Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison between the effect of music therapy and aromatherapy in sleep quality and physiological indices in myocardial infarection patients

Protocol summary

Summary

This study is a randomized clinical trial to determine the effect of aromatherapy (lavender) and music therapy (Music sounds of nature) On physiological parameters (pulse rate and respiration, blood pressure, body temperature, the blood, peripheral arterial oxyhemoglobin Sachvryshn) and sleep quality in patients with myocardial infarction , This study randomly samples three groups (music, Aromatherapy and control) in blocks of six with a sample size of 129 will perform, After obtaining informed consent from patients and if there is inclusion criteria (absence of any known allergies, lack of smell or hearing disorders, etc.) will be done for three consecutive nights, Physiological indicators in all three groups before and after an hour of sleep and six oclock in morning wii be measuurd and sleep quality questionnaire twice, once before the start of the study and a second time after completion of the study are evaluated The band an hour before the usual patients sleep through the hands of Sony music players for 30 to 45 minutes . And for aromatherapy, aromatherapy with essential oils of Lavender of an hour before six in the morning will wake up, The control group will not be any interference from the researcher, all data will be collected and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122019919N8**
Registration date: **2016-09-10, 1395/06/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-10, 1395/06/20

Registrant information

Name

Arefeh Davoodi Bavil Oliaii

Name of organization / entity

Nursing and Midwifery of Faculty, Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Center of Tabriz University of Medical Sciences

Expected recruitment start date

2016-03-29, 1395/01/10

Expected recruitment end date

2016-08-31, 1395/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of music therapy and aromatherapy in sleep quality and physiological indices in myocardial infarection patients

Public title

Comparison between the effect of music therapy and aromatherapy in sleep quality and physiological indices in myocardial infarection patients

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: Would like to participate in the study

and signed an informed consent form: male and female patients aged 30 to 75 years who are hospitalized in the intensive care unit with a diagnosis of myocardial infarction: complete consciousness and awareness of time, place or person: Auditory and olfactory disorder, according to the patient and not be a member of the immediate family: History of eczema, hives or respiratory problems such as allergies to flowers and plants and not name: Any serious mental disorder, according to the patient or is not a member of the immediate family: scores from the initial assessment questionnaire Pittsburgh Sleep Quality Index is equal to or less than 5. Exclusion criteria: Avoid proceeding at any stage of intervention: drug addiction (according to the patient or a family member): employment health

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **129**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz medical sciences

Street address
tabriz university of scinces - university street -= univrsity gate- tabriz

City
Tabriz

Postal code

Approval date
2016-03-02, 1394/12/12

Ethics committee reference number
TBZMED.REC.1395.3

Health conditions studied

1

Description of health condition studied
myocard infarction

ICD-10 code
I21

ICD-10 code description
Acute myocardial infarction

Primary outcomes

1

Description
improve the quality of life and mean arterial presure

Timepoint
Sleep quality: on the first evening and the morning were the fourth day Inclusion

Method of measurement
Pittsburgh Sleep Quality Index

2

Description
mean arterial presure

Timepoint
One hour before and one hour after 6 am after the intervention and intervention for three consecutive nights

Method of measurement
Using calibrated monitoring devices available in the cardiac care unit

Secondary outcomes

1

Description
Improve the physiological (arterial systolic and diastolic blood pressure), body temperature, arterial oxyhemoglobin saturation, heart rate and respiration disease

Timepoint
One hour before and one hour after the experimental intervention and at 6 am after a period of three consecutive nights

Method of measurement
Using standard monitoring devices available in the tympanic thermometer devices

Intervention groups

1

Description
In the music therapy in patients for three consecutive nights, music of your choice that evening, the first day of the intervention of the music list which is approved by the Ministry of Islamic GuidanceThe hearing through headphones, choose and one hour before sleep for 30 to 45 minutes via the hands-free type Sony will hear in your bed And physiological index patients one hour before

and one hour after 6 am after music therapy and the use of monitoring devices measuring and marking Alborz 7b in the chart will be provided in the table, the process is carried out for three consecutive nights will be The patient's sleep quality using the Pittsburgh Sleep Quality Index intervention once before and again after the third night will be completed by the patients.

Category

Prevention

2

Description

In the control group with no intervention will be done by the researcher, only routine interventions and treatments that can be performed for all patients receive.

Category

N/A

3

Description

Patients in the aromatherapy group for three consecutive nights, each night an hour before sleep four drops of essential oil on a cotton ball spilled pure lavender After two minutes inhaling from a distance of two inches of the pin nose up at 6 am to Dickey install and notes of treated patients, cotton balls at six of Dickey patients will be isolated.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

The Cardiac Care Unit 1 at Shahid Madani Hospital

Full name of responsible person

Afkham Vargaeei

Street address

Madani Martyr Hospital - University Street - University

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences (Primary Sponsor)

Full name of responsible person

Dr.Rashidi Mohammad Reza

Street address

University Street- University

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences (Primary Sponsor)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical scinces - School of Nursing and Midwifery

Full name of responsible person

Suri Jafarlu Vahid

Position

MSc student -Expert

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty