

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Investigation the effectiveness of counselling with Dialectical Behavioral approach on Sexual inefficient beliefs and Sexual Dysfunction in couples who are on the verge of marriage

#### Protocol summary

##### Study aim

Investigation the effectiveness of counselling with Dialectical Behavioral approach on Sexual inefficient beliefs and Sexual Dysfunction in couples who are on the verge of marriage

##### Design

A controlled clinical trial, with parallel, randomized groups, on 50 couples who are on the verge of marriage . Individuals will be divided into tow groups for randomization using online software to generate random sequences and by block random allocation method with four blocks.

##### Settings and conduct

First the researcher , after obtaining the code of ethics from the ethics committee of Kerman University of Medical Sciences and obtaining the code of clinical trial and presenting it to Kerman University of Medical Sciences, the researcher with a letter of introduction ,refers to Sina Premarital Counseling Center in Sirjan . A list of all referring couples will be provided to the researcher and they will be included in the study randomly and if they have inclusion criteria and conscious satisfaction . The random sampling method will be simple.

##### Participants/Inclusion and exclusion criteria

minimum age: 15 years old , Having at least the fifth grade elementary , Be one's first marriage , Lack of any known physical illnesses, Lack of any significant psychiatric disorders. No addiction or smoking,

##### Intervention groups

The counseling group will receive10 sessions of 90 minutes ( two sessions per week) , The man and woman will receive Dialectical Behavioral Therapy counseling together. The control group does not receive any intervention .

##### Main outcome variables

Sexual inefficient beliefs and Sexual Dysfunction in

couples who are on the verge of marriage

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201027049164N5**

Registration date: **2021-12-16, 1400/09/25**

Registration timing: **prospective**

Last update: **2021-12-16, 1400/09/25**

Update count: **0**

##### Registration date

2021-12-16, 1400/09/25

##### Registrant information

##### Name

Masumeh Ghazanfarpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5856

##### Email address

m.ghazanfarpour@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-05, 1400/10/15

##### Expected recruitment end date

2022-04-20, 1401/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Investigation the effectiveness of counselling with Dialectical Behavioral approach on Sexual inefficient beliefs and Sexual Dysfunction in couples who are on the verge of marriage

**Public title**

Investigation the effectiveness of counselling with Dialectical Behavioral approach on Sexual inefficient beliefs and Sexual Dysfunction in couples who are on the verge of marriage

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

minimum age: 15 years old at least having the fifth grade elementary Be one's first marriage Lack of any known physical illnesses such as diabetes and vascular disease and chronic diseases and hormonal disorders and cancer diseases Lack of any significant psychiatric disorders of anxiety and depression and significant psychiatric neurological symptoms No addiction or smoking

**Exclusion criteria:**

Absence of more than two sessions in counseling sessions Failure to follow instructions and relevant exercises in sessions Lack of cooperation of authorities and lack of answers to questionnaire questions Occurrence of acute accidents and unexpected at each stage of the plan Acute and chronic diseases infection during the study

**Age**

From **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomizing the selection: numbers from 1 to 100 will be allocated to the participants, respectively, then using the random block allocation method with four blocks, individuals will be divided into two groups of 50. How to place people in each of the counseling groups and control will be random, which will be done using online software to generate random sequences ([www.randomizer.org/](http://www.randomizer.org/)). In order to hide the process of random allocation and prevent bias, the selection of this action will be done after the final list is prepared by a person other than the main researcher and the researcher will be obliged to act exactly accordingly.

**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 Kerman University of Medical Sciences

**Street address**

Deputy of Research and Technology; ebne-e-Sina St., Jihad Blvd., Kerman, Iran

**City**

Kerman

**Province**

Kerman

**Postal code**

7619813159

**Approval date**

2021-11-19, 1400/08/28

**Ethics committee reference number**

IR.KMU.REC.1400.458

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

Sexual inefficient beliefs

**ICD-10 code**

Z70

**ICD-10 code description**

Counseling related to sexual attitude, behavior and orientation

**Primary outcomes****1****Description**

Sexual inefficient beliefs

**Timepoint**

Beginning of the study (before the start of the intervention) and end of the intervention and three months after the end of the intervention ( after the marriage of the couples )

**Method of measurement**

Sexual dysfunctional beliefs questionnaire pinto-Gouveia -Nuber (SDBQ)

**Secondary outcomes**

## 1

### Description

Sexual dysfunction

### Timepoint

Three months after the end of the Counseling sessions (after the marriage of the couples)

### Method of measurement

Female sexual function index questionnaire and international index of erectile function questionnaire

## Intervention groups

## 1

### Description

Intervention group: The counseling group will receive 10 sessions of 90 minutes (two sessions per week). The man and woman will receive Dialectical Behavioral Therapy counseling together.

### Category

Treatment - Other

## 2

### Description

Control group: They will only receive routine classes Premarital without any other interventions.

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Sirjan Premarital Counseling Center

#### Full name of responsible person

Rezvan Khaleghi

#### Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

#### City

Sirjan

#### Province

Kerman

#### Postal code

7616913555

#### Phone

+98 34 3132 5278

#### Email

rkhaleghi87@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Dr. Abbas Pardakhti

### Street address

Tahmasbabad cross road, Vice Chancellor for Research and Technology building

### City

Kerman

### Province

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### Postal code

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### Phone

+98 34 3132 5856

### Email

rkhaleghi87@gmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Kerman 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

Kerman University of Medical Sciences

#### Full name of responsible person

Rezvan Khaleghi

#### Position

Masters student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Midwifery

#### Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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#### Email

rkhaleghi87@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Masumeh Ghazanfarpour

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Rezvan Khaleghi

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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Kerman

**Province**

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**Postal code**

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**Phone**

+98 34 3132 5700

**Email**

rkhaleghi87@gmail.com

## 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