

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3763 4651

Email address

baradarann941@mums.ac.ir

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

Street address

9th street, Kamyab Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen tafaghodi

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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

Full name of responsible person

Nasim Baradaran Akbarzadeh

Position

Master of Midwifery (student)

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, Doktora Crossroads, Ebne Sina Street,

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahin Tafazoli

Position

Midwifery Master

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Web page address

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