Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effects of Mandela Coloring and Music Therapy on the Anxiety of Primiparous Women

Protocol summary

Study aim
Comparison of the Effects of Mandala Coloring and Music Therapy on the Consumption of Primiparous Women

Design
This research is a clinical trial with a control group, with parallel groups, with a sample size of 150 people who are divided into three color therapy, music therapy and control groups by simple random assignment.

Settings and conduct
This research will be done in the health clinics of Zabul city. The researcher identified pregnant women eligible to enter the study, and after obtaining informed consent, they were asked to complete the demographic and obstetric information checklist and the Spielberger anxiety questionnaire.In the color therapy group, people will be given a box of 6 colored pencils and a coloring book with mandala designs. became.

Participants/Inclusion and exclusion criteria
First Pregnancy, Singleton and Desire Gestational age 20-28 Pregnancy Age 18-35 years Absence of Fetal abnormalities No History of Depression and Anxiety Before Pregnancy No History of Infertility Absence of Acute and Chronic illness of the Mother Have not Had an Accident in the Past 9 Months Not Having a High-Risk Pregnancy

Intervention groups
The present study includes two intervention groups. The participants will be divided into two groups: color therapy and music therapy. In the color therapy group, people will be given a box of 6 colors and a coloring book with mandala designs. In the music therapy group, a CD containing soothing wordless music with a slow rhythm will be given to the participants.

Main outcome variables
Anxiety of primiparous women

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241202063915N1**
Registration date: **2024-12-22, 1403/10/02**
Registration timing: **prospective**

Last update: **2024-12-22, 1403/10/02**
Update count: **0**

Registration date
2024-12-22, 1403/10/02

Registrant information

Name
Zeynab Sheikh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 54 3328 0551

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-30, 1403/10/10

Expected recruitment end date
2025-05-22, 1404/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effects of Mandela Coloring and Music Therapy on the Anxiety of Primiparous Women

Public title
Comparison of the Effects of Mandela Coloring and Music Therapy on the Anxiety of Primiparous Women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
First Pregnancy, Singleton and Desire Gestational age 20-28 Pregnancy Age 18-35 years Absence of Fetal abnormalities No History of Depression and Anxiety Before Pregnancy No History of Infertility Absence of Acute and Chronic illness of the Mother Have not Had an Accident in the Past 9 Months Not Having a High-Risk Pregnancy
Exclusion criteria:
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be done with a purpose-based method. For this purpose, all referring pregnant mothers who meet the study entry criteria will be selected as a sample and this work will continue until the final sample size is reached.People who meet the criteria for entering the research will be selected and then randomly assigned using the list prepared by random assignment software, will be divided into one of two groups: coloring and music therapy. The samples are placed in the designated group in the order of entry into the study based on the prepared list.
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 Zabol University of Medical Sciences
Street address
Zabol University of Medical Sciences Headquarters, Shahid Bagheri St, Jihad Square, Zabol
City
Zabol
Province
Sistan-va-Balouchestan
Postal code
9861663335
Approval date
2024-11-23, 1403/09/03
Ethics committee reference number
IR.ZBMU.REC.1403.903

Health conditions studied

1

Description of health condition studied
Anxiety of Primiparous Women
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Anxiety
Timepoint
Before and After the Intervention
Method of measurement
Demographic and Midwifery Information Questionnaire and Spielberger

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First intervention group: In the color therapy group, people will be given a box of 6 colors and a coloring book with mandala designs. The designs used will be provided to the research units for 20 minutes during 8 consecutive weeks (2 sessions per week) after the approval of the counseling and guidance professors and a psychologist.
Category
Other

2

Description
Intervention group: The second intervention group: In the music therapy group, a CD containing relaxing music without words with a slow rhythm (60 to 75 beats per minute measured with a metronome) will be provided to the participants. In the current study, the participants

will be asked to listen to the iguana piece of music that has a uniform, gentle theme and away from any kind of music for 8 weeks (twice a week) for 20 minutes in a quiet and dimly lit environment and in a comfortable position. The emotions are melodic and rhythmic and the rhythm is less than 80 beats per second. Listen using the device. Participants are advised not to use hands-free and the volume should be in the range of 65-70 dB.

Category
Other

3

Description
Control group: prenatal care during pregnancy is performed routinely for the participants.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Health Center

Full name of responsible person
Zeynab sheikh

Street address
Imam Khomeini 68, Imam Khomeini st, Zabol

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2

Recruitment center

Name of recruitment center
Hazrat Ali (AS) Health Center

Full name of responsible person
zeynab sheikh

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next to Mosli Al-Mohdi (AJ), Shahid Sargolzaei St, zabol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zabol University of Medical Sciences

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
Zabol 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
Zabol University of Medical Sciences

Full name of responsible person
Zeynab sheikh

Position
Midwifery undergraduate student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

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Latest degree
Bachelor

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Person responsible for updating data

Contact

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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