

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effects of aroma therapy and music therapy on sleep quality of burned patients

Protocol summary

Summary

The type of this study is clinical trial. The purpose of this study is comparison of the effects of aroma therapy and music therapy on sleep quality of burned patients. The number of samples are 48 burned patients that will hospitalize in burn ward in Shahid Sadoughi Burn Hospital in Yazd. The process of sampling will do during five month using the method of purposive sampling and the samples will place in two test groups (24 patients) using the software of random allocation. Inclusion criteria in this study is the patients that are in the range of 20 - 65 years old that can speak Persian and also clearly. The patients also should have a burn in the range of 25 % - 60 % and the depth of it are 2 and 3 grade. Exclusion criteria is the patients that have psychological disorders, allergic rhinitis, respiratory disorders, sinusitis, sleep disorders and a disorder that affect sense of smell and hearing and also; the patients that use Psychotic drugs and have have Inhalation burns or burn in head, neck and face exclude from the study. after knowing that the patients have inclusion criteria, the researcher will give them clear and understandable information about the method of study and then catch them a testimonial. In two groups, in the first three nights hospitalized in burn ward, researcher will not do no intervention on patients and only, patients fill the questionnaire that check out their sleep quality in last night, on the next morning. then in forth night for 3 nights (20 minutes), the patients will listen to their favorite and light music by choosing it from a list by a MP3player that has a headphone and then fill the questionnaire on the next morning. In aroma therapy group, in forth night for 3 nights (20 minutes), (the reasercher pure seven drops of lavand essence on the kleenex and then place the Kleenex on the plastic label and ask the patients to Inhalate it normally) and then fill the questionnaire on the next morning. The patients in both two test groups also use sedative and sleeping drugs if they needed. Finally, the average of sleep quality grade of patients in two test groups analyze

both before and after music therapy and aroma therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070818395N1**

Registration date: **2014-08-24, 1393/06/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-24, 1393/06/02

Registrant information

Name

Akram Amrollahi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 1751

Email address

amrollahi.akram@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2013-11-04, 1392/08/13

Expected recruitment end date

2014-04-04, 1393/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of aroma therapy and music therapy on sleep quality of burned patients

Public title

Comparison of the effects of aroma therapy and music therapy on sleep quality of burned patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: age of patients:20-65; language: persian; the ability to speak clearly; depth of burn:2,3 grade; total burn surface area: %25 - %60 Exclusion Criteria: the patients that have psychological disorders; the patients that have allergic rhinitis, respiratory disorders,sinosis; the patients that have a disorder that affect sense of smell and hearing; the patients that have sleep disorders; the patients that use Psychotic drugs; the patients that have Inhalation burns or burn in head, neck and face

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Sciences,
Building Number 2, Shahid Sadoughi Street, Bahonar
Square, Yazd, Iran

City

Yazd

Postal code

8916877441

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

119551

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

BURN

ICD-10 code

T30.0

ICD-10 code description

Burn of unspecified body region, unspecified degree

Primary outcomes**1****Description**

Quality of sleep

Timepoint

before and after intervention

Method of measurement

The questionnaire that check out quality of sleep in burned patients

Secondary outcomes

empty

Intervention groups**1****Description**

In music therapy group, the reasercher will not do no intervention on patients in first three nights that patients are hospitalized in burn ward and only, on the next morning, patients fill a questionnaire that check out their sleep quality in last night, then in forth night for 3 nights (20 minutes), the patients will listen to their favorite and light music by choosing it from a list by a MP3player that has a headphone and then fill the questionnaire on the next morning.

Category

Treatment - Other

2**Description**

In aroma therapy group, the reasercher will not do no intervention on patients in first three nights that patients are hospitalized in burn ward and only, on the next morning, patients fill a questionnaire that check out their sleep quality in last night, then in forth night for 3 nights (20 minutes),(the reasercher pure seven drops of lavand essence on the kleenex and then place the Kleenex on the plastic lable and ask the patients to Inhalate it

normally) and then fill the questionnaire on the next morning

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Burn Hospital

Full name of responsible person

Akram Amrollahi

Street address

Shahid Sadoughi Burn Hospital, Paknejad Street,
Moalem Street, Yazd, Iran

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Fatemeh Ezoddini

Street address

Shahid Sadoughi University of Medical Sciences,
Building No 2, Shahid Sadoughi Street,
BahonarSquare, Yazd, Iran

City

Yazd

Grant name

Grant code / Reference number

2902

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences

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

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Akram Amrollahi

Position

Student Critical Care Nursing Master

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Tahere Salimi

Position

Faculty member

Other areas of specialty/work

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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