

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Oct 2026

Comparison of the efficacy of Fluency Rules Program with and without parent-child interaction training in pre-school children who stutter

Protocol summary

Study aim

This study aimed to evaluate the efficacy of the Fluency Rules Program (FRP) with parent-child interaction training in the experimental group and compare it with the FRP without parent-child interaction training in the control group.

Design

This study consists of the experimental group and the control group and the sample size in each group is 26 individuals. All eligible individuals will be divided into two groups using the Block Randomization Method with the size of 4 blocks with and without parent-child interaction training. To generate a randomization list the online randomization service Sealed Envelope Ltd. 2019 will be used.

Settings and conduct

At first, the preschool children with stuttering who go to the clinics of speech-therapy in Yazd or are on a waiting list will be evaluated by a speech-language pathologist. According to the results of the stuttering severity test, if the child is diagnosed with stuttering and meets other inclusion criteria, he / she will be included in the study. The subjects will be divided into Fluency Rules Program (FRP) groups with/without parent-child interaction training. Therapy in each group consists of two 45-minute sessions per week for 3 months.

Participants/Inclusion and exclusion criteria

Inclusion: Children with stuttering in the age range of 3 to 7 years Passing six months or more since the onset of stuttering . Exclusion: Use of any psychiatric medications The hearing impairment, speech-language, and neurological disorders

Intervention groups

A therapy session in the control group consists of working with the child according to the instructions of the Fluency Rules Program (FRP) . A therapy session in the experimental group consists of working with the child according to the instructions of the FRP, using the parent-centered and interactive strategies.

Main outcome variables

In this study, the severity of stuttering is the main outcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210403050816N1**

Registration date: **2021-10-31, 1400/08/09**

Registration timing: **prospective**

Last update: **2021-10-31, 1400/08/09**

Update count: **0**

Registration date

2021-10-31, 1400/08/09

Registrant information

Name

Ebrahim Barzegar Bafrooei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of Fluency Rules Program with and without parent-child interaction training in pre-school children who stutter

Public title
The effects of parent-child interaction training on children's stuttering severity.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Children with stuttering in the age range of 3 to 7 years old. Having stutter at a speech-language pathologist's discretion based on the Stuttering Severity Instrument-Third Edition (SSI-3) Passing six months or more since the onset of stuttering. The child is monolingual and Persian-speaking. Not having any other treatment plan for stuttering while studying Literate parent The parent has enough time and necessary cooperation to read book and educational video files
Exclusion criteria:
 Use of any psychiatric medications as reported by parents and clients' record The hearing impairment, speech-language, and neurological disorders

Age
From **3 years** old to **7 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
All eligible individuals will be divided equally into two groups of the Fluency Rules Program with and without parent-child interaction training using a simple block randomization method with a size of four blocks (including two individuals in each group). The online randomization service Sealed Envelope Ltd will be used to generate the randomization allocation sequence. sequentially numbered, opaque, sealed envelopes (SNOSE) will also be used to conceal the allocation.

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 University of Social Welfare and Rehabilitation Sciences

Street address

No. 14, 25rd Street, Resalat Avenue, Yazd Town

City

Yazd

Province

Yazd

Postal code

8963116116

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

IR.USWR.REC.1399.260

Health conditions studied

1

Description of health condition studied

Stuttering

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The child's stuttering severity score is an initial outcome and it is determined by using the stuttering severity instrument test.

Timepoint

The severity of children's stuttering will be measured before the intervention and at the end of the study.

Method of measurement

The stuttering measurement instrument of this study is the Stuttering Severity Instrument (SSI), which determines the severity of stuttering.

Secondary outcomes

1

Description

The impact of stuttering on your child

Timepoint

The impacts of stuttering on the child will be assessed at the beginning and end of the study.

Method of measurement

It will be measured by using the Palin Parent Rating Scales.

2

Description

The impact of stuttering on parents

Timepoint

The impact of stuttering on parents will be assessed at the beginning and end of the study.

Method of measurement

It will be measured by using the Palin Parent Rating Scales.

3

Description

Parents' knowledge and confidence about managing stuttering

Timepoint

It will be assessed at the beginning and end of the study.

Method of measurement

It will be measured by using the Palin Parent Rating Scales.

Intervention groups

1

Description

Intervention group: A treatment session in the experimental group includes working with the child according to the instructions of the Fluency Rules Program (FRP) using parent-centered and interactive strategies. The parent-child interaction training package will be provided to the parents in the experimental group. At the beginning of each session, the therapist uses parent-centered strategies to train the parents about stuttering and controlling their concerns, then trains the interactive strategies for the parents. At the end of the session, the child will be treated according to the instructions of the FRP. Treatment in this group includes two 45-minute sessions per week for three months

Category

Rehabilitation

2

Description

Control group: A treatment session in the control group includes working with the child according to the instructions of the Fluency Rules Program (FRP). Treatment in this group includes two 45-minute sessions per week for three months.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Negah No Speech Therapy Clinic

Full name of responsible person

Shahab Hosseini

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No. 1, 12rd Street, Jomhoori Avenue, Yazd Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamidreza Khorram Khorshid

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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

University of social welfare and rehabilitation sciences

Full name of responsible person

Ebrahim Barzegar

Position

PhD student
Latest degree
Master
Other areas of specialty/work
Speech therapy
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The individual data of the research participants: All of the data could be shared after making the individuals unidentifiable. Study execution protocol: The detailed study execution protocol could be shared in both the control and experimental groups. Statistical analysis map: The statistical analysis plan of the present study could be published without any restrictions. Informed consent form: The informed consent form which is designed for this study could be shared after making the individuals unidentifiable. Clinical reports of this study: After the end of the study, the clinical reports which are related to this study could be published without any restrictions. Analysis codes of this study: After the end of the study, the analysis codes of this study could be published without any restrictions. Data coding systems: After the study, the data coding systems could be published without any restrictions.

When the data will become available and for how long

All documents related to this study are available 6 months after the publication of the results.

To whom data/document is available

Academic researchers and speech-language pathologists could request the documentation of this study.

Under which criteria data/document could be used

There are no restrictions on using the data and analysis. Any research or clinical use of the data is allowed.

From where data/document is obtainable

first author:slp.barzegar@yahoo.com Corresponding Author:adarouie@hotmail.com

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

The applicant must send the application to the e-mail of the lead or the corresponding author. After reviewing the email and consulting with the research team, the files will be provided to the applicant within 10 days.

Comments