

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of personal safety education to mothers on the knowledge and skills on sexual abuse prevention of preschool girls

Protocol summary

Study aim

To determine whether preschool girls could learn personal safety skills when taught by their mothers.

Design

Participants included 56 preschool girls and their mothers. Eligible samples were chosen through systematic random sampling from two health centers, which served the largest and most diverse population in terms of cultural, economic, and social levels. The demographic databases were provided by the health system, and households with a preschool girl were identified (N = 336). To achieve the required sample size of 56, eligible mothers were chosen through systematic random sampling from the list using sampling distance (k), $[k=N/n = 336/56 = 6]$. From 1 to 6, the number 2 was chosen randomly as the first sample. The second sample was selected by adding the number 6 to the first mother and this process continued until the end. First, the samples were identified. By using a randomized test, the intervention group was selected between the intervention and control groups. Then, the first name was randomly selected of the names of the mothers. The first name was placed in the intervention group, and then the next names sequentially were placed in the control and intervention groups.

Settings and conduct

This study was performed in Golha Health Center in Gorgan city and blinding was not performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criterion: preschool girls

Intervention groups

Intervention group: receiving education by mothers.
Control group: receiving no intervention

Main outcome variables

Knowledge, skills

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190307042958N1**

Registration date: **2020-10-20, 1399/07/29**

Registration timing: **retrospective**

Last update: **2020-10-20, 1399/07/29**

Update count: **0**

Registration date

2020-10-20, 1399/07/29

Registrant information

Name

somayeh Gholam farkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4721 2046

Email address

somayeh.farkhani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-19, 1395/03/30

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

2016-06-18, 1395/03/29

Actual recruitment end date

2016-10-20, 1395/07/29

Trial completion date

2016-10-20, 1395/07/29

Scientific title

The effect of personal safety education to mothers on the knowledge and skills on sexual abuse prevention of preschool girls

Public title

The effect of personal safety education to mothers on the knowledge and skills about sexual abuse prevention

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Preschool girls

Exclusion criteria:**Age**

From **5 years** old to **6 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible samples were chosen through systematic random sampling from two health centers, which served the largest and most diverse population in terms of cultural, economic, and social levels. The demographic databases were provided by the health system, and households with a preschool girl were identified (N = 336). To achieve the required sample size of 56, eligible mothers were chosen through systematic random sampling from the list using sampling distance (k), [k=N/n = 336/56 = 6]. From 1 to 6, the number 2 was chosen randomly as the first sample. The second sample was selected by adding the number 6 to the first mother and this process continued until the end. First, the samples were identified. By using a randomized test, the intervention group was selected between the intervention and control groups. Then, the first name was randomly selected of the names of the mothers. The first name was placed in the intervention group, and then the next names sequentially were placed in the 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 Golestan University of Medical Sciences

Street address

Fourth kilometer of Gorgan road

City

Gorgan

Province

Golestan

Postal code

934174515

Approval date

2016-05-03, 1395/02/14

Ethics committee reference number

941218332

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

Preventing child Sexual Abuse

ICD-10 code

T76.22XS

ICD-10 code description

Child sexual abuse, suspected, sequela

Primary outcomes**1****Description**

Knowledge

Timepoint

Pretest, post test (one week), follow-up test (one month)

Method of measurement

questionnaire

2**Description**

Skill

Timepoint

Pretest, post test (one week), follow-up test (one month)

Method of measurement

Questionnaire

Secondary outcomes

empty

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

Intervention group (Education by mother): After receiving informed and written consent from the parents. At the beginning of each interview, the concept of "private parts" of the body was taught to the children. After completing interviews with PSQ-P and WIST-P (Time 1), the mothers of the education group were invited to attend mothers' training classes offered the following

two days. The personal safety training session was held by the researcher for the mothers of the education group (in 4 groups of 4-8 people for 90-120 minutes), which focused on the importance of preventing CSA and the training needed to protect children's personal safety as well as how to educate their children at home using the Persian version of Body Safety Training workbook (BST; Wurtele, 2007). At the end of the class, each mother was given a copy of the Body Safety Training workbook to teach her daughter over the week. We asked the mothers in the educational group to teach their children at least one lesson a day. During one week of at-home training, the researcher contacted the mothers twice (days 2 and 5) to track the progress of educating their children and answer their questions, if any. Two days after the completion of the one week training by mothers to children, children were interviewed using the PSQ-P and WIST-P (Time 2). Follow-up testing (Time 3) was conducted for children one month after the post-test.

Category

N/A

2

Description

Control group: After receiving informed and written consent from the parents or legal guardians of the children. At the beginning of each interview, the concept of "private parts" of the body was taught to the children. After completing interviews with PSQ-P and WIST-P (time1). Mothers of the control group were thanked for their presence and cooperation, and were asked to revisit 11 days later for the post-test of the children. children in control groups were interviewed using the PSQ-P and WIST-P (Time 2). Follow-up testing (Time 3) was conducted for children in control group one month after the post-test. interested mothers of the control group were given a copy of the BST workbook.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Golha Health Center

Full name of responsible person

Elham Khoori, Somayeh Gholamfarkhani

Street address

At the end of Golbarg 1; Golha street

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Email

somayeh.farkhani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Elham Khoori

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At the beginning of Shastkolah road

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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

Gorgan 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

Mashhad University of Medical Sciences

Full name of responsible person

Somayeh Gholam Farkhani

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Elham Khoori
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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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midwife
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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

By anonymizing the participants in this study, all the research results can be shared.

When the data will become available and for how long

2019

To whom data/document is available

Public

Under which criteria data/document could be used

Researcher

From where data/document is obtainable

Golestan University of Medical Sciences

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

Send an e-mail request to the Dr.Elham Khoury, somayeh gholam farkhani

Comments