Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Mindfulness-based Art therapy and Routine Care on Severe Fear of Childbirth in Nulliparous Women

Protocol summary

Study aim
To determine the effect of mindfulness-based art therapy (MBAT) on severe fear of childbirth in primiparous women: a randomized controlled clinical trial

Design
A randomized controlled clinical trial, phase 3, on 58 nulliparous pregnant women (with a 20% drop). The random function of Excel software will be used for randomization.

Settings and conduct
The research community is primiparous women who go to health centers, clinics, and private clinics in Sari for prenatal care. In the first stage, eligible pregnant women will announce their readiness through advertisements that will be shared in the centers.The W-DEQ-A and the entry checklist for these individuals will be sent online. In women who get a score of 66 or higher and have other inclusion criteria, the researcher will introduce herself and explain the research objectives by sending an SMS. Due to the nature of the intervention, it will not be possible to keep the participants and the researcher responsible for the intervention blind during the intervention process. Therefore, in order to control the detection bias, the blinding process will be performed on the people who are responsible for collecting information and analyzing data.

Participants/Inclusion and exclusion criteria
Inclusion: Nulliparous Women with singleton pregnancy, Gestational age 28-26 weeks and W-DEQ-A score from 66 to 100; With written consent Exclusion: High-risk pregnancy; Getting pregnant through assisted reproductive techniques; Receive other treatments to control anxiety and fear

Intervention groups
The intervention group will receive a MBAT that will be performed in 8 sessions in women with a gestational age of 26-28 weeks and in groups. women in the control group will receive routine prenatal care. After completing the last questionnaire, a brief MBAT session will be held for the control group.

Main outcome variables
Fear of childbirth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160619028528N5**
Registration date: **2021-11-28, 1400/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-28, 1400/09/07**
Update count: **0**

Registration date
2021-11-28, 1400/09/07

Registrant information

Name
Zeinab Hamzehgardeshi

Name of organization / entity
Mazandaran University of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 11 3336 7342

Email address
z.hamzehgardeshi@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of Mindfulness-based Art therapy and Routine Care on Severe Fear of Childbirth in Nulliparous Women

Public title
The Effect of Mindfulness-Based Art therapy on Sever Fear of Childbirth in Nulliparous Women: A randomized controlled clinical trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Nulliparous Women Gestational age 28-26 weeks Wijma Delivery Expectancy Questionnaire (W-DEQ-A) score from 66 to 100 Single pregnancy Living together with a spouse Iranian nationality Persian language Having a written consent to participate in the research
Exclusion criteria:
High-risk pregnancy Getting pregnant through assisted reproductive techniques Repeated abortion experience (2 times or more) History of psychiatric illness (schizophrenia, bipolar disorder, and major depression) or get it at the time of the study by self-report or registration in the medical record Use of psychiatric drugs (such as antidepressants, anti-anxiety and anti-psychotic drugs), drug abuse, alcohol and psychotropic drugs Chronic physical illness (diabetes, cardiovascular disease, kidney disease, self-report or registration in the medical record) Receive other treatments or participate in other interventions (types of interventions including behavioral therapy, cognitive-behavioral therapy, psycho-education, etc.) to control stress, anxiety and fear
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
Blocked random allocation method will be used for random assignment of samples to two intervention groups (mindfulness-based art therapy) and control group (routine care). For this purpose, quadruple blocks will be considered. The six blocks may be TCTTCC, CTTC, CTCT, CCTT, TCTC, TCCT, with T being for the intervention group and C for the control group. The randbetween function in Excel will be used to randomly select blocks. Production numbers will be between 1 and 6 and will be selected based on the production number of the desired block and all 4 samples will be assigned to the intervention and control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the intervention, it will not be possible to keep the participants and the researcher responsible for the intervention blind during the intervention process. Therefore, in order to control the blinding bias at the evaluator level (detection bias), the blinding process will be performed on the people who are responsible for collecting information and analyzing data.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Moallem Square, Vice Chancellor for Research and Technology, Mazandaran University of Medical Sciences
City
Sari
Province
Mazandaran
Postal code
48178-57344
Approval date
2021-10-02, 1400/07/10
Ethics committee reference number
IR.MAZUMS.REC.1400.505

Health conditions studied

1

Description of health condition studied
Fear of childbirth in nulliparous women
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fear of childbirth

Timepoint
At the time of enrollment - immediately after the intervention - one month after the intervention
Method of measurement
Wijma Delivery Expectancy/ Experience Questionnaire (W-DEQ-A)

