

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Investigating The Effect Of The Family-centered Empowerment Model On Mothers' Parenting Self-efficacy In Relation To The Growth And Development Process of Toddlers

Protocol summary

Study aim

Determining the effect of the family-centered empowerment model on the parenting self-efficacy of mothers in relation to the growth and development process of toddlers

Design

Clinical trial with two control and intervention groups, randomized, phase one on 72 mothers of toddlers. Eighteen blocks of size 4 are used for randomization (block randomization).

Settings and conduct

The location of this study is in the children's ward of Amir Kabir Hospital in Arak, the study population is mothers of hospitalized toddlers. No blinding will be done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers with toddlers; The age range of the mothers is 20 to 45 years, the absence of mental and physical disabilities of the mother and the child, and having a 1 to 3 year old child hospitalized in the children's ward of Amir Kabir Hospital. Non-inclusion criteria: Simultaneous participation of subjects in similar educational programs

Intervention groups

The control group will receive only the care available in the ward. Intervention group: The researcher implements the family-centered empowerment model intervention

Main outcome variables

Family-centered empowerment model; Mother's parenting self-efficacy score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221230056985N1**

Registration date: **2023-02-05, 1401/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-05, 1401/11/16**

Update count: **0**

Registration date

2023-02-05, 1401/11/16

Registrant information

Name

Mohammad Reza Shamshiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 5522 2815

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The Effect Of The Family-centered Empowerment Model On Mothers' Parenting Self-efficacy In Relation To The Growth And Development Process of Toddlers

Public title

Effect Of Family-centered Empowerment On Mothers' Self-efficacy In Relation To The Growth And Development Of Toddlers

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The age range of mothers is 20 to 45 years No mental and physical disability of mother and child Having a 1-3 year old child hospitalized in the children's department of Amir Kabir Hospital The level of mother's education of middle school degree up to doctorate

Exclusion criteria:

Simultaneous participation of subjects in similar educational programs

Age

From **12 months** old to **36 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are divided into two control and intervention groups by the accessible and easy sampling method and by the block randomization method. 18 blocks of size 4 are used to randomize the sample allocation to the two control and intervention 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 Arak University Of Medical Sciences

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Apadana Complex, Niloofar3 Alley, Pardis1 Residential Site

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اراک

Province

Markazi

Postal code

3817686175

Approval date

2022-11-20, 1401/08/29

Ethics committee reference number

IR.ARAKMU.REC.1401.236

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

This research is in line with the self-efficacy of the family and childcare system and promoting the growth and development of the toddler

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Mother's parenting self-efficacy score

Timepoint

Before the intervention, after the intervention and one month later

Method of measurement

Parenting self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention researcher implements the family-centered empowerment model based on its four steps (threat understanding, self-efficacy, self-confidence and evaluation) in the form of group discussion in groups of four during five 60-minute sessions, one session every day for mothers. The content of the family-centered empowerment sessions related to the growth and development of toddlers is according to the valid references of children's growth and development, which has been approved by the professors of the children's department of the Arak Faculty of Nursing and Medical Sciences in terms of content validity.

Category

Other

2**Description**

Control group: The control group does not receive the intervention of family-centered empowerment in relation to the growth and development of the toddler, and they only receive the care available in the department, and all

children according to the national guidelines based on the Age and Stages of Development Questionnaire (ASQ). They are monitored by experts in health centers

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Amir Kabir Hospital

Full name of responsible person

Mohammad Reza Shamshiri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mohammad Reza Shamshiri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Science Committee

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Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable