

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessment the effect of midwife- led group consulting on parent 's practice and self- efficacy in prevention of sexual abuse among 2-6 years old children

Protocol summary

Summary

The two-group randomized control trial study, which aimed to evaluate the effectiveness of midwife- led group consulting on parent 's practice and self- efficacy in prevention of sexual abuse among 2-6 years old children. The study population will comprise parents by 2-6 years old children. A sample of 62 parents who met the inclusion criteria has been calculated. Inclusion criteria with block randomization placed in one of intervention and control groups. The intervention group perceive 3 weekly sessions of group counseling. Before and after the intervention and 1month after the last sessions, the parent 's practice and self- efficacy to be measured by questionnaire

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051227557N4**

Registration date: **2017-09-05, 1396/06/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-05, 1396/06/14

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

Alborz University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of midwife- led group consulting on parent 's practice and self- efficacy in prevention of sexual abuse among 2-6 years old children

Public title

Assessment the effect of midwife- led group consulting on parent 's practice and self- efficacy in prevention of sexual abuse among 2-6 years old children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: being main guardian; liberated; being Iranian ; living in Karaj; without history of sexual abuse and attending in related education. Exclusion criteria: not being interested to continue the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 62

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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

Department of Midwifery., Alborz University of Medical Science., Eshteraki St., Baghestan Blv

City

Karaj

Postal code

Approval date

2017-03-03, 1395/12/13

Ethics committee reference number

Abzums.Rec.1395.147

Health conditions studied

1

Description of health condition studied

Child sexual abuse

ICD-10 code

Y07.9

ICD-10 code description

Y07.9

Primary outcomes

1

Description

Knowledge

Timepoint

Before and after of intervention, 1 month after end of intervention

Method of measurement

Questionnaire

2

Description

Attitude

Timepoint

Before and after of intervention, 1 month after end of intervention

Method of measurement

Questionnaire

3

Description

Practice

Timepoint

Before and after of intervention, 1 month after end of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Self- efficacy

Timepoint

Before and after of intervention, 1 month after end of intervention

Method of measurement

Self- efficacy questionnaire

Intervention groups

1

Description

Control group will receive an evidence based booklet about child sexual abuse.

Category

Prevention

2

Description

Intervention group: Midwife-led counseling group, will receive 3 sessions group counseling intervention during 90 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Karaj welfare organization

Full name of responsible person

Marzie Navaei

Street address

Taleghani St

City
Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Noorisepehr

Street address

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

City

Karaj

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Marzie Navaei

Position

Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Dr. Mahnaz Akbari Kamrani

Position

Assistant Professor/ PhD

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty