

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The comparison of effectiveness of regular and irregular past tense treatment on sentence production and neural function in patients with agrammatic aphasia

Protocol summary

Study aim

1. Developing tests and tasks for the assessment of regular and irregular verb tense inflection in patients with agrammatic aphasia; 2. Developing a task for the assessment of sentence production; 3. Presenting a Persian verb tense inflection treatment for improving sentence production in patients with agrammatic aphasia.

Design

Applied-fundamental study with single subject experimental design (SSED)

Settings and conduct

After receiving the code of ethics committee from the Tehran University of Medical Sciences, the assessment and treatment tasks will be developed and standardized. Then according to inclusion and exclusion criteria the patients will be selected, assessed and treated. This study will perform in the faculty of rehabilitation at Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

1. Patient symptoms of non-fluent aphasia and aphasia quotient (AQ) between 51 to 75 on the test P-DAB-1 that represents the moderate aphasia; 2. difficulty in the verb tense inflection with less than 50 % in accuracy of regular and irregular verb tense inflection; 3. Patients who are Persian monolingual or are fluent in Persian if they are bilingual.

Intervention groups

The procedure of the ACTION treatment plan is first translated and prepared in Persian. Then, using the program instructions, the patients are treated. Each treatment session begins with the use of therapeutic probs that practices 10 sentences with training verbs in the past tense. Images designed for verbs will be used in the past tense. Assessment of therapeutic and generalization probes is performed every 3 sessions and includes 20 irregular verbs and 20 irregular verbs of the

past tense.

Main outcome variables

Trained and generalization verb tense inflection score; trained and generalization sentence production score; the place of the activated brain area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191112045415N1**

Registration date: **2019-12-08, 1398/09/17**

Registration timing: **prospective**

Last update: **2019-12-08, 1398/09/17**

Update count: **0**

Registration date

2019-12-08, 1398/09/17

Registrant information

Name

vahid valinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 2442 3269

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effectiveness of regular and irregular past tense treatment on sentence production and neural function in patients with agrammatic aphasia

Public title

Effect of verb treatment on sentence production in aggrammatism

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient symptoms of non-fluent aphasia and aphasia quotient (AQ) between 51 to 75 on the test P-DAB-1 that represents the moderate aphasia Earn more than 50% on the subscales of Auditory Comprehension and Continuous Instructions on the P-DAB-1 test Agrammatic sentence production according to descriptive speech (Bird's Nest) and story retelling (three kids) in a way that speech is distorted and non-fluent; the percentage of sentences is reduced, and production of grammatical morphemes and verbs is reduced Difficulty in the verb tense inflection with less than 50 % in accuracy of regular and irregular verb tense inflection The ability to read in the subtest of single word reading in Bilingual Aphasia Test (BAT) Right-handed patient (using Edinburgh scale) Patients who are Persian monolingual or are fluent in Persian if they are bilingual Normal or near normal visual ability Normal or near normal hearing Minimum 9th grade education The patient has a stroke lesion on the left side of the brain, which last at least six months of its occurrence Aged between 18 - 65 years old

Exclusion criteria:

History of neurological and psychological problems, speech and language problems, and learning problems Patients with apraxia Patients with Dysarthria in informal assessment Sign of claustrophobia Pregnant female subjects Subjects who have metal prosthesis

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **6**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Science

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

14179-33791

Approval date

2019-10-22, 1398/07/30

Ethics committee reference number

IR.TUMS.FNM.REC.1398.145

Health conditions studied**1****Description of health condition studied**

aphasia

ICD-10 code

R47.01

ICD-10 code description

Aphasia

Primary outcomes**1****Description**

trained and generalization verb tense inflection score

Timepoint

verb tense inflection assessment for 17 times: 3 baselines, 12 during treatment (once per week for 12 weeks), 14 and 30 days after treatment

Method of measurement

verb tense inflection assessment test

2**Description**

trained and generalization sentence production score

Timepoint

sentence production assessment for 17 times: 3

baselines, 12 during treatment (once per week for 12 weeks), 14 and 30 days after treatment

Method of measurement

sentence production test

3

Description

the place of the activated brain area

Timepoint

brain activation imaging 2 times: once pre-treatment and once after treatment

Method of measurement

functional magnetic resonance imaging

Secondary outcomes

1

Description

sentence production score

Timepoint

sentence production assessment for 17 times: 3 baselines, 12 during treatment (once per week for 12 weeks), 14 and 30 days after treatment

Method of measurement

sentence production assessment test

Intervention groups

1

Description

Intervention group: ACTION treatment will be performed on patients with agrammatic aphasia with a focus on verb learning and its tense inflection in sentence structure. The treatment steps are as follows: Stage 1 Syntactic Level: Recovery of nonverbal verbs in sentence context. a picture is shown with a sentence under it, in which the verb, in infinitival form, is left out. The participant reads the sentence (if necessary with the help of the therapist) and has to fill in the missing verb orally. Step 2: Syntactic-syntactic step: Retrieves the verb in the context of the sentence. As in step 1, but here the verb tense has to be inflected correctly . a picture is shown with a sentence under it, in which the verb, in infinitival form, is left out. The participant reads the sentence (if necessary with the help of the therapist) and has to fill in the missing verb orally. Step 3. Sentence construction: An image is shown to the participant and he or she must make a grammatical sentence.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation, Tehran University of Medical

science

Full name of responsible person

Vahid Valinejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Azar Mehri

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Vahid Valinejad

Position

Ph.D student

Latest degree

Master

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

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