

# 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)

##### Phone

+98 31 3236 2321

##### Email address

mohammadiii\_atiyeh@yahoo.com

##### 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.

##### **City**

Isfahan

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Isfahan

##### **Postal code**

8183975331

##### **Phone**

+98 31 3336 4601

##### **Fax**

+98 31 1336 0159

##### **Email**

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

#### **Street address**

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

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info@isfas.ir

#### **Web page address**

<http://www.isfas.ir/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Tahereh Changiz

##### **Street address**

School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jerib St.

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webmaster@nm.mui.ac.ir

#### **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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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Zahra Ghazavi/Atiyeh Mohammadi  
**Position**  
Faculty member of Isfahan University of Medical Sciences / M.Sc.  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**