

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating The Effectiveness of Mindfulness-Based Stress Reduction(MBSR) on the Rate of Anxiety, Depression and stress in women with first trimester leads to termination of pregnancy referred to Hazrat Zeynab Hospital in Shiraz in 2019 بررسی اثر مشاوره ذهن آشنایی بر کاهش اضطراب، افسردگی و استرس در زنان مبتلایان به سقط جنین در بیمارستان حضرت زینب شیراز در سال 1398

Protocol summary

Study aim

1- Determining and comparing the mean score of anxiety, stress and depression of women referred to hemorrhage leading to termination of pregnancy in intervention and control group before and after counseling in Hazrat Zeinab Hospital in Shiraz in 98

Design

A randomized controlled clinical trial was conducted with randomized groups that were divided into control and intervention groups using a random allocation table, each containing 57 individuals.

Settings and conduct

first trimester hemorrhage referred to Hazrat Zeinab Hospital in Shiraz Using a random allocation table, they are divided into two groups of control and intervention, with 8 sessions of mindfulness group counseling that will take place 2 to 2.5 hours per week, and even if they are discharged, they will be invited to attend the consultation by phone number. It will be done two weeks after the last test post session of intervention group and post test control group will be analyzed.

Participants/Inclusion and exclusion criteria

Women with first trimester hemorrhage who have lost their pregnancy, tendency to participate in research, no history of known mental illness, no use of psychological medication, no more than two months before the start of the study lack of an event that causes anxiety, depression And stress, no hearing-impaired speech and no addiction

Intervention groups

Eight sessions of mindfulness-based cognitive therapy on women with first trimester hemorrhage lead to termination of pregnancy in the intervention group to reduce or relieve stress, anxiety, and depression. Assume a control group with the same characteristics that no intervention is performed on them.

Main outcome variables

Stress, anxiety, depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190627044036N1**

Registration date: **2019-12-11, 1398/09/20**

Registration timing: **retrospective**

Last update: **2019-12-11, 1398/09/20**

Update count: **0**

Registration date

2019-12-11, 1398/09/20

Registrant information

Name

maasumeh nasrollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-11, 1398/04/20

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating The Effectiveness of Mindfulness-Based Stress Reduction(MBSR) on the Rate of Anxiety, Depression and stress in women with first trimester leads to termination of pregnancy referred to Hazrat Zeynab Hospital in Shiraz in 2019 بررسی اثر مشاوره ذهن آشنایی بر افسردگی و اضطراب و استرس در زنان مبتلا به سقط جنین در بیمارستان حضرت زینب شیراز 1398

Public title
The effect of mindfulness counseling on stress, anxiety and depression in pregnant women with first trimester bleeding who lose their pregnancy.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Women with first trimester hemorrhage who have lost their pregnancy desire to participate in research no known history of mental illness no use of psychological medication than two months before the start of the study no accident causing anxiety, Depression and stress hearing-impaired speech non-addiction
Exclusion criteria:
Pregnancy unwillingness to continue to cooperate with research An unfortunate event that causes anxiety, stress or depression Refusal to attend more than one meeting

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the random allocation table

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features
Experimental parameters of hemoglobin and beta-titers and quality of life are measured alongside the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University of Medical Sciences Student Ethics Committee

Street address

Kerman University of Medical Sciences, Kerman
University of Medical Sciences, Kerman, Iran Post Code 7616913555

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.KMU.REC.1398.217

Health conditions studied

1

Description of health condition studied

Stress, anxiety, depression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score in dass 21

Timepoint

Two weeks after MBSR Consulting

Method of measurement

Dass 21 questionnaire

2

Description

Depression score on dass 21

Timepoint

Two weeks after MBSR Consulting

Method of measurement

Dass 21 questionnaire

3

Description

Stress score in dass 21

Timepoint

Two weeks after MBSR Consulting

Method of measurement

Dass 21 questionnaire

Secondary outcomes

1

Description

Does not exist

Timepoint

Does not exist

Method of measurement

Does not exist

Intervention groups

1

Description

Intervention group 1: Three patients with abortion under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire followed by mindfulness-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And the same questionnaire as the test post is completed two weeks after the sessions the same questionnaire as the test post.

Category

Prevention

2

Description

Intervention group 2: Three patients with abortion under 14 weeks of gestation after filling out the pre-test DASS 21 psychiatric questionnaire then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And the same questionnaire as the test post is completed two weeks after the sessions.

Category

Prevention

3

Description

Intervention group 3: Three patients with H.mole under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire and then mindfulness-based counseling during 8 sessions of 2 to 2 and a half hours. And the same questionnaire as the test post is completed two weeks after the sessions.

Category

Prevention

4

Description

Intervention group 4: Three patients with abortion under 14 weeks of gestation after filling out the pre-test DASS 21 psychiatric questionnaire and then mindfulness-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And the same questionnaire as the test post is completed two weeks after the sessions.

