Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Mindfulness Based Stress Reduction(MBSR) approach on the fear of childbirth rate in one- child women

Protocol summary

Study aim

1. Determination of mean score of the childbirth fear in one- child women in intervention and control groups before intervention 2- Determination of mean score of the childbirth fear in one- child women in intervention and control groups after intervention 3- Comparison of mean score of the childbirth fear in one- child women in intervention and control groups before and after intervention

Design

In this study, 48 one-child women are selected and to each one is given a code. Then, they are divided to control or intervention groups by simple random method.

Settings and conduct

Kerman is divided into 2 areas and then 4 schools are chosen from these areas by cluster randomized. By attending in these schools, the invitations and demographic questionnaires (including inclusion criteria of the study) as well as the fear of childbirth questionnaire (Harman) will be available to the one-child students until they be completed by their mothers. After receiving the filled up questionnaires from the students, 48 mothers who do not want to be pregnant due to fear of giving birth (earning the minimum score of 28 from the fear of childbirth questionnaire) will be chosen and invited them to participate in the research.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age under 35 years old, Fertility capability, Having a husband, Wife's desire for pregnancy, Not having risk factors for pregnancy such as; heart, kidney, cancer diseases, mental health, substance abuse, ability to attend in group therapy sessions, not being pregnant , willingness to cooperate and fulfillment of the consent form. Exclusion criteria: Absences of more than 3 sessions, incidence of major stresses and unexpected events in each stage of the plan, catching acute psychological illness during of the plan.

Intervention groups

For the intervention group, the mindfulness-based stress reduction approach, would be performed in group sessions in eight 90- min sessions, twice a week. While there is no intervention for the control group during this period.

Main outcome variables

Fear of the childbirth, fear of the giving birth a physical or mental disabled child, fear of the changing in marital relationships, fear of the changes in mood and its consequences on the child, self-centered fears or fear of changes in the mother's personal life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171129037676N2**
Registration date: **2018-03-03, 1396/12/12**
Registration timing: **retrospective**

Last update: **2018-03-03, 1396/12/12**
Update count: **0**

Registration date

2018-03-03, 1396/12/12

Registrant information

Name

Parvin Salehinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3222 3876

Email address

p_salehinejad@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2017-09-06, 1396/06/15
Expected recruitment end date
2018-01-10, 1396/10/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Mindfulness Based Stress Reduction(MBSR) approach on the fear of childbirth rate in one- child women

Public title
Effect of "Mindfulness-Based Stress Reduction" on the fear of childbirth
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women who have a child aged 6 or older Age under 35 years old Capability of fertility Having husband
Exclusion criteria:
Being pregnant Having acute psychological illness
Age
To **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Selection of the schools by random cluster sampling, selection of the one-child women by available method and division o the women into two intervention and control groups by simple random sampling
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
Ethics Committee of Kerman University of Medical Sciences
Street address
Kerman Medical Sciences, Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2017-08-16, 1396/05/25
Ethics committee reference number
IR.KMU.REC.1396.1820

Health conditions studied

1

Description of health condition studied
Fear of childbirth
ICD-10 code
F40.232
ICD-10 code description
Fear of other medical care

Primary outcomes

1

Description
Fear of childbirth score equal or greater than 28
Timepoint
before and after the intervention
Method of measurement
Harman Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The Mindfulness-Based Stress Reduction approach will be performed in eight 90- min sessions, twice a week; The first session (auto-guidance): Description of the meeting nature and the purposes of the treatment, collecting information about the problems that have been causing turmoil, expression of the need to use mind-awareness training and providing a homework. The second session (encountering barriers): Review the lessons that learned in the first session, body review and providing feedback to the participants, providing meditation on the mind of breathing awareness. The third session (mindfulness of breathing): A review of the previous experiences and exercises, sitting meditation exercises and providing feedback to

the participants and a three-minute breathing exercise. The fourth session (stay in the present): Review previous lessons and homework, providing 5-minute training of "seeing or hearing exercise", repeating of rehearsing the mindfulness and body review. The fifth session (presence permission): A review of the previous experiences and exercises, breathing exercises, presentation of the sitting meditation "awareness of breathing, body, sounds and thoughts", explanations about stress and its relation to pain, awareness of pleasant and unpleasant events on feelings, thoughts and body feelings. The sixth session (thoughts are not truths): Review of the previous lessons, consciously Yoga exercise, and presenting topics of thought or substitute thoughts, and practice of the sitting meditation. The seventh session (how can I take care of myself better): Review of the previous exercises, providing sleep hygiene, prepare a list of pleasure activities. The eighth session (acceptation and Modification): Review of the previous learning and exercise, practice of the body review, discussion about the programs and continuation of the exercises.

Category

Behavior

2

Description

Control group: The control group does not receive any intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Primary Schools

Full name of responsible person

Parvin Salehinejad

Street address

No:13, 6 Alley, Khorsheed street

City

Kerman

Province

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Postal code

7619819945

Phone

+98 34 3222 3876

Email

p_salehinejad@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Research & Technology Department, Tahmasb-Abad Crossroad

City

Kerman

Province

Kerman

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7619813159

Phone

+98 34 3226 3855

Email

abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Parvin Salehinejad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

Street address

No:13, 6 Alley, Khorsheed Ave

City

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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
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Person responsible for updating data

Contact

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Kerman University of Medical Sciences

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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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All data will be shared

When the data will become available and for how long
Starting of the access period 3 months after printing the results

To whom data/document is available
All people who interested

Under which criteria data/document could be used
There is not any condition

From where data/document is obtainable
To correspondence

What processes are involved for a request to access data/document
Clear expression of the request and receiving the information by the applicant after 2 weeks

Comments