# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The effects of the psycho-sexual intervention on help-seeking in coping with sexual concerns of young women, a randomized controlled trial

## Protocol summary

**Study aim**
Determine the effects of psychosexual education on help-seeking of young adult women for sexual concerns

**Design**
Two arms parallel-group randomized trial. the sample size determine 70 for each group and a total of 140. In this study, the randomization method will be randomized block design with a block size of 4.

**Settings and conduct**
Women between 18-40 years old that registered for premarital classes in the only health center for premarital classes in Rasht city will be selected randomized in intervention and control groups and the content of the intervention will be taught using a mobile application

**Participants/Inclusion and exclusion criteria**
Reading and writing literacy Urbanization Marriage No pregnancy history Sexuality active At least one year of living together Not being pregnant and menopause Having a mobile phone with an Android system Access to Internet

**Intervention groups**
The intervention group will have access to the content of the intervention as a mobile application weekly for 6 weeks, and during this time, in peer's WhatsApp group, the content of the intervention will be analyzed Weekly by the researcher for further training and the asked questions of individuals will be solved in the group. We will ask them to share content with their husband standard questionnaires will be completed before and immediately after intervention and 2 months after the intervention. The control group will receive the mobile application but they did not access the intervention content until the end of the research. Then, based on the ethics of the research and their willingness can use the content of Intervention. Standard questionnaires will be completed before, immediately after 6 sessions of intervention, and 2 months after the intervention in the control group.

**Main outcome variables**
Help-seeking, help-seeking intention

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20160808029255N12**
Registration date: **2021-12-23, 1400/10/02**
Registration timing: **prospective**

Last update: **2021-12-23, 1400/10/02**
Update count: **0**

**Registration date**
2021-12-23, 1400/10/02

**Registrant information**

**Name**
Raziyeh Maasoumi

**Name of organization / entity**
Tehran University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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+98 21 6105 4214

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-01-05, 1400/10/15

**Expected recruitment end date**
2022-02-04, 1400/11/15

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of the psycho-sexual intervention on help-seeking in coping with sexual concerns of young women, a randomized controlled trial

**Public title**

The effects of the psycho-sexual intervention on help-seeking in coping with sexual concerns of young women

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Reading and writing literacy Urbanization Marriage No pregnancy history Sexuality active At least one year of living together Not being pregnant and menopause Having a mobile phone with Android system Internet access

**Exclusion criteria:**

Unwillingness of the women to continue participating in the study

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, the randomization method will be randomized block design with a block size of 4. The block randomization method is designed to randomize participants into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time. in this clinical trial with control and treatment groups, a randomized block procedure would be as follows: (1) block size of 4 will be chosen, (2) possible balanced combinations with 2 A (intervention) and 2 B (control) subjects will be calculated as 6 (BBAA, BABA, BAAB, ABBA, ABAB, AABB) and (3) blocks will be randomly chosen to determine the assignment of all participants.

**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 Shahroud University of Medical Sciences

**Street address**

Shahroud University of Medical Sciences and Health Services, Hafte Tir Square, Shahroud, Iran.

**City**

Shahroud

**Province**

Semnan

**Postal code**

3614773955

**Approval date**

2019-11-12, 1398/08/21

**Ethics committee reference number**

IR.SHMU.REC.1398.097

## Health conditions studied

### 1

**Description of health condition studied**

Help-seeking

**ICD-10 code**

**ICD-10 code description**

### 2

**Description of health condition studied**

Help-seeking intention

**ICD-10 code**

**ICD-10 code description**

### 3

**Description of health condition studied**

Openness to help-seeking

**ICD-10 code**

**ICD-10 code description**

### 4

**Description of health condition studied**

Self-stigma

**ICD-10 code**

**ICD-10 code description**

### 5

**Description of health condition studied**

Sexual assertiveness

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Help-seeking
**Timepoint**
Before the intervention, immediately and 2 months after the intervention
**Method of measurement**
Actual help-seeking questionnaire

**2**

**Description**
Help-seeking intention
**Timepoint**
Before the intervention, immediately and 2 months after the intervention
**Method of measurement**
General help-seeking questionnaire

**3**

**Description**
Openness to help-seeking
**Timepoint**
Before the intervention, immediately and 2 months after the intervention
**Method of measurement**
Modified version of attitudes toward professional help-seeking scale

**4**

**Description**
Self-stigma
**Timepoint**
Before the intervention, immediately and 2 months after the intervention
**Method of measurement**
Self-stigma questionnaire

**5**

**Description**
Sexual assertiveness
**Timepoint**
Before the intervention, immediately and 2 months after the intervention
**Method of measurement**
Hulbert sexual assertiveness questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
The intervention group will have access to the content of the intervention as a mobile application weekly for 6 weeks, and during this time, in peer's WhatsApp group, the content of the intervention will be analyzed weekly by the researcher for further training and the asked questions of individuals will be solved in the group. We will ask them to share content with their husband standard questionnaires will be completed before and immediately after intervention and 2 months after the intervention.
**Category**
N/A

**2**

**Description**
The control group will receive the mobile application but they did not access the intervention content until the end of the research. Then, based on the ethics of the research and their willingness can use the content of Intervention. Standard questionnaires will be completed before, immediately after 6 sessions of intervention, and 2 months after the intervention in the control group.
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Rasht referral health center for premarital education
**Full name of responsible person**
Shadi Sabetghadam
**Street address**
Health Center No. 8 - Daneshjoo Park.
**City**
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**Province**
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**Postal code**
4157648449
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**Email**
shadisabetghadam@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahroud University of Medical Sciences
**Full name of responsible person**
Mohammad Hassan Emamian
**Street address**
Shahroud University of Medical Sciences and Health Services, Hafte Tir Sq. Shahroud, Iran.
**City**
Shahroud
**Province**
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**Postal code**

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**Phone**
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pishgiri@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahroud University of Medical Sciences
**Proportion provided by this source**
30
**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**
Tehran University of Medical Sciences
**Full name of responsible person**
Raziyeh Maasoumi
**Position**
Associate Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Sexology, Reproductive Health
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## Person responsible for scientific inquiries

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**Latest degree**
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## Person responsible for updating data

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**Full name of responsible person**
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**Other areas of specialty/work**
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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**
Not applicable
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
Data of the study would be available after the unrecognizable process of participants.
**When the data will become available and for how**

**long**

Six months after publications of findings

**To whom data/document is available**

Data of this research would be available for academic researchers

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

Data of this study would be available for the same research

**From where data/document is obtainable**

Dr. Raziyeh Maasoumi- email: r_masoumi@sina.tums.ac.ir

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

Initial correspondence by email, on-site visit, and presentation of a proposal similar to the present study, provide sufficient evidence for the similarity of its research to the present study, study proposal by the present investigator, decision making and announcement of the result by the investigator to the researcher for access to data Providing the data file for use locally

**Comments**