

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The Effectiveness of Group Counseling Mindfulness-Based Cognitive Therapy on Marital Stress and Sexual Function in Women of Reproductive Age

Protocol summary

Study aim

This study was conducted to evaluate the effectiveness of counseling with mindfulness based cognitive therapy approach on women marital stress and their sexuality function.

Design

The study group includes women of reproductive age (aged 15-49) who are inclined to enter the study and have Inclusion criteria. This Study is a semi-experimental research with Pretest - Post Test Design and a Control Group and with Convenience Sampling Method. Among those who were willing to participate in the study, 50 subjects with higher scores in the Marital Stress Questionnaire and lower scores the Sexual Function Questionnaire were selected. then Subject are Divided in two Groups Randomly. Including 50 subject Experimental group (25subject) and Control Group (25subject) .

Settings and conduct

After determining the intervention group with randomization, the subjects in the Diabetes Center of Yazd spent mindfulness workshop in 8 consecutive week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being willing to Participate in the Study; Marital Status; Age 15-49; Have at least Ability to read and write; without the use of psychiatric drugs; do not participate in another workshop courses Simultaneously with this Course; Being Committed to Doing Homework and to Attend Regular Meetings either in Time or in the Place of Mindfulness Workshop. Exclusion criteria: Pregnancy; Divorce; a History of Severe Mental Illness; having severe illness such as cancer

Intervention groups

the 50 samples were divided into two groups and the intervention group received 8 sessions of the Mindfulness Workshop. The control group also included 25 subject who did not attend any of the Mindfulness

workshop, but the questionnaires of the project were similar to the intervention group and The same intervals are completed.

Main outcome variables

Marital stress, sexual function, Mindfulness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170326033140N2**

Registration date: **2018-02-12, 1396/11/23**

Registration timing: **retrospective**

Last update: **2018-02-12, 1396/11/23**

Update count: **0**

Registration date

2018-02-12, 1396/11/23

Registrant information

Name

ferdows mohammadalian

Name of organization / entity

shahid sadoughi university of medical sciences and healthservices

Country

Iran (Islamic Republic of)

Phone

+98 35 3628 5402

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences and Health Services

Expected recruitment start date

2017-12-23, 1396/10/02

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

2017-09-16, 1396/06/25

Actual recruitment end date

2017-10-17, 1396/07/25

Trial completion date

empty

Scientific title

The Effectiveness of Group Counseling Mindfulness-Based Cognitive Therapy on Marital Stress and Sexual Function in Women of Reproductive Age

Public title

The effectiveness of Mindfulness-Based Cognitive Therapy on Marital Stress and Sexual Function in Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Being willing to Participate in the Study Marital Status Age 15-49 Have at least Ability to read and write not using of psychiatric drugs Not attending in another workshop courses Simultaneously with this Course Being Committed to Doing Homework and to Attend Regular Meetings either in Time or in the Place of Mindfulness Workshop

Exclusion criteria:

Pregnancy Divorce a History of Severe Mental Illness having severe illness Such as Cancer

AgeFrom **15 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **50**Actual sample size reached: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

Among those who were willing to participate in the study, 50 subjects with higher scores in the Marital Stress Questionnaire and lower scores the Sexual Function Questionnaire were selected .then Subject are Divided in two Groups Randomly . Including 50 subject Experimental group (25subject)and Control Group(25subject) .

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**

Shahid Sadoughi University of Medical Sciences and Health Services

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Sahid Bahonar sq, Central department of Shahid Sadoughi University of Medical Sciences and Health Services'Yazd

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8916978477

Approval date

2016-12-26, 1395/10/06

Ethics committee reference number

IR.SSU.REC.1395.193

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

Sexual Function

ICD-10 code

F66.2

ICD-10 code description

Sexual Relationship Disorder

2**Description of health condition studied**

Marital Stress

ICD-10 code

Z63.0,Z63.

ICD-10 code description

Problems in Relationship With Spouse or Partner

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

Marital Stress

Timepoint

Before Intervention, in Eighth Week of Intervention, Four Week after Finish Workshop

Method of measurement

Marital Stress Questioner ESTM

2**Description**

Sexual Function
Timepoint
Before Intervention, in Eighth week of Intervention, Four
Week after Finish Workshop
Method of measurement
Sexual Function Questioner

Secondary outcomes

1
Description
Mindfulness
Timepoint
First Of Study and in end of Study (Eighth Week)
Method of measurement
Mindfulness Questioner

Intervention groups

1
Description
Intervention Group Have 90 Minutes Workshop Once a
Week That Continue 8 Week and Control Group Do Not
Have Intervention .
Category
Behavior

Recruitment centers

1
Recruitment center
Name of recruitment center
Yazd Diabetes Reserch Center and Clinics
Full name of responsible person
Dr Masoud Rahmanian, Endocrinologist
Street address
Bahonar sq, Yazd
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Province
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8917693571
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DRC@SSU.AC.IR

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
ALI SALARI
Street address

Yazd, Safaieh Nursingand Midwifery School
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Province
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916877443
Phone
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Email
MICROB_50@YAHOO.COM
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
ferdows mohammadalian
Position
MSc Student Counseling in Midwifery
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

Mahshid Bokaie

Position

Ph.D in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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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

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Ferdows Mohammadalian

Position

MSc Student Counseling in Midwifery Nursing and
Midwifery School, Department of Midwifery, Shahid Sa

Latest degree

Bachelor