

# 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)

###### Phone

+98 21 2294 9454

###### Email address

ferdosi@phd.pnu.ac.ir

##### 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

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

##### 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

##### Street address

Nezam St, Shahnazari St, Madar Sq, Mirdamad Ave.

##### City

Tehran

##### Postal code

##### Phone

+98 21 2222 1577

##### Fax

+98 21 2222 0946

##### Email

ashayerih.neuroscientist@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Payame Noor University

##### Full name of responsible person

Neda Ferdosi

##### Position

Ph.D. of Linguistics

##### Other areas of specialty/work

##### Street address

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

##### City

Tehran

##### Postal code

##### Phone

+98 21 2294 9454

##### Fax

+98 21 2294 3242

**Email**

n.ferd2000@gmail.com; n.ferd2000@yahoo.com;  
ferdosi@phd.pnu.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Payame Noor University

**Full name of responsible person**

Neda Ferdosi

**Position**

Ph.D. of Linguistics

**Other areas of specialty/work**

**Street address**

Linguistics Department, Central Organization of  
Payame Noor University, Nakhli St, Mini city Blvd.

**City**

Tehran

**Postal code**

**Phone**

+98 21 2294 9454

**Fax**

**Email**

n.ferd2000@gmail.com ; n.ferd2000@yahoo.com;  
ferdosi@phd.pnu.ac.ir

**Web page address**

**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*