Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Children's sexual Health Educational Program on Knowledge and Attitudes of Primary School Health Care Providers

Protocol summary

Study aim
Determining the effect of educational program on the knowledge and attitude of primary school health care provider about children's sexual health

Design
A clinical trial with a control group, with parallel groups, one blind, randomized

Settings and conduct
After introduction of Mazandaran University of Medical Sciences to Mazandaran Education Department, the names of primary school health care provider and their Phone numbers will be extracted. Coordination will be done by phone and the invitation will be sent. After reviewing entry and exit criteria, 60 providers will be considered for inclusion in the study. By using table of random numbers, individuals will be randomly assigned to two groups of intervention and control. Intervention will be done in intervention group; there is no intervention in the control group at the time of the study. The training will be at the Nursing and Midwifery School, Mazandaran University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Not interested in participating in the study Absence in at least one of the training sessions

Intervention groups
Intervention will done in intervention group, there is no intervention in the control group at the time of the study.

Main outcome variables
Knowledge and Attitudes of Primary School Health Care Providers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161126031117N8**
Registration date: **2019-01-14, 1397/10/24**
Registration timing: **prospective**
Last update: **2019-01-14, 1397/10/24**
Update count: **0**

Registration date
2019-01-14, 1397/10/24

Registrant information

Name
Soghra Khani

Name of organization / entity
Mazandaran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 11 3336 8918

Email address
s.khani@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-17, 1397/10/27

Expected recruitment end date
2019-02-21, 1397/12/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Children's sexual Health Educational Program on Knowledge and Attitudes of Primary School Health Care Providers

Public title
The Effect of Children's sexual Health Educational Program on Knowledge and Attitudes of Primary School Health Care Providers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Working in elementary school as a health care provider
Having at least one year teaching experiences

Exclusion criteria:

Not interested in participating in the study Absence in at least one of the training sessions

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

By using table of random numbers , individuals will be randomly assigned to two groups of intervention and control.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants were blind if they were in the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice –Chancellor for Research of Mazandaran University of Medical Sciences, Moalem Square

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.MAZUMS.REC.1397.3140

Health conditions studied

1

Description of health condition studied

Children's sexual Health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Knowledge f Primary School Health Care Providers about children's sexual health

Timepoint

Before the intervention, immediately after the intervention and 4 weeks after the intervention

Method of measurement

Knowledge of Primary School Health Care Providers about children's sexual health questionnaire

2

Description

Attitudes of Primary School Health Care Providers about children's sexual health

Timepoint

Before the intervention, immediately after the intervention and 4 weeks after the intervention

Method of measurement

Attitudes of Primary School Health Care Providers about children's sexual health questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After introduction of Mazandaran University of Medical Sciences to Mazandaran Education Department, the names of primary school health care provider and their Phone numbers will be extracted. Coordination will be done by phone and the invitation will be sent. After reviewing entry and exit criteria, 60 providers will be considered for inclusion in the study. By using table of random numbers, individuals will be randomly assigned to two groups of intervention and control. Intervention will be done in intervention group; there is no intervention in the control group at the time of the study. The training will be at the Nursing and Midwifery School, Mazandaran University of Medical Sciences.

Category

Other

2

Description
Control group: The control group does not receive any intervention during the study and receives educational intervention and booklet at the end of the study.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mazandaran Education Department
Full name of responsible person
Reza Safaee Tabalvandani
Street address
Farhang St
City
Sari
Province
Mazandaran
Postal code
4819719336
Phone
+98 11 3332 7981
Email
rezasafaee1356@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Ali Akbar Hedayati Zadeh
Street address
Vice Chancellor for Research of Mazandaran University of Medical Sciences, Moalem Square, Moalem Street. sari Mazandaran
City
Sari
Province
Mazandaran
Postal code
4817918479
Phone
+98 11 3325 7230
Email
akbar_hedayati@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
Zahra Barimani
Position
midwife
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
sexual and reproductive healthresearch center, Vesal street, Amir Mazandarani Boulevard
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Sari
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Mazandaran
Postal code
4817918479
Phone
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Fax
Email
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Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Soghra Khani
Position
PhD, Moderator (owner) of project
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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sexual and reproductive healthresearch center, Vesal street, Amir Mazandarani Boulevard
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Sari
Province
Mazandaran

Postal code
4817918479
Phone
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Fax
Email
s.khani@mazums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Soghra Khani
Position
PhD, Moderator (owner) of project
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
sexual and reproductive healthresearch center, Vesal street, Amir Mazandarani Boulevard
City
Sari
Province
Mazandaran
Postal code
4817918479
Phone
+98 11 3335 8918
Fax
Email
s.khani@mazums.ac.ir
Web page address

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
The total potential data can be shared after unidentifiable people.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
En Data will only be available to researchers in academia and academia.
Under which criteria data/document could be used
Meta-analysis is allowed on data
From where data/document is obtainable
Sexual and Reproductive Health Research Center, Nasibeh Nursing and Midwifery school, Vesal street, Amir Mazandarani Boulvard. khanisog343@gmail.com
What processes are involved for a request to access data/document
After emailing and sending the profile, it will be sent within a week.
Comments