Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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
Isfehan

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
Province
Isfehan
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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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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Fax
+98 31 1669 9398
Email
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

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

Street address

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

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Email

Zahra_ghazavi@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Ghazavi

Position

Faculty / Master

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Ghazavi/ Atiyeh Mohammadi

Position

Master / Faculty

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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

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Email

zahra_ghazavi@nm.mui.ac.ir

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: mohammadiii_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