Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Investigating the effectiveness of Phonological Processing Treatment on the fluency of speech of pre-school Persian-speaking children with stuttering: a Randomized Controlled Trial

Protocol summary

Study aim
Investigating the effectiveness of Phonological Processing Treatment on the fluency of speech of pre-school Persian-speaking children with stuttering: a Randomized Controlled Trial

Design
This study is a randomized clinical trial (RCT), with two parallel groups, in an assessor-blinded design. Thirty eligible patients were randomly assigned to two groups, intervention (phonological processing treatment) and control (no treatment), using a double-block randomization method stratified by disease severity.

Settings and conduct
The sample size of Persian-speaking preschool children will be selected in Tehran city. Written consent will be obtained from the participants. Then, three baseline assessments will be performed, and the participants will be assigned to three treatment groups randomly. The intervention group will receive the relevant treatment by the speech and language pathologist for 4 weeks (three sessions per week for a total of 12 sessions). Treatment sessions will be performed in speech therapy clinics in Tehran. After the completion of the intervention and during the one-month follow-up period, each group will be evaluated.

Participants/Inclusion and exclusion criteria
inclusion criteria: 1. Persian-speaking preschool children with stuttering 2. No history of treatment by this treatment methods. 3. Child with stuttering Non inclusion criteria: 1.Children who have incomplete medical documents. 2.Children with onset of stuttering less than 12 months.

Intervention groups
Group 1, phonological processing treatment, and Group 2, control(no treatment)

Main outcome variables
Percentage of stuttered syllables or ss% Severity of stuttering Communication attitude

General information

Reason for update
changing proposal

Acronym

IRCT registration information
IRCT registration number: **IRCT20230219057445N1**
Registration date: **2023-03-08, 1401/12/17**
Registration timing: **prospective**

Last update: **2026-06-14, 1405/03/24**
Update count: **1**

Registration date
2023-03-08, 1401/12/17

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2025-07-21, 1404/04/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of Phonological Processing Treatment on the fluency of speech of pre-school Persian-speaking children with stuttering: a Randomized Controlled Trial

Public title

The effectiveness of Phonological Processing Treatment on the fluency of speech of pre-school Persian-speaking children with stuttering: a Randomized Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least 12 months have passed since the start of stuttering according to the parents' report. Children should be in preschool age (4 to 6 years old). Considering that the participants are selected from the waiting list, they should not have a history of stuttering treatment using the program of gradually increasing the length and complexity of utterance and phonological processing treatment in the 12 months before the start of the study, and other treatments are past, at least one month . The child's stuttering is diagnosed based on all three diagnostic criteria of Yairi and Ambros, meaning that: a. A speech and language pathologist will diagnose the child as stuttering. b. The severity of the child's stuttering on the 8-point SR scale by the parents should be 2 or higher. c. The child should show at least three SLDs in the spontaneous speech sample of 100 syllables. Not neurological damage, language damage, sensory and motor damage ,according to parents' reports and the relevant tests by a speech and language pathologist and medical documents . Not social and emotional disorders according to the results of the Vineland Social Skill Scale by a psychologist. Not using drugs that affect the results according to parents' reports and medical documents. The child should be monolingual and Farsi speaking, according to the parents' report. Not cognitive disorders, according to Forward digit span and Wechsler's non-verbal and cubes tests. Based on the hearing screening test (audiometry of frequencies 2000, 250, 500, 1000 dB), the child should not have a hearing problem.

Exclusion criteria:

The child's medical document is not complete. According to the parents' report and the medical documents, the child has be a disease that affects the results of this study Less than 12 months have passed since the onset of stuttering.

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

For stratified randomization, first, randomization layers are formed based on the severity of stuttering (mild, moderate, severe) (in such a way that layers are formed and randomization is done in each layer separately), assignment of samples to treatment groups is done by the method of random blocks (using double blocks); In this way, according to the sample size of 30 participants and two intervention and control group, we will have 15 participants in each group. The randomization unit is individual, and this randomization was done using statistical software. For allocation concealment, the person who does not perform any of the evaluation and treatment steps, the samples are coded. These codes are placed on opaque sealed envelopes that will not be opened until the treatment begins.

