

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 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

#### **City**

Ilam

#### **Province**

Ilam

#### **Postal code**

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#### **Phone**

+98 84 3336 2173

#### **Email**

Zahrach9675@gmail.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Health Center

##### **Full name of responsible person**

Zahra Chenari

##### **Street address**

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##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

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##### **Email**

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### 3

#### **Recruitment center**

##### **Name of recruitment center**

Couples Counseling Center

##### **Full name of responsible person**

Mona Nami

##### **Street address**

Seiedo-Shohada Blvd., Ilam Town

##### **City**

Ilam

##### **Province**

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##### **Postal code**

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##### **Phone**

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##### **Email**

mona.namii@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Mohammad Hassan Emamian

**Street address**

Hafte-Tir Square

**City**

Shahroud

**Province**

Semnan

**Postal code**

3614773947

**Phone**

+98 23 3239 5054

**Fax**

**Email**

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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ar\_haseli@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Shariati

**Position**

Associate Professor of Community Medicine

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

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**Person responsible for updating data**

**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

**Street address**

Hafte-Tir Square

**City**

Shahroud

**Province**

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**Postal code**

693183437126

**Phone**

+98 84 3336 2173

**Fax**

**Email**

ar\_haseli@yahoo.com

**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**