

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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

najafi\_t@tums.ac.ir

#### 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

dressing change; 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

#### Street address

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

#### City

Tehran

#### Postal code

#### Phone

+98 21 6105 4323

#### Fax

#### Email

najafi\_t@tums.ac.ir

#### Web page address

## Person responsible for scientific 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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**Phone**  
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**Email**  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Faculty of Nursing and Midwifery, Tehran University of  
Medical Sciences  
**Full name of responsible person**  
Tahereh Najafi Ghezaljah  
**Position**  
PhD in nursing/faculty member  
**Other areas of specialty/work**  
**Street address**  
Faculty of Nursing and Midwifery, Tehran University of  
Medical Sciences, Nosrat St., Tohid Sq. ,1419733171,  
Tehran, Iran  
**City**  
Tehran  
**Postal code**

## 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*