Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of educational package on the sexual function of cold-temper women in the reproductive age

Protocol summary

Study aim
Effect of educational package on sexual function of female sexual frigidity of reproductive age

Design
Of two health centers, 80 women aged 20 to 40 are randomly selected. Participants are randomly assigned to two intervention and control groups and each participant is assigned a code, and the demographic data, the degree of depression, sexual function, and temperament of the sample are compiled.

Settings and conduct
In this research, two health care centers are selected by randomization. Then one is assigned for control and the other for intervention group by drawing method

Participants/Inclusion and exclusion criteria
Inclusion criteria: sexual function score (FSFI) <28; sexual frigidity determination score <14. Exclusion criteria in the beginning of the study: Taking medicine affecting sexual function; happening stressful events during the past 6 months for any of couples.

Intervention groups
In intervention group each participant take part in 2 sessions per week for 3 weeks. (each training class lasts for 60 minutes) while the control group do not take place in training classes. After four weeks sexual function, temperament assessment and depression questionnaires are given to both control and intervention groups.

Main outcome variables
Sexual function score with FSFI questionnaire

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20170623034717N1**
Registration date: **2018-01-02, 1396/10/12**
Registration timing: **retrospective**
Last update: **2018-01-02, 1396/10/12**
Update count: **0**

Registration date
2018-01-02, 1396/10/12

Registrant information

Name
Nasim Baradaran Akbarzadeh

Name of organization / entity
Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
University of Medical Sciences, Mashhad, Vice Chancellor for research

Expected recruitment start date
2017-11-22, 1396/09/01

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date
2017-08-05, 1396/05/14

Actual recruitment end date
2017-11-30, 1396/09/09

Trial completion date
empty

Scientific title
Effect of educational package on the sexual function of cold-temper women in the reproductive age

Public title
effect of education on sexual function

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

female gender havilranian cold-tempered womenng consent letter aged 18 to 40 Muslim the participants must be educated. living in Mashhad having sexual activity in the last 4 weeks Body mass index between 19.8_29 kg/m2 sexual function score (FSFI) <28 Tempered type determination score <14 The allocated groups are females whose scores in depression, anxiety and stress questionnaire are lesser than 14, 10 and 17, respectively

Exclusion criteria:

Taking medicine affecting sexual function happening stressful events during the past 6 months for any of couples being under psychiatric treatment for mental disorders having severe depression drug or alcohol addiction in any of couple No tendency to cooperate with research team having major conflicts with husband studying books or consulting about sexual issues during the past 6 months studying books or consulting about marital relations during the past 6 months being under treatment for sexual dysfunction in any of couple taking medicine lead to change in sexual desire during the past 3 months

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a simple random sampling method (random table number), two health centers are selected from five health centers in Mashhad. These centers assigned to the two group of intervention and control groups using coin throw.

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 Mashhad University of Medical Sciences

Street address

Daneshgah street, Ghoreshi building, Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2017-06-18, 1396/03/28

Ethics committee reference number

IR.MUMS.REC.1396.39

Health conditions studied

1

Description of health condition studied

Other sexual disorders

ICD-10 code

F66

ICD-10 code description

Other sexual disorders

Primary outcomes

1

Description

Improve female sexual function

Timepoint

Before intervention, immediately after intervention.

Method of measurement

Sexuality Questionnaire (FSFI).

Secondary outcomes

1

Description

pain

Timepoint

4 weeks after the end of the intervention

Method of measurement

Visual Analogue Scale (0 to 10)

Intervention groups

1

Description

Specific training will be given, three weeks, twice a week, each session 60 minutes to the intervention group by lecture, question and answer and group discussion

Category

Lifestyle

2

Description
Control group: without training
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Abas abad Health Center
Full name of responsible person
Dr Asna Ashar
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9th street, Kamyab Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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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
Mashhad 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
Mashhad University of Medical Sciences
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Position
Master of Midwifery (student)
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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
We have not a plan for publishing our individualized participants data.
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
No - There is not 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