

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigation the reproductive health needs of rural women in childbearing age: design and implementation

Protocol summary

Study aim

Determining the effect of educational intervention designed on sexual health of rural women in reproductive age in Neyshabur city 1396

Design

Three parallel group of rural women were selected to participate in this study (48 in the training group by the researcher, 47 in the control group and 50 in the training group by Behvarz). Data were collected by a validated and reliable questionnaire and before and 1 and 2 month after intervention. This study was not blind.

Settings and conduct

This study was conducted on 145 rural women in Neyshabur. The educational program was designed based on Sexual health model (SHM). At first, the primary test was performed in Three groups (2 intervention groups and control group) and then again, the test was performed 4 and 8 weeks after intervention with the same questionnaire in Three groups.

Participants/Inclusion and exclusion criteria

1- Be aged 15 to 45 years 2. Married and live with her husband. 3. Has no acute communication problems with his wife. 4- Not pregnant or breastfeeding. 5- permanent residents of the village (more than one year) 6. There is no known physical and mental illness 7. Have sex during the past month 8. Sexual dysfunction in women (28 and less than Gender Equity Index (FSFI) questionnaire). 9. Has not participated in any educational course in relation to marital problems.

Intervention groups

In intervention groups (Training by the researcher and training by Behvarz) was performed 3 educational intervention sessions for 90 minutes using lecturing method, question answer method, focus group discussion and slideshows, but the control group received no intervention.

Main outcome variables

Sexual dysfunction and sexual satisfaction in rural women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180415039315N1**

Registration date: **2018-06-06, 1397/03/16**

Registration timing: **retrospective**

Last update: **2018-06-06, 1397/03/16**

Update count: **0**

Registration date

2018-06-06, 1397/03/16

Registrant information

Name

khosheh khaleghinezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

Email address

khaleghi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2017-11-22, 1396/09/01

Actual recruitment end date

2018-04-20, 1397/01/31

Trial completion date

empty

Scientific title

Investigation the reproductive health needs of rural women in childbearing age: design and implementation

Public title

Investigation the reproductive health needs of rural women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Married rural women of reproductive age (15 to 45 years) History of settlement in the village more than a year ago The person's willingness to participate in the study There is no known physical and psychological illness Not pregnant or breastfeeding. Have sex during the past month Has not participated in any training course on marital problems. Existence of sexual dysfunction in women (Score 28 and less than female Sexual Function Index (FSFI))

Exclusion criteria:

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Actual sample size reached: **145**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Nursing and Midwifery School, Crossroads Valieaser with Niaiesh St.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2016-11-13, 1395/08/23

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.588

Health conditions studied

1

Description of health condition studied

Sexual dysfunction in women

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction

Primary outcomes

1

Description

Changes in female sexual function index score and female sexual satisfaction score

Timepoint

Before intervention and 1 and 2 months after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: educational intervention by the researcher: The intervention included 3 training sessions 90-minute that it was carried out by lecture, question and answer method, focused group discussion and slideshow. The intervention included the definition of Sexual health model (SHM), genital function and anatomy, sexual dysfunction, sexual transmitted diseases, health care and safer sex, challenges and barriers to sexual health, common cancers of women and communication skills.

Category

Behavior

2

Description

Control group: Control group: Before the intervention, questionnaires was given to the control group. There was no intervention in the control group. After the intervention, questionnaires were again completed by the control group (1 and 2 months after intervention).

Category

N/A

3

Description

Intervention group: educational intervention by the behvarz: The intervention included 3 training sessions 90-minute that it was carried out by lecture, question and answer method, focused group discussion and slideshow. The intervention included the definition of Sexual health model (SHM), genital function and anatomy, sexual dysfunction, sexual transmitted diseases, health care and safer sex, challenges and barriers to sexual health, common cancers of women and communication skills.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

خانه های بهداشت روستایی در شهرستان نیشابور

Full name of responsible person

دکتر عصمت تقی آبادی

Street address

خیابان شریعتی، خیابان جلال آل احمد، معاونت بهداشتی شبکه بهداشت و درمان نیشابور

City

نیشابور

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khoosheh7@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mahrokh Dolatyan

Street address

Shahid Beheshti University of Medical Sciences & Health Services, Faculty of Nursing and Midwifery

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mhdolatian@gmail.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

Dr. Noorsadat Kariman

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

دانشکده پرستاری و مامایی، چهار راه ولیعصر با نیایش، خیابان ولیعصر

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Noorsadat Kariman

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

khosheh khaleghinezhad

Position

PhD student

Latest degree

Master

Other areas of specialty/work

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Postal code

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+98 21 8820 2518

Email

khaleghi@sbmu.ac.ir

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