

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of counseling led by midwife on mother's participation in the sexual education of preschool children

Protocol summary

Study aim

Evaluate the effectiveness of counseling led by midwife on mother's participation in the sexual education of preschool children

Design

randomized controlled clinical trial with a pre-posttest design

Settings and conduct

Population comprise mothers with preschool children at Alborz University of Medical Sciences . A sample of 60 mothers who met the inclusion criteria will be selected by simple random. In intervention group, participants will attend weekly in group counselling session for 3 sessions (90 minutes) in groups of six people, according the active learning model. The participants will be evaluated before and two weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being Iranian, being iterated, being employed at Alborz university of medical sciences, being interested to contribute in the study. Exclusion criteria: failure to complete questionnaires, not attending at least 1 sessions of counseling sessions .

Intervention groups

In the study group, participants with entry criteria, who will receive weekly group counseling in 3 sessions (90 minutes). Control group no advice is given to individuals.

Main outcome variables

Mother's participation in child sexual education

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160424027557N7**

Registration date: **2018-08-20, 1397/05/29**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-20, 1397/05/29**

Update count: **0**

Registration date

2018-08-20, 1397/05/29

Registrant information

Name

Mahnaz Akbari Kamrani

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3433 6007

Email address

dr.akbarikamrani@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-18, 1397/04/27

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling led by midwife on mother's participation in the sexual education of preschool children

Public title

Effect of counseling on the child sexual education

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
being employed at Alborz university of medical sciences
being literated being Iranian not having a history of
attending child sexual training courses being interested
to contribute in the study

Exclusion criteria:
failure to complete questionnaires not attending at least
1 sessions of counseling sessions

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Use block randomization

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

Alborz University of Medical Sciences

Street address

Research& Technology Office., Alborz University of
Medical Science., Yasamin St., Poneh St., Golshahr
BLv

City

karaj

Province

Alborz

Postal code

3149779453

Approval date

2018-01-20, 1396/10/30

Ethics committee reference number

Abzums.Rec.1396.163

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mother's participation about child sexual education

Timepoint

Before and after intervention

Method of measurement

Mother's participation questionnaire on sex education for
children

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants will attend weekly in the
group counselling session for 3 sessions (90 minutes) in
groups of six people, according the active learning
model. Counselling content includes: the purpose of the
study, child sexual education, mother role in sexual
education, child sexual behaviour and child
communication skills.

Category

Behavior

2

Description

Control group: Participants will not receive any
intervention. After the study, a booklet containing the
content of the consultation is given to them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz University of Medical Sciences

Full name of responsible person

Hadis Fatehi Poladi

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Education Office., Alborz University of Medical
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Alborz 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
Alborz University of Medical Sciences
Full name of responsible person
Hadis Fatehi Poladi
Position
Student
Latest degree
Master
Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

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

all collected variables

When the data will become available and for how long

From 2019

To whom data/document is available

It is available only for people working in academic institutions.

Under which criteria data/document could be used

No Criterion

From where data/document is obtainable

By Email: Dr.akbarikamrani@abzums.ac.ir and Dr. Mahnaz Akbari Kamrani would be responsive

What processes are involved for a request to access data/document

By Email

Comments