Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Investigating the Effect of Rehabilitation Teaching by Augmentation Reality Pamphlet Method on the Quality of Life in Patients with Face and Neck Burn

Protocol summary

Study aim
Investigating the Effect of Rehabilitation Teaching by Augmentation Reality Pamphlet Method on the Quality of Life in Patients with Face and Neck Burn

Design
A randomized controlled trial with control group, parallel, without blinding, using random sequences generated by random number table

Settings and conduct
This study was performed in the burn ward of Imam Reza Hospital in Mashhad. Patients in the intervention group will use augmented reality pamphlet for one and a half months. In the control group, they will receive simple pamphlets and routine staff training. Then the questionnaire (BSHS-FN) will be completed in both groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient 18-65 years old has deep or superficial grade 2 burns to face and neck, overall burns up to 5% to 25%, mobile phone with Android OS.
Exclusion criteria: Has hearing or visual impairment, history of diabetes mellitus, skin allergy, MS disease, malignancy, deformity and movement disorders in the face and neck, mental disorders, use of psychotropic drugs from 6 months or drug use.

Intervention groups
Patients in the intervention group will use augmented reality pamphlet for one and a half months (2 days in hospital and one month at home). Patients will receive control, simple pamphlets and routine training by staff.

Main outcome variables
Quality of Life in Patients with Face and Neck Burn

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191017045143N1**
Registration date: **2020-08-21, 1399/05/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-21, 1399/05/31**
Update count: **0**

Registration date
2020-08-21, 1399/05/31

Registrant information

Name
Masoumeh Zal

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3621 7455

Email address
zalm2@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effect of Rehabilitation Teaching by Augmentation Reality Pamphlet Method on the Quality of

Life in Patients with Face and Neck Burn

Public title
Investigating the Effect of Rehabilitation Teaching by Augmentation Reality Pamphlet Method on the Quality of Life in Patients with Face and Neck Burn

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The patient should be alert The patient may have burns to the face and neck The patient has grade 2 or superficial burns The patient had a burn rate of 5 to 25 percent Patient will have access to mobile phone with Android OS The patient is literate to use software guidelines The patient has the ability to use their hands to use mobile phones and software The patient should have a telephone number to call the researcher The patient will be able to go to Imam Reza Hospital for a dressing change or re-visit after one month of discharge The patient has full consent to participate in the study The patient is between 18 and 65 years of age The patient should be resident in Mashhad

Exclusion criteria:
The patient may not be able to visit the hospital for a doctor's appointment or change of dressing Having auditory or visual problems history of diabetes mellitus, skin allergy, MS disease, malignancy, deformity and motor disorders in the face & neck, 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
Randomization method: From simple randomization model, each client is placed in intervention or control group. Randomization Unit: Individual Randomization Tool: Random Number Table

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The pamphlet design is augmented with the fact that the content of the software will be based on the latest educational guides and the collaboration of other medical team specialists in the field of face / neck sports (each area has 12 exercise movements). There will be educational images and pictures

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
2019-12-09, 1398/09/18

Ethics committee reference number
IR.MUMS.NURSE.REC.1398.074

Health conditions studied

1

Description of health condition studied
Face and Neck Burn

ICD-10 code
T20.20XA

ICD-10 code description
Burn of second degree of head, face, and neck, unspecified site

Primary outcomes

1

Description
The quality of life in patients with face and neck burn

Timepoint
Evaluation of the quality of life of patients with face and neck burn before , 1 month and half months after intervention.

Method of measurement
Burn Specific Health Scale. Face & Neck) BSHS-FN questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 48 hours after the acute phase of burn, this pamphlet and its mobile application will be

installed and run on the patient's mobile phone to familiarize the patient with the software during hospitalization. Use of the software will continue for 15 days during hospitalization and one month after discharge.

Category

Rehabilitation

2

Description

Control group: Patients in the control group will receive routine education, by the researcher, 48 hours after the acute phase.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for burns of Imam Reza Hospital

Full name of responsible person

Razieh Froutan

Street address

Imam Reza Hospital Square, Imam Reza Hospital

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9137913316

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froutanr@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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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

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

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Email

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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

Nursery

Street address

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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Masoumeh Zal
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