

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

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

Protocol summary

Registration timing: **registered_while_recruiting**

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**

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9784118478

Phone

+98 51 3609 8424

Email

Dehghanif@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Hashemian

Street address

Azad University, Tehran Medical Sciences Branch,
Khaghani St

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Email

hasanpoury2@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Jamileh Mohtashami

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Email

Jmohtashami@sbm.ac.ir

Person responsible for updating data

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

Street address

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

City

Tehran

Province

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1916893813

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+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