Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 21 5121 3071

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