Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Name
Alireza Salehpoor
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5323 9632
Email address
alirezasalehpoor@khuisf.ac.ir

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
Isfehan

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.

5

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

Street address

Azadi Square

City

Esfahan

Province

Isfehan

Postal code

8168633333

Phone

+98 31 3668 5838

Email

alirezasalehpoor.st@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad university Isfahan branch

Full name of responsible person

Isfahan Azad University Research Assistant

Street address

University Blvd, Arghwanieh, J St.

City

Esfahan

Province

Isfehan

Postal code

8155139998

Phone

+98 31 3535 4001

Fax

+98 31 3535 4060

Email

Info@khuisf.ac.ir

Web page address

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
Islamic Azad University, Isfahan branch

Full name of responsible person
AlirezaSalehpoor

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
No. 16, 44 alley, 45 meter st.

City
Shahreza

Province
Isfehan

Postal code
8615733333

Phone
+98 31 5323 9632

Email
Alirezasalehpoor.st@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University, Isfahan branch

Full name of responsible person
AlirezaSalehpoor

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Psychology

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Phone
+98 31 5323 9632

Email
alirezasalehpoor.st@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University, Isfahan branch

Full name of responsible person
Alirezasalehpoor

Position
PhD Student

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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