical activity

Date of first enrolment 23/02/2017

Date of final enrolment 24/03/2017

### Locations

**Countries of recruitment** China

**Study participating centre Medical Rehabilitation Center of Shanghai General Hospital** Haining Road Hongkou District Shanghai China 200080

### Sponsor information

**Organisation** Department of Neurology of First People's Hospital

**Sponsor details** Baoshan branch of Shanghai Shanghai China 200080

**Sponsor type** Hospital/treatment centre

ROR https://ror.org/04a46mh28

# Funder(s)

Funder type Hospital/treatment centre

Funder Name

# **Results and Publications**

#### Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

#### Intention to publish date

30/01/2019

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

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Wang Xiao Ping (wangxp018@njmu.edu.cn).

#### IPD sharing plan summary

Available on request