Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 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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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
Rasht
Province
Tehran
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4157648449
Phone
+98 13 3355 0990
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
Semnan
Postal code

36147-73947

Phone
+98 23 3239 5054

Email
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

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Raziyeh Maasoumi

Position
Associate Professor

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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Raziyeh Maasoumi

Position
Associate Professor

Latest degree
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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