

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of Remote Group intervention on sexual health literacy, sexual function, sexual self-efficacy and quality of sexual life of women in reproductive age: A randomized clinical trial study

Protocol summary

Study aim

The effect of Remote Group intervention on sexual health literacy, sexual function, sexual self-efficacy and quality of sexual life of women in reproductive age: A randomized clinical trial study

Design

This research is a randomized clinical trial with two groups; intervention and control. Sampling will be conducted by block design (with block size of 4) random allocation

Settings and conduct

Women of reproductive age from health centers in Amol city will be selected randomized in intervention and control groups and The content of the intervention will be taught offline mode by using WhatsApp.

Participants/Inclusion and exclusion criteria

1-Iranian originality, 2- reading and writing literacy, 3-marriage, 4-Not having physical or mental diseases affecting sexual health of the woman or her husband, 5- Not having critical marital conflicts or not being on the verge of divorce 6-Not previous participation in Sex education classes 7-Willingness to attend all meetings 8-to cross At least one year of living together 9- Not infection to Known sexual dysfunction like Vaginismus 10- not being pregnant and Menopause 11- Do not consume of Cigarettes, Alcohol and no addiction in woman or her husband 12-Do not take any Psychotropic or psychoactive drug or Drugs affecting the sexual response cycle during intervention by woman or her husband 13- Having a mobile phone with Android system 14-Access to internet

Intervention groups

The intervention group, will have access to the Content of the intervention as offline mode for 8 weeks, and during this time, in online and offline peer's Whatsapp group, the content of the intervention will be analyzed Weekly by researcher for further training and the asked

question in the group for further training .

Main outcome variables

sexual health literacy; Quality of sexual life; sexual self efficacy; sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160808029255N10**

Registration date: **2021-01-10, 1399/10/21**

Registration timing: **prospective**

Last update: **2021-01-10, 1399/10/21**

Update count: **0**

Registration date

2021-01-10, 1399/10/21

Registrant information

Name

Raziyeh Maasoumi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4214

Email address

r_masoumi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Remote Group intervention on sexual health literacy, sexual function, sexual self-efficacy and quality of sexual life of women in reproductive age: A randomized clinical trial study

Public title

The effect of Remote Group intervention on sexual health literacy, sexual function, sexual self-efficacy and quality of sexual life of women in reproductive age

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian originality reading and writing literacy marriage Not having physical or mental diseases affecting sexual health of the woman or her husband Not having critical marital conflicts or not being on the verge of divorce Not previous participation in Sex education classes Willingness to attend all meetings At least one year of living together Not infection to Known sexual dysfunction like Vaginismus not being pregnant and Menopause Do not consume of Cigarettes, Alcohol and no addiction in woman or her husband Do not take any Psychotropic or psychoactive drug or Drugs affecting the sexual response cycle during intervention by woman or her husband Having having a mobile phone with Android system Access to internet

Exclusion criteria:

exclusion criteria: Unwillingness of the women to continue participating in the study

AgeFrom **25 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **110****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, randomization method will be randomized block design with 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) a 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 Tehran University of Medical Sciences

Street address

East Nosrath., Towhid Sq

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2019-07-08, 1398/04/17

Ethics committee reference number

IR.TUMS.FNM.REC.1398.077

Health conditions studied**1****Description of health condition studied**

sexual health literacy

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

sexual function

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Quality of sexual life

ICD-10 code**ICD-10 code description****4****Description of health condition studied**

Sexual self-efficacy

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

sexual health literacy

Timepoint

Before the intervention, immediately and one month after the intervention

Method of measurement

Iranian Adult Sexual Health Literacy Standard Questionnaire

2

Description

sexual function

Timepoint

Before the intervention, immediately and one month after the intervention

Method of measurement

The standardized Persian version of the six-item women's sexual function index

3

Description

Quality of sexual life

Timepoint

Before the intervention, immediately and one month after the intervention

Method of measurement

Standardized questionnaire Quality of sexual life for Iranian women

4

Description

sexual self-efficacy

Timepoint

Before the intervention, immediately and one month after the intervention

Method of measurement

Standardized questionnaire of sexual self-efficacy for Iranian women

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group, will have access to the Content of the intervention as offline mode weekly for 8 weeks, and during this time, in online and offline peer's Whatsapp group, the content of the intervention will be analyzed Weekly by researcher for

further training and the asked questions of individuals will be solved in the group .Standard questionnaires will be complete before and immediately after 8 sessions of intervention and also one month after the intervention.

Category

N/A

2

Description

Control group: The control group will receive information about Covid-19 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 complete before and immediately after 8 sessions of intervention and also to one month after the intervention in control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Amol city

Full name of responsible person

Raziyeh Maasoumi

Street address

East Nosrath., Towhid Sq

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4214

Email

r_masoumi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammad Ali Sahraian

Street address

Keshavarz Blv., Qods St

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

msahrai@sina.tums.ac.ir

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

Ph.D.

Other areas of specialty/work

Sexology, Reproductive Health

Street address

East Nosrath., Towhid Sq

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4214

Email

r_masoumi@sina.tums.ac.ir

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

Latest degree

Ph.D.

Other areas of specialty/work

Sexology, Reproductive Health

Street address

East Nosrath., Towhid Sq

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4214

Email

r_masoumi@sina.tums.ac.ir

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

Ph.D.

Other areas of specialty/work

Sexology, Reproductive Health

Street address

East Nosrath., Towhid Sq

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4214

Email

r_masoumi@sina.tums.ac.ir

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 unrecognizable process of participants.

When the data will become available and for how long

6 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 same research

From where data/document is obtainable

Dr. Raziye 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 of project presentation the reasons for
similarity of two projects studying the proposal by
corresponding of project final decision making with
corresponding author access of data in office of
corresponding author

Comments