

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of mindfulness-based sex therapy on female sexual desire disorder, distress self-disclosure and sexual function

Protocol summary

Study aim

Determining the effect of mindfulness-based sex therapy on sexual desire disorder, distress, self-disclosure and sexual function

Design

This is a non-blind randomized clinical trial with two groups; intervention and control. Sampling will be done by random allocation using the four-way blocking method.

Settings and conduct

The research environment is three selected health-care centers affiliated Tehran University of Medical Sciences. The research population is women in reproductive age referring to these centers. An intervention group will be received sex education, mindfulness exercises, behavioral therapy related to the response to the sexual response cycle, and skills to increase self-control and sexual distress control through lectures, group discussions, CDs, and homework assignments. The control group will not receive an intervention until the end of the study. Evaluation of the effect of training sessions will be conducted before the intervention, immediately, 4 and 12 weeks after the last session.

Participants/Inclusion and exclusion criteria

Married women with age of 15-49 years Being sexually active High school educated Not having other sexual disorders except sexual desire disorder Not pregnant and not being in lactation period Do not use of drugs that effect sexual desire Lack of spouse's sexual problems and interpersonal and marital dissatisfaction Having well-known psycho-somatic diseases Not willing to participate in any of phases of research or do not attending more than one of the intervention sessions

Intervention groups

Intervention group will be received 4-weekly sessions during 90-120 minutes with content based on sex education, mindfulness exercises, and behavioral therapy. The control group will not receive an intervention until the end of the study.

Main outcome variables

sexual desire disorder, distress, self-disclosure and sexual function

General information

Reason for update

Best Regards The information related to the present study is part of the master's thesis. Due to the time constraints of researching in the form of a thesis, it was not possible to perform follow-up at longer intervals. Therefore, only short follow-ups were considered in the thesis and routine follow-ups with longer intervals of hypoactive sexual desire disorder were approved and continued as a research project in accordance with the thesis. Therefore, to report rutin follow-ups with longer intervals in the form of a scientific article, we request to update and record the approved follow-ups of the research project in accordance with the thesis.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160808029255N4**

Registration date: **2018-09-17, 1397/06/26**

Registration timing: **prospective**

Last update: **2021-06-15, 1400/03/25**

Update count: **1**

Registration date

2018-09-17, 1397/06/26

Registrant information

Name

Raziyeh Maasoumi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4214

Email address

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-15, 1397/02/25

Expected recruitment end date

2018-12-16, 1397/09/25

Actual recruitment start date

2018-09-19, 1397/06/28

Actual recruitment end date

2019-03-19, 1397/12/28

Trial completion date

2019-08-06, 1398/05/15

Scientific title

The effect of mindfulness-based sex therapy on female sexual desire disorder, distress self-disclosure and sexual function

Public title

The effect of mindfulness-based sex therapy on female sexual desire disorder, distress self-disclosure and sexual function

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 15-49 years have been married being sexually active having alive spouse not being pregnant not being in lactation period do not use contraceptive drugs that has an effect on sexual desire lack of spouse's sexual dysfunction having at least high school education having marital and interpersonal relationships satisfaction not having other sexual disorders except sexual desire disorder

Exclusion criteria:

having or positive history of well-known psycho-somatic diseases that interfere with marital relationships daily activities using sexually-suppressive drugs (such as low blood pressure, H2 blockers, Antihistamines, barbiturates, tri-cyclic antidepressants, SSRIs, etc.) using alcohol and drugs taking Simultaneous herbal medicines that affect sexual desire not willing to participate in any phase of research or not attending in more than one of the intervention sessions

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: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be conducted by random allocation using four-way blocking method.

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

Ethical Committee of the Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods St

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.TUMA.FNM.REC.1396.4743

Health conditions studied

1

Description of health condition studied

Sexual desire

ICD-10 code

F52.0

ICD-10 code description

Hypoactive sexual desire disorder

2

Description of health condition studied

sexual distress

ICD-10 code

F52.8

ICD-10 code description

Other sexual dysfunction, not caused by organic disorder or disease

3

Description of health condition studied

Sexual self-discloser

ICD-10 code

ICD-10 code description

4

Description of health condition studied

Sexual function

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual desire

Timepoint

Before the intervention, immediately, 4 and 12 weeks post-intervention

Method of measurement

Persian version of the Holbert Sexuality Questionnaire (HSID)

2

Description

Sexual distress

Timepoint

Before the intervention, immediately, 4 and 12 weeks post-intervention

Method of measurement

Female Sexual Distress Scale- Revised (FSDS-R)

3

Description

sexual self-disclosure

Timepoint

Before the intervention, immediately, 4 and 12 weeks post-intervention

Method of measurement

Researcher-made questionnaire

4

Description

sexual function

Timepoint

Before the intervention, immediately, 4 and 12 weeks post-intervention

Method of measurement

Persian version of Female Sexual Function Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be receive four-weekly sessions for 90 to 120 minutes.

intervention including sex education, mind-boggling exercises, behavioral therapy associated with the sexual response cycle, and skills to increase self-control and sexual distress through speech, group discussions, CDs, and homework assignments. In addition, the intervention content in the form of a booklet will be provided to the intervention group. At the end of each session, women have opportunity to talk about their perceptions of intervention and receive their answers of questions.

Category

Behavior

2

Description

Control group: The control group will not receive an intervention until at the end of the research. After that, based on the ethics of the research and their willingness the sexual counseling service will be presented by the researcher.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farmanfarmaian Community Health Care Center

Full name of responsible person

Raziyeh Maasoumi

Street address

Opposite the Melli Bank., near the Roshdiyeh crossroad., East Azerbaijan st

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2

Recruitment center

Name of recruitment center

Akbarabad Health care Center

Full name of responsible person

Raziyeh Maasoumi

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3

Recruitment center

Name of recruitment center

Shahid Vahedi Health care Center

Full name of responsible person

Raziyeh Maasoumi

Street address

Next to the Women's Organization., Yakhchy Abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Sahraian

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Raziyeh Maasoumi

Position

Pos.doc of Sexology, PhD of Reproductive Health,
Assisstant Professor of Reproductive Health Departm

Latest degree

Ph.D.

Other areas of specialty/work

Sexology, Sexual and Reproductive Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Study data after unidentifiable people can be shared

When the data will become available and for how long

six months after publication of findings

To whom data/document is available

The data will be available to researchers working in academic and academic institutions

Under which criteria data/document could be used

The data from this study will be available for similar studies only

From where data/document is obtainable

dr Raziyeh Masoomi:email:r_masoumi@sina.tums.ac.ir

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

Initial correspondence by email, on-site visit, and presentation of a proposal similar to the present study, provide sufficient evidence for the similarity of its research to the present study, study proposal by the present investigator, decision making and announcement of the result by the investigator to the researcher for access to data Providing the data file for use locally

Comments