Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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
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Province
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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 disstress
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
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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, Assisstent Professor of Reproductive Heaith Departm

Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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