

# 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

a.ahmadi@kmu.ac.ir

##### 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**

Haft-bagh Alavi

**City**

kerman

**Province**

Kerman

**Postal code**

7619813159

**Phone**

+98 31 3226 3815

**Email**

kmu-research@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Atefeh Ahmadi

**Street address**

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**Email**  
kmusrc@googlegroups.com

**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**  
Midwifery

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## Person responsible for scientific inquiries

**Contact**

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Kerman University of Medical Sciences

**Full name of responsible person**  
Atefe Ahmadi

**Position**

Proffesor assistant

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Psychology

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## Person responsible for updating data

**Contact**

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Kerman University of Medical Sciences

**Full name of responsible person**  
Atefe Ahmadi

**Position**  
Proffesor Assistant

**Latest degree**  
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**Other areas of specialty/work**  
Psychology

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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**