

# Comparing three types of training to improve language function in people with language problems following a stroke

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<b>Registration date</b> 10/01/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/02/2023	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Mirror neurons are nerve cells (neurons) in the brain that have been shown to be activated when a monkey performs an action and when the monkey sees or hears the same action being performed. It is thought that humans have mirror neurons too, because MRI scans show the same areas of the brain activated when a person performs an action and when they see someone else performing the action. The theory is that mirror neurons might also be activated when the word for a certain action or object is heard or spoken. People whose language has been affected by brain damage caused by a stroke might be helped to improve their language function by activating mirror neurons. This trial aims to investigate whether watching a video of a person handling and using an object while the name of the object is spoken on the video and repeated by the patient can help a patient with aphasia (loss of language function) regain language abilities more effectively than speech therapy or watching the object rotating on a turntable while its name is spoken on the video and repeated by the patient.

### Who can participate?

People aged 35-70 years who have only one stroke and have had problems with language following the stroke for 3 to 24 months. They must be right-handed and have completed at least 5 years of school education.

### What does the study involve?

Participants will be randomly allocated to one of three groups. Group A will watch videos showing an object being handled and used in the usual way (for example, a pen being used to write) and listen to the name of the object being spoken. They will watch the video of each object three times and will be asked to repeat the name of the object twice. Group B will watch videos of an object being rotated on a turntable and listen to the name of the object being spoken. They will watch the video of each object three times and will be asked to repeat the name of the object twice. Group C will receive speech therapy as usual from a trained speech therapist. Participants in all groups will undergo their therapy for 35 minutes a day, 5 days a week for 2 weeks.

What are the possible benefits and risks of participating?

There are no potential risks involved in the trial because participants will either be watching videos for a short time each day or undergoing speech therapy as usual. The participants might benefit from an improvement in their language ability.

Where is the study run from?

First Affiliated Hospital with Nanjing Medical University (China) and Zhongda Hospital, Southeast University (China)

When is the study starting and how long is it expected to run for?

January 2014 to January 2015

Who is funding the study?

National Natural Science Foundation of China, the General Project of University Philosophy and Social Science Research (China) and the Zhangjiagang city 2016 Science and Technology Plan Project (china)

Who is the main contact?

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## Contact information

### Type(s)

Public

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## Additional identifiers

### Protocol serial number

1.0

## Study information

### Scientific Title

# Aphasia rehabilitation based on mirror neuron theory: a randomized-block-design study of neuropsychology and functional magnetic resonance imaging

## Study objectives

The neuropsychology study was designed to evaluate the effect of hand-action-observation treatment on aphasia patients after stroke, and the functional magnetic resonance imaging (fMRI) study was applied to compare differences in brain activation between hand-action and dynamic-object observation and to reveal the corresponding mechanism related to mirror neuron system (MNS).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethical Committees of Nanjing Medical University, 11/03/2011, ref: 2011-SRFA-086

## Study design

Block-randomized study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Aphasia following stroke

## Interventions

24 patients with aphasia were randomly divided into 3 groups using Excel, and received hand-action observation and repetition, dynamic-object observation and repetition, and conventional speech therapy, respectively. All training was conducted for 5 days a week, 35 minutes daily, for 2 weeks. Picture naming test of objects and actions and Western Aphasia Battery were applied to evaluate language function. Among the participants, one patient, his wife and four healthy student volunteers underwent functional magnetic resonance imaging to analyze the changes in the brain regions during hand-action observation and dynamic-object observation.

### Group A Hand-action observation group

The patients in Group A were asked to watch a goal-directed transitive hand movements video (e.g., flapping a fan) and hear the name of the objects manipulated (e.g., fan), then repeat them. Treatment materials contained 175 videos showing different goal-directed dynamic hand movements and common objects in everyday life, such as cracking a fan, writing with a pen, peeling a boiled egg etc. Each video was shown for 12 seconds and was composed of triplicate hand-actions, meaning that each hand-action lasted for 4 seconds and was repeated three times. In each video, subjects were instructed to observe the hand-action carefully in the first 4 seconds, and then watch the same hand-actions twice in the second and third 4 seconds, meanwhile repeating the name of the object heard from the video twice.

