

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The efficacy of constraint language therapy on recovery of Speech & Language deficits in aphasic patients

#### Protocol summary

##### Summary

The present study will investigate the effect of intensive treatment on language skills. Patients consist of aphasia patients with at least one year post-stroke and able to produce one word. In terms of the study design (single-subject), and type of intervention, 2 patients will be entered to treatment for 9 weeks. In the first three weeks without treatment, and after every treatment week (from fourth week to seventh week), Persian Aphasia Test will be tested. Eighth and ninth week will be considered as follow up of effect of treatment. Patients will get treatment from fourth to seventh week, three days per week and for 150 minutes every day and totally 30 hours during the study. Treatment materials include 60 paired black and white pictures that patients should ask each other verbally only. Treatment activity is performed in a group consist 2 patients as well as one clinician.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201107317168N1**

Registration date: **2015-03-25, 1394/01/05**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-03-25, 1394/01/05

##### Registrant information

###### Name

Ahmad Reza Khatoonabadi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7798 2789

##### Email address

khatoonabadi@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2014-11-22, 1393/09/01

##### Expected recruitment end date

2015-04-20, 1394/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of constraint language therapy on recovery of Speech & Language deficits in aphasic patients

##### Public title

The treatment of speech and language disorders in patients with aphasia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: post-stroke>1 year, right handed, age<65, ability to produce single-word at least, normal or corrected to normal of vision and hearing, Exclusion criteria: more than once stroke, brain injury,

##### 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: 2

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Tehran-School of rehabilitation

##### City

Tehran

##### Postal code

-

#### Approval date

2014-08-19, 1393/05/28

#### Ethics committee reference number

92-03-32-24427

## Health conditions studied

### 1

#### Description of health condition studied

Aphasia

#### ICD-10 code

R47.8

#### ICD-10 code description

Other and unspecified speech disturbances

## Primary outcomes

### 1

#### Description

comprehension

#### Timepoint

pre-post- test

#### Method of measurement

test

### 2

#### Description

speaking

#### Timepoint

pre-post test

#### Method of measurement

test

### 3

#### Description

repetition

#### Timepoint

pre-post test

#### Method of measurement

test

## Secondary outcomes

### 1

#### Description

speaking

#### Timepoint

two weeks aftr entrance-one month after entrance

#### Method of measurement

test

### 2

#### Description

repetition

#### Timepoint

two weeks aftr entrance-one month after entrance

#### Method of measurement

test

## Intervention groups

### 1

#### Description

Constraint language therapy-30 hours-three sessions per week

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Speech Therapy Clinic of Tehran university of Medical sciences

##### Full name of responsible person

##### Street address

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

khatoonabadi

**Street address**

Enghelab st., piche shemiran, school of rehabilitation

**City**

tehran

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ahmad Reza Khatoonabadi

**Position**

PhD of speech therapy-Academic member

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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Assistant Professor

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*