

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of mindfulness-based cognitive counseling on the sexual distress and quality of sexual life of pregnant women

Protocol summary

Study aim

Determining the effect of mindfulness-based cognitive counseling on sexual distress and quality of sexual life in pregnant women

Design

Clinical trial with pretest- post test design with control groups, single- blind, and randomized with quadruple blocks on 84 pregnant women.

Settings and conduct

The statistical population of the study in this study includes all pregnant women who referred to health centers in Ahvaz who have referred to the mentioned centers to receive prenatal care. Samples will be selected taking into account the entry and exit criteria. Samples will be randomly assigned with a block design in two groups of experimental (n = 42) and control (n = 42) No blindness was observed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age 20 to 28 weeks
Noulipara Age range 20 to 35 years Have a minimum of middle school education Marital status A score of 11 or higher on the Sexual Distress Questionnaire Score below the community average of the Women's Sexual Quality of Life Questionnaire Exclusion criteria: Occurrence of an unfortunate event in the last 6 months Having a specific physical and mental illness Having midwifery problems Addiction to alcohol, drugs and other psychotropic drugs Taking medication (other than during pregnancy)

Intervention groups

The experimental group will receive 8 sessions of mindfulness-based cognitive counseling for 90 minutes, once a week and on a specific day. The control group did not receive any intervention.

Main outcome variables

Quality of women's sexual life; sexual distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200901048581N1**

Registration date: **2020-09-21, 1399/06/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-21, 1399/06/31**

Update count: **0**

Registration date

2020-09-21, 1399/06/31

Registrant information

Name

hedye ahmadiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4358 3660

Email address

ahmadiyan.h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-21, 1399/06/31

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness-based cognitive counseling on the sexual distress and quality of sexual life of pregnant women

Public title

The effect of mindfulness-based cognitive counseling on the sexual distress and quality of sexual life of pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age 20 to 28 weeks Noulipara Age range 20 to 35 years Have a minimum of middle school education Marital status Ability to have natural sex A score of 11 or higher on the Sexual Distress Questionnaire Score below the community average of the Women's Sexual Quality of Life Questionnaire

Exclusion criteria:

Occurrence of an unfortunate event (death of loved ones, accidents with disabilities, etc.) in the last 6 months Having a specific physical and mental illness Having midwifery problems Addiction to alcohol, drugs and other psychotropic drugs Taking medication (other than during pregnancy) Having sexual dysfunction in yourself and your spouse before pregnancy

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of samples to each of the intervention and control groups was performed by block random method using quadruple blocks (By the table for random permutations). Also, opaque envelops which are numbered sequentially, will be used to hide random allocations. Accordingly, the participants will be given codes and assigned in to the intervention and control groups.

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 Ahwaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences, School of Nursing and Midwifery

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2020-05-01, 1399/02/12

Ethics committee reference number

IR.AJUMS.REC.1399.135

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

Sexual distress

ICD-10 code

F52.9

ICD-10 code description

Sexual dysfunction

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

The Sexual Quality of Life and sexual distress

Timepoint

Before the intervention and after the intervention

Method of measurement

The Sexual Quality of Life-Female questionnaire and The Female Sexual Distress Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The test group will receive 8 90 minute sessions of group Mindfulness-based cognitive counseling, once a week and on a specific day. The sessions will be conducted by a researcher who has received The necessary training and certification in Mindfulness-based cognitive counseling and the consultant will attended some of the sessions to ensure the correctness of the intervention. Finally, After completion of the sessions post- test will be taken.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

17th Shahrivar Clinic

Full name of responsible person

Hediyeh Ahmadian

Street address

Shahid Gandami St., in front of Hoda Middle School,
between Rastegari and Vakili next to Mosalla

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2

Recruitment center

Name of recruitment center

Comprehensive Health Service Center No. 19

Full name of responsible person

Mojalal

Street address

Above Pediatric Clinic, Zavieh St.

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3

Recruitment center

Name of recruitment center

Comprehensive Health Center No. 9

Full name of responsible person

Hediyeh Ahmadian

Street address

Amaniyeh, corner of Bahman Street

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4

Recruitment center

Name of recruitment center

Comprehensive Health Center No. 4

Full name of responsible person

Hediyeh Ahmadian

Street address

Saadi alley, Bazaarcheh street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mehdi Ahmadi Moghadam

Street address

Golestan Blvd, Ahvaz Jundishapur University of
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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Hedye Ahmadiyan

Position

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

Dr Mina Iravani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Student

Latest degree

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Other areas of specialty/work

Midwifery

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After unrecognizable the participants, the information of original outcome will be shared.

When the data will become available and for how long

The publication of the information will be possible six months after the publication of the results.

To whom data/document is available

Access to research documentation for research centers and researchers and therapists is possible.

Under which criteria data/document could be used

Data are available with reference to the researcher's name and clinical and research procedures.

From where data/document is obtainable

Ahvaz University of Medical Sciences, School of Nursing and Midwifery, Dr. Mina Irvani, Tel: 00989163222899, Email: iravani-m@ajums.ac.ir, Postal Code: 61357-15794

What processes are involved for a request to access data/document

Following the correspondence with research deputy of Ahvaz University of Medical Sciences, the results will be available to applicants.

Comments