### Group B Dynamic-object observation group

The patients in Group B were required to observe the dynamic meaningless object-rotating

video (e.g., a fan rotating on an automatic turnplate) and hear the name of the objects manipulated (e.g., fan), then repeat corresponding nouns. Treatment materials contained 175 videos showing different objects in daily-use rotating on an automatic turnplate, such as a rotating fan, a rotating pen, a rotating egg etc. Each video was shown for 12 seconds and was composed of triplicate object-rotating fragments, meaning that each object rotation lasted for 4 seconds and was repeated three times. In each video, subjects were instructed to observe the rotating object carefully in the first 4 seconds, and then watch the same objects twice in the second and third 4-second film, meanwhile repeating the name of the object heard from the video twice.

175 hand-action videos displayed in group A and 175 object-rotating videos displayed in group B were identical exactly in selection of objects, content of repetitions, duration and play order of videos. 175 videos were divided randomly into 5 groups for 5 days a week, and the 35 videos were displayed with computer screen and repeated 5 times every day. Therefore, each patient trained 5 days a week for 35 minutes a day for a total of 2 weeks. The practice process of the second week was exactly the same as the first week.

#### **Group C Conventional speech therapy group**

The patients in Group C received routine speech therapy by speech therapists (or speech-language pathologists, SLP) who were qualified to at least bachelor degree level and had treatment experience of more than 2 years. The traditional aphasia training content contained Schuell's stimulation method, constraint-induced aphasia therapy (CIAT), promoting aphasics communication effectiveness (PACE), functional communication therapy (FCT), melodic intonation therapy (MIT) and so on. Each patient in group C trained 5 days a week for 35 minutes a day for a total of 2 weeks.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Language function assessed using the Western aphasia battery (WAB), including four sub-tests of oral language (i.e., spontaneous speech, auditory verbal comprehension, repetition, and naming) and aphasia quotient, before and after 2 weeks of training

### **Key secondary outcome(s)**

1. Naming of pictured objects. 180 pictures of objects selected from standardized picture naming norms in Mandarin were divided into three groups and used as the naming materials at 0 week (before treatment) and after 1 and 2 weeks of treatment.
2. Naming of pictured actions. 120 pictures of actions were selected from the Russian language and neuropsychological research online database (<http://neuroling.ru/en/analog.htm>), divided into three groups and used as the naming materials at 0 week (before treatment) and after 1 and 2 weeks of treatment.
3. Functional magnetic resonance imaging (fMRI) measurements. The fMRI experiment was carried out to investigate the influence of hand-action observation on language function and corresponding neurophysiology mechanism underlying MNS. This was done immediately after intervention.

### **Completion date**

05/01/2015

## **Eligibility**

**Key inclusion criteria**

Stroke patients with aphasia:

1. First occurrence of cerebral infarction or hemorrhage
2. Aged 35–70 years
3. Disease course lasting for 3–24 months
4. Right-handed according to the Edinburgh Handedness Inventory
5. Educated beyond primary school (more than 5 years of education)
6. Aphasia determined by Western Aphasia Battery (WAB) (aphasia quotient <93.8)
7. No obvious attention, memory, and visuo-spatial function disturbances (Non-language cognitive function assessment scale, 2013 >70)
8. Retaining part of the auditory ability and tolerance of more than 30 minutes to complete the daily training task

Healthy participants:

9. Right-handedness according to the Edinburgh Handedness Inventory
10. Aged 18–30 years
11. Over 12 years of education
12. Willing to participate in the experiment and able to tolerate the experiment

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

24

**Key exclusion criteria**

Stroke patients with aphasia:

1. Frenchay dysarthria assessment shows moderate to severe dysarthria
2. Serious speech apraxia or oral and maxillofacial apraxia
3. Anxiety determined by Hamilton Anxiety Scale or depression determined by Hamilton Depression Scale
4. Obvious dyssomnia or emotional disturbances
5. Other diseases likely to aggravate patient's functional status such as cancer, severe heart or lung disease
6. Refused training or no desire for training
7. Severe pain, i.e. pain >8 out of 10 on a visual analog scale (VAS)

Healthy participants:

- 7. Poor physical condition for any reason
- 8. Refused training or no desire for training

**Date of first enrolment**

15/01/2014

**Date of final enrolment**

30/06/2014

## **Locations**

**Countries of recruitment**

China

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## **Sponsor information**

**Organisation**

the First Affiliated Hospital with Nanjing Medical University

**ROR**

<https://ror.org/04py1g812>

# Funder(s)

## Funder type

Government

## Funder Name

National Natural Science Foundation of China

## Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

China

## Funder Name

the General Project of University Philosophy and Social Science Research, China, No. 2016SJB740015

## Funder Name

the Zhangjiagang city 2016 Science and Technology Plan Project, China, No. ZKS1615

# Results and Publications

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## 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	01/06/2019		Yes	No
	Participant information sheet				

