

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of massage and music on the fatigue of mothers of premature infants admitted to the neonatal intensive care unit

Protocol summary

Study aim

Comparison of the effect of massage and music on the fatigue of mothers of premature infants admitted to the neonatal intensive care unit

Design

Random assignment will be done by blocking method. In this block A, the first day of the control phase is performed and on the second day of the music intervention, and on the third day of massage intervention, and B will be done on the first day of the control phase. And on the second day of massage intervention and on the third day of music intervention). In this case, if the number of dice came, the sample would be AABB, if 2 came ABAB, if 3 came BABA, if 4 came ABBA, if 5 came BAAB And if 6 came to be grouped into BBAA.

Settings and conduct

The scope of this research is the neonatal intensive care unit of Valiasr Hospital. The choice of mothers for inclusion in the study is based on entry criteria and according to their entry number, there are a number of interventions A (control, music, massage) or B (control, massage, Music), each row of interventions takes place within three days.

Participants/Inclusion and exclusion criteria

Mothers with infants admitted to infants' care unit, infants from 30 to 37 weeks, newborns with RDS disease, mother's presence for three consecutive days, no history of premature newborns, no hearing problems based on mother's statements, no chronic conditions such as cardiovascular disease, Cancers, nervous and muscular disorders, etc. Having no infectious ulcer at the site of massage.

Intervention groups

The massage group use the Drowning Stroking Wronging. The Music Intervention Group receive the sound of nature, which combines the sounds of rain, river, waterfall and birds, with headphones. The control group relax on the bed.

Main outcome variables

Fatigue in mothers of premature infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180626040249N1**

Registration date: **2019-01-14, 1397/10/24**

Registration timing: **retrospective**

Last update: **2019-01-14, 1397/10/24**

Update count: **0**

Registration date

2019-01-14, 1397/10/24

Registrant information

Name

leila abadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5476 4695

Email address

leyla.abadian95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-11, 1397/04/20

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

2018-07-11, 1397/04/20

Actual recruitment end date

2018-08-21, 1397/05/30

Trial completion date

2018-09-05, 1397/06/14

Scientific title

Comparison of the effect of massage and music on the fatigue of mothers of premature infants admitted to the neonatal intensive care unit

Public title

Comparative study on the effect of massage and music on fatigue in mothers of premature infant in neonatal intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a newborn admitted to the Neonatal Care Unit
Mother's presence for three consecutive days

Exclusion criteria:

Not having a pregnancy history of a premature baby
Not having hearing problems based on mothers' statements
Not having chronic diseases like cardiovascular disease, cancers, nervous and muscular disorders
Not having an infective wound on the site of massage

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **41**

Actual sample size reached: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

Research units will be entered into the research according to the criteria for access to research. Random assignment will be done by blocking method. In this block A means (on the first day of the control phase and on the second day of music intervention and on the third day of massage intervention) and B will be done (on the first day of the control phase) On the second day of the massage, the massage will be performed on the third day of the music intervention). With each throw of dice and the arrival of a number on a dice, the rows of four moms are identified. If the number of dice 1 came in the sample as AABB, if 2 came ABAB, if 3 came BABA, if 4 came ABBA, if 5 came BAAB and if 6 came BBAA grouped.

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 Nursing and Midwifery & Rehabilitation _ Tehran University of Medical Science.

Street address

Tohid Square, Dr Mirkhani Avenue (Eastern Nusrat)

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-06-13, 1397/03/23

Ethics committee reference number

IR.TUMS.FNM.REC.1397.011

Health conditions studied**1****Description of health condition studied**

Fatigue

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fatigue score in multi-dimensional fatigue Inventory

Timepoint

15 minutes before the intervention and 15 minutes after intervention, massage and music and control

Method of measurement

To measure fatigue, mothers are asked to use the Multidimensional Fatigue Inventory (MFI). This questionnaire, by assessing 5 dimensions, provides a deeper and more accurate understanding of the person's fatigue. In the MFI fatigue questionnaire, the fatigue of individuals is also measured in the physical dimension in the psychological dimension. For this reason, this questionnaire is preferred to other existing fatigue questionnaires. This tool has 20 questions and it has 5 areas: general fatigue (4 items), physical exhaustion (4 items), mental fatigue (4 items), activity fatigue (4 items), and motivation decrease (4 items).

