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

Submission date
25/12/2018

Recruitment status
No longer recruiting

Registration date
10/01/2019

Overall study status
Completed

Last Edited
27/02/2023

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Mirron 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 and 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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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 AHand-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 BDynamic-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 CConventional speech therapy group
The patients in Group C received routine speech therapy by speech therapists (or speech-language pathologists, SLP) 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 measure
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

Secondary outcome measures

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.

Overall study start date
01/01/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
29

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

Study participating centre
First Affiliated Hospital with Nanjing Medical University
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Study participating centre
Zhongda Hospital, Southeast University
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Sponsor type
University/education

Website
http://www.jsph.org.cn/

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 Wěiyuánhuì, 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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/06/2019

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?
Results article	results	01/06/2019		Yes	No