Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

The Effect of aromatherapy and music on the Non-Stress Test and anxiety in primiparous women.

Protocol summary

Study aim
Comparison of aromatherapy and music on the Non-Stress Test (NST) and anxiety in primiparous women.

Design
This study is a randomized, single-blind three-group clinical trial (two intervention groups and one control group - 65 participants in each group). Random sampling will be performed using six blocks among primiparous women who referred to performing NST for the first time.

Settings and conduct
This study will be performed in the prenatal clinic of Shahid Akbar-abadi Hospital in Tehran. Twenty minutes before performing the NST, four drops of 10% Lavender essential oil will be dripped on a 10*10 Polyethylene napkin and attach to the mother's collar of clothes. In aroma and music group simultaneously with Lavender aroma, the music (sounds of nature) will be played through headphones for 20 minutes. In the control group, distilled water as a placebo will be used Instead of aroma. For mothers of aroma and control groups, headphones will be placed without playing music to eliminate the ambient sounds. After 20 minutes implementation of intervention, the NST will be performed for all mothers

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian primiparous women, Gestational age of 32 to 41 weeks of pregnancy.
Exclusion criteria: a history of infertility, mental illness.

Intervention groups
Aromatherapy group= Aromatherapy will be done with 10% Lavender essential oil. To eliminate the ambient sounds, headphones will be placed without playing music. Aromatherapy- music group = Simultaneously with the aroma of lavender, sounds of nature selected by mother will be played through headphones for 20 minutes. Control group=Distilled water will be used Instead of aroma, as a placebo, also to eliminate the ambient sounds, headphones will be placed without playing music.

Main outcome variables
State anxiety, trait anxiety, results of non – stress test.

General information

Reason for update
To Change the sampling location, also start and end time of sampling

Acronym

IRCT registration information
IRCT registration number: **IRCT20090810002324N17**
Registration date: **2020-12-22, 1399/10/02**
Registration timing: **prospective**

Last update: **2021-01-10, 1399/10/21**
Update count: **1**

Registration date
2020-12-22, 1399/10/02

Registrant information

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Maryam Keshavarz

Name of organization / entity
Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-08, 1399/11/20

Expected recruitment end date
2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of aromatherapy and music on the Non-Stress Test and anxiety in primiparous women.

Public title

Aromatherapy and music on the Non-Stress Test and anxiety.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Maternal age 18 - 40 years. Gestational age of 32 - 41 weeks of pregnancy (from accurate Last menstruation period or first - trimester ultrasound). Wanted pregnancy. Stable hemodynamic status in mother (blood pressure higher than 80/60 mm/Hg). passage of at least 1.5 - 2 hours from the last meal.

Exclusion criteria:

History of infertility or the use of assisted reproductive techniques. Vaginal bleeding and uterine contraction. Any fetal abnormalities and amniotic fluid disorders. Using painkillers and sedatives in the last 24 hours. Hearing disorders. Addiction to drugs, psychotropic substances, and cigarettes. Neurological problems. Respiratory diseases and a history of allergies to plant essential oils.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **195**

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the two intervention and the control groups will be assigned one of the codes A, B or C. Randomization will be done using six blocks and determination of blocks will be done using R statistical program. For concealment, each block will be placed in an opaque envelope. Each envelope will be randomly selected by one of the study participants. Participants will be placed in one of the two intervention or the control groups based on the codes in each of the specified blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

Interpretation of non - stress tests in all groups will be done by two research assistants (Specialist in perinatology) who unaware of the group's allocation. All questionnaires will be gathered by the research assistant who unaware of the group's allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی ایران

Street address

تهران، بزرگراه همت جنب برج میلاد، دانشگاه علوم پزشکی ایران

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Province

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Postal code

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Approval date

2020-10-21, 1399/07/30

Ethics committee reference number

IR.IUMS.REC.1399.675

Health conditions studied

1

Description of health condition studied

State and trait anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The mean Score and severity of State anxiety of Spielberger questionnaire.

Timepoint

Before the intervention, 15 minutes after the end of NST.

Method of measurement

The State anxiety of Spielberger questionnaire.

2

Description

The mean score and severity of trait anxiety of Spielberger questionnaire.

Timepoint

Before the intervention, after the end of NST.

Method of measurement

The trait anxiety of Spielberger questionnaire.

3

Description
reactive and non- reactive of NST.
Timepoint
After the end of NST.
Method of measurement
Checklist

4

Description
The number of acceleration of fetal heart rate.
Timepoint
During the NST Procedure.
Method of measurement
Checklist

5

Description
The number of fetal movement.
Timepoint
During the NST Procedure.
Method of measurement
Checklist

6

Description
Minimum time for the test to be positive.
Timepoint
During the NST Procedure.
Method of measurement
Checklist

Secondary outcomes

1

Description
Blood pressure
Timepoint
Measuring the blood pressure will be done in a sitting position before performing the intervention. After completing the NST, on the left side of the supine position, the blood pressure will be re-measured.
Method of measurement
Digital sphygmomanometer

Intervention groups

1

Description
Intervention group: The first Intervention group aromatherapy: At first, the mother will be placed in a quiet room. Twenty minutes before performing the non-stress test (NST), four drops of 10% Lavender essential oil (Made by the Barij Essence Pharmaceutical Company) will be dripped on a 10*10 Polyethylene napkin and attach to the mother’s collar of clothes. For the mothers of this group, to eliminate the ambient sounds, headphones will be placed without playing music. The mother will typically inhale the aroma for 20 minutes. After removing the Polyethylene napkin and headphones, the mother will be ready for the test. The NST will be performed for 20 minutes using a Fetal monitoring device.
Category
Prevention

2

Description
Intervention group: aromatherapy and music: At first, the mother will be placed in a quiet room. Twenty minutes before performing the NST, four drops of 10% Lavender essential oil (Made by the Barij Essence Pharmaceutical Company) will be dripped on a 10*10 Polyethylene napkin and attach to the mother’s collar of clothes. Simultaneously with the aroma of lavender, the music (sounds of nature) will be played through headphones for 20 minutes by selecting the type of music and the volume of the tuning sound according to the mother's desire (with a maximum of 45 dB). After removing the Polyethylene napkin and headphones, the mother will be ready for the test. The NST will be performed for 20 minutes using a Fetal monitoring device.
Category
Prevention

3

Description
Control group: At first, the mother will be placed in a quiet room. Twenty minutes before performing the NST, four drops of distilled water, as a placebo, will be dripped on a 10*10 Polyethylene napkin and attach to the mother’s collar of clothes. The mother will typically inhale it for 20 minutes. For the mothers of this group, to eliminate the ambient sounds, headphones will be placed without playing music. After removing the Polyethylene napkin and headphones, the mother will be ready for the test. The NST will be performed for 20 minutes using a Fetal monitoring device.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar-abadi hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Maryam Keshavarz

Position
Associated Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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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