

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effectiveness of mindfulness-based pregnancy counseling on Prenatal Distress and marital satisfaction among Nulliparous pregnant women

Protocol summary

Summary

This research is a clinical trial with parallel control and control group. The population of the study is pregnant nulliparous women referring to Yazd medical centers, 30 eligible pregnant women are selected. Then, using random allocation software, the research samples were randomly divided into two groups of test and control in each group of 15 people. Pregnancy rate for women 20-30 weeks, Nullipar 2 - Ability to speak and understand the English language 3-Low-risk pregnancy 4-single-person 5-Having physical and mental health Exit criteria: 1. Having pregnancy complications 2- Having a history Severe psychiatric disorders and affliction with depression and depression 3. Having a history of infertility 4. Use of assisted reproductive techniques 5. Use of psychiatric drugs 6. Drug dependence and use of psychiatric drugs before or during pregnancy 7. Dependence on substance and use of psychiatric drugs by Spouse (According to the person) 8. No sudden onset of abnormal stress due to adverse events In the last 1 month, such as: the death of a spouse, divorce, separation and spouse's husband, imprisonment, the death of a close member of the family of the intervention group, participate in 8 sessions of mind-awareness, once a week for one and a half hours, organized by the researcher. . The control group does not receive any intervention other than routine care. Before the intervention and after the end of the session, one month after the intervention, the marital satisfaction and pregnancy agility questionnaires were completed by the samples in both groups. Aims: To determine and compare the mean score of marital satisfaction in the test group at the time before, immediately and one month after the intervention. 3- Determination and comparison of the mean score of the pregnancy concern in the test group before, immediately after and one month after the intervention. 4. Determination and

comparison of the mean score. Marital satisfaction in the control group before, immediately and one month after the intervention. 5- Determination and comparison of the mean score of the pregnancy concern in the two groups of the test and control before, immediately after and one month afterwards. Variable parameters: Marital satisfaction with the Inrich marital satisfaction questionnaire is measured 2 - Concerns about pregnancy are measured by the pregnancy concern questionnaire. 3- Mindfulness counseling. It's about doing or not doing it Summary in 250 words:

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070534906N1**

Registration date: **2017-09-20, 1396/06/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-20, 1396/06/29

Registrant information

Name

Fatemeh Shabani

Name of organization / entity

Shahid Sadoughi University of Medical Sciences Yazd

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 1751

Email address

shabanifatemeh69@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Shahid Sadoughi University of Medical Sciences, Yazd

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-08-26, 1396/06/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of mindfulness-based pregnancy counseling on Prenatal Distress and marital satisfaction among Nulliparous pregnant women

Public title

effectiveness of mindfulness-based pregnancy counseling on Prenatal Distress and marital satisfaction

Purpose

Other

Inclusion/Exclusion criteria

Entry criterion: 1- Pregnant women 20-30 weeks, 2- Nullity Par 3 Low-risk pregnancies 4-Unicorns 5- Having physical and mental health 6-Ability to read and write 7- presence of spouse during pregnancy Exit criteria: Having pregnancy complications 2. Having a history of serious psychiatric disorders and having symptoms of depression and depression 3. Having a history of infertility 4. Using fertility methods 5. Using psychiatric drugs 6- Depending on drugs and taking medications before or during Pregnancy 7- Dependence on substance and use of psychiatric drugs by the spouse 8. According to the person's statement, sudden absence of abnormal stress due to adverse events of life in the last 1 month, such as: the death of the spouse, divorce, separation and wife's husband, imprisonment , The death of a close member of the family

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Shahid Sadoughi University of Medical Sciences Yazd

Street address

Yazd, Bahonar Square, Shahid Sadoughi Blvd.

City

Yazd

Postal code**Approval date**

2017-06-20, 1396/03/30

Ethics committee reference number

IR.SSU.REC.1396.78

Health conditions studied**1****Description of health condition studied**

pregnancy distress and marital satisfaction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pregnancy distress

Timepoint

Before the intervention. At the end of the intervention, one month after the intervention

Method of measurement

pregnancy distress questionnaire

2**Description**

marital satisfaction

Timepoint

Before the intervention at the end of the intervention one month after the intervention

Method of measurement

Inrich Marital Satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the control group there is no consultation

Category

N/A

2

Description

Random samples of the intervention group, sessions for 8 sessions, each week for a period of 1.5 hours, will consist of 5 minutes of hiatus and voice, 30 minutes of the theory, 30-40 minutes of mindfulness training and 10 minutes of questions and answers. The content of the sessions, including greetings, the expression of natural and physical changes in pregnancy, including gastrointestinal changes, skin presentation, definition of mental consciousness, the expression of the relationship of stress and changes, and the practice of eating raisins, and the explanations of home activity in the first session, the second session of the homework review, genital mutilation, Body Surveillance and Home Health Indicators, Third Session: Homework, Counseling on Cardiovascular, Respiratory, and Neurogens, Sitting Meditation and Home Living Exposure, Session Four: Reviewing homework, expressing sexual relationships, sleeping and having a rest and work, and consciousness breathing and home-living explanations, at the fifth session : Home homework, practice hat Yoga and counseling for emotional and psychological changes, anxiety, fear, depression, sixth session: homework, skeletal muscle, practice of thoughts of truth, explaining home activity, seventh session: recording pleasing and unhealthy notes, explaining the process of labor and the eighth session of using learning and aggregation Past is

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center of Shahid-Ja'fari community of Rahmat Abad

Full name of responsible person

Ms. Jalali, Midwifery expert

Street address

Yazd Rahmat Abad Shahid Dashti blvd

City

yazd

2

Recruitment center

Name of recruitment center

Health center of Musa bin Ja'far Azadshahr

Full name of responsible person

Ms. Khazalpour, Midwifery expert

Street address

Yazd Azadshahr Telecommunication Alley

City

YAZD

3

Recruitment center

Name of recruitment center

Farabi Community Health Center

Full name of responsible person

Miss Bacon Midwifery

Street address

Yazd Blvd. Dashti Alley Shahidan Dashti

City

YAZD

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

دانشگاه علوم پزشکی شهید صدوقی

Street address

Yazd, Bahonar Square, Shahid Sadoughi Blvd.

City

yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd Nursing Midwifery Faculty

Full name of responsible person

fatemeh shabani

Position

Student

Other areas of specialty/work

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd Nursing Midwifery Faculty

Full name of responsible person

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Position

Doctor of Reproductive Health

Other areas of specialty/work**Street address**

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Person responsible for updating data**Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty