Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Family-based Empowerment Program on Self-Efficacy and Mental Health of Autistic Mothers

Protocol summary

Study aim
The aim of this study was to the effect of family-based empowerment program on self-efficacy and mental health of autistic mothers.

Design
This study was a randomized clinical trial with two groups (intervention and control), pre and post-test design, and not-blinded.

Settings and conduct
This study was conducted on 60 mothers with autism child that were randomly divided into two groups (n = 30).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Non-participation in similar programs before and after intervention. Exclusion criteria: Absence of more than 2 sessions in the training program.

Intervention groups
Intervention group: in intervention group was conducted the family-centered empowerment program in four stages (increasing knowledge, promoting self-efficacy, self-esteem and mental health and evaluation), and during 11 sessions training with face-to-face method, one week's session for 60 to 90 minutes, during 11 weeks. Control group: in control group, was conducted routine education for 11 weeks, too.

Main outcome variables
The main outcome variables in this study included: clinical competence and satisfaction that in both groups was assessed before the intervention and the end of eleventh session with General Health Questionnaire-28 (GHQ-28) and General Self- Efficacy Scale.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181009041294N1**
Registration date: **2018-10-16, 1397/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-16, 1397/07/24**
Update count: **0**

Registration date
2018-10-16, 1397/07/24

Registrant information

Name
Nesa Hasanpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3223 1061

Email address
hasanpoury2@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-12, 1397/07/20

Expected recruitment end date
2019-01-10, 1397/10/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Family-based Empowerment Program on Self-Efficacy and Mental Health of Autistic Mothers

Public title
The Effect of Empowerment Program on Self-Efficacy and Mental Health of Mothers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Non-participation in similar programs before and after intervention

Exclusion criteria:

Absence of more than 2 sessions in the training program

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The mothers divided to intervention and control group with simple randomization method (with random digits table). In this way, each mother assigned a code and mothers randomly divided into two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Azad University, Tehran Medical Sciences Branch

Street address

Azad University, Tehran Medical Sciences Branch, Khaghani St.

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2018-10-06, 1397/07/14

Ethics committee reference number

IR.IAU.TMU.REC.1397.165

Health conditions studied

1

Description of health condition studied

Self-Efficacy

ICD-10 code

-

ICD-10 code description

-

2

Description of health condition studied

Mental Health

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Self-Efficacy

Timepoint

Before the intervention and the end of eleventh session

Method of measurement

General Self- Efficacy Scale

2

Description

Mental Health

Timepoint

Before the intervention and the end of eleventh session

Method of measurement

General Health Questionnaire-28 (GHQ-28)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in intervention group was conducted the family-centered empowerment program in four stages (increasing knowledge, promoting self-efficacy, self-esteem and mental health and evaluation), and during 11 sessions training with face-to-face method, one week's session for 60 to 90 minutes, during 11 weeks.

Category

Prevention

2

Description

Control group: in control group, was conducted routine education for 11 weeks, too.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Ava

Full name of responsible person
Reza Dehghani

Street address
Ava Autism Center, Daneshamouz St

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Mashhad

Province
Razavi Khorasan

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9784118478

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Dehghanif@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Farshad Hashemian

Street address
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Email
HashemianF@aiu.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Nesa Hasanpour

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Azad University, Tehran Medical Sciences Branch, Faculty of Nursing and Midwifery, Khaghani St

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Assistant professor

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Other areas of specialty/work
Nursery

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Tehran, Shahid Chamran Highway, Shahid Arabi St., Yemen St,

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Tehran
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1916893813
Phone
+98 21 2200 6660
Email
Hasanpoury2@mums.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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The study report published in the dissertation form and article for researcher.
When the data will become available and for how long
The start of access is 6 months after the announcement of the results.
To whom data/document is available
Researchers at university centers
Under which criteria data/document could be used
Data is authorized only with permission from the author of the articles and with the source.
From where data/document is obtainable
Nesa Hasanpour, School of Nursing and Midwifery, Contact Number: 00989153007114, Email: Hasanpour.nesa@gmail.com
What processes are involved for a request to access data/document
After submitting a request, the request is reviewed and, if the request is accepted, is answered within 1 month.
Comments