

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/). 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., Jahad 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

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7616913555

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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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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

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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