

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of virtual training stress management education on sexual function of women around menopause

Protocol summary

Study aim

Determining the effect of virtual stress management training on sexual performance of women around menopause

Design

Quasi-experimental study of a group before and after

Settings and conduct

this study is a quasi-experimental study that on 50 women aged 40 to 50 years referred to Sohrab Ali Bakhshi Health Center under the auspices of Iran University of Medical Sciences located in the Shahriar city of Tehran will be done. After obtaining permission from the ethics committee of Iran University of Medical Sciences and referring to the research environment among the qualified women who refer to the above center who after providing the necessary explanations about the objectives and how to conduct research, want to participate in the study. , Informed consent will be received Sampling will be done continuously for 12 weeks (3 months), with reference to electronic household records and sampling in 5 groups of 10 people. The samples will first complete the demographic and sexual function questionnaires. Questionnaires will be completed virtually and . Stress management training will be held in the form of 8 30-minute virtual sessions, twice a week for 4 weeks, using the WhatsApp social network. Sexual function will be determined before, 4 and 8 weeks after the intervention.

Participants/Inclusion and exclusion criteria

1. Have a minimum literacy: Current pregnancy and lactation and one year before the start of the study
2. Having a cell phone and smartphone line or computer or laptop or iPad during the intervention: Occurrence of stressful experiences during the last 3 months for couples

Intervention groups

Intervention groups include women around menopause with the age of 40 to 50 years referred to Sohrab Ali Bakhshi Comprehensive Health Center in Shahriar city.

After filling in the informed consent form by the samples, sampling will be done continuously. Stress management training will be in the form of 8 virtual 30-minute sessions.

Main outcome variables

Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140823018903N2**

Registration date: **2021-11-17, 1400/08/26**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-17, 1400/08/26**

Update count: **0**

Registration date

2021-11-17, 1400/08/26

Registrant information

Name

Leila Neisani Samani

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 2846

Email address

nneysani@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of virtual training stress management education on sexual function of women around menopause

Public title
Studying the effect of virtual training stress management education on sexual function of women around menopause

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Have a minimum literacy Having a cell phone and smartphone line or computer or laptop or iPad during the intervention Living with spouse for the past 6 months Failure to receive hormone therapy or complementary medicine related to fertility and menopause for the past 6 months No known mental health problems or systemic illnesses (such as diabetes, hypertension, kidney disease) Having sex with spouse during the study and one month before Monogamy The couple's first marriage Have at least one period in the last 3 months
Exclusion criteria:
 Current pregnancy and lactation and one year before the start of the study Occurrence of stressful experiences during the last 3 months for couples Alcohol use or drug abuse in couples (while studying and in the history of couples)

Age
From **40 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of iran university of medical sciences

Street address

Hemmat Highway between Chamran and Sheikh Fazlollah Iran University of Medical Sciences Headquarters Fifth Floor

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-10-03, 1400/07/11

Ethics committee reference number

IR.IUMS.REC.1400.620

Health conditions studied

1

Description of health condition studied

Stress management training on sexual function

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual function score of women around menopause using Rosen et al.'s sexual function questionnaire

Timepoint

Determining the score of sexual function at the beginning of the study (before the intervention), 4 and 8 weeks after the intervention.

Method of measurement

Rosen et al. Female sexual function index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Implementing a virtual training program for stress management for 5 groups of 10 women around menopause in 8 sessions of 30 minutes 2 times a week for 4 weeks using WhatsApp social network.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Sohrab Ali Bakhshi Shahriar Comprehensive Health Center

Full name of responsible person

Dr Afsaneh Bagheri

Street address

Tehran Province, Shahriar, Enghelab St., next to Imamzadeh Ismail, not far from Ansar Alley, Sohrab Ali Bakhshi Health Center

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Shahriyar

Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. hossein Keyvani

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences, fifth floor of the headquarters

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Research_m@iums.ac.ir

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Leila neysani samani

Position

Faculty of medical sciences

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Tehran School of Nursing and Midwifery, Rashid Yasemi St., above Vanak Square, Vali Asr St., Tehran

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Failure to disclose information in order to maintain confidentiality

When the data will become available and for how long

Failure to disclose information in order to maintain confidentiality

To whom data/document is available

Failure to disclose information in order to maintain confidentiality

Under which criteria data/document could be used

Failure to disclose information in order to maintain confidentiality

From where data/document is obtainable

Failure to disclose information in order to maintain confidentiality

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

Failure to disclose information in order to maintain confidentiality

Comments

In the clinical study report section, according to the university guide, the report will be presented to the research system.