

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jul 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

intrace: 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 between 15-49 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 method 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

پرسشنامه 21-dass

## 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 Khajoei 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

**Postal code**

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**

Nursing and Midwifery Collage

**City**

Kerman

**Province**

Kerman

**Postal code**

7619613555

**Phone**

+98 34 3132 5219

**Email**

Alidoosti@kmu.ac.ir

## Person responsible for scientific 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**

Nursing and Midwifery Collage

**City**

kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5219

**Email**

Alidoosti@kmu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Fateme Khajoei 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

**Postal code**

7816857999

**Phone**

+98 34 4230 6483

**Email**

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