

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Compare auditory distraction and visual distraction on pain, anxiety and vital sign undergoing dressing changes of burns in elderly people

Protocol summary

Study aim

Compare auditory distraction and visual distraction on pain and anxiety associated with dressing changes in elderly patients with burns during wound dressing change

Design

Single-blind clinical trial with block randomized allocation and parallel group design

Settings and conduct

The population of all burn elderly patients referred to the Motahari hospital for dressing change burn wounds. Assignment of patients to three groups is carried out by a statistical expert by using blocks. Each sample group includes 35 patients. Demographic and clinical characteristics of the patients will be recorded with questionnaire. For the auditory distraction intervention group nature based sounds and in visual distraction intervention group films about nature will be done for 20 minutes.

Participants/Inclusion and exclusion criteria

The desire to participate in the study: Age between 60-75 years old! Lack of addiction to drugs and alcohol! Lack of cognitive impairment! Lack of vision or hearing problems! Lack of psychosocial disorders! No other injury except of burning lesion! No previous record of burns! Burn of less than 25% second-degree! Burns on the upper and lower extremities! Less than 72 hours from the burns happening! Absence of self-immolation. Exclusion criteria: patient dissatisfaction to continue participation in the study pain! existence in the other parts of body

Intervention groups

In the auditory distraction intervention group, nature based sounds will be done for 20 minutes before dressing. In the visual distraction intervention group, films about nature will be done for 20 minutes before dressing. In the control group, before dressing no intervention will be done for the patients.

Main outcome variables

In each group the intensity of pain, anxiety, and vital signs will be evaluated before intervention, after intervention and finally after dressing change.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110912007529N21**

Registration date: **2020-02-17, 1398/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-17, 1398/11/28**

Update count: **0**

Registration date

2020-02-17, 1398/11/28

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-22, 1398/05/31

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare auditory distraction and visual distraction on pain, anxiety and vital sign undergoing dressing changes of burns in elderly people

Public title

The effect distraction on patients undergoing dressing change

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The desire to participate in the study Age between 60-75 years old Lack of addiction to drugs and alcohol Lack of cognitive impairment Lack of vision or hearing problems Lack of psychosocial disorders No other injury except of burning lesion No previous record of burns Burn of less than 25% Second-degree burns on the upper and lower extremities Less than 72 hours from the burns happening Absence of self-immolation

Exclusion criteria:

patient dissatisfaction to continue participation in the study pain existence in the other parts of body

Age

From **60 years** old to **75 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization which the patient was the randomization unit. Assignment of patients to the intervention and control group is carried out by a statistical expert by using blocks of 3 with with the help of statistical software minitab and using random numbers

Blinding (investigator's opinion)

Single blinded

Blinding description

Samplers and the statistical analyzer will be blind to patients 'allocation of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shaded University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2019-06-30, 1398/04/09

Ethics committee reference number

IR.SHAHEED.REEC.1398.049

Health conditions studied**1****Description of health condition studied**

Burn

ICD-10 code

Burns and

ICD-10 code description

T20-- T25

Primary outcomes**1****Description**

intensity of pain

Timepoint

The intensity of pain will be evaluated before intervention, after intervention and finally after dressing change.

Method of measurement

Visual Pain Scale

2**Description**

Pain Anxiety

Timepoint

The intensity of pain will be evaluated before intervention, after intervention and finally after dressing change.

Method of measurement

Burn Specific Pain Anxiety Scale (BSPAS)

Secondary outcomes

1

Description

Blood pressure

Timepoint

The blood pressure will be evaluated before intervention, after intervention and finally after dressing change.

Method of measurement

Check list

2

Description

Respiratory rate

Timepoint

The respiratory rate will be evaluated before intervention, after intervention and finally after dressing change

Method of measurement

Check list

3

Description

heart rate

Timepoint

The heart rate will be evaluated before intervention, after intervention and finally after dressing change

Method of measurement

Check list

Intervention groups

1

Description

In the auditory distraction intervention group, nature based sounds about nature will be done for 20 minutes. Dressing wound will be change. The intensity of pain, anxiety, and vital signs will be evaluated before intervention, after intervention and finally after dressing change.

Category

Prevention

2

Description

In the visual distraction intervention group, films about nature will be done for 20 minutes. Dressing wound will be change. The intensity of pain, anxiety, and vital signs will be evaluated before intervention, after intervention and finally after dressing change.

Category

Prevention

3

Description

Control group: before dressing no intervention will be done for the patients. The intensity of pain, anxiety, and

vital signs will be evaluated before intervention, after intervention and finally after dressing change

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital

Full name of responsible person

Yaghob Moradipoor

Street address

Motahhari Hospital, Rashid Yasimi Street, Valiasr Ave.

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8877 0037

Email

hospital.motahari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Zahra Kiasalari

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way, Tehran, Iran.

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3319118651

Phone

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Email

nrejeh@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

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**

Shahed University

Full name of responsible person

Nahid Rejeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All statistical data is available after being unidentifiable

When the data will become available and for how long

The access period is up to one year after the publication of the results

To whom data/document is available

The access period is up to one year after the publication of the results

Under which criteria data/document could be used

Use of information for academic research projects is allowed

From where data/document is obtainable

Corresponding author; Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way, Tehran, Iran

What processes are involved for a request to access data/document

Requests for specific information should be sent by an

email to the responsible author along with an

explanation of why the data is needed
Comments