Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 envelops 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

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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
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
City
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 relashionship
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
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Health Center of Seyyed Hamza, infront 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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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
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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