

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of peer education on anxiety and background pain in patients with burns

Protocol summary

Study aim

Determining the Effect of Peer Education on Anxiety and Background Pain in Patients with Burn

Design

A simple randomized Clinical trial with control group, sample of 86 people in two groups

Settings and conduct

Sampling was performed among burn patients hospitalized at Shahid Motahari Hospital of Tehran affiliated to Iran University of Medical Sciences. Participants were randomly assigned to participate in the study by simple random sampling and divided into two groups of control and intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 65 years; Awareness of time and place; Being able to speak and understand Persian language; Having reading and writing skills; Percentage of burns from 15% to 45% (recorded in the case); ; Expiring Acute Period (Approximately one week according to Burning Reference); burns grade 1 and 2 and 3-level burns; Exclusion criteria: use any anxiolytic, psychoactive and anti-depressant drugs; Untreated Depression and Cognitive Disease (recorded in the case); having chronic disease like diabetes and arthritis and having physical disabilities, self burning or burning by others

Intervention groups

First group (intervention group): In this group, training will be done on reducing the burn complications by peer. Group 2 (control group): This group will receive routine training during the study.

Main outcome variables

background pain, Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190312043034N1**

Registration date: **2019-08-20, 1398/05/29**

Registration timing: **retrospective**

Last update: **2019-08-20, 1398/05/29**

Update count: **0**

Registration date

2019-08-20, 1398/05/29

Registrant information

Name

Mohammad Rahim khani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 86701

Email address

rahimkhani.m@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-24, 1398/02/04

Expected recruitment end date

2019-08-06, 1398/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of peer education on anxiety and background pain in patients with burns

Public title

The effect of peer education on anxiety and background

pain

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 18 and 65 years Awareness of time and place Percentage of burns from 15% to 45% (recorded in the case) burns grade 1 and 2 and 3-level burns Burns due to an accident
Exclusion criteria:
 Admitted to Burn Intensive Care Unit (BICU) Not Expiring Acute Period (Approximately one week according to Burning Reference) Use any anxiolytic, psychoactive and anti-depressant drugs Having chronic disease like diabetes and arthritis and having no physical disabilities Having Depression and Cognitive Disease (recorded in the case) Not having reading and writing skills Unable to speak and understand Persian language

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization and Draw method

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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, beside Milad Tower, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2019-03-13, 1397/12/22

Ethics committee reference number

IR.IUMS.REC.1397.1314

Health conditions studied

1

Description of health condition studied

burn

ICD-10 code

T30.0

ICD-10 code description

Burn of unspecified body region, unspecified degree

Primary outcomes

1

Description

Anxiety Scale in the spielberger anxiety questionnaire

Timepoint

Before and after intervention

Method of measurement

spielberger anxiety questionnaire

2

Description

Score of the background pain in the Visual Analogue Scale

Timepoint

Before and after intervention

Method of measurement

Visual Analogue Scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At first, among the clients at the Shahid Motahari Hospital burnout clinic 6 eligible peers Qualified to participate in the study as a peer. The training in the intervention group by the peer is held during 3 sessions for 45 to 60 minutes on a day-to-day basis. Anxiety and underlying pain will be measured before and after intervention.

Category

Rehabilitation

2

Description

Control group: The control group will only receive routine training during the intervention. background pain and anxiety will be measured before and after intervention.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Motahari hospital

Full name of responsible person

Dr Mostafa Dehmorede

Street addressMotahari hospital, Rashid yasami st, Vali e asr st,
Tehran**City**

Tehran

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Postal code

۱۹۹۶۷۱۳۸۸۳

Phone

+98 21 8877 0031

Fax**Email**

hospital.motahari@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Kazem Malakouti

Street addressIran University Of Medical Science, Beside of Milad
tower, Hemat highway**City**

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Email

admins@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Mohammad Rahim khani

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street addressIran university of medical science, side of milad
tower, hemat highway**City**

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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Rahim khani

Position

Master Student of nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Full name of responsible person

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The amount of anxiety, the intensity of the background pain, the percentage of age and sex of burn patients, percentage and burn factor

When the data will become available and for how long

Start the access period 5 months after the results edition

محققین

To whom data/document is available

researchers

Under which criteria data/document could be used

Data usage is allowed by mentioning the source

From where data/document is obtainable

rahimkhani.m@tak.iums.ac.ir

m.rahimkhani5854@gmail.com Mohammad rahim khani

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

Send documentation requests and how to use them to email

Comments