

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

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

Protocol summary

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

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

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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Web page address

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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

Street address

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Web page address

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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

Contact

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Tehran University of Medical Sciences

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Assistant professor

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Ph.D.

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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