Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the effectiveness of speech therapy interventions and Arm Ability Training (AAT) on naming skill, sentence comprehension, memory and hand dexterity in people with mild to moderate aphasia

Protocol summary

Study aim

Evaluation of naming skill, sentence comprehension, memory and hand dexterity scores after performing two different treatment protocols in people with mild to moderate aphasia

Design

Clinical trial without a control group, with parallel groups, double-blinded, randomized on 45 patients. A random number table will be used for randomization.

Settings and conduct

Samples will be patients with aphasia of Ghaem hospital in Mashhad who will be randomly divided into three groups of fifteen. The first group will receive protocol "A" including speech therapy, the second group will receive protocol "B" including Arm Ability Training and the third group will receive protocol "A" and "B" simultaneously. The study is double-blinded including evaluators and analysts.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of the lesions in the frontal and temporal lobes of the left hemisphere/ Confirmation of impairment in language skills and motor weakness in the right hand Exclusion criteria: Presence of psychiatric symptoms

Intervention groups

First group: speech therapy Second group: Arm Ability Training Third group: speech therapy and Arm Ability Training simultaneously

Main outcome variables

1) The changes rate in naming skill, sentence comprehension, memory and hand dexterity before and after implementing the treatment protocol 2) The changes rate in naming skill, sentence comprehension, memory and hand dexterity during the first and second weeks of study in each group 3) Comparison of changes in naming skill, sentence comprehension, memory and hand dexterity during the first and second weeks of study between groups 4) Examine the process of changes in naming skill, sentence comprehension, memory and hand dexterity of each week studied in each group 5) Compare the process of changes in naming skill, sentence comprehension, memory and hand dexterity of each week studied between groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200114046134N1**
Registration date: **2020-07-29, 1399/05/08**
Registration timing: **prospective**

Last update: **2020-07-29, 1399/05/08**
Update count: **0**

Registration date

2020-07-29, 1399/05/08

Registrant information

Name

Reihane Sabermoghadam Majidzade

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of speech therapy interventions and Arm Ability Training (AAT) on naming skill, sentence comprehension, memory and hand dexterity in people with mild to moderate aphasia

Public title

Evaluation of the effectiveness of speech therapy and Arm Ability Training (AAT) in aphasia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of lesion in frontal and temporal lobes of left hemisphere using Magnetic Resonance Imaging (MRI) findings of brain/ The right hand is the recipient/ Confirmation of impairment in language skills (comprehension and expression) through speech therapy using aphasia test of Dr Nilipour/ Mild to moderate confirmation of aphasia by speech therapy using Dr Nilipour aphasia test/ Mild to moderate of mental status by MiniMental Status Evaluation (MMSE) test/ Assessment of right-hand motor weakness by a physiotherapist/ At least one month to two years after stroke/ Patients with age spectrum 35-70/ Patients' satisfaction and willingness to enter the study

Exclusion criteria:

Severe upper extremity disorders/ Psychiatric symptoms such as mood and emotional disorders, sleep disorders, depression, cognitive disorders, etc./ Chronic liver, kidney and heart disease/ Progressive diseases/ Subsequent strokes/ Patient non-cooperation

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using a table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, due to the inability to hide the type of treatment from the samples and therapists, evaluators will not know the type of treatment that samples receive when assessing the skills before the start of treatment and on days 7,14 and 21 after starting treatment. Analysts will also not know the type of treatment that samples receive when analyzing the data from the evaluation of the skills.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Across the No. 18 ,Daneshgah Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-07-19, 1399/04/29

Ethics committee reference number

IR.MUMS.REC.1399.363

Health conditions studied

1

Description of health condition studied

aphasia

ICD-10 code

R47.01

ICD-10 code description

Aphasia

Primary outcomes

1

Description

score of naming skill

Timepoint

Before starting the intervention and 7,14 and 21 days after starting the treatment

Method of measurement

Subtest of picture naming from Dr. Nilipour's set of aphasia batteries

2

Description
Score of sentences comprehension
Timepoint
Before starting the intervention and 7,14 and 21 days after starting the treatment
Method of measurement
Subtest of sentences comprehension from a Bilingual Aphasia Test (BAT)

3

Description
Score of memory skill
Timepoint
Before starting the intervention and 7, 14 and 21 days after starting treatment
Method of measurement
Wechesler test

4

Description
Hand dexterity
Timepoint
Before starting the intervention and 7, 14 and 21 days after starting treatment
Method of measurement
Test d'Evaluation des Membres suprrieurs des Personnes Agres (TEMPA)

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: nine sessions of speech therapy and each session lasts for 40 minutes. After evaluating the patient, each of the different levels of language, including semantics, phonology, morphology and syntax, reading and writing is targeted according to the degree of damage in each person.
Category
Rehabilitation

2

Description
Second intervention group: nine sessions of Arm Ability Training (AAT) and each session lasts for 40 minutes. Due to the individual limitations, eight-step exercises are performed with the aim of increasing speed, accuracy and coordination.
Category
Rehabilitation

3

Description
Third intervention group: nine speech therapy and Arm Ability Training (AAT) are simultaneous, 20 minutes of speech therapy sessions and 20 minutes of Arm Ability Training sessions.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology clinic of Ghaem hospital
Full name of responsible person
Sobhani-rad Davood
Street address
Paramedicine school, Mashhad University of Medical Scients
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
https://v-research.mums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reihane Sabermoghadam Majidzade

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available