

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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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Province

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6517838695

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+98 81 3828 3939

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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

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Batool Khodakarami

Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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zahrabatul2006@yahoo.com

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