

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of mindfulness - based stress reduction” approach on anxiety level of pregnancy in one- child women in Sirjan , 2017

Protocol summary

Study aim

1.Evaluation of anxiety level of pregnancy in one-child women in control group 2. Evaluation of anxiety level of pregnancy in one-child women in intervention group 3. Comparison of anxiety of pregnancy in one-child women in control group with intervention group

Design

In this research, 100 one-child women were chosen and a code was allocated to each of them. Then, the women were randomly divided into control and intervention groups.

Settings and conduct

Sirjan was divided into four area and then four schools were chosen by cluster randomize.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women of childbearing age (18-35 years old) with a child (32), Iranian with spouse status, ability to complete a questionnaire and conversation in Farsi (36), having upper secondary education (35) Lack of history of known neuropsychiatric disorders, non-use of psychosocial drugs, substance abuse, lack of secondary infertility, lack of pregnancy during the course of the project, and lack of decision on pregnancy in the future. Exclusion criteria: Absence in more than three sessions in the group training process (35), making important psychological and emotional changes during the study, such as death, sudden financial problems, marital and divorce problems, drug addiction.

Intervention groups

For the experimental group, the intervention of mindfulness-based stress reduction, would be performed in group sessions in 8 sessions 2.5 hours, once a week. While there is no intervention for the control group during this period.

Main outcome variables

Anxiety caused by pregnancy; Fear of childbirth, fear of having a physical or mental disability child, fear of changing marital relationships, Fear of 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: **IRCT20171129037676N1**

Registration date: **2017-12-18, 1396/09/27**

Registration timing: **retrospective**

Last update: **2017-12-18, 1396/09/27**

Update count: **0**

Registration date

2017-12-18, 1396/09/27

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

2017-10-17, 1396/07/25

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of mindfulness - based stress reduction" approach on anxiety level of pregnancy in one- child women in Sirjan , 2017

Public title
mindfulness - based stress reduction" on anxiety level of pregnancy

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Women have a child 6 years of age or older Women in reproductive age (18 to 35 years old) Iranian and being married Earning a score of 18 or more in the Pregnancy Anxiety Questionnaire
Exclusion criteria:
Being pregnant Having a secondary infertility record Use of psychiatric drugs and substance abuse

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
divided in two 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
Kerman University of Medical Sciences ethics committee
Street address
Kerman Medical Sciences, Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province

Kerman
Postal code
7616913555
Approval date
2017-08-08, 1396/05/17
Ethics committee reference number
1396.1705

Health conditions studied

1

Description of health condition studied
Pregnancy Anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Anxiety score equal or greater than 18
Timepoint
before and after the intervention
Method of measurement
Pregnancy Anxiety Questionnaire

Secondary outcomes

1

Description
Noting
Timepoint
Noting
Method of measurement
Noting

Intervention groups

1

Description
Experimental group: the Mindfulness-Based Stress Reduction approach should be performed in a group of 8 sessions 2.5 hours, once a week.
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

دبستانها

Full name of responsible person

پروین صالحی نژاد

Street address

No:13, 6 Alley, Khorsheed street

City

Kerman

Province

Kerman

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Parvin Salehinejad

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Person responsible for updating data

Contact

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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 after unidentifiable people

When the data will become available and for how long

Start the access period 3 months after printing the results

To whom data/document is available

People who interested

Under which criteria data/document could be used

No condition

From where data/document is obtainable

To correspondence

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

Express clear request and after 2 weeks of receiving information by the applicant

Comments