

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Sep 2026

### The impact of counseling based on protection motivation theory on self care of teenage girls reproductive health

#### Protocol summary

##### Study aim

Determining the Effect of counseling based on protective motivation theory on reproductive health self care of girl adolescent students in Alborz university Of Medical Sciences

##### Design

Clinical trials with a control group, community based and pragmatic, with parallel, Not blind , randomized groups

##### Settings and conduct

The study will be conducted on the girl students of the Alborz University of Medical Sciences. The colleges will be selected by cluster sampling, and then from among eligible girl students, the sample will be determined. Initially, the researcher will go to the relevant colleges, and the students will meet the entry criteria Identifies. Then the goals of the study are expressed to them and if they are willing to participate in the study, they will receive written consent. Subjects will be randomly assigned to two intervention and control groups according to the random numbers table. The intervention group has six counseling sessions With protective motivational approach, each one will receive 90 minutes . Meetings will be held once a week

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: single, girl, first or second year of university, Maximum 21 years old ; mental illnesses

##### Intervention groups

The intervention group will receive six counseling sessions with a protective motivational approach for 90 minutes each. Meetings will be held once a week. The teaching method will be group discussion, question and answer, and role play. Immediately after the end of the session and then one month after the end of the interventions, the questionnaire will be completed by the group members

##### Main outcome variables

Determine rate of reproductive health self-care adolescent girls in the intervention group before, after and one month after counseling Determine rate of

reproductive health self-care adolescent girls in the control group before, one month after counseling Comparison rate of reproductive health self-care in adolescents in two groups Determine rate of reproductive health self-care adolescent girls based on self efficacy before, after and one month after counseling Determination of self-care level of teenagers' reproductive health based on Perceived response efficiency in intervention group before, after and one month after counseling Determination of self-care level of reproductive health in adolescent girls based on perceived vulnerability in intervention group before, after and one month after counseling Determination of self-care fertility in adolescent girls based on severity of perception in intervention group before, after and one month after counseling. Determination of self-care level of reproductive health in adolescent girls based on Cost of response in intervention group before, after and one month after counseling.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150119020719N7**

Registration date: **2018-05-09, 1397/02/19**

Registration timing: **retrospective**

Last update: **2018-05-09, 1397/02/19**

Update count: **0**

##### Registration date

2018-05-09, 1397/02/19

##### Registrant information

##### Name

Sara Esmaelzadeh Saeieh

##### Name of organization / entity

Alborz University of Medical Sciences

##### Country

Iran (Islamic Republic of)  
**Phone**  
+98 26 3433 6007  
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**Recruitment status**  
**Recruitment complete**  
**Funding source**

**Expected recruitment start date**  
2018-02-04, 1396/11/15  
**Expected recruitment end date**  
2018-04-19, 1397/01/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The impact of counseling based on protection motivation theory on self care of teenage girls reproductive health

**Public title**  
impact of counseling on teenagers reproductive health

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Be female Be single The maximum age should be 21 years The first or second year of university  
**Exclusion criteria:**  
mental illnesses

**Age**  
From **18 years** old to **21 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
4 digit block randomization

**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

Alborz University of Medical Sciences

##### Street address

Alborz University of Medical Sciences,Azimieh,,Alborz,Iran

##### City

Alborz

##### Province

Alborz

##### Postal code

0098

#### Approval date

2018-01-29, 1396/11/09

#### Ethics committee reference number

Abzums.Rec.1396.164

## Health conditions studied

### 1

#### Description of health condition studied

##### ICD-10 code

##### ICD-10 code description

## Primary outcomes

### 1

#### Description

reproductive health of Adolescents behavior

#### Timepoint

before intervention,after intervention,one month after intervention

#### Method of measurement

reproductive health questionnaire of the World Health Organization.Adolescent Reproductive Health Questionnaire which was validated by Alimoradi.The Protection Motivation Theory Questionnaire which validated by faculty members of Alborz midwifery University

## Secondary outcomes

### 1

#### Description

adolescence sexual behavior

#### Timepoint

before intervention, after intervention , one month after intervention

#### Method of measurement

world health organization questionnaire

## Intervention groups

## 1

### Description

Intervention group: Receiving six sessions will be held once a week, in each session they have consultation for 90 minutes. The content of the sessions will be as follows: Session 1: definition of reproductive and sexual health, genital anatomy and physiology, counseling about normal and abnormal menstruation, premenstrual syndrome, will include the sharing of information and experiences of girl students in this part. Session 2: The Importance of pregnancy methods and sexual dangers (Understanding the threat and the severity of the vulnerability) Unplanned pregnancy complications at an early age, complications of abortion and bleeding, contraceptive methods, the danger of sexually transmitted diseases. Session 3: ( Understanding the internal rewards and external rewards ) sexual cycle, Sexual relationships, sexual health benefits and their impact on the body and mind, safe pregnancy, intended pregnancy, safe sex, self-restraint, loyalty, the benefits of saying no to sexual relationships before marriage from the perspective of students, reasons for doing sexual activity Pre-marriage from the perspective of students and researcher, efficiency improvement of the answer. session 4: Understanding the vulnerability of sexually transmitted diseases, high-risk sexual behavior, its complications, prevention strategies, and the spread of diseases, especially HIV. session 5: Understanding the severity of the risk of high-risk behaviors, sexual rapes, Ways to prevent sexual rape and measures after rape, the ways of protecting against high-risk behaviors (such as smoking and addiction) and their impact on reproductive health. The sixth session : Effectiveness of responses, HIV prevention and counseling ways to reduce the risk of HIV transmission. It includes consultation of negotiation with the sexual partner for using condom and also skill of using condom. understanding self-efficacy, and receiving feedback from prevention methods, self-control skills, skill in control risky behavior and understanding the effectiveness of recommended preventive behavior. The sessions will be validated by the faculty members of the midwifery department at the university.

### Category

Lifestyle

## 2

### Description

"Control group": For ethical consideration, after complete the questionnaires in one month after intervention, they will receive sexual and reproductive health book.

### Category

Lifestyle

## Recruitment centers

## 1

### Recruitment center

Name of recruitment center

Alborz university of Medical Sciences

### Full name of responsible person

Marjan Havaie

### Street address

Alborz University of Medical Sciences, Taleghani avenue, Alborz, Iran

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marjan.havaie23@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Aloraz University of Medical Sciences-vice President of Research

#### Full name of responsible person

Mohammad Noorisepehr

#### Street address

The research Chonsellor Department of Alborz Medical University, Azimieh Square, Alborz, Iran

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### Grant name

Aloraz University of Medical Sciences-vice President of Research

### Grant code / Reference number

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

Yes

### Title of funding source

Aloraz University of Medical Sciences-vice President of Research

### 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**

Alborz University of Medical Sciences

**Full name of responsible person**

Sara Esmaelzadeh Saeieh

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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**

All participants data can be shared after being unidentified

**When the data will become available and for how long**

Start the access period after publishing the results

**To whom data/document is available**

Public

**Under which criteria data/document could be used**

For use in studies

**From where data/document is obtainable**

Marjan havaie Marjane.havaie23@Gmail.com  
00989199184356

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

The application will be sent to the project implementer by email and within 24 hours will receive the necessary items

**Comments**