

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 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 suprieurs 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 Sciences

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Sponsors / Funding sources

1

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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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Person responsible for updating data

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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