# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jun 2026

## The Comparison between Occupational Therapy Interventions based on ICF Model vs Conventional Interventions on Participation and Satisfaction of Patients with Hand Burns in Occupational Areas

## Protocol summary

**Study aim**
The Comparison between Occupational Therapy Interventions based on ICF Model vs Conventional Interventions on Participation and Satisfaction of Patients with Hand Burns in Occupational Areas

**Design**
Two arm parallel group randomised trial with blinded outcome assessor, on 30 patients. For randomization, blocks of 4 will be used on "randomization.com "website.

**Settings and conduct**
The samples will be selected from Shahid Motahari and Shohadaye Yaft Abad Hospital in Tehran, who will randomly receive the interventions after completing the informed consent form. The outcome assessor is blinded. The evaluation will be done in 3 time points: the beginning, after 8 weeks and follow-up 4 weeks later.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 2nd and 3rd degree burns with at least 0.5% TBSA and involve the palmar/dorsal of the hand, in the age range of 18 to 60 years, 1 week after skin graft surgery, cognitive level above 21 based on MMSE.
Exclusion criteria: face and respiratory tracts burns, tendon injuries, fractures, infection in the surgery area

**Intervention groups**
The intervention group will receive occupational therapy interventions based on the ICF model and ICF coreset for people with burn injuries, which includes interventions in the most important areas of body structure and functions, participation in activities and changes in environmental factors, and interactive goal setting with clients. The control group will receive conventional occupational therapy interventions based on Dang Tang et al., including stretching, ROM exercises, improving sensation, increasing muscle strength and endurance, scar and edema management, and splinting. The treatment duration will be 8 weeks, 2 sessions per week and each session will be 45 minutes.

**Main outcome variables**
Occupational Performance; Satisfaction with occupational performance

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20231212060341N1**
Registration date: **2023-12-30, 1402/10/09**
Registration timing: **prospective**

Last update: **2023-12-30, 1402/10/09**
Update count: **0**

**Registration date**
2023-12-30, 1402/10/09

**Registrant information**
**Name**
Dorsa Hamedi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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+98 21 2222 8051
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2024-04-03, 1403/01/15
**Expected recruitment end date**
2025-02-03, 1403/11/15
**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The Comparison between Occupational Therapy Interventions based on ICF Model vs Conventional Interventions on Participation and Satisfaction of Patients with Hand Burns in Occupational Areas

**Public title**
Effect of Occupational Therapy Interventions in Patients with Hand Burns
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
depth of burn: 2 and 3 degree Estimated burn size based on TBSA: 0.5% which including anterior or posterior of hand Thermal burn injuries semi thickness skin graft surgery at least on week after skin graft surgery no comorbidities such as fractures, tendon injuries, amputations and etc. the burn site should not include the face and respiratory tracts score of 21 and above in Mini Mental Status Examination
**Exclusion criteria:**
missing more than two therapy sessions lake of willingness or cooperation for continuing the study
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **30**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
block balance randomization method with block size of 4 and allocation ratio of 1:1 will be used in this study. The "Randomization.com" website will be used for generation of random sequence. The Sequentially Numbered Selected Opaque Envelopes(SNSOE) will be used in order to allocation concealment.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
In this study, the outcome assessor will be blinded. Due to nature of the interventions, the blinding of participants and therapist is not possible.
**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**
No. 5, Rehabilitation Sciences School, Madadkaran Ave., Shahnazari Ave., Mother Sq., Mirdamad Blvd
**City**
Tehran
**Province**
Tehran
**Postal code**
1545913487
**Approval date**
2023-10-23, 1402/08/01
**Ethics committee reference number**
IR.IUMS.REC.1402.644

## Health conditions studied

### 1

**Description of health condition studied**
Burns of upper extremity
**ICD-10 code**
T23.0
**ICD-10 code description**
Burn of unspecified degree of wrist and hand

## Primary outcomes

### 1

**Description**
Occupational Performance (participation): Performing (achieving) the occupations chosen by the individual, which is the result of the dynamic interaction of the individual, the contexts , and the occupation.
**Timepoint**
The measurement of occupational performance would be at the beginning of the study, 8 weeks (after interventions), and 12 weeks (follow up).
**Method of measurement**
Canadian Occupational Performance Measure (COPM)

### 2

**Description**
Satisfaction with Occupational Performance: The level of satisfaction with performance in the most important occupations from the individual's own perspective.
**Timepoint**
The measurement of occupational performance would be at the beginning of the study, 8 weeks (after

interventions), and 12 weeks (follow up).

