

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparing the effect of cognitive-behavioral therapy and education based on sexual health self care needs on sexual assertiveness and satisfaction in recently married women: a randomized clinical trial

Protocol summary

Study aim

Determining the effect of cognitive behavior therapy (CBT) and education based on sexual health self-care needs on sexual assertiveness and satisfaction of newly married women

Design

A randomized controlled clinical trial with three parallel groups, non-blind will be conducted on 66 recently married women. The participants will be assigned into three groups by blocked randomization using RAS with block sizes of 9, 6 and the allocation ratio of 1:1:1.

Settings and conduct

Sampling will be performed on newly married women who had referred to Asadabadi and Haft-Tir marriage counseling centers in Tabriz. There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Newly married women during 1 to 3 years ago; Above 18 years of age; Living in one house with husband. Exclusion criteria: Pregnancy; being in the postpartum period

Intervention groups

For the first intervention group, CBT will be held in eight sessions including initial sexual evaluation, identifying maladaptive sexual thoughts and beliefs. For the second intervention group, 5-8 group education sessions, including training about sexual and reproductive system and the stages of the sexual cycle and etc will be held. Control group: will not receive any intervention.

Main outcome variables

The mean score of sexual satisfaction; The mean score of sexual assertiveness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170506033834N8**

Registration date: **2021-09-11, 1400/06/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-11, 1400/06/20**

Update count: **0**

Registration date

2021-09-11, 1400/06/20

Registrant information

Name

Roghaiyeh Nourizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3479 6770

Email address

nourizadehr@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-27, 1400/06/05

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of cognitive-behavioral therapy and

education based on sexual health self care needs on sexual assertiveness and satisfaction in recently married women: a randomized clinical trial

Public title
Comparing the effect of cognitive-behavioral therapy and education based on sexual health self care needs on sexual assertiveness and satisfaction

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Recently married (1 to 3 years after marriage) Living in Tabriz Has at least middle school education First time marriage Monogamy Living in one house with husband
Exclusion criteria:
Experiencing a severe psychological crisis during the last 6 months, such as the death of relatives Under 18 years old Suffering from severe physical diseases (cancers, etc.) Pregnancy and the postpartum period Divorce request Forced marriage Addiction in One of couples Mental disorders such as depression or taking psychiatric drugs according to the woman's statement

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned in three groups of cognitive behavioral therapy, education based on sexual health self care needs and control by blocked randomization using Random allocation software with block sizes of 6, 9 and the allocation ratio of 1:1:1. The type of assignment will be written on paper, put in opaque envelopes based on the allocation sequence (allocation concealment). The envelopes will be prepared by a person uninvolved in the sampling process.

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 Committees of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences; Azadi Street
City
Tabriz
Province
East Azarbaijan
Postal code
0415138947
Approval date
2021-04-26, 1400/02/06
Ethics committee reference number
IR.TBZMED.REC.1400.102

Health conditions studied

1
Description of health condition studied
Sexual assertiveness
ICD-10 code
ICD-10 code description

2
Description of health condition studied
Sexual satisfaction
ICD-10 code
ICD-10 code description

3
Description of health condition studied
Marital Satisfaction
ICD-10 code
ICD-10 code description

4
Description of health condition studied
Sexual self-efficacy
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
Score of sexual assertiveness
Timepoint
Before the intervention, and four weeks after the intervention
Method of measurement
Halbert Sexual Assertiveness Questionnaire

2

Description

Score of sexual satisfaction

Timepoint

Before the intervention, and four weeks after the intervention

Method of measurement

Larson sexual satisfaction questionnaire

Secondary outcomes

1

Description

Score of sexual self efficacy

Timepoint

Before the intervention, and four weeks after the intervention

Method of measurement

Vaziri and Lotfi Sexual Self Efficacy Questionnaire

2

Description

Score of marital satisfaction

Timepoint

Before the intervention, and four weeks after the intervention

Method of measurement

Enrich Marital Satisfaction Questionnaire

Intervention groups

1

Description

For the first intervention group, 8 sessions of cognitive-behavioral therapy, once a week for 60 to 90 minutes, which includes initial sexual evaluation, rearrangement of sexual concepts, training sexual rights, and strengthening sexual skills, analyzing the reasons of decreased sexual self-efficacy and its importance in sexual relationship, follow-up and evaluation after the intervention.

Category

Behavior

2

Description

For the second intervention group, 5-8 training sessions based on sexual health self-care needs will be held once a week for 60 minutes, which includes education and information about structure and function of the reproductive system and the stages of the sexual cycle, information about women's rights on sexual and reproductive issues and sexual violence against women and how to achieve sexual assertiveness, healthy and responsible sexual behavior and promoting self-efficacy and Sexual skills.

Category

Behavior

3

Description

Control group: will not receive any intervention. At the end of the study, the most effective intervention will be conducted for the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Asadabadi marriage counseling center

Full name of responsible person

Dr. Nahid Azimzadeh

Street address

Asadabadi marriage counseling center; Next to the agricultural conservatory; Bahar Street

City

Tabriz

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5184743613

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2

Recruitment center

Name of recruitment center

7- Tir marriage counseling center

Full name of responsible person

Dr. Ziba Najafi pour

Street address

7- Tir marriage counseling center; Before Nasser Crossroads; Monajjem Street

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5166614766

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

Street address

Central Building; Tabriz University of Medical Sciences; Golgasht Street

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Samiei.moh@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Sanaz Jangi

Position

MSc student of Counseling in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

PhD in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

No more 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