

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Determining effects of massage and music with relaxation on pain intensity, anxiety and relaxation responses in burned patients

Protocol summary

Summary

The purpose of this study is to investigate the effect of massage and music with relaxation on pain intensity, anxiety and relaxation responses in burned patients. This is a randomized clinical trial with control group. Participants will be assigned randomly through random block sampling technique (quaternary units) without permutation to four groups: music therapy with relaxation, music with massage, massage and control group. During 3 days, these groups will be compared according to the effects of interventions on pain intensity, anxiety, pain anxiety and relaxation. Sample size in each group will be 57 and in total it will be 228 patients with burn who have eligibility criteria (including, every day dressing change, able to speak and oriented to time, person and place, and not in acute phase of burning) and signed consent form to take part in the study. Before and after the intervention and after changing dressing, co-researcher will collect data related to pain intensity, anxiety, pain anxiety and relaxation by questionnaire and visual scale. Validity and reliability of questionnaires will be evaluated prior to gathering data. Finally data will be analyzed by statistical tests.

General information

Acronym

complementary therapy in burn patients

IRCT registration information

IRCT registration number: **IRCT201202269143N1**

Registration date: **2012-07-04, 1391/04/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-04, 1391/04/14

Registrant information

Name

Tahereh Najafi Ghezeljeh

Name of organization / entity

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4323

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining effects of massage and music with relaxation on pain intensity, anxiety and relaxation responses in burned patients

Public title

Determining effects of massage and music with relaxation on pain intensity, anxiety and relaxation responses in burned patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian burn patients with every day

burns; without respiratory damage; TBSA 10-45%, burn degree 2 or 3; able to speak (oriented to time, person and place); not in acute phase of burning; with background pain; without visual and hearing deficiency; without nerve damage in burn places; not taking cardiovascular drugs. Exclusion criteria: patients with psychological and cognitive disorders; infection in burn wound; critical situation for patient during study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **228**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavars Blvd., Ghods St., Central Office of Tehran
University of Medical Sciences

City

Tehran

Postal code

Approval date

2012-06-13, 1391/03/24

Ethics committee reference number

56689

Health conditions studied

1

Description of health condition studied

Burn patients

ICD-10 code

T29

ICD-10 code description

Burns and corrosions of multiple body regions

2

Description of health condition studied

Burning

ICD-10 code

T30

ICD-10 code description

Burn and corrosion, body region unspecified

Primary outcomes

1

Description

relaxation

Timepoint

before, after intervention and after dressing change

Method of measurement

VAS

2

Description

Pain Anxiety

Timepoint

before dressing change

Method of measurement

BSPAR

3

Description

Anxiety

Timepoint

before, after intervention and before dressing change

Method of measurement

VAS

4

Description

pain intensity

Timepoint

before, after intervention and dressing change

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

control group: without intervention

Category

Other

2

Description

music therapy: Patient preferred music, listening for 10 minutes by headphone with patient preferred music volume, once a day and prior to changing dressing

Category

Other

3

Description

music with massage: Patient preferred music, listening for 10 minutes by headphone with patient preferred music volume, simultaneous with Swedish massage for 10 minutes with patient privacy protection on patient's healthy (not burned) parts of body, once a day and prior to changing dressing

Category

Other

4

Description

massage: Swedish massage for 10 minutes with patient privacy protection on patient's healthy (not burned) parts of body, once a day and prior to changing dressing

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Clinical Educational Center

Full name of responsible person

fatemeh mohaddes ardabili

Street address

Motahari Hospital, Rashid Yasemi street, Valiasr street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Tahereh Najafi Ghezeljeh

Street address

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Sq. ,1419733171, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Tehran 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

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Tahereh Najafi Ghezeljeh

Position

PhD in Nursing/Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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