**Method of measurement**

Canadian Occupational Performance Measure (COPM)

## Secondary outcomes

### 1

**Description**

Quality of Life (QoL)

**Timepoint**

The measurement of quality of life would be at the beginning of the study, 8 weeks (after interventions), and 12 weeks (follow up).

**Method of measurement**

Burn Specific Health Scale-Brief (BSHS-B)

### 2

**Description**

Social Participation

**Timepoint**

The measurement of social participation would be at the beginning of the study, 8 weeks (after interventions), and 12 weeks (follow up).

**Method of measurement**

Participation Scale (P-scale)

### 3

**Description**

Hand Function

**Timepoint**

The measurement of hand function would be at the beginning of the study, 8 weeks (after interventions), and 12 weeks (follow up).

**Method of measurement**

Disabilities of Hand, Arm and Shoulder (DASH)

### 4

**Description**

Pain

**Timepoint**

The measurement of pain would be at the beginning of the study, 8 weeks (after interventions), and 12 weeks (follow up).

**Method of measurement**

Visual Analogue Scale (VAS)

### 5

**Description**

Range of Motion in Upper extremity's joints

**Timepoint**

The measurement of range of motion in upper extremity's joints would be at the beginning of the study, 8 weeks (after interventions), and 12 weeks (follow up).

**Method of measurement**

Goniometry

### 6

**Description**

Edema

**Timepoint**

The measurement of edema would be at the beginning of the study, 8 weeks (after interventions), and 12 weeks (follow up).

**Method of measurement**

Tape Measure

## Intervention groups

### 1

**Description**

Intervention group: Occupational therapy interventions based on the ICF Model: Participants with hand burn injuries, who are included in the study according to the inclusion criteria, will receive occupational therapy interventions based on the ICF model and the comprehensive ICF-coreset for the rehabilitation of patients with burn injuries. In this type of interventions, the entire treatment process is applied interactively with clients according to the "rehabilitation cycle" described by the ICF. In the beginning of intervention process, ICF-based documentation forms and ICF-Categorical Profile are completed. Then, in the step of evaluating and setting treatment goals, ICF-Assessment Sheet and ICF-Intervention Table will be used and completed in the implementation of interventions and ICF-Evaluation Display in the evaluation step. By using the ICF-based documentation forms, through participation with clients and the therapist's clinical reasoning, it is determined which body structures and functions are impaired, what are the restrictions and limitations in the client's participation and activities, and finally, which environmental factors are seen as facilitating or restricting in the treatment of clients. Then, according to the clients' prioritization, occupational therapy interventions will be provided for 8 weeks and 2 sessions per week and each session will last 45 minutes.

**Category**

Rehabilitation

### 2

**Description**

Control group: Conventional Occupational Therapy Interventions : The control group received conventional interventions based on the protocol of Dang Tang et al. These interventions include stretching, active and passive range of motion exercises, sensory improvement exercises, muscle strength and endurance exercises, scar and edema management, and splints. Conventional occupational therapy interventions will be provided for 8 weeks and 2 sessions per week and each session will last 45 minutes.

**Category**

Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Shahid Motahari Hospital
**Full name of responsible person**
Laleh Lajevardi
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**2**

**Recruitment center**

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## Sponsors / Funding sources

**1**

**Sponsor**

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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**
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**Full name of responsible person**
Dorsa Hamedi
**Position**
Ph.D Candidate
**Latest degree**
Master
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
No - There is not 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**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is 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**
Yes - There is a plan to make this available
**Title and more details about the data/document**
The data related to the primary and secondary outcome of the individuals participating in the research after anonymization, and the publication of the articles from the clinical trial, will be made available to the academic researchers upon their request.
**When the data will become available and for how long**
At least 6 months after the publication of the articles resulting from the clinical trial.
**To whom data/document is available**
Researchers working in research centers and universities.
**Under which criteria data/document could be used**
In order to carry out systematic review and meta-analysis studies, by maintaining the intellectual property right of the data and referring to the study of the data, it is made available to people from scientific and academic institutions.
**From where data/document is obtainable**
To receive data, researchers should contact the authors by e-mail or refer to the following address: Mrs. Dorsa Hamedi, email: d.hamedi.ot@gmail.com Dr. Laleh Lajevardi, email: laleh23275@yahoo.com address: Occupational Therapy Dep., Rehabilitation Sciences School, No. 5, Madadkaran Ave., Shahnazari Ave., Mother Sq., Mirdamad Blvd., Tehran.
**What processes are involved for a request to access data/document**
The researcher must send his request to the authors in an official form on behalf of the organization working in it. The request should include the purpose of accessing the data, and the resulting consequences.
**Comments**