

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The effect of Functionally Oriented Music Therapy on motor and cognitive skills in children with specific learning disability

Protocol summary

Study aim

Evaluating the effect of the Functionally Oriented Music Therapy on motor and cognitive skills in children with specific learning disability.

Design

Randomized clinical trial with a with blinded outcome assessment

Settings and conduct

Through interview with parents whose children has been registered in learning disability centers , samples with inclusion criteria and a letter of consent will be selected. Using random digit tables, samples will be divided into experimental and control group. Assessments includes Clinical Observation of Motor and Postural Skills, Bruininks-Oseretsky Test of Motor Proficiency, Wechsler Memory Scale and Continuous Performance Test will be taken from 26 participants. Behavior Rating Inventory of Executive Function will be answered by parents. The assessments is conducted by blinded/trained elevators.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Specific learning disability diagnosed by experts, Age 7- 11 years, Education at least fifth grade and ability of reading, writing and speaking in Persian for respondent parent. Exclusion criteria: Untreated physical, visual and auditory impairments, Co-morbidity of attention deficit-hyper activity disorder, Co-morbidity of problem behaviors

Intervention groups

The experimental group will receive the Functionally Oriented Music Therapy (FMT) in which specific melody structures are played on a piano by the therapist and the client plays on certain drums and cymbals. Treatment will be implemented individually and there is no oral instruction. The sessions will take 4 months, 16 sessions and 1 day per week for 20 minutes per session. The control group will not receive any intervention.

Main outcome variables

attention, memory, executive function, motor-postural skills

General information

Reason for update

Acronym

FMT

IRCT registration information

IRCT registration number: **IRCT20100224003419N5**

Registration date: **2020-04-05, 1399/01/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-05, 1399/01/17**

Update count: **0**

Registration date

2020-04-05, 1399/01/17

Registrant information

Name

Mitra Khalafbeigi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7124

Email address

khalafbeigi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-17, 1398/09/26

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Functionally Oriented Music Therapy on motor and cognitive skills in children with specific learning disability

Public title

Functionally Oriented Music Therapy in Learning disability

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Specific learning disability diagnosed by expert Age 7- 11 years Education at least fifth grade and ability of reading, writing and speaking in Persian for respondent parent

Exclusion criteria:

Untreated physical, visual and auditory impairments Co-morbidity of attention deficit-hyper activity disorder Co-morbidity of problem behaviors

Age

From **7 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is convenience and based on inclusion criteria. Then samples are assigned randomly into two groups of experimental and control through random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assessors who are allocated to gather data.

Placebo

Not used

Assignment

Parallel

Other design features

Functionally Oriented Music Therapy, FMT, belongs to Sweden. It will be utilized with the permission of its developers and by providing the maximum principles of original version out of Sweden.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran University of Medical Sciences

Street address

School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

15459-13487

Approval date

2019-12-16, 1398/09/25

Ethics committee reference number

IR.IUMS.REC.1398.974

Health conditions studied**1****Description of health condition studied**

Specific Learning Disability

ICD-10 code

R48

ICD-10 code description

Dyslexia and other symbolic dysfunctions, not elsewhere classified

Primary outcomes**1****Description**

Changes in sustained attention, ability to maintain consistent behavioral response during a repetitive or continues task.

Timepoint

Before and after the intervention

Method of measurement

Continuous performance Test (CPT), software version

2**Description**

Changes in memory capacity (7+/-2)

Timepoint

Before and after the intervention

Method of measurement

Wechsler Working Memory Scale (WMS)

3**Description**

Changes in executive function

Timepoint

Before and after the intervention

Method of measurement

Behavior Rating Inventory of Executive Function(BRIEF)

4**Description**

Changes in motor- postural skills

Timepoint

Before and after the intervention

Method of measurement

Clinical Observation of Motor and Postural Skills (COMPS)

5**Description**

Changes in gross and fine motor skills

Timepoint

Before and after the intervention

Method of measurement

Bruininks-Oseretsky Test of Motor Proficiency (BOT), Sub scale of gross and fine motor skills

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This group will receive FMT approach in which specific melody structures are played on acoustic piano by the therapist to stimulate the overall natural development of fundamental function in the body of the client. Treatment is implemented individually and the client will be developed in motor, cognitive, perception and emotion areas by playing on certain drums and cymbals. The approach has no oral instruction at all, instead melody structures are used to stimulate the client's natural development. The length of each session is 20 minutes which will be done for 16 sessions weekly.

Category

Treatment - Other

2**Description**

Control group: This group will not receive any specific intervention

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

The center of education and rehabilitation for specific learning disabilities 1, Due to the SNEO

Full name of responsible person

Mrs. Khazraei

Street address

No. 289, Farhang Square, Sayed Jamal al-Din Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

ناموجود

Phone

+98 21 8806 0329

Email

seo@medu.ir

2**Recruitment center****Name of recruitment center**

The center of education and rehabilitation for specific learning disabilities 2, Due to the SNEO

Full name of responsible person

Mrs. Afshar

Street address

No. 3, Rose Alley, South Golestan, Movahed St, Artesh Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

ناموجود

Phone

+98 21 2228 3888

Email

seo@medu.ir

3**Recruitment center****Name of recruitment center**

The center of education and rehabilitation for specific learning disabilities 3, Due to the SNEO

Full name of responsible person

Mrs. Abedini

Street address

No. 12, Oji Alley, Azizi Street, Pirooz Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

ناموجود

Phone

+98 21 3325 0021

Email

seo@medu.ir

4**Recruitment center****Name of recruitment center**

The center of education and rehabilitation for specific learning disabilities 4, Due to the SNEO

Full name of responsible person

Mrs. Soleymani

Street address

No. 369, West Yadgar Street, Takhti St, Moallem Blvd,

Yaft Abad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

ناموجود

Phone

+98 21 6610 2055

Email

seo@medu.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Vice-chancellor for Research

Street address

School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

15459-13487

Phone

+98 21 2222 7124

Email

kamyab.m@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Samaneh Karamali Esmaili

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

15459-13487

Phone

+98 21 2222 7124

Email

esmaeili.s@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mitra Khalafbeigi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, Tehran, Iran

City

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Province

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Postal code

15459-13487

Phone

+98 21 2222 7124

Email

khalafbeigi.m@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mitra Khalafbeigi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

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School of Rehabilitation Sciences, Iran University of
Medical Sciences, Maddadkaran St., Shahid Nazari St.,
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Province

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Postal code

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Phone

+98 21 2222 7124

Email

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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

There is no more 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

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 data that are related to primary outcome will be
available.

When the data will become available and for how long

Immediately after publication.

To whom data/document is available

Researchers working in academic institutions.

Under which criteria data/document could be used

With permission of developers of approach in Sweden.

From where data/document is obtainable

The head director of FMT education center. Elin
Svanström info@fmtutbildning.se

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

Sending e-mail

Comments