

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The Effect of Therapeutic Recreation Program on pain-anxiety and disability burn patient

Protocol summary

Study aim

The effect of a therapeutic recreation program on pain-anxiety and disability in burn patient

Design

Clinical clinical practice with control group, with parallel groups, blind, randomized, randomized software.

Settings and conduct

This study was conducted in the burn ward of Imam Reza Hospital in Mashhad. Patients in the intervention group will use the recreational therapy program for two weeks. In the control group, in the control group, according to routine, activities such as walking in the department, raising, lowering and opening, closing of the hands are done. The burn injuries questionnaire and WHO Disability Assessment Questionnaire will be completed in both groups.

Participants/Inclusion and exclusion criteria

Entry criteria: aged 20 and under 65 Refueling at least 5% and up to 30% Not having Burn on the legs, wrists and knees No electrical burn Mental and physical disability Exit criteria: Severe cardiovascular, pulmonary and vascular disorders The patient's lack of interest in continuing the study

Intervention groups

In the intervention group, a therapeutic recreation program is held for two weeks each week, three sessions of each session for one hour in the evening, after the meeting hour in the department.

Main outcome variables

pain anxiety and disability in burn patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181016041359N1**

Registration date: **2019-01-17, 1397/10/27**

Registration timing: **prospective**

Last update: **2019-01-17, 1397/10/27**

Update count: **0**

Registration date

2019-01-17, 1397/10/27

Registrant information

Name

abolfazl saberi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30

Expected recruitment end date

2019-03-05, 1397/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Therapeutic Recreation Program on pain-anxiety and disability burn patient

Public title

The Effect of Therapeutic Recreation Program on pain-anxiety and disability burn patient

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with burns 5 to 30%

Exclusion criteria:
Burn in legs, wrists and knees Electrical burn Mental and physical disability

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization: This method uses simple randomization models such as milk or line, random number table, or use of computerized randomization methods, and each user can, for example, by dropping coins, milk and line-ups in The intervention group or the control group. The implementation of this method is very simple. The disadvantages of this method is that the sample size of a group may be more than the other. One type of intervention may be given early in the study and a type of intervention at the end of the study. Randomization unit is parallel Software is a statistical software randomization tool Hiding with sealed envelopes

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the researchers and participants are blinded

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Ebn sina Street, Faculty of Nursing and Midwifery, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2018-12-31, 1397/10/10

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.073

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T20

ICD-10 code description

Burn and corrosion of head, face, and neck

Primary outcomes

1

Description

Pain Anxiety and Disability

Timepoint

Before the intervention, after the study and two weeks after the discharge

Method of measurement

burn specific pain anxiety scale - burn specific health scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A therapeutic recreation program for two weeks each week. Three sessions per session for one hour in the evening, after an appointment, in the intended room in the department so that the first hour of the men and then the women for the next time to perform the activity They enter the room, held in the department. The content of the program consists of six sessions, each session starting with the presentation of the contents of each session to patients and performing stretching, which lasts 10 minutes, the continuation of the program with games that cause mental and physical activity and laugh and joy that is 40 It takes a minute. The main activity of the sessions is: the first session of the game of the tail (a game in which the person should try to catch a scoop tailored for the other person), the second session of the coin and the bowling game with the feet, the third session of the darts throw, Playing Mannequa, Fourth Session Scissors, Volleyball, Fifth Floor Playing Cup, Handball, Sporty Gymnastics, and Sixth Session Using your fingers to remove the sticker behind the card and put it on the board, walking, running

tennis table. Finally, the sessions end with sharing the feelings of patients after an activity that lasts 10 minutes. The main content of each session is determined according to the available facilities and patient selection.

Category

Rehabilitation

2

Description

Control group: Control group: According to the routine, activities such as walking in the department, up / down and opening / closing hands are done.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital burn center

Full name of responsible person

Razieh Foroutan(phd)

Street address

Imam Reza Hospital Square-Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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University of Mashhad University of Medical Sciences,
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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Razieh Frootan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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razieh forootan

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of patient information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable