

# 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)

##### Phone

+98 21 4365 1000

##### Email address

saydshohadai@yahoo.com

##### 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**

Tehran

**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

##### **Street address**

Shahid Motahari Burns Hospital, Rashid Yasemi st., Valiasr St., Tehran, Iran

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##### **Province**

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##### **Postal code**

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##### **Phone**

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##### **Email**

seyedoshohadaee.m@iums.ac.ir

## **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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

14496-14535

##### **Phone**

+98 21 8670 2504

##### **Email**

motevalian.a@iums.ac.ir

##### **Web page address**

<https://vcr.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**

Mahnaz Seyedoshohadaee

##### **Position**

Instructor

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Nursery

##### **Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

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**Web page address**<https://fnm.iums.ac.ir/fa?sid=31>

## 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**