

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of self-care educational software on the quality of life of the patients with hand burns

Protocol summary

Study aim

The effect of self-care educational software on the quality of life of the patients with hand burns

Design

A randomized controlled trial with control group, parallel, without blinding, using random sequences generated by SPSS software.

Settings and conduct

This study will be conducted in the burn unit of Imam Reza Hospital in Mashhad. Patients in the intervention group will use self-care software for two and half months. In the routine training group, they will be trained by nursing personnel. The questionnaire (BSHS-B) will be completed in both groups.

Participants/Inclusion and exclusion criteria

Inclusion: patients 18-65 years old with deep second or third degree burn in hands, total burn percent less than 25%, lack of deformity and motor disorders of the hands and fingers, having cell phone with internet connection. Exclusion: Having auditory or visual problems, history of diabetes mellitus, skin allergy, MS disease, malignancy, deformity and motor disorders in the hands and fingers, mental disorders, psychoactive drugs consumption since 6 months ago and positive history of drug abuse.

Intervention groups

Patients in the intervention group will use self-care educational software for two and half months (15 days during hospitalization and 2 months after discharge). Patients of control group will receive routine training program by nursing personnel.

Main outcome variables

Quality of life of burn patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181020041386N1**

Registration date: **2018-11-24, 1397/09/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-24, 1397/09/03**

Update count: **0**

Registration date

2018-11-24, 1397/09/03

Registrant information

Name

nayereh kargar kakhki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3217 8589

Email address

kargarn951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care educational software on the quality of life of the patients with hand burns

Public title

The effect of self-care educational software on the quality of life of the patients with hand burns

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Be alert Patients with hand burns (deep second degree or third degree) Having access to mobile phones (with Android OS) Having the ability to use cell phone and its Apps. Having internet access. Signing the consent form to participate in the study Age between 18 to 65 years Total burn percentage is less than 25% Patients with a thermal burn Patients reside in Mashhad

Exclusion criteria:

Having auditory (deaf, despite the use of auxiliary equipment) and visual problem (inability to read a newspaper at a distance of 30 centimeters with glasses). History of diabetes mellitus , skin allergy, MS disease, malignancy, deformity and motor disorders in the hands and fingers. History of mental disorders, psychoactive drugs consumption since 6 months ago and positive history of drug abuse.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment using random sequence generated by SPSS software is implemented to select patients for intervention and control group.

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 Mashhad University of Medical Sciences

Street address

Daneshgah street, Ghoreyshi building.

City

mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2018-09-18, 1397/06/27

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.048

Health conditions studied

1

Description of health condition studied

Hand burns

ICD-10 code

T20-T25

ICD-10 code description

Burns and corrosions of external body surface, specified by site

Primary outcomes

1

Description

The quality of life of burn patients

Timepoint

Evaluation of the quality of life of burn patients before, 1 month and two and half months after intervention.

Method of measurement

Burn Specific Health Scale-Brief (BSHS-B) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The self-care educational software will be installed and run after introduction process in the acute phase of burn. Contents of this software will be based of the most updated educational guidelines and a team collaboration of clinicians, surgeons and physiotherapists. After discharge, the software can be used with the healthy hand or healthy fingers of patient or patient's family. The use of the software will continue for two months after the discharge. To ensure the correct running of the software, Event Log and making phone calls will be used.

Category

Rehabilitation

2

Description

Control group: Patients of the control group will receive routine patient education about burn care of hands from nursing personnel.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for burns of Imam Reza Hospital

Full name of responsible person

Ali Ahmadabadi

Street address

Imam Reza Hospital Square, Imam Reza Hospital

City

Mashhad

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9137913316

Phone

+98 51 3854 3031

Email

emamreza@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen tafaghodi

Street address

Daneshgah Street, Mashhad University of Medical Sciences, Deputy of Research

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vcresearch@mums.ac.ir

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 Froutan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery. Ebn-e-sina St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Razieh Froutan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nayereh Kargar kakhki

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

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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

"There is no further 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