

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of brief Mindfulness-based Cognitive Therapy (b-MBCT) on the married women's body image and quality of sexual life after hysterectomy in Kerman, 2020

Protocol summary

Study aim

investigating the effect of b-MBSR on body image and quality of life after hysterectomy in married women in Kerman

Design

The research is an applied research with pre-test, post-test and intervention and control group which will be done after the approval of the code of ethics by Kerman University of Medical Sciences. Then, to obtain the statistical population of all hospitals in Kerman where hysterectomy will be performed. They will be enrolled in the study and will be randomly selected from 4 hospitals. Then, women who live in Kerman province who have undergone hysterectomy in these 4 hospitals will be evaluated for at least 2 months and up to 2 years after their hysterectomy.

Settings and conduct

PLACE OF SESSIONS: hysterectomy hospitals. post-test will be given to the two groups again after the end of the training sessions and again a month later.

Participants/Inclusion and exclusion criteria

Specimens were at least two months after hysterectomy

- They are under 65 years of age.
- Married and sexually active
- The ability to understand your body image
- Not be counseled about other psychological problems during the study or after the hysterectomy and prior to this consultation.
- Non-addiction to drugs, stimulants and alcohol based on an individual report
- Be literate
- Lack of chronic illness such as: psychotic disorders, physical and mental disabilities
- Reside in Kerman province.
- Lack of psychiatric medication
- Maximum 2 years since hysterectomy

Exclusion criteria: There is a reluctance to participate in the study at any stage of the study Have more than two sessions of counseling sessions

Intervention groups

Intervention group will receive short mindfulness-based cognitive counseling program consisting of 4 120-minute

sessions that will be held once a week.

Main outcome variables

mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170611034452N10**

Registration date: **2020-03-07, 1398/12/17**

Registration timing: **prospective**

Last update: **2020-03-07, 1398/12/17**

Update count: **0**

Registration date

2020-03-07, 1398/12/17

Registrant information

Name

Atefeh Ahmadi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5205

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-24, 1399/01/05

Expected recruitment end date

2021-04-25, 1400/02/05

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of brief Mindfulness-based Cognitive Therapy (b-MBCT) on the married women's body image and quality of sexual life after hysterectomy in Kerman, 2020

Public title
the effect of brief Mindfulness-based Cognitive Therapy (b-MBCT) on the married women's body image and quality of sexual life after hysterectomy

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Sample subjects at least two months after their hysterectomy Married Ability to self-perceive self Not attending in counseling sessions for her psychological problems during this study No self-report drug, stimulant and alcohol dependence Primary literacy Not suffering from chronic illnesses No medication Psychiatry surgery are younger than 65. must be at least 2 years since the hysterectomy sexually active with her husband
Exclusion criteria:
Do not attend two or more counseling sessions Not willing to continue participating in the study while doing research.

Age
To 65 years old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: 74

Randomization (investigator's opinion)
Randomized

Randomization description
simple individual randomization through randomization table of random numbers. allocation concealment will be done

Blinding (investigator's opinion)
Single blinded

Blinding description
Intervention group samples do not meet with control group samples at any point in the study, so the probability of individuals in the intervention group being in control is very low and information exchange is not likely to occur. for data analyzer we send the data to him/her without mentioning intervention and control group and instead we will label them with A and B. for data and safety monitoring board we will not aware them

about the group of intervention as it is possible only if they request for checking the accuracy of the intervention. for outcome assessor, they only asked the posttest questions by telephone without being aware that which woman is in which group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Kerman University of Medical Sciences

Street address

kerman-first of Haft Bagh Alavi-Pardis of Kerman University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

76169135555

Approval date

2020-02-17, 1398/11/28

Ethics committee reference number

IR.KMU.REC.1398.597

Health conditions studied

1

Description of health condition studied

Hysterectomy

ICD-10 code

Z90.7

ICD-10 code description

Acquired absence of genital organ(s)

Primary outcomes

1

Description

Body image in hysterectomy women

Timepoint

Befor intervation after the intervation

Method of measurement

Multidimensional Body-Self Relation Questionnaire

2

Description

Quality of sex life in hysterectomy women

Timepoint

Before intervention

Method of measurement

Sexual Quality of Life Questionnaire

3

Description

Body image in hysterectomy women

Timepoint

after intervention

Method of measurement

Multidimensional Body-Self Relation Questionnaire

4

Description

Quality of sex life in hysterectomy women

Timepoint

after intervention

Method of measurement

Sexual Quality of Life Questionnaire

5

Description

Quality of sex life in hysterectomy women

Timepoint

one month after intervention

Method of measurement

Sexual Quality of Life Questionnaire

6

Description

body image in women undergone hysterectomy

Timepoint

one month after intervention

Method of measurement

Multidimensional Body-Self Relation Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention as a Mind-Based Cognitive Counseling Short-Awareness on Body Image After Hysterectomy. intervention is brief-mindfulness based cognitive therapy for women between 2 months to 2 years after their hysterectomy (4 sessions 120 minutes). The sessions will hold in the hospital they undergone hysterectomy or any other places that they are eager to be hold. content of counseling sessions: first session: greeting and definition of sessions rules, definition of b-mbct, body image, quality of sexual life and related factors among women undergone hysterectomy, stress and mindfulness. body scan

technique, home work session two: review of previous session, influence of our interpretation of our emotions, self-awareness and body-awareness, focus on breathing, hearing and vision, homework session 3: definition of cognitive errors, negative and positive thoughts, mindful walking, homework session 4: influence of love. though acceptance automatic pilot, mountain meditation, homework

Category

Treatment - Other

2

Description

Control group: After the intervention they can attend the sessions

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals where hysterectomies were performed or as requested by research units

Full name of responsible person

Elahe Bahador

Street address

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kerman

Province

Kerman

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7619813159

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Web page address
http://vresearch.kmu.ac.ir/fa
Grant name
deputy of research Kerman University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
deputy of research Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Elahe Bahador
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data on the main outcomes of the research after the completion of research work can be published.

When the data will become available and for how long

Data on the main outcomes of the research after the completion of research work can be published.

To whom data/document is available

Starting access to the data above is immediately after publishing the results.

Under which criteria data/document could be used

Researchers in academia and scientific institute are able to access research data.

From where data/document is obtainable

atefeahmadi59@gmail.com

monashirzad1992@yahoo.com

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

پس از ارسال درخواست کتبی از جانب متقاضی، داده ها در اسرع وقت در اختیار ایشان قرار خواهد گرفت

Comments