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

Submission date	Recruitment status	[ ] Prospectively registered
17/04/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/07/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/07/2018	Circulatory System	[ ] Record 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
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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)
Measured at baseline, 8 weeks and 6 months:
1. 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.
2. 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 in-congruent (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.
3. 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.

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

ROR
https://ror.org/04a46mh28

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of neurology of Baoshan branch of Shanghai First People's Hospital

Results and Publications

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