

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 Hamed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8051

Email address

hamed.d@iums.ac.ir

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 lack 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

Street address

Shahid Rashid Yasemi Ave., Valiasr St., Vanak Sq.

City

Tehran

Province

Tehran

Postal code

1996714353

Phone

+98 21 8877 0031

Email

laleh23275@yahoo.com

2

Recruitment center

Name of recruitment center

Shohadaye Yaft Abad Hospital

Full name of responsible person

Laleh lajevardi

Street address

Southern Alghadir Blv., Alghadid Sq., Moalem Aq.,
Yaft Abad

City

Tehran

Province

Tehran

Postal code

1377714775

Phone

+98 21 6680 7851

Email

laleh23275@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

Street address

Deputy of research and Technology, Iran University of
Medical Sciences, Hemat Highway, next to Milad
Tower

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2503

Email

laleh23275@yahoo.com

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

Dorsa Hamedi

Position

Ph.D Candidate

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

Street address

Rehabilitation Sciences School, No. 5, Madadkaran
Ave., Shahnazari Ave., Mother Sq., Mirdamad Blvd

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 8051

Email

d.hamedi.ot@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Laleh Lajevardi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

Rehabilitation Sciences School, No. 5, Madadkaran Ave., Shahnazari Ave., Mother Sq., Mirdamad Blvd

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 8051

Email

laleh23275@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dorsa Hamedi

Position

Ph.D Candidate

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

Street address

Rehabilitation Sciences School, No. 5, Madadkaran Ave., Shahnazari Ave., Mother Sq., Mirdamad Blvd

City

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Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 8051

Email

d.hamedi.ot@gmail.com

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