

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of mindfulness on postpartum blues of primiparous women with normal delivery

Protocol summary

Study aim

Determining the effect of postnatal consciousness on prenatal women with normal delivery in Yasuj city

Design

An interventional study is a clinical trial that will be carried out on 90 pregnant women at the entrance to the study, referring to health centers and Imam Sajjad Educational Hospital. Participants will be assigned into two groups using block randomization.

Settings and conduct

The group is divided into three groups of 15 in one of the "Saturday", "Monday" or "Wednesday" time groups. During the eight sessions, the researcher will intervene at the conference hall of the Imam Sajjad Hospital in accordance with the guidebook "Mindfulness-based cognitive therapy for depression" in each of these days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Normal delivery; Primipara women; 18-35 years old; Pregnancy age 30-33 weeks; Literate; Inhabitant of Yasuj City; Iranian; Wanted pregnancy; single fetus; The lack of severe pregnancy complications; The lack of high risk pregnancies; Having mental health; The desire to participate in the study. Exit criteria include: Mother's dissatisfaction; immigration; Mother's Fatigue; Severe complications of pregnancy; Severe complications during and after childbirth.

Intervention groups

There will be no intervention in the control group. The researcher will present the executive and content schedules contained in the protocol in eight sessions of the two-hour week for the subject group. They will all be intercepted by a single person, with the same content and methodology, based on the guidebook "Mindfulness-based cognitive therapy for depression."

Main outcome variables

Postpartum blues

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170613034511N2**

Registration date: **2018-07-02, 1397/04/11**

Registration timing: **prospective**

Last update: **2018-07-02, 1397/04/11**

Update count: **0**

Registration date

2018-07-02, 1397/04/11

Registrant information

Name

Fatemeh Karami mahmoodabad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 6872

Email address

fatemeh.karami@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-06, 1397/04/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of mindfulness on postpartum blues of primiparous women with normal delivery		7591958435
Public title	The impact of mindfulness on postpartum blues.	Approval date 2017-08-05, 1396/05/14
Purpose	Prevention	Ethics committee reference number IR.YUMS.REC.1396.86
Inclusion/Exclusion criteria	Health conditions studied	
Inclusion criteria: Primipara women 18-35 Years old Literate (at least read and write) Inhabitant of Yasuj City Iranian Wanted pregnancy To have single fetus Lack of severe pregnancy complications Lack of high risk pregnancy Having a mental health Lack of depression The desire to participate in the study	1 Description of health condition studied Postpartum blues	
Exclusion criteria: Dissatisfaction of mother Mother's immigration Lack of motivation to participate in the study Having severe pregnancy complications High-risk pregnancy	ICD-10 code O99.3	
Age From 18 years old to 35 years old	ICD-10 code description Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium	
Gender Female	Primary outcomes	
Phase N/A	1	
Groups that have been masked <i>No information</i>	Description Postpartum blues	
Sample size Target sample size: 90	Timepoint Measure the blues after the day in the third, seventh and Tenth days after the delivery	
Randomization (investigator's opinion) Randomized	Method of measurement Stein's Maternity Blues Scale	
Randomization description Participants will be assigned into one of two groups using block randomization.	Secondary outcomes	
Blinding (investigator's opinion) Not blinded	1	
Blinding description	Description Mindfulness score	
Placebo Not used	Timepoint Before and after the beginning of the intervention	
Assignment Parallel	Method of measurement Five Point Questionnaire of Mindfulness	
Other design features	Intervention groups	
Secondary Ids empty	1	
Ethics committees	Description Intervention group:After identifying the subjects in the group, the researcher implemented the executive and content protocols in the eight sessions of the two-weekly weekly, based on the book "Mindfulness-based cognitive therapy for depression.The topics of the first to fourth sessions: 1-Explaining the importance of being present at the moment of being and being here and now, and opening the concept of mindfulness to members using a variety of techniques, and learning to do everyday things, along with their attention2-Getting to the minds of wandering and practicing attention to the body, physical and physical sensation, and attention to breathing3-Relax the wandering mind by practicing breathing and brainstorming, sitting meditations and doing exercises that bring attention to the moment4-	
1		
Ethics committee		
Name of ethics committee Ethics committee of Yasuj University of Medical Sciences		
Street address No.1, Reyhan 1 Ave., Mahmooodabad		
City Yasuj		
Province Kohgiluyeh-va-Boyrhmad		
Postal code		

.Learning to stay at the moment in a moment without escaping and avoiding people, and watching the turmoil of thoughts
The subject of the fifth to eighth sessions:1-A full knowledge of thoughts and feelings and their acceptance of judgment and direct involvement2- Changing mood and thoughts through the perception of thought as just thought and not reality3-Being aware of the sad signs and adjusting the program for a possible encounter with sad signs4-Planning for the future and using the presence techniques to continue their lives and generalize them to the whole life cycle.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajad hospital

Full name of responsible person

Karami Mahmoodabad Fatemeh

Street address

NO.1, Reyhan1 Ave., Mahmoodabad

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591958435

Phone

+98 74 3322 7606

Email

fatemeh.karami@yums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr Zoladl Mohammad

Street address

Motahari Blvd, University of Medical Sciences

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Phone

+98 74 3333 7230

Email

zoladl@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Karami Mahmoodabad Fatemeh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No.1, Reyhan 1 Ave., Mahmoodabad

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591958435

Phone

+98 74 3322 7606

Email

fatemeh.karami@yums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Karami Mahmoodabad Fatemeh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No.1, Reyhan 1Ave., Mahmoodabad

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591958435

Phone
+98 74 3322 7606
Email
fatemeh.karami@yums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Karami Mahmoodabad Fatemeh
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No.1, Reyhan1 Ave., Mahmoodabad
City
Yasuj
Province
Kohgiluyeh-va-Boyer-Ahmad
Postal code
7591958435
Phone
+98 74 3322 7606
Email
fatemeh.karami@yums.ac.ir

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

There is a possibility to share some of the data, such as information about the message.

When the data will become available and for how long

Available 6 months after the results are printed.

To whom data/document is available

The research data will be available to researchers working in academic and academic institutions.

Under which criteria data/document could be used

Use of data and documentation to conduct more research and access to more complete results

From where data/document is obtainable

You can use e-mail to receive data from the Homestay.

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

Requests for data and documentation are sent by email. As soon as possible, access to the requested files is available

Comments