

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of emotions label training to Autism children with high-function on their Quality of life and Mother-Child Relation

Protocol summary

Study aim

The effect of emotions label training in autism children with high-function on their quality of life and mother-child relation.

Design

This study is a single-group and targeted sampling. The number of samples is 5 high-function autistic children. Intervention will have 2 general phases. Basic phase and test phase. The first phase will be without intervention and only the questionnaires will be completed, and the second phase will be in two stages, and the Lets Face It educational software and emotions labeling will be taught.

Settings and conduct

One of The autism schools in Tehran city- first phase will be without intervention and only the questionnaires will be completed, and the second phase will be in two stages, and the Lets Face It educational software and the emotions labeling will be taught.

Participants/Inclusion and exclusion criteria

Having high-performance autism -Ability to respond to linguistic instructions -Calendar age between 8-12 years -Mental Intelligence above 80 -No training for emotional control - Mother and child tendency to participate in the study / lack of vision and hearing problem

Intervention groups

Includes two phases of software training and emotion labeling.

Main outcome variables

Quality of life; Mother-Child Relationship

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180429039464N4**

Registration date: **2019-02-19, 1397/11/30**

Registration timing: **retrospective**

Last update: **2019-02-19, 1397/11/30**

Update count: **0**

Registration date

2019-02-19, 1397/11/30

Registrant information

Name

Marzieh Hasanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4413

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-26, 1397/10/05

Expected recruitment end date

2019-01-12, 1397/10/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of emotions label training to Autism children with high-function on their Quality of life and Mother-Child Relation

Public title

Effect of emotions label training in Autism children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

having Autism with high-function be able react to Language instructions age in 8-12 years IQ upper than 80 Not having emotions control training Mother and child desire to participate in intervention No having vision and hearing problems

Exclusion criteria:

Having moderate autism History of non-collaboration with a researcher in previous studies The accompanying illnesses disrupt the normal life situation

Age

From **8 years** old to **12 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **5**

Actual sample size reached: **5**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

This study is done with the single-subject design, according to different sources, the number of samples is between 2-10 and without computational formulas, as well as these types of designs are single-grouped and to study the effect of different education in children Autism has many uses in and out of the country.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Science

Street address

Faculty of Nursing & Midwifery, East Norsrat(Mirkhani) St, Enghelab St

City

Tehran

Province

Tehran

Postal code

45718-74496

Approval date

2018-08-29, 1397/06/07

Ethics committee reference number

IR.TUMS.FNM.REC.1397.089

Health conditions studied

1

Description of health condition studied

Autism with high-function

ICD-10 code

F84.5

ICD-10 code description

Asperger's syndrome

Primary outcomes

1

Description

Quality of life in children with High Function Autism

Timepoint

Questionnaire will be measured three, two and one weeks before the test, as well as the first day of the test, two weeks after the start of the test and the final day of the test

Method of measurement

Children's Quality of Life Questionnaire (PedsQL)

2

Description

Mother-child relation in autism children with high-function

Timepoint

Questionnaire will be measured three, two and one weeks before the test, as well as the first day of the test, two weeks after the start of the test and the final day of the test

Method of measurement

Mother-child relation questionnaire (MCRE)

Secondary outcomes

empty

Intervention groups

1

Description

Lets Face It (LFI) Educational Software Training performance: This software will be taught for each child for 3 hours and 15 hours total. In this way, the software is trained by a Lap Top devise in the presence of child's instructor in an appropriate room, and the score will be recorded after the game is completed. Emotions label performance: Test will include 3 happy, sadness and nervousness emotion cards and 40 situation cards related to these emotional states and include of 2 steps. At each stage, all children, a child instructor and researcher will be in the room. 1- several emotional situations cards will be placed on the board. Then an emotional card will be given to one of the children in

random and will be asked to identify the associated emotional state from the cards on the board. Then the emotions situation cards are replaced and the emotional card will be changed, and the same process will be implemented for the next child. 2- In reverse of previous step, emotion cards will place on board and request from child to find the emotional situation related to it. Each step is performed in 3 rounds and each round consist of 40 tests for each child. All emotions label training will be performed within 30 hours. Each child is trained for 6 hours in total.

Category

Treatment - Other

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

Peyk Honar School of Autism

Full name of responsible person

Mrs Zeinab Chavosh Zadeh

Street address

44 west st, Kalantary Square, Yosef Abad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Room No 604, Floor 6, Central Building of Tehran University of Medical Sciences, Corner of Ghods Street, Keshavarz Blvd

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr Marzieh Hasanpour

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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School of Nursing and Midwifery of Tehran, Mirkhani St, Tohid Square

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Marzieh Hasanpour

Position

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Marzieh Hasanpour

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street addressSchool of Nursing and Midwifery of Tehran, Mirkhani
St, Tohid Square**City**

Tehran

Province**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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