

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of rehabilitation nursing intervention model on the comprehensive health and daily performance of patients with hand burns

Protocol summary

Study aim

Evaluating the effect of rehabilitation nursing intervention model on the comprehensive health and daily performance of patients with hand burns

Design

A clinical trial with a control group, with parallel groups, randomized postoperative care, and outcome assessment on 60 patients. The method of allocating samples in groups is in the form of four random blocks without permutation. The lottery method was used for the randomization of blocks.

Settings and conduct

This study is performed in Shahid Motahari Burns Hospital in Tehran, affiliated to Iran University of Medical Sciences. Patients are divided into experimental and control groups by four random blocks without permutation.

Participants/Inclusion and exclusion criteria

Inclusion criteria; hand burns, Age over 18 years, No history of mental illness, Interested to participate in the study, Being literate. Exclusion criteria: Serious damage to upper limbs muscles, tendons, skeletons and nerves, Patients with severe heart disease who were unconscious before the burn, Patients with heart, lung and brain diseases, Unwillingness to participate the study.

Intervention groups

Intervention group: Receiving rehabilitation nursing model in 3 steps: 1- Acute stage: social support, health education, psychological counseling and passive hand movements. 2- Recovery stage: psychological counseling, intellectual-emotional therapy and active hand exercises. 3- Post-discharge stage: Conversation about re-employment and intellectual-emotional support. The control group receives routine nursing care.

Main outcome variables

The quality of life in patients with hand burn

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201207049634N1**

Registration date: **2021-11-28, 1400/09/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-28, 1400/09/07**

Update count: **0**

Registration date

2021-11-28, 1400/09/07

Registrant information

Name

Mahnaz Seyedshohadaee

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4365 1000

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of rehabilitation nursing intervention model on the comprehensive health and daily performance of patients with hand burns

Public title

The effect of rehabilitation nursing intervention on the health of patients with hand burns

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

hand burns Deep burns Age over 18 years No history of mental illness Interested to participate in the study Being literate

Exclusion criteria:

Serious damage to the muscles of the upper limbs, tendons, skeletons and nerves Patients with severe heart disease who were unconscious before the burn Patients with heart, lung, and brain diseases Unwillingness to participate in the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of allocating samples in groups is in the form of four random blocks without permutation. The letter A for the control group and the letter B are considered for the test group. Different modes of two groups (ABBA-BABA-ABAB-BAAB-BBAA-AABB) are written on six cards. Each card is placed in a sealed envelope. These envelopes are placed in a box and the researcher does not know in which group the research units will be located until the card is selected. A person who is not aware of the study and the groups, by selecting one of the envelopes from the box, determines in which group the patients will be located. This process is continued until all six cards are taken out of the box and the cards are returned to the box and this random selection is repeated to provide the desired sample size.

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

Faculty of Nursing and Midwifery of Iran University of Medical Sciences, Rashid Yasemi St., above Mirdamad, Vali Asr St., Tehran, Iran

City

Tehran

Province

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Postal code

19967-13883

Approval date

2020-10-27, 1399/08/06

Ethics committee reference number

IR.IUMS.REC.1399.715

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

Hand burns

ICD-10 code

M61.34

ICD-10 code description

Calcification and ossification of muscles associated with burns, hand

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

The quality of life in patients with hand burn

Timepoint

At the time of admission, recovery and post discharge from the hospital

Method of measurement

Quality of life questionnaire for burn patients: This questionnaire includes 40 questions in the areas of skin sensitivity to heat, body image, hand function, how to care for burned areas, job-communication, ability to perform simple activities, sexual function and emotional dimension and It has a 5-point Likert scale (severe, high, medium, low and not at all) that scaled from one to five and each question has the minimum score of 1 and the maximum of 5 . Out of 40 questionnaire questions, 18 questions are related to the physical dimension of quality of life, 11 questions are related to the psychological dimension of quality of life and 11 questions are related to the social dimension of quality of life. The quality of life is assessed for each dimension separately and also in all dimensions. The quality of life is based on the scores' average, the higher the mean, the better the quality of life and the lower mean represents lower quality of life.

2

Description

Activities of Daily Living

Timepoint

At the time of admission; recovery: the first four weeks (once a week); post discharge from the hospital: six months post discharge (once a month)

Method of measurement

The Lawton Instrumental Activities of Daily Living Scale (IADL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group, in addition to routine hospital treatment-rehabilitation programs, receive a rehabilitation nursing model in 3 stages: 1- Acute stage: social support, health education, psychological counseling and passive hand movements. 2- Recovery stage: psychological counseling, treatment. Rational-emotional and active hand exercises. 3- Post-discharge stage: 1- Talk about re-employment and intellectual-emotional support.

Category

Rehabilitation

2

Description

Control group: Patients in the control group receive only routine nursing care for 5 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Burns Hospital

Full name of responsible person

Mahnaz Seyedoshohadaee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motevalian

Street address

Hemmat Highway next to Milad Tower, Iran University of Medical Sciences, Tehran, Iran

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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

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

Mahnaz Seyedoshohadaee

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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

Not applicable

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

Part of the data on the primary outcome is for sharing

When the data will become available and for how long

One year after the publication the data will be available.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Meta-analysis is allowed on the data of this study.

From where data/document is obtainable

Ms, Mahnaz Seyedoshohadaee, Faculty of Nursing and Midwifery of Iran University of Medical Sciences, Rashid yasemi St., above Mirdamad, Vali Asr St., Tehran, Iran , Email: seyedoshohadaee.m@iums.ac.ir

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

After one year of publishing the article and publishing the results, those who need the data of this study, could apply via email.

Comments