Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of listening to music versus no listening to music on the results of non-stress test in pregnant women: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of listening to music versus no listening to music on the results of non-stress test in pregnant women

Design
This is a randomized clinical trial, in which 160 eligible pregnant women will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible pregnant women who will refer to Fatemieh Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 35 years, Gestational age 37 to 40 weeks, Singleton, First pregnancy, Low fetal motions Exclusion criteria: Pregnancy complications, Congenital anomalies of the fetus, Smoking, Taking sedative or narcotic or anti-anxiety drugs, Hearing disorder

Intervention groups
Intervention group: Routine prenatal care as well as listening to the wordless Iranian music called Roohafza generated by Shahram Tavakoli with the IRIB Symphony once for 30 minutes using headphone in a silent room Control group: Just routine prenatal care

Main outcome variables
Primary outcome: The number of fetal heart rate, The number of fetal movement

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N319**
Registration date: **2019-12-05, 1398/09/14**
Registration timing: **registered_while_recruiting**
Last update: **2019-12-05, 1398/09/14**
Update count: **0**

Registration date
2019-12-05, 1398/09/14

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-23, 1398/08/01

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of listening to music versus no listening to music on the results of non-stress test in pregnant women: a randomized clinical trial

Public title
Effect of listening to music versus no listening to music on the results of non-stress test in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 35 years, Gestational age 37 to 40 weeks, Singleton, First pregnancy, Low fetal motions

Exclusion criteria:

Pregnancy complications, Congenital anomalies of the fetus, Smoking, Taking sedative or narcotic or anti-anxiety drugs, Hearing disorder

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: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-09-21, 1398/06/30

Ethics committee reference number

IR.UMSHA.REC.1398.426

Health conditions studied

1

Description of health condition studied

Fetal stress

ICD-10 code

O77

ICD-10 code description

Other fetal stress complicating labor and delivery

Primary outcomes

1

Description

The number of fetal heart rate

Timepoint

Before the intervention and 30 minutes after the intervention

Method of measurement

Thorough physical examination

2

Description

The number of fetal movement

Timepoint

Before the intervention and 30 minutes after the intervention

Method of measurement

Thorough physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine prenatal care as well as listening to the wordless Iranian music called Roohafza generated by Shahram Tavakoli with the IRIB Symphony once for 30 minutes using headphone in a silent room

Category

Treatment - Other

2

Description

Control group: Just routine prenatal care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh Hospital in Hamadan City

Full name of responsible person
Marzieh Janesari

Street address
Fatemieh Hospital, Pasdaran Ave.

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6517838695

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Janesar.m556@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr Saeid Bashirian

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Marzieh Janesari Ladani

Position
Midwifery Student

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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