Secondary outcomes

1

Description
Childbirth self-efficacy
Timepoint
At the time of enrollment - immediately after the intervention - one month after the intervention
Method of measurement
Iranian Childbirth Self-Efficacy Inventory (ICBSEI-36)

2

Description
Mindfulness
Timepoint
At the time of enrollment - immediately after the intervention - one month after the intervention
Method of measurement
Five Factor Mindfulness Questionnaire (FFMQ)

3

Description
Preferred childbirth method
Timepoint
At the time of enrollment - immediately after the intervention - one month after the intervention
Method of measurement
Socio-demographic-fertility Characteristics

4

Description
Treatment (Intervention) Adherence
Timepoint
One month after the intervention
Method of measurement
3 criteria for adherence to the intervention: the number of mindfulness-based art therapy sessions that women participate in the intervention group, the number of participants who do their homework and the number of participants who complete the questionnaires completely.

5

Description
Treatment (Intervention) Satisfaction
Timepoint
One month after the intervention
Method of measurement
Satisfaction Visual Analog Scale

Intervention groups

1

Description
Intervention group: The intervention is mindfulness-based art therapy, which will be performed by a Master of Midwifery Counseling in 8 sessions in women with a "gestational age" of 26-26 weeks. Group meetings are held for 4 weeks (2 sessions per week). Each session will take 90 minutes. The groups will be 3-5 people. The research team includes a reproductive health specialist, a reproductive epidemiologist, a psychiatrist, a clinical psychologist, an art therapist, and a graduate student in midwifery counseling who will assist in the design and implementation of the protocol. The content of the program of the present research sessions is as follows: 1. Familiarity with mindfulness technique, exploring the relationship between mind and body and understanding pregnancy and the existence of a child 2. Recognizing and accepting their feelings by focusing on feelings about childbirth and child 3. Recognizing and understanding the feelings and perceptions about the birth process 4. Recognizing and understanding the feelings towards the baby 5. Recognizing and understanding the feelings and perceptions about parenting 6. Recognizing and understanding the feelings and perceptions towards the delivery room and staff 7. Recognizing perceptions related to the person's self-confidence and abilities, recognizing obstacles in order to help him on the journey to delivery 8. Recognizing and understanding the feelings and perceptions of the person Life after childbirth. Content validity of the protocol of this 8-session program will be reviewed by relevant experts (psychiatrist, psychologist, art therapist, reproductive health specialist, gynecologist). In these sessions, techniques of painting, collage and working with clay or dough will be used. The tools used in this research include painting supplies such as paper, crayons, watercolors and pastels, and collage supplies such as cardboard, pieces of fabric, newspapers, magazines, photographs, disposables, glue and clay or dough. Exercises are also considered as homework. This protocol is implemented practically in Iran and its effect on the study outcome (fear of childbirth) will be calculated through indicators such as the Effect Size index.
Category
Treatment - Other

2

Description
Control group: Women in the control group will receive routine prenatal care (Prenatal periodic visits). After completing the last questionnaire (four weeks after the intervention), in order to enjoy the benefits of the study, a mindfulness-based art therapy session will be held for the control group participants and their possible questions about fear of childbirth will be answered.
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Sari health centers, Private clinics in Sari

Full name of responsible person
Zeinab Hamzehgardeshi

Street address
Nasibeh Nursing and Midwifery Faculty, Vesal Street, Amir Mazandarani Boulevard

City
Sari

Province
Mazandaran

Postal code
4843163181

Phone
+98 11 3336 7342

Fax
+98 11 3336 8915

Email
Z.hamzehgardeshi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Majid Saeedi

Street address
Moalem Street, Vice chancellor for research

City
Sari

Province
Mazandaran

Postal code
48431-63181

Phone
+98 11 4443 4210

Email
majsaeedi@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Kosar Miraei Mohammadi

Position
Student (MSc)

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Piroozi Alley 12, Piroozi St., Taleghani Blvd.

City
Sari

Province
Mazandaran

Postal code
48187-68977

Phone
+98 11 3310 6053

Email
kosarmohammadi1371@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Zeinab Hamzehgardeshi

Position
Associated Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Nasibeh Nursing and Midwifery Faculty, Amir Mazandarani Street

City
Sari

Province
Mazandaran

Postal code
48431-63181

Phone
009833367342

Fax
+98 11 3337 8915

Email
z.hamzehgardeshi@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Kosar Miraei Mohammadi
Position
Student (MSc)
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Piroozi Alley 12, Piroozi St., Taleghani Blvd.
City
Sari
Province
Mazandaran
Postal code
48187-68977
Phone
+98 11 3310 6053
Email
kosarmohammadi1371@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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
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