Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of sexual health education package on the sexual life of working women

Protocol summary

Study aim

Assessing the effect of sexual health education package on the sexual life of employed women

Design

A randomized controlled clinical trial with parallel groups, without blinding, was performed on 70 employed women. The random number table of Rand Company was used for randomization.

Settings and conduct

The present study will be conducted as a clinical trial with the participation of 70 women working in the municipality of District 10 of Tehran in 1399. Employed women will be randomly assigned to intervention and control groups. In the intervention group, the sexual health training package (prepared by the research team) will be done in 8 sessions in 8 weeks as a group to women working in the municipality of District 10 of Tehran. In the control group, no action will be taken.

Participants/Inclusion and exclusion criteria

Major conditions for entering the study before randomization: married employed women living in Tehran, having age 20 to 45, having literacy in Persian, no known underlying disease, no history of psychiatric interventions, no stressful event during the past month, no history of pelvic surgery, no uterine prolapse, cystocele, rectocele and genital infections, no history of depression and anxiety, no consumption of alcohol, drugs and cigarettes (based on self-expression of the samples) and having desire to participate in the study. Major conditions for not entering the study before randomization: Do not attend training sessions (at least two absentee sessions)

Intervention groups

In the intervention group, the sexual health training package (prepared by the research team) will be done in 8 sessions in 8 weeks as a group to women working in the municipality of District 10 of Tehran. In the control group, no action will be taken.

Main outcome variables

Promoting the sexual health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200927048854N1**
Registration date: **2020-10-29, 1399/08/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-04, 1399/11/16**
Update count: **1**

Registration date

2020-10-29, 1399/08/08

Registrant information

Name

khadige abadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4495 8982

Email address

kh_abadian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of sexual health education package on the sexual life of working women

Public title
Investigating the effect of sexual health education on sexual life

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Married employed women living in Tehran having age 20 to 45 having literacy in Persian Desire to participate in the study

Exclusion criteria:
known underlying disease history of psychiatric interventions stressful events during the past month history of pelvic surgery uterine prolapse, cystocele, rectocele and genital infections history of depression and anxiety, Consumption of alcohol, drugs and cigarettes (based on self-expression of the samples)

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is generated by random or random number tables and by computers that randomly set numbers. One of these programs is the Rand Company Random Number Table. To use a table of random numbers, the researcher must first define the framework of his / her statistical community; That is, determine the exact number of people in the community and give them a code or number, respectively. Because the total number of people in the community is 70, the codes and numbers assigned to people in the community will also be double digits, such as 01, 02, 03 And we enter these two-digit hunts into the software, then we randomly start from a point in the table in the direction of a row or column to select sample people from the table. The selection of the point can be done by closing the eyes and placing a finger or the tip of a pen on the table. The movement does not differ in the direction of the row or column, and this is up to the researcher. But according to the type of code digits (two digits) he must select the same number of digits in the row or column direction. It then controls the route numbers. He will inevitably encounter two types of numbers, one of which is smaller than the number of the study population and the other of which is larger than the number of the population. It should only consider and select smaller numbers. The selected number is in fact the individual code of the community that is selected as the sample. This should be continued until a small number can be selected based on the number of sample people (35). After the sample size is completed, the sampling work is completed. The 35 people selected are the intervention group and the rest of the codes are the control group.

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 Shahid Beheshti University of Medical Sciences

Street address
Shahid Chamran Highway, Shahid Beheshti University of Medical Sciences,Tehran

City
Tehran

Province
Tehran

Postal code
38698-65178

Approval date
2020-08-23, 1399/06/02

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1398.200

Health conditions studied

1

Description of health condition studied
sexual health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Promoting the sexual health of working women

Timepoint
Before, immediately and 4 weeks after the intervention

Method of measurement
Female Sexual Function Index and and Marital Satisfaction Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Training sessions will be held by the researcher for 8 weeks and 8 sessions (each session is 90 minutes) in groups and for women working in the municipality of District 10 of Tehran. The contact numbers will be obtained from the participants and in the virtual group formed by the researcher in WhatsApp software; To better understand the content by employed women, at the beginning of each session, time will be allocated to women for expressing their opinions and questions, as well as questions and answers about the topics discussed in the previous session. "Women's Sexual Function Index" and "Marital Satisfaction Scale" It will be measured simultaneously with the control group before, immediately and 3 weeks after the study.

Category

N/A

2

Description

Control group: In the control group without any educational intervention, "Women's Sexual Function Index" and "Marital Satisfaction Scale" will be measured simultaneously with the intervention group before, immediately and 3 weeks after the study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran District 10 Municipality

Full name of responsible person

Zohre Keshavarz

Street address

Shahid Chamran Highway, Shahid Beheshti University of Medical Sciences, Tehran

City

Tehran

Province

Tehran

Postal code

38698-65178

Phone

+98 21 4495 8982

Email

keshavarzzohre57@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Masoumeh Simbar

Street address

Shahid Chamran Highway, Shahid Beheshti University of Medical Sciences, Tehran

City

Tehran

Province

Tehran

Postal code

1996835119

Phone

+98 21 8820 2512

Email

msimbar@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zohre Keshavarz

Position

Associate Professor Shahid Beheshti University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Valiasr St. - Niayesh Intersection - Opposite to Shahid Rajaei Heart Hospital - School of Nursing and Midwifery

City

Tehran

Province

Tehran
Postal code
1985717443
Phone
+98 21 8820 2512
Email
z.keshavarz@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zohre Keshavarz
Position
Associate Professor Shahid Beheshti University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Valiasr St. - Niayesh Intersection - Opposite to Shahid Rajaei Heart Hospital - School of Nursing and Midwifery
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8820 2512
Email
z.keshavarz@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Khadige Abadian
Position
PhD in Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Valiasr St. - Niayesh Intersection - Opposite to Shahid Rajaei Heart Hospital - School of Nursing and Midwifery
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 4495 8982
Email
kh_abadiaN@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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