Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Mindfulness-Based Stress Reduction on stress, anxiety and depression of unintended pregnancy in women referred to health care centers.

Protocol summary

Study aim

Determination Effect of Mindfulness-Based Stress Reduction on stress, anxiety and depression of unintended pregnancy in women referred to health care centers in Sirjan, 2017

Design

Clinical trial with control and intervention group, simple randomization, 30 patients under consultation and 30 controls, one blind.

Settings and conduct

Health care Centers of Sirjan. Individuals fill out the anxiety, stress and depression dass questionnaire, then they are randomly assigned to two groups of control and intercourse. The intervention group is counseled and then, all individuals in the intervention and control group fill out again questionnaire.

Participants/Inclusion and exclusion criteria

intrance: Having a Wife. Age between15-49 Years. Pregnancy Age 10-32 Weeks. Absence of Neurological and Mental Disorder and Substance Abuse. Readiness and Satisfaction to Participate in the Research. exist: Having at Least One Item of Stress Score 0-7 or Anxiety 0-3 or Depression 0-4. Absence More Than the two Sessions. Not Doing Practices. Unwillingness to Continue the Sessions. Indication Major Stresses and Acute Accidents. Getting Acute Psychotic Illnesses, incidence of pregnancy complications such as bleeding, high blood pressure, preterm delivery and intrauterine death.

Intervention groups

Mindfulness-Based Stress Reduction on stress, anxiety and depression of unintended pregnancy.

Main outcome variables

Condition of Anxiety, Stress and Depression of Unintended Pregnancy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151103024866N14**
Registration date: **2019-03-16, 1397/12/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-16, 1397/12/25**
Update count: **0**

Registration date

2019-03-16, 1397/12/25

Registrant information

Name

Katayoun Alidousti

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5219

Email address

alidoosti@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-19, 1397/11/30

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Mindfulness-Based Stress Reduction on stress, anxiety and depression of unintended pregnancy in women referred to health care centers.

Public title
Effect of Mindfulness-Based Stress Reduction on stress, anxiety and depression of unintended pregnancy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having a Wife. Age between15-49 Years. Pregnancy Age 10-32 Weeks. Absence of Neurological and Mental Disorder and Substance Abuse. Readiness and Satisfaction to Participate in the Research.
Exclusion criteria:
Having at Least One Item of Stress Score 0-7 or Anxiety 0-3 or Depression 0-4. Absence More Than the two Sessions. Not Doing Practices. Unwillingness to Continue the Sessions. Indication Major Stresses and Acute Accidents. Getting Acute Psychotic Illnesses.
Age
From **15 years** old to **49 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
After selecting the sample from the available sampling method, we divide them into a simple randomized draw metod into two groups of intervention and control.
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
Nursing and Midwifery Collage
City
Kerman
Province
Kerman
Postal code
7419476196
Approval date
2019-02-18, 1397/11/29
Ethics committee reference number
IR.KMU.REC.1397.487

Health conditions studied

1

Description of health condition studied
mental health in unintended pregnancy
ICD-10 code
z64.0
ICD-10 code description
problems related to unwanted pregnancy

Primary outcomes

1

Description
anxiety, stress, depression
Timepoint
At the beginning of the study and one week after the completion of the intervention
Method of measurement
dass-21پرسشنامه

Secondary outcomes

empty

Intervention groups

1

Description
Control group: People who do not get any consultation
Category
N/A

2

Description
Intervention group: 30 People are available for consultation on mindfulness based-stress reduction, which will be held in 8 sessions of 2 hours (weekly one session).
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Health care centers

Full name of responsible person
Fatemeh Khajoie Nejad

Street address
Kerman Nursing & Midwifery

City
Sirjan

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5219

Email
Alidoosti@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr Pardakhti

Street address
Jahad street

City
kerman

Province
Kerman

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7419476196

Phone
+98 34 3132 5219

Email
pardakhti@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
Kobra Alidoosti

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Fateme Khajoie Nejad

Position
Master Degree Student in Midwifery

Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Golestan22, Boulevar Golestan, Sirjan
City
Sirjan
Province
Kerman
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7816857999
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khajoei.fateme@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable