

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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

###### Name

Maryam Keshavarz

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4365 1813

###### Email address

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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

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### 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**

Nasrin Rezaei

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Mowlavi St. Tehran, Iran

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

کاظم ملکوتی

**Street address**

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

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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

**Street address**

School of Nursing & Midwifery, Rashid Yasemi st.,

Valiasr St., Tehran, IRAN

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## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**

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**Position**

Associated Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

نسرین رضائی

**Position**

Midwife

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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salamat Hospital, Gilan, Rostam abad, end of Shahid  
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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