

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of an educational program based on health belief model on self-protection against sexual harassment in children of vulnerable families

Protocol summary

Study aim

Determining the effect of an educational program based on health belief model on protecting oneself against sexual harassment in children of vulnerable families

Design

A clinical trial with an intervention and control group, one-sided, randomized, will be selected for randomization based on a lottery of four centers and the research units will be selected by tapping a card or letter.

Settings and conduct

The research is done in child support centers in Isfahan. Sampling of children will be done by the researcher, but in order to complete the study, the questionnaire will be done by another person. (Key) and attractiveness that this method can be used in various ways to prevent sexual harassment

Participants/Inclusion and exclusion criteria

Children aged 8-11 years, research units residing in Isfahan, research units should not participate in any simultaneous counseling or psychotherapy program, no obvious symptoms of psychosis in children and mothers, no chronic illness or other mental disorders in Research units

Intervention groups

Educating children to protect themselves from sexual harassment will be used by showing movies, theater, role-playing, etc., and the control group will be provided with an educational package after completing the research.

Main outcome variables

Protecting yourself (awareness and skills) against sexual abuse in children

General information

Reason for update

Acronym

CSA

IRCT registration information

IRCT registration number: **IRCT20210130050180N1**

Registration date: **2021-10-02, 1400/07/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-02, 1400/07/10**

Update count: **0**

Registration date

2021-10-02, 1400/07/10

Registrant information

Name

Zahra Shafizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3663 5234

Email address

shzahra95@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an educational program based on health belief model on self-protection against sexual harassment in children of vulnerable families		conclude with orientation and identification and sampling of children and their parents will be done by the researcher but for a blinding study, questioning by another person who has the necessary training to complete the questionnaire The goals and objectives of the research seen will be accomplished	
Public title	The effect of a health belief model-based educational program on protecting oneself against sexual harassment in children from vulnerable families		
Purpose	Education/Guidance		
Inclusion/Exclusion criteria			
Inclusion criteria:	Conscious satisfaction and willingness to participate in educational sessions from parents and children The studied units have 8-11 years old child (third period of childhood) The research units currently reside in the city of Isfahan Research units should not participate in any counseling or psychotherapy program during the treatment intervention Lack of obvious symptoms of psychosis in children and mothers according to the head of the center No chronic illness or other concomitant mental disorders in the research units The presence of the mother in all public educational sessions is mandatory		
Exclusion criteria:	Absence from more than one session in training sessions Parents or children do not want to participate in further study Lack of access to the research units during the study for any reason		
Age	From 8 years old to 11 years old		
Gender	Both		
Phase	N/A		
Groups that have been masked	- Investigator - Outcome assessor		
Sample size	Target sample size: 84		
Randomization (investigator's opinion)	Randomized		
Randomization description	Randomization method: cards or envelops shuffling Randomization unit: individual Randomization tool: sealed envelope How to make a random sequence: From among child protection centers, four centers will be selected by lottery. In the centers selected according to the inclusion criteria, among the child protection centers, four centers will be selected based on the lottery. Or the letter chosen by the researcher as the first group and the same number for the second group is considered, then by merging the cards together (folding the cards) a card is taken out and its allocation is recorded, then the cards are merged again. And another card is issued to reach 84 samples		
Blinding (investigator's opinion)	Single blinded		
Blinding description	The researcher and evaluator of the research outcome is the responsibility of the researcher is blind not to		
Placebo	Not used		
Assignment	Parallel		
Other design features	Two groups (intervention and control), three stages (before, immediately and 3 months after training)		
Secondary Ids			
empty			
Ethics committees			
<u>1</u>			
Ethics committee			
Name of ethics committee			
Ethics committee of Isfahan University of Medical Sciences			
Street address			
No. 53, Bahar Complex,Asiab Alley,Sheikh Sadough St. North,Isfahan			
City			
Isfahan			
Province			
Isfahan			
Postal code			
8145913151			
Approval date			
2021-05-24, 1400/03/03			
Ethics committee reference number			
IR.MUI.NUREMA.REC.1400.026			
Health conditions studied			
<u>1</u>			
Description of health condition studied			
Child sexual Abuse			
ICD-10 code			
ICD-10 code description			
Primary outcomes			
<u>1</u>			
Description			
Self-protection score (awareness and skills) against sexual abuse in children			
Timepoint			
Before, immediately and 3 months after the intervention (self-protection trainings)			
Method of measurement			
Self-protection questionnaire (awareness and skills)			

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: "Intervention group 1:" 6 groups of 7 girls, "Intervention group 2:" 6 groups of 7 boys, training will be shown by showing films related to self-protection, theater, role play. This training will be done in 4 sessions of one and a half hours with a break every 15 minutes for 5 minutes. In the first two sessions, the mother will be present. The mother will not be present. There will also be two special sessions for parents on sex education in the form of lectures and group discussions.

Category

Behavior

2

Description

Control group:"Control group 1:" 6 groups of 7 girls, "Control group 2:" 6 groups of 7 boys, at the end of the study, the training package and the training of the intervention group will be provided to the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Emma

Full name of responsible person

Mohammad Mostajeran

Street address

Omid Educational Complex,Gol Yas Alley,North Hess,
North Hess, Roudaki St,Under Third Passage,Airport
Highway

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Province

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Fax

Email

ima.ngo.society@gmail.com

Web page address

2

Recruitment center

Name of recruitment center

Mehre Zenderood

Full name of responsible person

Somayeh Yakhchali

Street address

No. 19, ground floor,dead end (Hamedani),Talab 2
alley,Dark,Isfahan

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Web page address

3

Recruitment center

Name of recruitment center

Population of the people of Salva

Full name of responsible person

Saed Yousefi

Street address

Salva Training Center,Second Hessa,
UnderpassAirport Highway,Isfahan

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4

Recruitment center

Name of recruitment center

Chatrenili

Full name of responsible person

Navid Babaei Kharzooqi

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No. 134, Ground Floor, Nasser Khosrow St., Shahid
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blue.umbrella.for.children@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Kianpour

Street address

School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jerib St., Isfahan

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kianpour@mail.mui.ac.ir

Web page address

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Boroumandfar

Position

Faculty of Midwifery and Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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No. 62, Shahid Mazaheri Alley, Khaghani St.

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Faculty of Midwifery and Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Shafizadeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Email

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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

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