Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 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 Deign: 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

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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
Befor 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
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Person responsible for updating data

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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