Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 2026

Evaluation of the effectiveness of a smartphone-based educational program on the clinical outcomes of children with severe burns and their caregivers

Protocol summary

Study aim
a
Design
A clinical trial study with an intervention and control group, with parallel, randomized groups on 90 patients. For randomization, the block randomization method with placement will be used.
Settings and conduct
The study population will be all caregivers of children with severe burns referred to Velayat hospital in Rasht. The intervention starts from the time of the patient's discharge. The study will be double-blind in which the caregivers and the analyst will be blind.
Participants/Inclusion and exclusion criteria
Caregivers of children with severe burns have a smartphone, at least primary education, and a burn diagnosis of more than 20% were included in the study, and patients with other chronic diseases and injuries other than burns were excluded.
Intervention groups
The control group includes patients who receive their usual treatment, and the intervention group uses a smartphone-based application in addition to the usual treatment.
Main outcome variables
scar recovery rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220404054409N1**
Registration date: **2022-04-17, 1401/01/28**
Registration timing: **prospective**

Last update: **2022-04-17, 1401/01/28**
Update count: **0**
Registration date
2022-04-17, 1401/01/28

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-05, 1401/02/15
Expected recruitment end date
2023-03-21, 1402/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of a smartphone-based educational program on the clinical outcomes of children with severe burns and their caregivers

Public title
Evaluation of the effectiveness of a smartphone-based educational program on the clinical outcomes of children with severe burns and their caregivers
Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Caregivers of children with burns who have an Android-based smartphone and at least a basic education. TBSA >20% No mental illness or mental retardation Start of intervention from the time of discharge to 2 months after discharge.

Exclusion criteria:

Children with diabetes, anemia, vascular disorders, hypotension, heart failure, various types of immunodeficiency, and malignancy. Caregivers of children who do not have the knowledge to use a smartphone properly.

Age

From **1 day** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization will be used. First, all blocks of size 4 consisted of two codes A and two codes B, are prepared (6 blocks). Then, using a table of random numbers, random blocks are selected by replacement. These blocks form a sequence of 90 codes A and B, each of which is randomly assigned to one of the control or intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

An interventional study is performed with caregivers and analyst blindness to evaluate the impact of the application on the clinical outcomes of children with severe burns and their caregivers. Caregivers are blinded in such a way that an application is installed on the phones of both intervention and control patients. But the program that is installed for caregivers in the control group only contains online questionnaires that patients must complete and submit at specified intervals. Online questionnaires include some questionnaires used to measure the target variables and include VAS and GAD questionnaires that were answered self-reportedly by caregivers in both groups and as posted online. Also, the VSS questionnaire will also be completed to assess the patient's scar status by the treating physician during the patient examination. But the program installed on the phones of caregivers in the intervention group has all the capabilities of intervention. But caregivers do not know the nature of the program installed on the phones of the opposite group. Numerical codes are also used for the analyst and intervention groups, and the letters A and B will be used for the control and intervention groups when we want to send information for analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Kashan University of Medical Sciences

Street address

Qotb-e Ravandi Blvd

City

Kashan

Province

Isfehan

Postal code

8715973474

Approval date

2021-06-26, 1400/04/05

Ethics committee reference number

IR.KAUMS.REC.1400.020

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T20

ICD-10 code description

Burn and corrosion of head, face, and neck

Primary outcomes

1

Description

scar recovery rate

Timepoint

First (discharge time), 7, 14, 21, 28, 35, 42, 49, and 56 days after discharge.

Method of measurement

Vancouver Scar Scale (VSS), Visual Analogue Scale (VAS) for pain and itch.

Secondary outcomes

1

Description
Child caregivers' anxiety
Timepoint
First (discharge time), 7, 14, 21, 28, 35, 42, 49, and 56 days after discharge.
Method of measurement
Generalized anxiety disorder questionnaire (GAD)

Intervention groups

1

Description
Control group: The control group includes patients who receive their usual treatment.
Category
Other

2

Description
Intervention group: Group receiving educational smartphone-based application. The intervention includes an application containing instructional text, audio, and video files. Also, reminder programs for medications and visits are set up for caregivers.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Dr. Mohammad Reza Mobayen
Street address
Namjoo Street, Velayat Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamid Reza Banafsheh
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Rangraz Jedi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Information Management
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Person responsible for scientific inquiries

Contact
Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Mobayen

Position
Director of the Department of Surgery, Head of the Burn and Plastic Surgery Hospital, Head of the Bu

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

Contact

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Latest degree
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Other areas of specialty/work
Health Information Management

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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
Yes - There is a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Participants' data file, statistical analysis and codes used in the analysis will be available in SPSS file format. Clinical study and protocol will be published by open paper.

When the data will become available and for how long
6 months after study publication

To whom data/document is available
Final results and protocol for all people and data file and statistical file on scientific centers request

Under which criteria data/document could be used
Only scientific centers can send a request for access to data for academic analysis

From where data/document is obtainable
Kashan University of Medical Sciences, Paramedical School, Department of Health Information Management and Technology, Parissa Bagheri

What processes are involved for a request to access data/document
Request must be sent to school by post or sent to follow email: Bagheri-p@nums.ac.ir

Comments