

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparing the effectiveness of mindfulness-based stress reduction, meta-cognition, acceptance and commitment training on social anxiety, locus of behavioral control, executive function, self-compassion and emotion regulation in adults who stutter

Protocol summary

Study aim

Determining the effectiveness of mindfulness training based on stress reduction, meta-cognition and acceptance and commitment on social anxiety, source of behavior control, executive function, self-compassion and emotion regulation in adults with stuttering

Design

A controlled, parallel-group, single-blind, randomized clinical trial on 60 patients

Settings and conduct

The study will be carried out in the psychological and speech therapy clinics of Isfahan city. People are selected from among the clients with adult stuttering, and then people are randomly placed in the test and control groups without knowing the allocation of the groups.

Participants/Inclusion and exclusion criteria

Entry requirements: 1- Adults must be between 18 and 40 years old, 2- Stuttering must be confirmed by a speech and language pathologist, 3- They must have at least a diploma, 4- They must not suffer from psychiatric disorders (except social anxiety) at the same time. Conditions of non-entry: 1- He is participating in another psychotherapy. 2- Not interested in cooperation.

Intervention groups

In the intervention groups, the people present receive psychological and behavioral training and learn ways to change their behavior according to their conditions. The control group does not receive any of the psychological and behavioral training of the other three groups.

Main outcome variables

Reducing social anxiety, improving executive functioning, improving the source of behavioral control, increasing self-compassion, increasing emotion regulation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230215057422N1**

Registration date: **2023-03-04, 1401/12/13**

Registration timing: **prospective**

Last update: **2023-03-04, 1401/12/13**

Update count: **0**

Registration date

2023-03-04, 1401/12/13

Registrant information

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Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-11, 1401/12/20

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparing the effectiveness of mindfulness-based stress reduction, meta-cognition, acceptance and commitment training on social anxiety, locus of behavioral control, executive function, self-compassion and emotion regulation in adults who stutter
Public title	Investigating the effect of psychological interventions on stuttering
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: 1- Adults must be between 18 and 40 years old, 2- Stuttering must be confirmed by a speech and language pathologist, 3- They must have at least a diploma, 4- They must not suffer from psychiatric disorders (except social anxiety) at the same time. Exclusion criteria: 1- He is participating in another group psychotherapy, 2- He is not interested in cooperation.
Age	From 18 years old to 40 years old
Gender	Both
Phase	N/A
Groups that have been masked	- Participant - Data analyser
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Stratified randomization: Referees entered into the study will be stratified by gender and then randomly placed in groups. After stratification, a lottery will be used to randomly place people in groups. The lottery will be done by people other than the researcher.
Blinding (investigator's opinion)	Single blinded
Blinding description	The participants are unaware of the allocation of the study groups, as well as the person who is in charge of the data analysis.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	Ethics committee Name of ethics committee Research Ethics Committee of Islamic Azad University- Isfahan(Khorasgan) Branch Street address University Blvd , Arghwanieh , J St. City Esfahan Province Isfahan Postal code 8155139998 Approval date 2022-12-19, 1401/09/28 Ethics committee reference number IR.IAU.KHUISF.REC.1401.289
Health conditions studied	
1	Description of health condition studied Stuttering Disorder ICD-10 code ICD-10 code description
Primary outcomes	
1	Description Social anxiety score in Canver's social anxiety questionnaire Timepoint Before the start of the intervention, after the end of the intervention, 45 days after the end of the intervention Method of measurement To evaluate the social anxiety of the participants, the Social anxiety questionnaire of Conor (2000) will be used.
2	Description The score of locus of control in the locus of control questionnaire Timepoint Before the start of the intervention, after the end of the intervention, 45 days after the end of the intervention Method of measurement To evaluate the locus of control of the participants' behavior, the scale of the Locus of Control of the Behavior of Craig et al. (1984) will be used.
3	Description Executive function score in the executive function

questionnaire

Timepoint

Before the start of the intervention, after the end of the intervention, 45 days after the end of the intervention

Method of measurement

To evaluate the Executive function of the participants, the Behavioral rating questionnaire of executive functions (Brief, 2000, adult comparative version) will be used.

4

Description

The self-compassion score in the Neff self-compassion questionnaire

Timepoint

Before the start of the intervention, after the end of the intervention, 45 days after the end of the intervention

Method of measurement

To evaluate the Self-compassion of the participants, the Neff (2003) Self-compassion scale will be used.

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Description

Emotion regulation score in Gross and John questionnaire

Timepoint

Before the start of the intervention, after the end of the intervention, 45 days after the end of the intervention

Method of measurement

To evaluate the Emotion Regulation of the participants, the emotion regulation questionnaire of Gross and John (2003) will be used.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: mindfulness training based on stress reduction, 8 90-minute training sessions once a week

Category

Treatment - Other

2

Description

The second intervention group: meta-cognitive training, 8 90-minute training sessions once a week

Category

Treatment - Other

3

Description

The third intervention group: acceptance and commitment training, 8 90-minute training sessions once a week

Category

Treatment - Other

4

Description

Control group: without receiving any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Raha comprehensive rehabilitation center

Full name of responsible person

Mohammad Saadatnia

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Azadi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad university Isfahan branch

Full name of responsible person

Isfahan Azad University Research Assistant

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Grant name

Grant code / Reference number

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

No

Title of funding source

Personal financial resources
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
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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
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
A part of individual data, such as the main result, can be shared. The study protocol can be shared in summary.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
The data is accessible for further research on the subject.
From where data/document is obtainable

To receive data and information, call 09130955248 or refer to the address of Isfahan Islamic Azad University, Counseling Department.

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

After checking the validity of the person's employment in a scientific institution or university and knowing the purpose of data access, access will be possible within a few days.

Comments