Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of intervention with psychosexual approach on sexual self-care of unmarried young girls

Protocol summary

Study aim
Investigating the effect of intervention with psychosexual approach on sexual self-care of young girls
Design
Two-arm parallel-group randomized trial. The sample size was determined 60 for each group and a total of 120. In this study, the randomization method will be a randomized block design with a block of size 4.
Settings and conduct
The place of study is Tehran University of Medical Sciences. The study population is the first-year unmarried female students of Tehran University of Medical Sciences. Blinding is not done in this study.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Being female; Being single; Freshman in medical science Exclusion criterion: Participation in another clinical trial
Intervention groups
The intervention group will have access to the intervention content weekly for 4 weeks. The control group will receive content unrelated to the research and will not have access to the content of the self-care promotion intervention until the end of the research.
Main outcome variables
Sexual self-care

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160808029255N14**
Registration date: **2023-10-29, 1402/08/07**
Registration timing: **prospective**

Last update: **2023-10-29, 1402/08/07**
Update count: **0**
Registration date
2023-10-29, 1402/08/07

Registrant information
Name
Raziyeh Maasoumi
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-01-21, 1402/11/01
Expected recruitment end date
2024-04-19, 1403/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of intervention with psychosexual approach on sexual self-care of unmarried young girls

Public title
The effect of psychosexual intervention on girls' sexual self-care
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being female Being single Freshman in medical science
Exclusion criteria:

Participation in other clinical trials

Age

From **18 years** old to **29 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by block method and using the randomization table made with Random Allocation Software with blocks of four and individual randomization units. In order to hide the random allocation from the researcher, envelopes are prepared as many as the sample size, and each of the random sequences created is recorded on paper and placed inside the envelope, and finally, the lids of the envelopes are glued. At the time of registration of people, based on the order of samples, one of the envelopes will be opened and the assigned group of that sample will be determined.

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 Tehran University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, East Nosrat Ave., Towhid Sq. Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2023-09-03, 1402/06/12

Ethics committee reference number

IR.TUMS.FNM.REC.1402.122

Health conditions studied

1

Description of health condition studied

Sexual self-care

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual self-care

Timepoint

Before the intervention, immediately after the intervention and 3 months after the intervention

Method of measurement

Sexual self-care questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will have access to the intervention content online and offline weekly for 4 weeks (8 sessions). The content of the intervention includes training in the dimensions of sexual and gender identity of girls and boys, sexual and reproductive rights, meeting sexual needs, marriage, sexually transmitted infections, unwanted pregnancy, unsafe abortion, and life skills. During the intervention period, the researcher will answer questions related to the intervention in a WhatsApp support group to follow up and prevent people from dropping out. The standard questionnaires will be completed again before and after the end of the intervention, as well as 3 months after the end of the intervention.

Category

N/A

2

Description

Control group: The control group will receive content unrelated to the research and will not have access to the content of the intervention promoting self-care until the end of the research, but after that, to comply with the principles of research ethics, they can use the content of the intervention if needed and desired. The standard questionnaires will be completed again before and after the completion of 8 intervention sessions, as well as 3 months after the completion of the intervention in the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran University of Medical Sciences
Full name of responsible person
Raziyeh Masoumi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Akbar Fotouhi
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Qods street; Keshavarz boulevard
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Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Raziyeh Maasoumi
Position
Associate professor
Latest degree
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Other areas of specialty/work
Reproductive Health
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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
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
6 months after publishing the results
To whom data/document is available
Research results would be available for academic researchers
Under which criteria data/document could be used
Research results 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
Sending a request by email attendance to the office of corresponding project presentation the reasons for the similarity of two projects studying the proposal by corresponding of project final decision making with corresponding author access of data in the office of the corresponding author
Comments