

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Investigating The Effect of Happiness Educational Program on Expressed emotions and Quality of Life of Mothers of Children with Autism spectrum disorders

Protocol summary

Study aim

Determining the effect of happiness education program on the expressed emotion and quality of life of mothers of children with autism spectrum disorder in selected centers of Isfahan in 2020

Design

Single blind, three-stage clinical trial with control and intervention groups, randomized on 70 samples

Settings and conduct

Ordibehesht Autism Clinic; Autism Association (Hazrat Zahra Center) under 14 years old and sample size 70 people (35 people in each group)

Participants/Inclusion and exclusion criteria

Inclusion criteria: the mother of a child with autism spectrum disorder should be considered as his / her primary caregiver and should have all his / her responsibilities; the mother should care for only one chronic patient, such as autism spectrum disorder, in the family; the child should be in the age group of 3-13 years. Criteria for non-inclusion: drug addiction or Consumption of psychiatric drugs; participate in similar research programs or workshops at the same time; the mother of a child with autism spectrum disorder has experienced a crisis or stressors in the last 6 months.

Intervention groups

The experimental group will be performed by the researcher in the presence of the supervisor of the training program in 6 sessions of 60 minutes and one day a week in small groups following the health protocols during corona time. Control group: They will not receive what was intended for the experimental group and will talk about their problems, feelings and experiences at a time after the intervention group during the session.

Main outcome variables

Quality of Life; Excitement expressed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200614047773N1**

Registration date: **2020-09-13, 1399/06/23**

Registration timing: **prospective**

Last update: **2020-09-13, 1399/06/23**

Update count: **0**

Registration date

2020-09-13, 1399/06/23

Registrant information

Name

Atiyeh Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3236 2321

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-26, 1399/07/05

Expected recruitment end date

2020-11-30, 1399/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The Effect of Happiness Educational Program on Expressed emotions and Quality of Life of Mothers of Children with Autism spectrum disorders

Public title

The Effect of Happiness Educational on Expressed emotions and Quality of Life of Mothers of Children with Autism spectrum disorders

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The mother of a child with autism spectrum disorder should be considered as his / her primary caregiver and should have all his / her responsibilities. Be interested in participating in the study. Be able to communicate and follow the rules of training sessions. The mother should care for only one chronic patient in the family, such as autism spectrum disorder. Be able to speak, read and write in Persian. The child is in the age group of 3-13 years

Exclusion criteria:

Drug addiction or Consumption of psychiatric drugs
Experience crisis or stressors in the last 6 months
Participate in similar research programs or workshops

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of samples in the experimental and control groups will be done using envelopes that will be prepared in advance using a random number table, so that the researcher will first determine that all the people to whom the odd number belongs. The control group and those to whom the even number belongs will be in the test group, then we close our eyes and place our finger on one of the digits in the table of random numbers, while the direction of movement will be determined in advance. The researcher is selected by moving in the table of random numbers to the required number of even and odd numbers. All numbers will be placed in separate envelopes and all will be placed in one box. When the sample enters the study easily with the entry conditions, then the number one card is opened for him and depending on whether this card is even or odd, he will be placed in one of the two groups of test and control. Thus, sampling will continue until the specified sample volume is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

Given that in experimental interventions there is a possibility of dissemination of the intervention and the possibility that the control group will somehow become aware of the intervention and there will be a possibility of influencing the results and the study is one-sided blind. However, there is a possibility of interaction between the two groups, which is beyond the power of the researcher.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-09-02, 1399/06/12

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.348

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

Autism Spectrum disorders

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

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

Expressed Emotion

Timepoint

Before the intervention, after the intervention, one month after the intervention

Method of measurement

Family questioner (FQ)

2

Description

Quality of Life

Timepoint

Before the intervention, after the intervention, one month after the intervention

Method of measurement

World Health Organization Quality of Life Questionnaire of 26 questions (WHOQOL-BREF)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The training program will be performed in 6 sessions of 60 minutes and one day a week in small groups according to the health protocols during the corona.

Category

Prevention

2

Description

Control group: They will not receive the intervention that was intended for the experimental group and will talk about their problems, feelings and experiences in a session sometime after the intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ordibehesht Autism Center

Full name of responsible person

Mehdi Fouladgar

Street address

No. 148, after Bahmanyar Alley., East Jami St., 5th Ramazan St., Seyed Mosque St., Isfahan.

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info@Autism-clinic.com

Web page address

<https://autism-clinic.com/>

2

Recruitment center

Name of recruitment center

Isfahan Association for the Support of Autistic Children

Full name of responsible person

Jamshid Ebrahimifar

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End of Shahid Javanmardi Alley, 17th Alley., next to Fadak Cultural Center., Sheikh Mofid Sharghi St., Isfahan.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Tahereh Changiz

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Grant name

Thesis

Grant code / Reference number

IR.MUI.RESEARCH.REC.1399.348

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

Yes

Title of funding source

Esfahan 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is shared upon request.

When the data will become available and for how long

Access will start 6 months after the article is published

To whom data/document is available

For researchers and institutions upon request

Under which criteria data/document could be used

The use of data for research purposes will be allowed

From where data/document is obtainable

In addition, request via e-mail to the following address:
mohammadii_atiyeh@yahoo.com

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

The applicant must submit a letter approving the research plan

Comments