

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 of 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

Postal code

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

Kerman

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Email

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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

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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