

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effects of relaxation on anxiety and Quality of sleep in patients with burns: a randomized clinical trial.

Protocol summary

Study aim

Objectives: effects of relaxation methods on Quality of sleep and anxiety of patients with burns

Design

80 of patients with burns will be selected for samples available and by using a randomized complete block will be divided in to intervention and control group.

Settings and conduct

This study is a randomized clinical trial from patients admitted in the ward Burns of Valiasr Hospital in Arak and Sampling is conventional and eligible patients to enter the study will be allocated by lottery to experiment and control groups gradually. For the intervention group initially pre-test questionnaire will be completed. Then educational content will be presented during the one sessions of 30 minutes and the patients this technique will applied With follow-up researcher for 3 days. The curriculum includes providing a quiet environment and education tighten and relax muscles from head to toe or vice versa will be accompanied by deep breathing. The questionnaires after 3 days will be completed for this group, again. Intervention 2: For the control group initially pre-test questionnaire will be completed. While during this period control group only will receive their routine cares and cures, the questionnaires after 3 days will be completed for this group, again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: a) age 15 to 65 years; b) burns degree of 1 to 2 with 15 to 65 percent burn level; c) stability of hemodynamic status. Exclusion criteria: a) Lack of patient cooperation during the intervention for any reason; b) creation dangerous conditions of disease during the intervention.

Intervention groups

Intervention 1: For the intervention group initially pre-test questionnaire will be completed. Then educational content will be presented during the one sessions of 30 minutes and the patients this technique will applied With follow-up researcher for 3 days. The curriculum includes

providing a quiet environment and education tighten and relax muscles from head to toe or vice versa will be accompanied by deep breathing. The questionnaires after 3 days will be completed for this group, again. Intervention 2: For the control group initially pre-test questionnaire will be completed. While during this period control group only will receive their routine cares and cures, the questionnaires after 3 days will be completed for this group, again.

Main outcome variables

Anxiety; sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130424013110N4**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

Mehdi Harorani

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

m.harorany@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of relaxation on anxiety and Quality of sleep in patients with burns: a randomized clinical trial.

Public title

Effects of relaxation on anxiety and Quality of sleep in patients with burns

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age 15 to 65 years burns degree of 1 to 3 with 15 to 65 percent burn level stability of hemodynamic status

Exclusion criteria:

Lack of patient cooperation during the intervention for any reason creation dangerous conditions of disease during the intervention

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be by using random blocks.

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 Arak University of Medical Sciences

Street address

Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

City

Arak

Province

Markazi

Postal code

38481-76941

Approval date

2017-08-16, 1396/05/25

Ethics committee reference number

IR.ARAKMU.REC.1396.134

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

Burns

ICD-10 code

T30.0

ICD-10 code description

Burn of unspecified body region, unspecified degree

2**Description of health condition studied**

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

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

Anxiety

Timepoint

Before and 3 days after the intervention

Method of measurement

Spielberger questionnaire

2**Description**

Quality Of Sleep

Timepoint

Before and 3 days after the intervention

Method of measurement

St. Mary's Hospital Sleep Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group initially pre-test questionnaire will be completed. Then educational content will be presented during the one sessions of 30 minutes and the patients this technique will applied with follow-up researcher for 3 days. The curriculum includes providing a quiet environment and education tighten and relax muscles from head to toe or vice versa will be accompanied by deep breathing. The questionnaires after 3 days will be completed for this group, again

Category

N/A

2

Description

Control group: For the control group initially pre-test questionnaire will be completed. While during this period control group only will receive their routine cares and cures, the questionnaires after 3 days will be completed for this group, again.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital Arak

Full name of responsible person

Mehdi Harorani

Street address

Valiasr Hospital, Valieasr Square, Arak

City

Arak

Province

Markazi

Postal code

38149 - 5 - 7558

Phone

+98 86 3222 2003

Fax

+98 86 3223 1283

Email

m.harorani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr.Mohammad Arjomandzadegan

Street address

Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

City

Arak

Province

Markazi

Postal code

38149 - 5 - 7558

Phone

+98 86 3417 3506

Email

m.harorani@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mehdi Harorani

Position

Academic instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

City

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Phone

+98 86 3417 3506

Email

m.harorani@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Position

Academic instructor

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Sq, Arak

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Person responsible for updating data

Contact

Name of organization / entity

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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