

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of counseling based on sexual self-efficacy on sexual function and sexual satisfaction in newly married women: a randomized controlled trial

Protocol summary

Summary

Objective: to determine the effect of counseling on sexual function and sexual satisfaction in newly married women. Design: randomized controlled trial. Setting and conduct: this study will be conducted on newly married women covered by the premarital counseling center in Zanjan City. Researcher will be attended in premarital counseling center and listed contact number of couple who have been married previous six months to 3 years through health file. Then, they will be invited for participation in study through telephone call. After attending in the counseling center and completing consent form, the pretest questionnaires will be completed by self-administered method. Participants will be randomly assigned into two groups (one intervention group receiving sexual counseling and a control group) with block sizes of 4 and 6. A person from research team not involved in the sampling will generate allocation sequence. Participants: 88 newly married women aged at 20 to 35 years old. Intervention: Educational intervention based on social cognitive theory of Bandura will be provided for intervention group. An individual counseling (30 minutes per session) and five group counseling (90 minutes per session for eight small groups) will be carried out within six weeks (one session in each week) for intervention group. Primary outcome variables include sexual function and sexual satisfaction and secondary outcome variables include sexual quality of life and sexual self-efficacy that will be evaluated before and eight weeks after intervention through questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121010324N26**

Registration date: **2016-01-23, 1394/11/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-23, 1394/11/03

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling based on sexual self-efficacy on

sexual function and sexual satisfaction in newly married women: a randomized controlled trial

Public title
The effect of counseling based on sexual self-efficacy on sexual function and sexual satisfaction in newly married women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: women aged at 20 to 35 years old; women married and living with spouse; having at least a high school education; having at least six months and a maximum of three-year experience of marital life; being interested in participating the study; marital monogamy; having the first experience of marriage; no pregnancy and lactation and no planning for pregnancy at least in the next 12 month; at least 7 years old age difference among couples. Exclusion criteria: catching each of the spouses to certain physical diseases and mental disorders; medicine consumption that affect their sexual function (currently or within the last six months); husband 's addiction to drugs and psychotropic substances (according to wife); changing location and being in trouble for participation; having experience of disaster during six-month age (death of a child or loved one, serious illness of a close relative, the prison sentences of one member of a family, experience of depression); unwanted marriage crisis (divorce, wrath, long official mission); being relations of cousin, co-worker or neighbor between participants of intervention and control groups; forced marriage and Emotional divorce.

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
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 Tabriz University of Medical sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

City

Tabriz

Postal code

Approval date

2015-11-30, 1394/09/09

Ethics committee reference number

54/9709

Health conditions studied

1

Description of health condition studied

Sexual function

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

Sexual Function

Timepoint

Befor of intervention/ 8 weeks after end of intervention

Method of measurement

Female Sexual Function Index-FSFI

2

Description

Sexual Satisfaction

Timepoint

Befor of intervention/ 8 weeks after end of intervention

Method of measurement

Sexual Satisfaction Scale for Women

Secondary outcomes

1

Description

Sexual Quality Of Life

Timepoint

Befor of intervention/ 8 weeks after end of intervention

Method of measurement

Sexual Quality Of Life-Female- SQOL-F

2

Description

Sexual Self-efficacy

Timepoint

Before of intervention/ 8 weeks after end of intervention

Method of measurement

Sexual Self-efficacy Scale

Intervention groups

1

Description

Educational intervention based on social cognitive theory of Bandura will be provided for intervention group. An individual counseling (30 minutes per session) and five group counseling (90 minutes per session for eight small groups) will be carried out within six weeks (one session in each week) for intervention group.

Category

Behavior

2

Description

The control will receive no intervention. If the results of research show the positive effect of counseling, the content of counseling as booklet will be provided for control group at the end of study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Premarital Counseling Center

Full name of responsible person

Badrolmonir Safari

Street address

Health Center of Number 14

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

Street address

Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Nursing & Midwifery Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Leila Alimohammadi

Position

Ms Student of Counseling in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

PhD of Reproductive Health

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Mohammad Masoud Vakili
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Ph.D of Health Education & Health Promotion
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty