

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effectiveness of Mindfulness and Acceptance Group Therapy in comparison with Cognitive Behavioral Group Therapy on severity of social anxiety, quality of life, and verbal fluency in adults with stuttering

#### Protocol summary

##### Study aim

To determine the effectiveness of Mindfulness and Acceptance Group Therapy plus Speech Therapy in comparison to Cognitive Behavioral Group Therapy plus Speech therapy and speech therapy as control group on the severity of social anxiety, quality of life, and verbal fluency in adults with stuttering

##### Design

The present study will be a randomly assigned clinical trial with control group and each group will have 18 participants. First, All three groups will evaluate simultaneously. After the completion of psychotherapy in the treatment groups, all three groups will be reevaluated and speech therapy will begin for all three groups. Upon completion of speech therapy, the evaluations will be done at the end.

##### Settings and conduct

This research will be done in a speech therapy clinic. Each treatment group will consist of 8 to 10 participants randomly assigned and will receive 10 sessions of psychotherapy.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Developmental Stuttering diagnosed by speech pathologist; Fluency in speaking Persian; Age more than 20 years; The level of education above 9th grade (because patients less than 9 years education may have problems with exercises). The social anxiety score must be higher than the average according to SPAI; Exclusion criteria: Psychotic disorders; Dependence or drug abuse; Other psychiatric disorders in such an intensity that have priority for participants and/or participants could not bear group therapy.

##### Intervention groups

Research groups 1. Mindfulness and Acceptance Group Therapy plus speech therapy 2. Cognitive Behavioral Group Therapy plus speech therapy 3. Speech Therapy Group as Control Group

#### Main outcome variables

The severity of social anxiety; Quality of life; Verbal Fluency.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181206041868N1**

Registration date: **2020-03-27, 1399/01/08**

Registration timing: **prospective**

Last update: **2020-03-27, 1399/01/08**

Update count: **0**

##### Registration date

2020-03-27, 1399/01/08

##### Registrant information

##### Name

Soroush Khoshnam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5543 3154

##### Email address

khoshnam.s@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-09-21, 1399/06/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of Mindfulness and Acceptance Group Therapy in comparison with Cognitive Behavioral Group Therapy on severity of social anxiety, quality of life, and verbal fluency in adults with stuttering

**Public title**

Mindfulness and Acceptance and Cognitive Behavioral Group Therapy on adult stuttering

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis: developmental stuttering language: Persian  
Age: more than 20 years Education: more than 8 classes  
Social phobia: moderate and severe

**Exclusion criteria:**

Psychotic disorders Drug dependency disorders Any other primary psychiatric disorders which be so severe that the participant could not tolerate group therapies

**Age**

From **20 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **54**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done using blocked randomization with fixed block sizes. The size of the blocks will be 6 and randomization will be performed using [www.sealedenvelope.com](http://www.sealedenvelope.com). We will have 9 blocks which every one of them has 6 members (n=54) and the members will be replaced by random sequences created by the website. In each block, two participants will be randomly assigned to group A (Mindfulness and Acceptance Group Therapy), two participants to group B (Cognitive Behavioral Group Therapy), and two participants to group C (Control Group).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2019-03-17, 1397/12/26

**Ethics committee reference number**

IR.IUMS.REC.1397.1315

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

adult stuttering

**ICD-10 code**

F98.5

**ICD-10 code description**

Stuttering [stammering: ]Speech that is characterized by frequent repetition or prolongation of sounds or syllables or words, or by frequent hesitations or pauses that disrupt the rhythmic flow of speech. It should be classified as a disorder only if its

**2****Description of health condition studied**

social phobia

**ICD-10 code**

F40.1

**ICD-10 code description**

Social phobias: Fear of scrutiny by other people leading to avoidance of social situations. More pervasive social phobias are usually associated with low self-esteem and fear of criticism. They may present as a complaint of blushing, hand tremor, nausea,

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

severity of social anxiety

**Timepoint**

The evaluation of severity of social anxiety before the start of psychotherapy, after the termination of psychotherapy, after speech therapy, and after 3 month follow up

**Method of measurement**

Social Phobia and Anxiety Inventory

## 2

### **Description**

Quality of life

### **Timepoint**

The evaluation of quality of life before the start of psychotherapy, after the termination of psychotherapy, after speech therapy, and after 3 month follow up

### **Method of measurement**

Overall Assessment of the Speaker's Experience of Stuttering-Adults

## 3

### **Description**

Severity of Stuttering

### **Timepoint**

The evaluation of severity of stuttering before the start of psychotherapy, after the termination of psychotherapy, after speech therapy, and after 3 month follow up

### **Method of measurement**

Stuttering Severity Instrument-3

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

First Intervention group: Mindfulness and Acceptance Group Therapy plus speech therapy (Smooth Speech); This group, in psychotherapy stage, will be under 10 consecutive weekly 2 hrs sessions group therapy which will have two parts; In first 5 sessions, participants will practice Mindful exercises in addition to learning therapy concepts and in second 5 sessions, Vital Actions. After post test evaluation, participants will be under 4 weekly 4 hrs Smooth Speech Therapy which include teaching principal techniques of the therapy and using these techniques gradually from low to high speed until they can use these techniques in reading and daily speech with normal speed range.

#### **Category**

Treatment - Other

### 2

#### **Description**

Second Intervention group: Cognitive Behavioral Group Therapy plus speech therapy (Smooth Speech); This group, in psychotherapy stage, will be under 10 consecutive weekly 2 hrs session group therapy which will have two parts. In first 5 sessions, participants will learn cognitive restructuring and in second 5 sessions practice Behavioral experiments and exposures. After post test evaluation, participants will be under 4 weekly 4 hrs Smooth Speech Therapy which include teaching

principal techniques of the therapy and using these techniques gradually from low to high speed until participants can use them in reading and daily speech with normal speed range.

#### **Category**

Treatment - Other

### 3

#### **Description**

Control group: Speech Therapy (Smooth Speech); After being in waiting list and post test evaluation, participants will be under 4 weekly 4 hrs Smooth Speech Therapy which include teaching principal techniques of the therapy and using these techniques gradually from low to high speed until participants can use them in reading and daily speech with normal speed range.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

School of Behavioral Sciences and Mental Health (Tehran Institute of psychiatry)

##### **Full name of responsible person**

Soroush Khoshnam

##### **Street address**

No, 1, Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue, Tehran

##### **City**

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##### **Province**

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##### **Postal code**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Seyed kazem Malakouti

##### **Street address**

School of Behavioral Sciences and Mental Health., No. 1., Mansoori Alley ., Niyaeesh Ave ., Sattarkhan St., Tehran

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**Phone**

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**Email**

Ertebat.tip@iums.ac.ir

**Web page address**

http://tip.iums.ac.ir/fa?sid=35

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Soroush Khoshnam

**Position**

PhD Student of Clinical Psychology

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Banafshe Gharraee

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Associate Professor

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Ph.D.

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## Person responsible for updating data

**Contact**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

1. Study protocols 2. Clinical study report 3. Statistical Analysis Map 4. Consent Conscious Form

**When the data will become available and for how long**

No more information

**To whom data/document is available**

No more information

**Under which criteria data/document could be used**

No more information

**From where data/document is obtainable**

No more information

**What processes are involved for a request to access data/document**

No more information

**Comments**

The results of this research will be published in the form of Ph.D. thesis and an ISI Article.