

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of traditional face computer training on children with autism on mother-child relationships and parental competence in autism centers

Protocol summary

Study aim

Comparison of the effect of traditional and computerized emotional facial education training on children with autism on mother-child relationships and parental competence

Design

Clinical trial with two intervention groups and one control group with parallel, two-way blind groups, randomized

Settings and conduct

This study will be conducted in autism centers affiliated with Hamedan University of Medical Sciences in two blind directions, the person who completes the questionnaires and the person who will analyze the data will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 6-15 years old with moderate to severe autism who have the ability to work with the computer at an early age and whose mothers are able to participate in the child's education. Exclusion criteria: Absence of children in three sessions or more during training

Intervention groups

The traditional intervention group includes children with autism who will use 40 images related to different situations to teach emotional facial recognition, and the child must choose the appropriate emotional state with the help of the researcher and the mother. When it recognizes one image correctly, it is encouraged and the next image is displayed. However, in case of a wrong answer, the researcher points out that "try again" and an indirect reference is given to the correct answer. The computer intervention group includes children with autism who will be taught the Let's Face It educational software (6 stages of play) in such a way that each child is trained by the researcher together with the mother and plays all the stages of the software independently. At the end of all games, the child's score will be estimated. The control group will receive routine training.

Main outcome variables

Mother-child relationship: Parental competence

General information

Reason for update

Complete the information in the sampling section

Acronym

IRCT registration information

IRCT registration number: **IRCT20190703044082N2**

Registration date: **2020-06-06, 1399/03/17**

Registration timing: **prospective**

Last update: **2020-07-26, 1399/05/05**

Update count: **1**

Registration date

2020-06-06, 1399/03/17

Registrant information

Name

Fateme Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of traditional face computer training on children with autism on mother-child relationships and parental competence in autism centers

Public title

Comparison of the effect of traditional and computerized emotional facial education training on children with autism

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Based on the DSM-IV Manual of Psychiatric Disorders, according to a psychiatrist's assessment of a child and adolescent child with high and moderate performance autism In the pediatric medical records, they received 22 scores from the instructor or 19 scores from the mother based on the Autism Scale questionnaire Has the ability to understand and practice experimental exercises Lack of mental retardation or other known physical, cognitive, evolutionary-disease Lack of visual impairment Their mothers are satisfied with the child's participation in the study Their mothers are able to participate in the child's education and participate in the study Ability to work with computers at elementary level

Exclusion criteria:

Absence of children in three sessions or more during training

AgeFrom **6 years** old to **15 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Parallel block random allocation will be used to randomly allocate high and moderate performance autistic children to traditional, computerized and control groups. Write the names of the three groups on a piece of paper and randomize them and specify the order of sampling. For random allocation of samples in three traditional, computerized and control groups, 20 blocks of 6 blocks will be used as random block allocation. Thus, the letter A for the computer group, the letter B for the traditional group and the letter C for the control group will be considered. On the pieces of paper, WILL write the blocks and put them in the envelope and we will randomly remove the the pieces of paper. next according to the

probable order of sampling will start.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who completes the questionnaires will be blinded by the allocation of individuals in the intervention groups. In addition, the person who analyzes the data will be blinded to the allocation of individuals to the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research ethics committee of Hamedan University of Medical Sciences

Street address

Beginning of Khajeh Rashid Blvd, Hamedan University of Medical Sciences

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6517838698

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.UMSHA.REC.1399.215

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

Autism

ICD-10 code

f84

ICD-10 code description

childhood autism

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

Maternal-child relationships with autism 6-12 years in Ross questionnaire

Timepoint

1 day before training and 1 and 7 days after training

Method of measurement

Ross questionnaire

2

Description

Parental Competence in Parents of Autistic Children in (PCS)questionnaire

Timepoint

1 day before training and 1 and 7 days after training

Method of measurement

(PCS)questionnaire

3

Description

Emotional face identification in children with autism

Timepoint

1 day before training and 1 and 7 days after training

Method of measurement

Modified Benton Face Recognition Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group(traditional method) : In this method, the children will be trained by the researcher with the mother in 10 sessions of 30 to 60 minutes.It will be used To train 40 different images related to 4 positions of happiness, sadness, anger and fear (From each mode, 10 images) and The child should, with the help of the researcher and the mother, select the right emotional state appropriate to the target's face.All faces are a picture of a boy in size A5 and colorful.Images are displayed individually and from the front view to the child and without any explanation, the child is asked to select any image appropriate to the target's face. Every time they recognize a picture correctly, they will be encouraged by the mother and the researcher, and the next image will be shown. But in the event of a wrong answer, the researcher or the mother reminds you to "try again" and an indirect reference to the correct answer And if the wrong answer is repeated, direct reference is given to the correct answer And this process will be repeated until the participant gives the correct answer.In each session, four pictures (one image of each emotional state) are taught to the child. The mother is present with the researcher and learns how to train. Whenever a mother expresses her willingness to educate the child, the researcher assigns one or more of the images to her And supervises the child's education by the mother so that the training is done correctly. In this case, the researcher will express it if it is necessary to provide a point. At the end of each training session, if the mothers have ambiguity and questions about the trained images in each session, the researcher will respond to them.

Category

Rehabilitation

2

Description

Intervention group (computer method): To teach computer method, the participants will be trained by a researcher with the mother with LFI software in 30 to 60 minutes during 10 sessions.In this method, the researcher teaches Let's Face It educational software (6 game stages) for each of the participants independently, using a laptop device in each session. Each child will independently play all the steps of the software with the help and guidance of a researcher.This software consists of 8 links, the logo of each link is the face of an animal that enters the game by clicking on it. game links include: Lion, Stork, Zebra, Monkey, Rhinoceros, Crocodile, Elephant and Blue Horse, all of which will improve the understanding and recognition of emotions in all its dimensions.Each stage of the game has many advantages that are set to encourage the child to play more and more.At the end of all games, each participant's score will be added and the child's score will be estimated. At the end of each training session, if the mothers have any ambiguities or questions about the images taught in each session, the researcher will answer them.

Category

Rehabilitation

3

Description

Control group: The control group receives routine training

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Autism Centers affiliated to Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Mirzaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Latest degree

Ph.D.

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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
Not applicable

Data Dictionary
Not applicable