Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Effectiveness of fluency rules program in preschool age children with stuttering:A single subject study

Protocol summary

Study aim
Effectiveness of fluency rules program in preschool age children with stuttering:A single subject study

Design
This study is a clinical trial without a control group, which will be carried out with a single subject design on children with stuttering before elementary school age.

Settings and conduct
The rehabilitation clinic of Semnan University of Medical Sciences, located in Semnan city, will be conducted on 3 stuttering participants before elementary school who meet the inclusion criteria. And intervention sessions will be held for 30 minutes and 2 days a week.

Participants/Inclusion and exclusion criteria
The child has a stutter and is between 5 and 7 years old and speaks Persian. Must not be bilingual. Must not have mental retardation, hearing problems, or psychiatric disorders such as autism. Also, must not have a history of treatment with the program of mental laws, and the conditions for not entering the study include: the child suffering from any type of disease that prevents cooperation in the continuation of the intervention. . Non-cooperation of parents to continue the research and the patient should use other methods of stuttering treatment at the same time.

Intervention groups
This intervention will be implemented on 3 participants, it consists of 3 stages. In the baseline stage, the child's performance is recorded, then we implement the intervention, and after the intervention stage is completed, it enters the withdrawal phase and the child's performance is determined again

Main outcome variables
Measuring the severity of stuttering with the help of SS and SR

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220813055676N1**
Registration date: **2022-08-20, 1401/05/29**
Registration timing: **prospective**

Last update: **2022-08-20, 1401/05/29**
Update count: **0**

Registration date
2022-08-20, 1401/05/29

Registrant information

Name
Mozhgan Asadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3336 2190

Email address
mozhgan.asadist@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of fluency rules program in preschool age children with stuttering:A single subject study

Public title
Effectiveness of fluency rules program with stuttering.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The child has a stutter. Be in the age range of 4 to 7 years and speak Farsi Not bilingual. He does not have mental retardation, hearing problems, and psychiatric disorders such as autism. He does not have a history of treatment with the psychological rules program. The conditions for not entering the study include: the child suffering from any kind of disease that prevents cooperation in the continuation of the intervention. Non-cooperation of parents to continue the research.
Exclusion criteria:
The child is in school The child is being treated with other treatment methods for stuttering.
Age
From **4 years** old to **7 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **4**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Semnan University of Medical Sciences
Street address
Faculty of Rehabilitation., Senman University of Medical., 5KM of Damghan road,. Semnan., Iran
City
Semnam
Province
Semnan
Postal code
3513138111
Approval date
2022-06-27, 1401/04/06
Ethics committee reference number
IR.SEMUMS.REC.1401.080

Health conditions studied

1

Description of health condition studied
Stuttering
ICD-10 code
F80.81
ICD-10 code description
Childhood onset fluency disorder

Primary outcomes

1

Description
The percentage of stuttered syllables (SS), which is the number of times a child stutters, which is calculated per minute.
Timepoint
Before starting the intervention, during the implementation of the treatment and after the completion of the treatment, it is in the withdrawal phase.
Method of measurement
The severity of stuttering in this study is measured with the help of the Stuttering Severity Instrument (SSI-4)

Secondary outcomes

1

Description
The severity of stuttering will be determined with the help of the Stuttering Severity Tool (SSI-4) (based on a 15-minute speech sample of the child during free play with the therapist) and the examination of the child's communication attitude will be done with the help of the Kiddy CAT
Timepoint
Before starting the intervention, during the implementation of the treatment and after the completion of the treatment, it is in the withdrawal phase
Method of measurement
The severity of stuttering in this study is measured with the help of the Stuttering Severity Tool (SSI-4)

Intervention groups

1

Description
A single group consists of 3 preschool children with stuttering for whom the psychological rules program is carried out for their treatment. Depending on which of these rules the child has broken, the relevant law will be taught to the child. And the level of stuttering will be

checked before, during and at the end of the program. They will be videotaped to be used later to determine the severity of the child's stuttering. Therapy sessions will be held 2 days a week for 30 minutes. The intervention phase will be until the severity of stuttering is reduced to SR zero and one for three consecutive weeks, with at least 4 points in the last week. Zero SR based on daily parent reports will continue to exisT

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabatabai Rehabilitation Clinic, Semnan

Full name of responsible person
Dr.Mozhgan.Asadi

Street address
Quds St., Semnan

City
Semnan

Province
Semnan

Postal code
3513138111

Phone
+98 23 3365 4180

Email
www.mozhgan.asadist@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Dr.Majid Mir Mohammad KHani

Street address
Faculty Rehabilitation،, Semnan University of Medical Sciences،, 5km Damghan roads،, Semnan

City
Semnan

Province
Semnan

Postal code
3513138111

Phone
+98 23 3365 4180

Email
majidmirmohammadkhani@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Semnan University of Medical 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
Semnan University of Medical Sciences

Full name of responsible person
Dr.Mozhgan.Asadi

Position
Member Faculty

Latest degree
Ph.D.

Other areas of specialty/work
Speech therapy

Street address
Faculty of Rehabilitation., Semnan University of Medical Sciences., 5km Damghan road., Semnan., Iran es., 5km Damghan road., Semnan., Iran

City
Semnan

Province
Semnan

Postal code
3513138111

Phone
+98 23 3365 4180

Email
www.mozhgan.asadist@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Dr.Mozhgan.asadi

Position
Member Faculty

Latest degree
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Other areas of specialty/work
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City
Semnan

Province
Semnan

Postal code
3213138111
Phone
+98 23 3365 4180
Email
www.mozhgan.asadist@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr.Mozhgan.Asadi
Position
Member Faculty
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Other areas of specialty/work
Speech therapy
Street address
Faculty of Rehabilitation., Semnan University of Medical Sciences., 5km Damghan road., Semnan., Iran es., 5km Damghan road., Semnan., Iran
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Phone
+98 23 3365 4180
Email
www.mozhgan.asadist@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be 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
it's not specified yet
When the data will become available and for how long
it's not specified yet
To whom data/document is available
speech and language pathologist
Under which criteria data/document could be used
it's not specified yet
From where data/document is obtainable
Executors of the plan
What processes are involved for a request to access data/document
it's not specified yet
Comments