Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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 effectivnes 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
Age
From **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
Street address
Sahid Bahonar sq, Central department of Shahid Sadoughi University of Medical Sciences and Health Services'Yazd
City
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Province
Yazd
Postal code
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

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Bahonar sq, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

ALI SALARI

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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

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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Name of organization / entity
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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