Blinding (investigator's opinion)

Single blinded

Blinding description

Given the nature of the intervention and the control group (which received no treatment), blinding of participants and therapists was not possible. However, the study was designed as an assessor-blinded study. The assessor, who will assess the main outcomes at pretest, posttest, and follow-up, will be unaware of the group assignment of participants. To maintain assessor blinding: 1. Before each assessment session, participants will be strictly reminded not to discuss the type of treatment they received with the assessor. 2. The data analyst will also be blinded to the coding of the groups. 3. The success of assessor blinding will be assessed at the end of the study by asking the assessor directly about their guess at group assignment.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of university of social welfare and rehabilitation sciences

Street address

University of social welfare and rehabilitation sciences, Kodakyar St , Daneshju Blvd

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1985713834
Approval date
2023-03-02, 1401/12/11
Ethics committee reference number
IR.USWR.REC.1401.235

Health conditions studied

1

Description of health condition studied
Stuttering
ICD-10 code
F98.5
ICD-10 code description
Adult onset fluency disorder

Primary outcomes

1

Description
percentage of stuttered syllables or ss%
Timepoint
Three times before the start of the intervention and once after the end of the intervention and once in the follow-up phase one month after the intervention
Method of measurement
A speech sample is taken (the child should speak continuously about a topic while the child's voice is recorded). The amount of the speech sample should be at least 200 syllables. Then the total number of syllables is counted. The number of stuttered syllables is also determined. To obtain the ss%, the number of stuttered syllables is divided by the total number of syllables spoken and multiplied by 100.

2

Description
Stuttering severity(SR)
Timepoint
Three times before the start of the intervention and once after the end of the intervention and once in the follow-up phase one month after the intervention
Method of measurement
To measure this variable, parents complete a stuttering severity form. This form is scored using a Likert-type scoring system from 1 to 10, with 1 being when the child does not stutter at all and 10 being the most severe form of stuttering.

Secondary outcomes

1

Description
Communication attitude
Timepoint
Before the start of the intervention, after the end of the intervention, in the follow-up phase one month after the end of the intervention
Method of measurement
To assess this outcome, the Preschool Children's Communication Attitude Test (KiddyCAT) is used. It is a 12-question questionnaire that the child answers with yes or no.

Intervention groups

1

Description
Intervention group: The recipient of the phonological processing treatment The phonological processing treatment is designed to support the phonological system to produce speech in Persian-speaking children with stuttering. According to literatures, three sources of non-word packets, phonological priming and phoneme monitoring are used to treat phonological processing skills. The non-word packages contain 60 types of non-words that are selected from the non-word repetition test of Yazdani et al. These non-words will be used in non-word packages in 12 sessions. The order of presentation of non-words is from simple to complex so that it starts with two-syllable non-words and gradually the number and complexity of non-words increases until end with the repetition of four-syllable non-words. Phonological priming has been used during picture naming to investigate phonological encoding. In this task, the speaker first says the onset syllable or first consonant and or the offset syllable of the word, and the listener must name the image related to the target word from the images presented. Phoneme monitoring is also used to investigate the encoding of sounds. In this task, a word (in visual or audio form) is presented to the person, Then the speaker presents a phoneme or syllable to the patient or person, the person must answer whether that phoneme or syllable is present in the presented word or not. The given phoneme or syllable can be anywhere in the word. This treatment method aims to strengthen working memory and phonological encoding.
Category
Rehabilitation

2

Description
Control group: During the treatment period, the control group will not receive any treatment, and after the treatment is completed, a speech sample will be taken from this group and then their SS% will be calculated. Parents will also be asked to complete the SR form to determine the severity of stuttering.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center

Speech therapy clinics in Tehran

Full name of responsible person
Akram Valizadeh

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Sponsors / Funding sources

1

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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
University of social welfare and rehabilitation 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
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
According to the conditions of the participants, in the informed consent section, the participants have been given a commitment not to publish their personal information.
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
No - There is not 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
Only outcome data will be published and there are no plans to publish individual participant data.
When the data will become available and for how long
From 2026 to 2 years after the article was published
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
The data will be used only in educational, research and therapeutic situations
From where data/document is obtainable
first author
What processes are involved for a request to access data/document
The applicant can submit his application via email or by visiting the University of Social Health and Rehabilitation Sciences , Speech Therapy Department
Comments