

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of education intervention designed based on pen-3 model on menstrual health behavioral promotion in girl students 13-16years

Protocol summary

Summary

The goal of this study is determine the effect of education intervention designed based on pen-3 model on menstrual health behavioral promotion in girl students 13-16years in Bam. This study designed in two stages of Qualitative and quantitative. Inclusion criteria conclude to fill consent form, over 35 years old in mothers group, active participants and able to comment in qualitative sessions and educational, to have minimum experiment of 3 menstruations in students and Exclusion criteria conclude Lack of willingness to cooperation, no access to participants for posttest. In trial stage, sample select by correlated formula and statically consultation from secondary schools (90 people in every group). Then is gave them consent form and researcher made questionnaire (demographic and pen-3 model constructs questions) that have identification code and invitation for educational session. Educational sessions implement and it content prepare based on need assessment of qualitative stage and pretest results. Then posttest questionnaires distribute immediately and two months after intervention. Finally, before and after data of educational intervention, analysis separately in two groups in order to change perceptions, enablers and reinforcements and health behaviors change of students (constructs of pen-3 model).

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017041533432N1**

Registration date: **2017-07-14, 1396/04/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-14, 1396/04/23

Registrant information

Name

Neda Mohammadinia

Name of organization / entity

Bam University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 4421 6037

Email address

nedamohammadinia@mubam.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education intervention designed based on pen-3 model on menstrual health behavioral promotion in girl students 13-16years

Public title

The effect of education on menstrual health behavioral promotion in girls

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria:to fill consent form; over 35 years old in mothers group;active participants and to Ability to comment;to have minimum experiment of 3 menstruation in students group. Exclusion Criteria:Lack of willingness to cooperation;no access to participants for post test

Age
From **13 years** old to **16 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
this study designed in two stages : 1)first stage(qualitative study):directed content analysis
2)second stage(quantitative study)intervention study (before and after intervention)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd University of Medical Sciences

Street address

shahid sedoghi University of Medical Sciences and Health Services, Bahonar square,Yazd

City

Yazd

Postal code

-

Approval date

2017-02-02, 1395/11/14

Ethics committee reference number

ir.ssu.sph.rec.1395.148

Health conditions studied

1

Description of health condition studied

menstruation

ICD-10 code

Z30.3

ICD-10 code description

Menstrual extraction

Primary outcomes

1

Description

menstrual health behavioral promotion

Timepoint

pre intervention,post intervention,2 month post intervention

Method of measurement

quastionaire

Secondary outcomes

1

Description

enablers and reinforcements of health behavioral

Timepoint

pre intervention,post intervention,2 month post intervention

Method of measurement

quastionaire

Intervention groups

1

Description

educating sessions based on the needs assessment from Qualitative Study and first stage of Quantitative Study

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bam Secondary Girl Schools

Full name of responsible person

Neda Mohammadinia

Street address

Nursing and Midwifery School, Blv khali j fars, Bam

City

Bam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargouei

Street address

Yazd University of Medical Sciences, Bahonar square

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Bam University of Medical Sciences

Full name of responsible person

Neda Mohammadinia

Position

Faculty member

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