Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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,sinositis; 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 questionaire 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 Amrollhi

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 Amrollhi

Position
Student Critical Care Nursing Master

Other areas of specialty/work

Street address
Shahid Sadoughi University of Medical Sciences, Building No 2, Shahid Sadoughi Street, Bahonar Square, Yazd, Iran

City
Yazd

Postal code
8916978477

Phone
+98 35 1824 1751

Fax
+98 35 1824 9705

Email
amrollahi.akram@ssu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Sadoughi University of Medical Sciences

Full name of responsible person
Tahere Salimi

Position
Faculty member

Other areas of specialty/work

Street address
Nursing and Midwifery College, Bouali Street, Safaieh, Yazd

City
Yazd

Postal code
8916877441

Phone
+98 35 1824 1751

Fax
+98 35 1824 9705

Email
salimi_tahere@yahoo.com

Web page address

Person responsible for updating data

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

Street address
Shahid Sadoughi university of Medical Sciences ,Building No 2, Shahid Sadoughi Street , Bahonar Square, Yazd, Iran

City
Yazd

Postal code

8916978477

Phone

+98 35 1824 1751

Fax

+98 35 1824 9705

Email

amrollahi.akram@ssu.ac.ir

Web page address

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