

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Benson Relaxation therapy on anxiety pain and pain intensity of dressing changes In burn patients

Protocol summary

Summary

This study is done to evaluate the effect of Benson relaxation on pain anxiety and pain intensity of dressing change in burn patients. The sample group consist of 90 patients who are randomly divided equally into two intervention and control group (the member of each group=45). The members of intervention group listen to relaxation audio files 30 minutes and they do what they hear after completing a training course and on the next turn of dressing change before entering the dressing room. People with 2 and 3 burn degree by age of 18-60 can participate in this study. People who have skin surgery or they are in the list of biological dressing can't participate in the study. Primary outcome: It is expected that Benson's relaxation be effective on pain intensity and pain associated with dressing change in burn patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091429817N1**

Registration date: **2017-02-11, 1395/11/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-11, 1395/11/23

Registrant information

Name

Esmat Nuhi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Is paid privately

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-12-19, 1395/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Benson Relaxation therapy on anxiety pain and pain intensity of dressing changes In burn patients

Public title

The effect of Muscular Relaxation therapy on anxiety pain and pain intensity of dressing changes in burn patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: They have 2 or 2 and 3 degree burn wounds; their ages are between 18 to 60; they able to understand and speak Persian; they don't have burns in their heads and necks; they experience one dressing at least; they have no history of mental illness; no absence of neurological disorders; no numbness in the limbs burned and they also don't have hearing or vision problems. Exclusion criteria: patients who are not able to cooperate in order to implement the method for whatever reasons are excluded; they don't able to

achieve necessary skills relaxation Benson; they are selected to skin graft surgery; their names are in the biological dressing list.

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: **90**

Randomization (investigator's opinion)

Randomized

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

Kerman University of Medical Sciences Ethics Committee

Street address

Campus University of Medical Sciences, beginning around seven gardens Alavi, Kerman

City

Kerman

Postal code

Approval date

2016-04-18, 1395/01/30

Ethics committee reference number

IR.Kmu.REC.1395.01

Health conditions studied

1

Description of health condition studied

burning

ICD-10 code

T29.6

ICD-10 code description

Corrosions of multiple regions, no more than second-degree corrosions mentioned

2

Description of health condition studied

burning

ICD-10 code

T29.7

ICD-10 code description

Corrosions of multiple regions, at least one corrosion of third degree mentioned

Primary outcomes

1

Description

pain intensity

Timepoint

before intervention and half an hour after the intervention

Method of measurement

Linear scale pain

2

Description

Anxiety pain

Timepoint

Before intervention and half immediately after the intervention

Method of measurement

Burn Specific Pain Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

The members of intervention group listen to relaxation audio files 30 minutes and they do what they hear after completing a training course and on the next turn of dressing change before entering the dressing room.

Category

Behavior

2

Description

The control group, only routine procedures done

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shifa Hospital

Full name of responsible person

Azam Shahabi

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Medical Education Center Shifa, Kosar Blvd, Kerman

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Doctor Esmat. Nouhi

Position

PhD

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences VCR

Full name of responsible person

Dr.Abbas Pardakhty

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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

Kerman University of Medical Sciences VCR

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**

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Master Of Medical Sergical Nersing

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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