

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the Effectiveness of Schema Therapy and Cognitive-Speech Integrative Approach on Emotional Regulation and Negative Emotions and distress tolerance of People with Stuttering

Protocol summary

Study aim

Comparison of the effectiveness of schema therapy and integrated cognitive- speech approach on emotional regulation, negative emotions and anxiety tolerance of people with stuttering

Design

In this study, two experimental groups, Schema Therapy(10), Cognitive-Speech Integrative Approach(10) and one control group were selected by simple and parallel randomaly.

Settings and conduct

The method of this research is quasi-experimental and its design is pre-test, post-test and follow-up plan with the control group. Access will be replaced in three simple random groups. The experimental group will complete the schema therapy and the experimental group will complete the integrated cognitive-verbal approach of emotion regulation questionnaires and positive and negative emotions and distress tolerance (pre-test). Then the experimental groups will be treated and the control group will be on a waiting list. At the end of the post-test is done. In the last sessions, the tests will be followed up. Finally, the data will be collected and statistically analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with stuttering, aged 18 to 30 years. Criteria for non-admission: at least two sessions absent; use of psychotropic drugs, medical and personality disorders, receiving simultaneous drug therapy courses.

Intervention groups

1- Control Schema therapy, 2- Control Integrated cognitive-verbal approach 3- Control group

Main outcome variables

Emotional Regulation, Negative Emotions, distress tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191028045261N1**

Registration date: **2020-08-25, 1399/06/04**

Registration timing: **retrospective**

Last update: **2020-08-25, 1399/06/04**

Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

Kazem Farzin far

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4423 3094

Email address

kfarzinfar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

2020-04-20, 1399/02/01

Actual recruitment end date

2020-07-22, 1399/05/01

Trial completion date

2020-07-22, 1399/05/01

Scientific title

Comparison of the Effectiveness of Schema Therapy and Cognitive-Speech Integrative Approach on Emotional Regulation and Negative → Emotions and distress tolerance of People with Stuttering

Public title

Comparison of the Effectiveness of Schema Therapy and Cognitive-Speech Integrative Approach on Emotional Regulation and Negative → Emotions and distress tolerance of People with Stuttering

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The Participants with stuttering The Participants between 18- 30 years of age The Participants should not have any psychological problems

Exclusion criteria:

Absent more than two sessions, Use of psychotropic drugs, Clinical and personality disorders, Receiving simultaneous drug therapy courses

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The selected people are given a unique code, we write the specific codes of the whole sample size on separate sheets, put them in a box and then take them out of the box one by one and put them in order into experimental group of schema therapy, the experimental group of integrated cognitive-speech approach and the control group. We continue this method until a total of 30 people are randomly divided into three groups.

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

Research Ethics Committee of Islamic Azad University, NEYSHABUR.

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Ebne Yamine Street - Ebne Yamine 40 Corner-Pezhvak Rehabilitation Center

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Approval date

2020-07-31, 1399/05/10

Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1399.006

Health conditions studied

1

Description of health condition studied

People with Stuttering

ICD-10 code

F80.81

ICD-10 code description

Childhood onset fluency disorder

Primary outcomes

1

Description

Emotional regulation variables

Timepoint

- Pre-test: at the beginning of the study (before the intervention) - Post-test: three months after the beginning of intervention - Follow-up test: 2 months after the intervention

Method of measurement

Questionnaire: consist of two subscales of 6-item reassessment and 4-item repression. Participants respond on a 7-point Likert scale from strongly disagree (with a score of 1) to strongly agree (with a score of 7).

2

Description

The negative emotions variable

Timepoint

Post-test, pre-test, follow-up test

Method of measurement

Questionnaire: consist of 10 items. In front of each item, there is a range of 5 options from very low (score 1) and very high (score 5), which is ranked by the subject and the range of scores for each subscale is 10 to 50.

3

Description

The distress tolerance variable

Timepoint

- Pre-test: at the beginning of the study (before the intervention) - Post-test: three months after the intervention - Follow-up test: 2 months after the intervention

Method of measurement

Questionnaire: consist of 15 items and four sub-scales of tolerance (emotional distress tolerance), absorption (absorption of stress by negative emotions), evaluation (mental estimation of distress) and adjustment (adjustment of efforts to relieve distress). The scoring method is scored on a five-point scale (1: strongly agree; 2: slightly agree; 3: neither agree nor disagree; 4: slightly disagree and 5: strongly disagree).

Secondary outcomes

1

Description

Quality of life variable has 4 subscales and an overall score. These subscales include: physical health, mental health, social relationships, environmental health, and an overall score. Initially, a raw score is obtained for each subscale, which must be converted to a standard score between 0 and 100 through a formula. A higher score indicates a higher quality of life

Timepoint

Second Quarter of 2019

Method of measurement

Questionnaire

Intervention groups

1

Description

Schema therapy: Schema therapy consists of a set of techniques that will be performed in a 12-session course of treatment, each session will last 90 minutes (Young et al., 2003).

Category

Behavior

2

Description

Integrated cognitive-speech approach: This therapeutic approach was formulated by Farazi (2013) in a structured manner. Our intervention will be included 12 specific treatment sessions (initial assessment, individual and group therapeutic interventions and final assessment) on stuttering in adults aged 18-30 years in an organized manner. , Purposeful and coherent in four sections, psychological reconstruction of speech and reading, psychological reconstruction of stuttering, cognitive reconstruction and group therapy sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Pezhvak Rehabilitation Center

Full name of responsible person

Fateme Kuhestani

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2

Recruitment center

Name of recruitment center

Newsha Speech Therapy Clinic

Full name of responsible person

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3

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Pezhvak Rehabilitation Center

Proportion provided by this source

50

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

Full name of responsible person

Kazem Farzinfar

Position

Visiting professor at Sabzevar Azad University and Payame Noor

Latest degree

Master

Other areas of specialty/work

Psychology

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Hamid Nejat

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

Part of the participants' personal data in an unrecognizable way related to the main outcome - Informing the study protocol (schema therapy and integrated cognitive-speech approach) in group therapy - Publication of comparison results of analysis and statistical analysis of the study - Informally scan the consent form and share it in the group. - The clinical study report should be provided to the subject based on the conclusions and findings.

When the data will become available and for how long

After the end of the research

To whom data/document is available

public

Under which criteria data/document could be used

With payment terms and in order to research and increase knowledge

From where data/document is obtainable

Neishabour Azad University

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

Login to Neishabour Azad University - Thesis Portal - Department of Psychology - Research Name

Comments