Category

Prevention

5

Description

Intervention group 5: Three patients with ectopic pregnancy and under 14 weeks of gestation after filling out the DASS 21 psychiatric questionnaire completed as a pre-test followed by (same) mindfulness counseling during 8 sessions 2 It takes up to 2 and a half hours, and the same questionnaire as the test post is done again two weeks after the sessions.

Category

Prevention

6

Description

Intervention group 6: Three patients with abortion under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire then administered (identical) mindfulness counseling during 8 sessions of 2 to 2 and a half hours. And two weeks after the end of the sessions, the same questionnaire as the test post is performed again.

Category

Prevention

7

Description

Intervention group 7: Three patients with abortion under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And two weeks after the end of the sessions, the same questionnaire as the test post is performed again.

Category

Prevention

8

Description

Intervention group 8: Three patients with H.mole under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And two weeks after the end of the sessions, the same questionnaire as the test post is performed again.

Category

Prevention

9

Description

Intervention group 9: Three patients with abortion under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And two weeks after the end of the sessions, the same questionnaire as the test post is performed again.

Category

Prevention

10

Description

Intervention group 10": Three patients with abortion under 14 weeks of gestation after molar pregnancy, after filling out the DASS 21 psychiatric questionnaire completed as a pre-test, then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half It is done hourly and again two weeks after the end of the sessions, the same questionnaire as the test post.

Category

Prevention

11

Description

Intervention group 11: Three patients with abortion under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire, then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And two weeks after the end of the sessions, the same questionnaire as the test post is performed again.

Category

Prevention

12

Description

Intervention group 12 : Three patients with lost ectopic pregnancy and under 14 weeks of gestation after filling in pre-test DASS 21 psychological questionnaire then mindfulness-based counseling during 8 sessions 2 It takes up to 2 and a half hours, and the same questionnaire as the test post is done again two weeks after the sessions.

Category

Prevention

13

Description

Intervention group 13: Three patients with abortion under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And two weeks after the end of the sessions, the same questionnaire as the test post is performed again.

Category

Prevention

14

Description

Intervention group 14: Three patients with abortion under 14 weeks of gestation and mole pregnancy after filling out a pre-test DASS 21 psychological questionnaire then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half It is done hourly and again two weeks after the end of the sessions, the same questionnaire as the test post.

Category

Prevention

15

Description

Intervention group 15": Three patients with mole under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And two weeks after the end of the sessions, the same questionnaire as the test post is performed again.

Category

Prevention

16

Description

Intervention group 16: Three patients with missing ectopic pregnancy and under 14 weeks of gestation after filling in the DASS 21 psychiatric questionnaire completed as a pre-test then mindfulness-based counseling during 8 sessions 2 It takes up to 2 and a half hours, and the same questionnaire as the test post is done again two weeks after the sessions.

Category

Prevention

17

Description

Intervention group 17: Three patients with abortion under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And the same questionnaire as the test post is completed two weeks after the sessions.

Category

Prevention

18

Description

Intervention group: 18: Three patients with abortion under 14 weeks of gestation after filling out a pre-test DASS 21 psychiatric questionnaire then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And the same questionnaire as the test post is completed two weeks after the sessions.

Category

Prevention

19

Description

Intervention group 19: Three patients with H. mole under 14 weeks of gestation after filling out the pre-test DASS 21 psychiatric questionnaire then mind-based (identical) counseling during 8 sessions of 2 to 2 and a half hours. And the same questionnaire as the test post is completed two weeks after the sessions

Category

Prevention

20

Description

Control group: In the control group, the Dass 21 questionnaire is first filled out and after one and a half months the same questionnaire is checked again, meaning that without any grouping and intervention only the questionnaire is checked.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zeinab Hospital

Full name of responsible person

Alidousti Katayun

Street address

Hazrat Zeinab Hospital , Khatun square , Sibuyeh Blvd;

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Alidousti Katayun

Position

Group Manager and Supervisor

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Nasrollahi Masoumeh
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Student Of Midwifery And Medical Student Of Shiraz
Latest degree
Bachelor
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Since one of the most effective factors in improving the mental status of women during pregnancy and afterwards is social support and mindfulness counseling is a newer and more practical way to get a room to continue this program at Hazrat Zeinab Hospital To be considered.

When the data will become available and for how long

Early in the year 2020

To whom data/document is available

assistance Health Shiraz and Kerman university of medical sciences and head of the hospital of hazrat zainab

Under which criteria data/document could be used

If the research is effective and has a positive impact on mothers' mental health

From where data/document is obtainable

Kerman University of Medical Sciences or Shiraz University of Medical Sciences

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

Kerman University of Medical Sciences - Razi School of Midwifery - Vice Chancellor for Research - Research Thesis in 2019

Comments