# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Effects of guided imagery on level of anxiety, pain and comfort in patients with burns

## Protocol summary

**Study aim**

Determining the effect of guided mental imagery on the level of anxiety and pain in hospitalized burn patients

**Design**

Clinical trial with control and intervention group; parallel groups; without blinding; non-randomized and accessible; on 76 patients.

**Settings and conduct**

We have a small research environment (Taleghani hospital in Ahvaz), it is not possible to blind the samples, so first the control group will be studied and after their discharge, the intervention group will be sampled. We have 38 samples in each of the control groups.The method of sampling is available. For each sample of the intervention group, 10 intervention sessions will be conducted.The control group will only receive routine care. The anxiety, pain intensity and comfort of the patients were measured by the Spielberger anxiety, McGill pain and Kolkaba general comfort questionnaires before and after the intervention in the group. In the control group, the intervention is completed first and after five days according to the patients' statements by the researcher.

**Participants/Inclusion and exclusion criteria**

Patients with: Age 18-60 third or fourth degree burns (with any percentage of burns) In the second week of hospitalization Ability to speak Persian Smartphone and headphones; Patients without: History of hospitalization in the burn ward head burn

**Intervention groups**

In the intervention group, in addition to routine care for each sample, 10 sessions of guided mental imagery will be performed on five consecutive days, twice a day in the patient's room. In each session, the patient listens to the educational file for about 20 minutes and closes his eyes, takes deep breaths and relaxes his muscles to completely relax. For the control group, no intervention was done and they will receive routine care.

**Main outcome variables**

Guided mental imagery; Anxiety ;Intensity of pain ;Quality of pain ;Burn patients; Convenience

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220912055951N1**
Registration date: **2022-09-24, 1401/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-24, 1401/07/02**
Update count: **0**

**Registration date**

2022-09-24, 1401/07/02

**Registrant information**

**Name**
Negin Saremi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 2252 4627
**Email address**
neginsary@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-09-23, 1401/07/01

**Expected recruitment end date**

2022-11-22, 1401/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Effects of guided imagery on level of anxiety, pain and comfort in patients with burns

**Public title**
The effect of guided imagery on anxiety, pain and comfort of burn patients
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients should be in the age group of 18-60. Have third and fourth degree burns (with any percentage of burns) Have the ability to speak Persian Have the desire to participate in the study Having a smartphone and headphones
**Exclusion criteria:**
Have neck and face burns Have severe hearing and vision impairment Having mental illnesses based on self-report Have a history of hospitalization in the burn ward Burn patients who have undergone a graft
**Age**
From **18 years** old to **60 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **76**
**Randomization (investigator's opinion)**
N/A
**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**
Ethics Committee of the Faculty of Nursing and Midwifery, University of Medical Sciences, Tehran Uni
**Street address**
Tehran University of Medical Sciences, Qods corner, Keshavarz Blvd
**City**
Tehran
**Province**
Tehran
**Postal code**
1417653761
**Approval date**
2022-05-01, 1401/02/11
**Ethics committee reference number**
IR.TUMS.FNM.REC.1401.007

## Health conditions studied

**1**

**Description of health condition studied**
Burn patients
**ICD-10 code**
T21
**ICD-10 code description**
Burn and corrosion of trunk

## Primary outcomes

**1**

**Description**
Patient anxiety score
**Timepoint**
At the beginning of the study, before the intervention and at the end of the intervention (the end of the fifth day)
**Method of measurement**
State-trait anxiety inventory

**2**

**Description**
Patient comfort level
**Timepoint**
At the beginning of the study, before the intervention and at the end of the intervention (the end of the fifth day)
**Method of measurement**
Kolkaba General Comfort Questionnaire

**3**

**Description**
Pain level of patients
**Timepoint**
At the beginning of the study, before the intervention and at the end of the intervention (the end of the fifth day)
**Method of measurement**
McGill pain questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Intervention group: in the intervention group, in addition to routine care for each sample, 10 guided mental imagery sessions will be performed in five consecutive days, twice a day in the patient's room. During each session, the patient is directed to the mental imagery training file for about 20 minutes, listens and closes his eyes according to the sentences that will be played, takes deep breaths and relaxes his muscles until he completely relaxes.

**Category**
N/A

### 2

**Description**
Control group: For the control group, no intervention was performed and they will receive routine care.

**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Burn Accidents Hospital Ayat Allah Taleghani Ahwaz

**Full name of responsible person**
Negin Saremi

**Street address**
Ayat Allah Taleghani Hospital, Mustaan St, Amaniyeh Neighborhood, Ahwaz, Khuzestan

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Docor fotoohi

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**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**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Negin Saremi

**Position**
Nursing graduate student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nursing

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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)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available