Secondary outcomes

empty

Intervention groups

1

Description

Since the study design is cross-type, both groups receive the desired interventions in a different order. After the mothers are divided into two groups using block randomization method. Group one: For the first group, baseline, music and massage are performed in three consecutive days (one intervention per day). At the control stage (the first day), the mothers first fill the fatigue questionnaire, then rest for 20 minutes on the bed and complete the fatigue questionnaire 15 minutes after the rest. At the music stage (the second day), the mothers first fill the fatigue questionnaire, then for 20 minutes, the sound of nature (the combination of the sounds of rain, river, waterfall and birds) is played out through the headphones for 20 minutes, and 15 minutes after the completion of the music, the fatigue questionnaire Mothers complete. It should be noted that the amount of sound is adjusted according to the mother and also, to prevent the transmission of infection (due to the use of headphones), after each use, headphones are disinfected. At the massage stage (third day), the mothers first fill the fatigue questionnaire. Then they were fitted with a comfortable and comfortable dressing on the bed. In order to create relaxation and massage, two methods of stroke massage (including percolation and stroke surface and deep) And Rolling. In the massage, the stroke of the palm of the hand is placed on the tissue in the organs and the back of the patient, and is applied to the lymphatic drainage path to a superficial and deep pressure without going into the bony mass points. In Rolling Massage, the muscle tissue is placed in rolls between the thumb and the mark in different places and moves. Rolling on the skin and muscles can affect relaxation. In the ringing massage, the muscle tissue between the thumb and the mark (between both hands) will move in opposite directions; each move will be three to five times, and the massage time will be 20 minutes. 15 minutes after completion of massage, the fatigue questionnaire was completed again by the mothers.

Category

Other

2

Description

Group 2: For the second group, the steps of control, massage and music are performed in three consecutive days (one intervention per day). At the control stage (the first day), the mothers first fill the fatigue questionnaire, then rest for 20 minutes on the bed and complete the fatigue questionnaire 15 minutes after the rest. At the massage stage (the second day), the mothers first fill the fatigue questionnaire. Then they were fitted with a comfortable and comfortable dressing on the bed. In order to create relaxation and massage, two methods of stroke massage (including percolation and stroke surface and deep) And Rolling. In the massage, the stroke of the palm of the hand is placed on the tissue in the organs

and the back of the patient, and is applied to the lymphatic drainage path to a superficial and deep pressure without going into the bony mass points. In Rolling Massage, the muscle tissue is placed in rolls between the thumb and the mark in different places and moves. Rolling on the skin and muscles can affect relaxation. In the ringing massage, the muscle tissue between the thumb and the mark (between both hands) will move in opposite directions; each move will be three to five times, and the massage time will be 20 minutes. 15 minutes after completion of massage, the fatigue questionnaire was completed again by the mothers. At the music stage (third day), the mothers first fill the fatigue questionnaire, then for 20 minutes, the sound of nature (the combination of the sounds of rain, river, waterfall and birds) is played out through the headphones for 20 minutes, and 15 minutes after the completion of the music, the fatigue questionnaire Mothers complete. It should be noted that the amount of sound is adjusted according to the mother and also, to prevent the transmission of infection (due to the use of headphones), after each use, headphones are disinfected.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Batul Pour Aboli Sharaf Abadi

Street address

End of keshavarz Blvd. Imam Khomeini Hospital Complex

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1631

Email

hosp_valiasr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sayed Ahmad Rezai

Street address

Keshavarz Blvd, Ghods St, Central Organization of the University, Sixth Department of Research and Technology

City
Tehran

Province
Tehran

Postal code
1417653761

Phone
+98 21 8163 4061

Fax
+98 21 8163 3654

Email
rcco@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
medical University Tehran

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
Tehran University of Medical Sciences

Full name of responsible person
Leila Abadian

Position
Student Master

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Tavid Square, Dr Mirkhani St. (Eastern Nusrat)

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 6692 7171

Fax
+98 21 6690 4252

Email
leyla.abadian95@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Batuol Pur Aboli Sharaf Abadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Tavid Square, Dr Mirkhani St. (Eastern Nusrat)

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 6105 4411

Fax
+98 21 6690 4252

Email
b_pouraboli@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Leila Abadaian

Position
Student Master

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Tohid Square, Street doctor Myrkhany (N. Eastern),
School of Nursing and Midwifery, Tehran

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 6692 7171

Fax
+98 21 6690 4252

Email
leyla.abadian95@gmail.com

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