Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of the integrative cognitive-behavioral art therapy approach and the cognitive-behavioral approach versus control group on sexual anxiety, sexual self-efficacy, and sexual quality-of-life in newly married women: a randomized clinical trial

Protocol summary

Study aim

To compare the effectiveness of the integrative cognitive-behavioral art therapy approach and the cognitive-behavioral approach versus control group on sexual anxiety, sexual self-efficacy, and sexual quality of life in newly married women

Design

This is a randomized clinical trial with a control group with parallel groups without blinding, in which 36 eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Urmia Consulting Center before Marriage, involving 36 eligible newly married women. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will not be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 14 to 45 years, First marriage, Educated, Exclusion criteria: Psychiatric disorders

Intervention groups

Intervention group 1: Routine education and care of the newly married couples plus integrative cognitive-behavioral art therapy approach for 90 minutes, one session per week for 7 weeks Intervention group 2: Routine education and care of the newly married couples plus cognitive-behavioral approach for 90 minutes, one session per week for 6 weeks Control group: Routine education and care of the newly married couples

Main outcome variables

Primary outcome: Average sexual anxiety score; Average sexual self-efficacy score; Average quality of sextual life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N599**
Registration date: **2026-04-08, 1405/01/19**
Registration timing: **prospective**

Last update: **2026-04-08, 1405/01/19**
Update count: **0**

Registration date

2026-04-08, 1405/01/19

Registrant information

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Jalal Poorolajal

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-05, 1405/02/15

Expected recruitment end date

2026-06-05, 1405/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of the integrative cognitive-behavioral art therapy approach and the cognitive-behavioral approach versus control group on sexual anxiety, sexual self-efficacy, and sexual quality-of-life in newly married women: a randomized clinical trial

Public title

Comparison of the effectiveness of the integrative cognitive-behavioral art therapy approach and the cognitive-behavioral approach versus control group on sexual anxiety, sexual self-efficacy, and sexual quality-of-life in newly married women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 14 to 45 years, First marriage, Educated,

Exclusion criteria:

Psychiatric disorders

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be performed using block randomization. To achieve this, six sheets of paper will be prepared - two with the name of "Intervention 1," two with the name of "Intervention 2," and two with the name of "Control." These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

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 Urmia University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Urmia University of Medical Sciences, Pardis Nazlo Road

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2026-02-18, 1404/11/29

Ethics committee reference number

IR.UMSU.REC.1404.521

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Average sexual anxiety score

Timepoint

Before intervention and 7 weeks later

Method of measurement

Using the sexual anxiety questionnaire

2

Description

Average sexual self-efficacy score

Timepoint

Before intervention and 7 weeks later

Method of measurement

Using the sexual self-efficacy questionnaire

3

Description

Average quality of sextual life score

Timepoint

Before intervention and 7 weeks later

Method of measurement

Using the sextual quality-of-life questionnaire for women

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Routine education and care of the newly married couples plus integrative cognitive-behavioral art therapy approach for 90 minutes, one session per week for 7 weeks (including: designing a sensation map of the body with anxiety concept using water paint, designing negative thoughts, mapping a face presenting negative believes and writing negative words and placing them around the picture using color pencil, painting with closed ees, painting with freely movement of the hands, writing a letter to yourself about needs, desire, and emotion in respect to sextual relationship)
Category
Treatment - Other

2

Description
Intervention group 2: Routine education and care of the newly married couples plus cognitive-behavioral approach for 90 minutes, one session per week for 6 weeks (including: definition of concept of sextual anxiety, training technique of relaxation, detecting anxiety situation and ranking them and training who the deal with them, realizing the strengthening factors of sextual self-confidence, training how the talk and expressing emotion to your husband, training effective relationship about sextual needs and desire, identifying ways of increasing pleasure and intimacy)
Category
Treatment - Other

3

Description
Control group: Routine education and care of the newly married couples
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Consulting Center before Marriage
Full name of responsible person
Hasti Jafari
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Sponsors / Funding sources

1

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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
Urmia 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
Urmia University of Medical Sciences
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Hasti Jafari
Position
Midwifery Student
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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