Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 21 6105 4413

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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
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44 west st, Kalantary Square, Yosef Abad
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58159-65849
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Kardan Moghadam
Street address
Room No 604, Floor 6, Central Building of Tehran University of Medical Sciences, Corner of Ghods Street, Keshavarz Blvd
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Fax
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rmo@tums.ac.ir
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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Person responsible for updating data

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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