

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of the effectiveness of education and counselling of relationship enhancement on promoting intimate relationship and sexual motivation and function of menopausal wives and their husbands: a randomized controlled clinical trial

Protocol summary

Study aim

To determine the effect of relationship enhancement education and counselling on improving the intimate relationship and sexual motivation and function among menopausal-aged couples

Design

In this randomized controlled trial 28 couples, who their wives are at the peri-menopause or menopause period (40 -60 years old), will be randomly allocated into two groups, using a computerized table of random numbers and randomized blocking with block sizes of four. The type of intervention will be written on a piece of paper and inserted into opaque and consecutively-numbered envelopes. Blocking and preparation of the envelopes will be performed by a person uninvolved in sampling and data analysis

Settings and conduct

This study will be conducted in Tabriz health centers on menopausal couples. The researcher will attend the healthcare centers in Tabriz and will select eligible women through convenience sampling method. If a woman will tend to participate in the study with her husband, written consent will be obtained

Participants/Inclusion and exclusion criteria

Inclusion criteria including couples who their wives are at the peri-menopause or menopause period (40 -60 years old) exclusion criteria including addicted couples; couples with specific mental and psychosomatic disabilities; couples who have experienced bad events during the last six months such as death of a child or loved ones

Intervention groups

For the intervention group (n= 14 couples), eight 90 to 120 minute group education and counseling once a week will be provided. The control group (n= 14 couples) will receive educational booklet at the end of study

Main outcome variables

The primary outcome include interpersonal intimacy and secondary outcomes variable include sexual motivation and sexual Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171024036982N1**

Registration date: **2018-01-15, 1396/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-15, 1396/10/25**

Update count: **0**

Registration date

2018-01-15, 1396/10/25

Registrant information

Name

Zeinab Javadivala

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of education and counselling of relationship enhancement on promoting intimate relationship and sexual motivation and function of menopausal wives and their husbands: a randomized controlled clinical trial

Public title

The effect of education and counselling about relationship enhancement on promoting intimate relationship and sexual motivation and function of menopausal wives and their husbands

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

60-40 year old women who have menstrual irregularities

60-40 year old women who are menopause

Exclusion criteria:

Couples with specific mental and psychosomatic disabilities which influence their sexual performance

Addicted couples The incidence of bad events during the last six months such as the death of a child or loved ones

Women with certain cancers of women Men with certain diseases, including prostate disorders Women with the history of using hormones in the last six months

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, a randomized blocking with block sizes of four and 6 blocks will be used. Then, to allocation concealment, the type of intervention will be written on a sheet of paper and will be inserted into opaque and consecutively-numbered envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The online statistical computing web programming (www.randomization.com) will be used to perform a block randomization with randomly selected block sizes of 4.

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

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Tabriz

Province

East Azarbaijan

Postal code

14711

Approval date

2015-11-23, 1394/09/02

Ethics committee reference number

IR.TBZMED.REC.1394.735

Health conditions studied**1****Description of health condition studied**

Sexual function

ICD-10 code

F52.9

ICD-10 code description

Unspecified sexual dysfunction not due to a substance or known physiological condition

2**Description of health condition studied**

Sexual motivation

ICD-10 code

F52.0

ICD-10 code description

Lack or loss of sexual desire

3**Description of health condition studied**

Couple's relationship

ICD-10 code

F66.2

ICD-10 code description

Sexual relationship disorder

Primary outcomes

1

Description

Relationship intimacy

Timepoint

Before intervention, one and eight weeks after intervention

Method of measurement

Personal Assessment of Intimacy in Relationships (PAIR)

Secondary outcomes

1

Description

Sexual function

Timepoint

Before intervention, one and 3 weeks after intervention

Method of measurement

Female Sexual Function Index-FSFI

2

Description

Sexual motivation

Timepoint

Before intervention, one and 3 weeks after intervention

Method of measurement

Sexual motivation questionnaire

Intervention groups

1

Description

For the intervention group, eight 90 to 120 minute group education and counseling once a week will be provided

Category

Behavior

2

Description

For control group educational booklet will be provided at the end of the study.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyyed Hamzeh Health Center

Full name of responsible person

Zeinab Javadivala

Street address

Health Center of Seyyed Hamza, in front of Maghbar Shoara, Saghataleslam Street, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

Zeinab Javadivala

Position

PhD student in Health Education and Promotion

Latest degree

Master

Other areas of specialty/work

Health Promotion

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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