Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Comprehensive Couple Education (CCE) in Attitude Extramarital Relations and Couple's Satisfaction and Conflict in Couple's Sexual Dysfunction

Protocol summary

Study aim
The Effect of Comprehensive Couple Education (CCE) Program on Attitude Extramarital Relations, Marital Satisfaction, and Conflict in Couples with Sexual Dysfunction

Design
A Triple-blinded, Randomized, Placebo-controlled Trial with parallel groups

Settings and conduct
This study will be conducted on 100 couples with sexual dysfunction, referred to health or counseling centers in Ilam. Assistance's researchers who will perform registration of samples in different centers, in the case of a couple in accordance with the criteria for entering the study, in a phone call with the assistance's researchers 1, according to a computer table, the couple will be placed in one of the intervention or control groups. In order to blindness, registration, allocation of participants in the intervention (comprehensive couple education) and control (nutritional education) groups, coding, gathering questionnaires and data-entering and data-analyzing is done by different people. Educators don,t know the educational content and the nature of the training for each group.

Participants/Inclusion and exclusion criteria
All Iranian couples with sexual dysfunction who do not have a drug dependency and mental illness.

Intervention groups
The intervention and control group will receive 12 hours of education (6 days 2 hours in three weeks). In the intervention group, CCE by the specialist team includes life skills, skill training for intimate and sexual partnership, mutual respect, spouse care, modern technology damage, and the proper use of social networks, recognition of sexual, emotional and Psychological and social values will be implemented. But in the control group, nutrition education is given about hypertension, kidney, thyroid, diabetic, gastrointestinal diseases and AIDS.

Main outcome variables
Attitude toward extramarital relationship

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190603043804N1**
Registration date: **2019-08-25, 1398/06/03**
Registration timing: **retrospective**

Last update: **2019-08-25, 1398/06/03**
Update count: **0**

Registration date
2019-08-25, 1398/06/03

Registrant information

Name
Arezoo Haseli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 84 3336 2173

Email address
ar_haseli@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-11, 1398/04/20

Expected recruitment end date
2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Comprehensive Couple Education (CCE) in Attitude Extramarital Relations and Couple's Satisfaction and Conflict in Couple's Sexual Dysfunction

Public title

Effect of Comprehensive Couple Education in Prevention of Extramarital Relations

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

- Iranian couples with sexual dysfunction at least in one of the spouses

Exclusion criteria:

- lack of reading and writing literacy Addiction to drugs at least in one of the spouses based on self-reporting History of mental illness at least in one of the spouses based on self-reporting

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

More than 1 sample in each individual

Number of samples in each individual: **2**

couple

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization unit is a couple. Randomization method will be blocked by using the site "www.rct.com" in four blocks. None of the samples know that will be allocated in which groups (allocation concealment).

Blinding (investigator's opinion)

Double blinded

Blinding description

Random allocation carried out by the researcher's assistance 1 and using www.rct.com. Registration and allocation of participants in intervention and control groups by the researcher's assistance 2 (2 people). The coding and collecting of questionnaires and data entry into the software will be done by the researcher's assistance 3. Implementation of the intervention (educators) will be conducted by the specialist team based on the specialized heading. Based on ethics, couples will be not blinded to the intervention. Educators will also be blind to this study. Providers only know that two types of training are given to the two groups of participants, but they will be unaware of the educational content and the nature of each training for each group. A person who measures the outcomes in two groups of intervention and control is a person other than the educators (researcher's assistance 3). For this purpose, the samples will complete their questionnaires but the researcher's assistance 3 will collect questionnaires and data entry into the software. Additionally, the person analyzing the results will be someone other than the people above so he will not know which one is intervention or control group it is using the A and B groups in the SPSS software.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

Street address

Hafte-Tir Square

City

Shahroud

Province

Semnan

Postal code

3614773947

Approval date

2018-06-19, 1397/03/29

Ethics committee reference number

IR.SHMU.REC.1397.016

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

Attitude Towards Extramarital Relationships

Timepoint

Before and after intervention, one month, one year and five years after intervention

Method of measurement

Attitudes toward infidelity scale

Secondary outcomes

1

Description

Marital Satisfaction

Timepoint

Before and after intervention, one month, one year and five years after intervention

Method of measurement

ENRICH Marital Inventory

2

Description

Marital Conflict

Timepoint

Before and after intervention, one month, one year and five years after intervention

Method of measurement

Marital Conflict Questionnaire

Intervention groups

1

Description

Intervention group: The intervention group will receive 12 hours of education (6 days 2 hours in three weeks). Comprehensive Couple Education by the specialist team based on heading includes life skills, skill training for intimate and sexual partnership, mutual respect, spouse care, modern technology damage, and the proper use of social networks, recognition of sexual, emotional and Psychological and social and spiritual values will be implemented.

Category

Behavior

2

Description

Control group: The control group will receive 12 hours of nutrition education (6 days 2 hours in three weeks) about hypertension, kidney, thyroid, diabetic, gastrointestinal diseases and AIDS.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

urologists offices

Full name of responsible person

Zahra Chenari

Street address

22-Bahman square

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2

Recruitment center

Name of recruitment center

Health Center

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Couples Counseling Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person
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Fax

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info@shmu.ac.ir

Web page address
http://www.shmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Arezoo Haseli

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Not applicable
Title and more details about the data/document
All of data
When the data will become available and for how long
After publication articles
To whom data/document is available
Researchers in academic Center
Under which criteria data/document could be used
None
From where data/document is obtainable
Responsible Author
What processes are involved for a request to access data/document
By Mail
Comments