

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effects of melodic intonation therapy in decreasing autistic symptoms on 7-10 year old Persian male children

Protocol summary

Summary

1) Objectives: The aim of the study is investigating the effectiveness of Melodic Intonation Therapy (MIT) on Persian autistic children's speech. (2) Design: An easy version of Melodic Intonation Therapy (MIT) based on Albert, et al.'s model (1973), adapted for Persian language is designed. All participants undergone MIT for 48 sessions, each 20-30 minute during 16 weeks. A single-subject design is employed to provide proof of concept of this intervention as a quasi-experimental study. All subjects are selected as available samples. (3) Setting and conduct: After a pilot, case study, on a 10 years old boy for one month, 13 subjects are selected for the main study in the Autism Center of Isfahan. (4) Participants: 13 Male; 7-10 year- old; Monolingual; Persian speaker; Right-handed; With a diagnosis of autism (diagnosis made by pediatric neurologists or psycho-neurologist prior to enrollment); Without major medical conditions other than ASD, Previously received speech therapy at least 12 months, Receptive language skills of >20 months, based on the Newsha developmental scale(Persian), (5) Intervention: Melodic intonation therapy. (6) Main outcome measures (variables): Speech quality variables such as; MLU (Mean Length of Utterance);speech rate, number of verbs and echolalia are measured after phonetic transcription. NEWSHA; Persian developmental scale is used for assessing the receptive and expressive language and speech skills.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091614684N1**

Registration date: **2013-11-16, 1392/08/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-16, 1392/08/25

Registrant information

Name

Neda Ferdosi

Name of organization / entity

Payame Noor University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2011-10-22, 1390/07/30

Expected recruitment end date

2012-02-19, 1390/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of melodic intonation therapy in decreasing autistic symptoms on 7-10 year old Persian male children

Public title

Melodic Intonation Therapy in the Persian Autistic Children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male; 7-10 years; Monolingual; Persian speaker; Right-handed; With a diagnosis of autism (diagnosis made by pediatric neurologists or psycho-neurologist prior to enrollment; Without major medical conditions such as motor disabilities (e.g., cerebral palsy or tuberous sclerosis), Sensory disabilities (e.g., blindness or deafness), Genetic disorders (e.g., Down Syndrome) other than ASD; Previously received speech therapy at least 12 months; Receptive language skills of >20 months, based on the Newsha developmental scale(Persian); The ability to sit in a chair for more than 15 minutes; follow one-step commands without prompting; and imitate simple gross motor and oral motor movements such as clapping their hands; stomping their feet, and opening their mouth. exclusion criteria: New interventions based on prescription of child's physician.

Age

From **7 years** old to **10 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **13**

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

Ethics committee of Payame Noor University

Street address

Central Organization of Payame Noor University.
Nakhl St, Mini city Blvd.

City

Tehran

Postal code

Approval date

2011-04-25, 1390/02/05

Ethics committee reference number

00

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84

ICD-10 code description

Pervasive developmental disorders. Childhood autism A type of pervasive developmental disorder that is defined by: (a) the presence of abnormal or impaired development that is manifest before the age of three years, and (b) the characteristic type of abno

Primary outcomes

1

Description

Echolalia

Timepoint

Before MIT(T1), After MIT(T2) (4 months after T1)

Method of measurement

Record of Speech, Phonetic Transcription, Morpheme Count, Calculating echolalia percentage in speech output

2

Description

Mean Length of Utterance (MLU)

Timepoint

Before MIT(T1), After MIT(T2) (4 months after T1)

Method of measurement

Record of Speech, Phonetic Transcription, Morpheme Count, It is calculated by collecting 100 utterances spoken by a child and dividing the number of morphemes by the number of utterances.

3

Description

Speech Rate

Timepoint

Before MIT(T1), After MIT(T2) (4 months after T1)

Method of measurement

Record of Speech, Calculating word per minute in speech output

4

Description

Verb number average in sentence.

Timepoint

Before MIT(T1), After MIT(T2) (4 months after T1)

Method of measurement

Record of Speech, It is calculated by collecting the utterances spoken by a child and dividing the number of verbs by the number of utterances in speech output.

Secondary outcomes

1

Description

vowel frequency

Timepoint

Before MIT(T1), after MIT(T2) 4 months after T1.

Method of measurement

Record of single vowels, assessing fundamental frequency by using Praat software of acoustic phonetics.

2

Description

vowel Intensity

Timepoint

Before MIT(T1), after MIT(T2) 4 months after T1.

Method of measurement

Record of single vowels, assessing intensity by using Praat software of acoustic phonetics.

Intervention groups

1

Description

Intervention: Melodic Intonation Therapy (Speech Therapy). Each participant will observe as his control. A single-subject design.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Autism Centre of Isfahan

Full name of responsible person

Mansureh Hemmatian

Street address

Shahin St, Imam Khomeini Ave, Jomhuri Sq.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Payame Noor University

Full name of responsible person

Ali Khodashahi

Street address

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City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Payame Noor University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hassan Ashayeri

Position

Professor, Dr.MD. of Neuropsychiatry

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty