Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

The effect of mindfulness-based sexual counseling on knowledge, attitude and sexual function of postmenopausal women

Protocol summary

Study aim
The effect of mindfulness-based sexual counseling on knowledge, attitude and sexual function of postmenopausal women referred to Ahvaz menopause clinic

Design
Pre-post-test trial, follow-up with control group, with parallel groups, randomized

Settings and conduct
The study on postmenopausal women referred to the clinic of Imam Khomeini Hospital in Ahvaz, will be performed as a trial with two groups of experiments and controls, then the demographic questionnaire, Sexual Knowledge and Attitude Scale (SKAS), and Female Sexual Function Index (FSFI) will be completed by people who meet the inclusion criteria. If they score less than 26.55 on the FSFI, they will be included in the study as a final sample. Counseling sessions will be held under the supervision of the counselor. Questionnaires are completed before, Immediately and four weeks after the last consultation session in both experimental and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-Complete cessation of menopause in the last 12 months without the use of medication or surgery 2-Age range between 45 to 65 3-At least fifth grade education 4-Get a score lower than 26.55 on the Female Sexual Function Index Exclusion criteria: 1-History of mental illness or use of antidepressants 2-The simultaneous existence of chronic disease (diabetes) and... 3-Taking herbal medicines containing estrogen or sex supplements 4-Spouse with impotence or premature ejaculation 5-Stressful experience in the last three months

Intervention groups
Intervention group: The intervention group will be 42 people who will participate in eight 120-minute sessions of sexual counseling based on mindfulness. Control group: The control group will be 42 people who will not receive any counseling.

Main outcome variables
Knowledge, attitude and sexual function of postmenopausal women

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211216053425N1**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date
2022-01-09, 1400/10/19

Registrant information

Name
Mahin Bandari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-02, 1400/10/12

Expected recruitment end date
2022-02-01, 1400/11/12

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of mindfulness-based sexual counseling on knowledge, attitude and sexual function of postmenopausal women

Public title
The effect of mindfulness on sexual function of postmenopausal women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Complete cessation of menopause in the last 12 months without the use of medication or surgery Age range between 45-65 years At least fifth grade elementary education Get a score lower than 26.55 on the Female Sexual Function Index
Exclusion criteria:
History of mental illness or taking antidepressants Concurrent existence of chronic disease (diabetes) and... Taking herbal medicines containing estrogen or sex supplements Spouse with impotence or premature ejaculation Stressful experience in the last three months
Age
From **45 years** old to **65 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
Sampling will be done by non-probability easy method. In this way, from the beginning of the study, all postmenopausal women who meet the inclusion criteria and obtain a score lower than 26.55 of the sexual function index, will be included in the study as a final sample. Then, using the random block method and using 6 blocks, they are divided into two groups of experimental and control. The letter A is used to place people in the experimental group and the letter B is used to place the control group. The size of all blocks is equal and there will be 6 people in each block, of which 3 will be from the experimental group and 3 will be from the control group. The order of their placement in each block is random and this will be done using winpepi software. This software provides the possibility balanced randomization of successive blocks by specifying the number of groups, size and number of blocks. confidential envelopes with alphabetical letters A (experimental) and B (control) are used to hide random allocation. In this method, each of the random sequences created is recorded on a card and the cards are placed in the letter envelopes, respectively. In order to maintain a random sequence, the letters are recorded in the same way on the outer surface of the envelopes. Then, the envelopes are then opened according to the order in which the participants entered the study and is revealed the assigned group of the participant.
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
Ahvaz Jundishapur University of Medical Sciences
Street address
Khuzestan, Ahvaz, Golestan Boulevard, Jundishapur University of Medical Sciences, Research Deputy
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Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2021-12-14, 1400/09/23
Ethics committee reference number
IR.AJUMS.REC.1400.569

Health conditions studied

1

Description of health condition studied
Female Sexual dysfunction
ICD-10 code
F52
ICD-10 code description
Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description
Sexual knowledge and attitude, Sexual function
Timepoint
Before, immediately and one month after the intervention
Method of measurement

SKAS Questionnaire, FSFI Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group is divided into 6 groups of 7 people and each group is subjected to 8 weekly 120-minute sessions (five in-person sessions and three online sessions) of mindfulness-based sexual counseling group therapy training. However, in the control group, no training and counseling is given except for routine care. Finally, to appreciate them, an intensive sexual counseling session with an introductory introduction to the basics of mindfulness is organized and all participants in the research are given an educational CD containing mindfulness exercises. The sessions will be held by the researcher who has received the necessary training and certification in mindfulness-based cognitive counseling, under the supervision of the counselor and in compliance with health protocols. Finally, the post-test will be taken immediately and one months after the completion of the sessions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Azadegan Street, Imam Khomeini Hospital in Ahvaz

Full name of responsible person

Research Deputy of Ahvaz University of Medical Sciences

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Imam Khomeini Women`s Clinic, Azadegan Street, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Parvaneh Mousavi

Position

Instructor of Midwifery

Latest degree

Master

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