Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Oct 2026

Comparison of Effectiveness of Mobile-based Self-management Application with Usual Care on Rehabilitation of Patients with Stroke

Protocol summary

Study aim

Evaluation of stroke self-management application effect on the patients

Design

The clinical trial will have an intervention and a control group, with parallel groups, randomized; single blind (patient or caregiver and analyst) performing among 60 patients. For randomization, the permuted block randomization method with replacement will be used.

Settings and conduct

The study population was all patients with stroke referred to Shahid Beheshti Hospital in Kashan in whom at least 72 hours has passed since the stroke. The study will be single blind in which the participants, their caregivers as well as the analyst will be blind.

Participants/Inclusion and exclusion criteria

Patients with hemiparesis due to recent stroke are included in the study, and patients in the acute phase of the disease (first 72 hours after stroke) are not included in the study.

Intervention groups

Intervention group: Receiving a self-management application containing educational files and games (determined according to experts panel in the Delphi study phase) and performing the exercises in that for one hour in a day and 5 days in a week for two months totally (a total of 40 Session). Control group: Patients receiving usual medical care and receiving application without self-management education capabilities. These patients receive only usual care based on the attending physician's opinion.

Main outcome variables

Stroke severity score; Ability to perform daily activities score; Quality of life score; Depression score; Medication adherence rate score; Treatment satisfaction score; Frequency of stroke complications

General information

Reason for update

Changing the recruitment start date is expected for two reasons. Firstly, due to the delay in the design of the application, which is an intervention tool, and secondly, due to the temporary closure of the neurology department of the hospital due to the COVID-19 pandemic.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201015049037N1**
Registration date: **2020-11-07, 1399/08/17**
Registration timing: **prospective**

Last update: **2021-11-02, 1400/08/11**
Update count: **1**

Registration date

2020-11-07, 1399/08/17

Registrant information

Name
Hamidreza Tadayon
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 4452 6568
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tadayonh1@nums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Effectiveness of Mobile-based Self-management Application with Usual Care on Rehabilitation of Patients with Stroke

Public title
Effect of mobile-based self-management application on stroke outcomes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Hemiplegia or hemiparesis due to current stroke having android-based mobile by patient or him/her caregiver acute phase of stroke has been passed appropriate consciousness and hearing willingness to participation
Exclusion criteria:
Disorders of consciousness level Cognitive disorders for example dementia or memory disturbance Patients with global aphasia
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **60**
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 (15 blocks). These blocks form a sequence of 60 codes A and B, each of which is randomly assigned to one of the control or intervention groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
An interventional study is performed with patient and analyst blindness to evaluate the impact of the application on patients' self-care. Patients are blinded in such a way that an application is installed on the phone of both intervention and control patients. But the program that is installed for patients 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 BDI-II, EQ-5D-3L, MMAS-8 and PSQ questionnaires that were answered self-reportedly by patients in both groups and as posted online. But the program installed on the phones of patients in the intervention group has all the capabilities of intervention. But patients do not know the nature of the program installed on the phone 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
Kashan University of Medical Sciences
Street address
Qotb-e Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973474
Approval date
2020-10-10, 1399/07/19
Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1399.055

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
I63
ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
Stroke severity score in NIHSS
Timepoint
First, after 2 months, after 3 months
Method of measurement
NIHSS Completion by Neurologist

2

Description
Barthel daily activity score
Timepoint
First, after 2 months, after 3 months
Method of measurement
BI (Barthel Index) questionnaire completion by Neurologist

3

Description
Quality of life score in EQ-5D
Timepoint
First, after 2 months, after 3 months
Method of measurement
EQ-5D questionnaire completion by patients

4

Description
Beck-II depression score
Timepoint
First, after 2 months, after 3 months
Method of measurement
Beck II Depression questionnaire completion by patients

5

Description
PSQ treatment satisfaction score
Timepoint
First, after 2 months, after 3 months
Method of measurement
PSQ questionnaire completion by patients

6

Description
Morisky medication adherence score (MMAS-8)
Timepoint
First, after 2 months, after 3 months
Method of measurement
MMAS-8 questionnaire completion by patients

7

Description
Frequency of stroke complications
Timepoint
First, after 2 months, after 3 months
Method of measurement
Stroke complication checklist completion by Neurologist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: group receiving self-management application. The intervention includes an application containing instructional text, audio, and video files, and possibly games to improve upper and lower limbs function. Reminder programs for medications and reminders for visits will also be set up for patients. The functional requirements of the program are specified in detail in the design phase of the program. The number of sessions offered to patients will be 5 days in a week and every day for one hour and a total of 2 months (40 sessions in total).
Category
Rehabilitation

2

Description
Control group: Receiving medical usual care based on the opinion of the attending neurologist and receiving an application without educational files and only containing electronic questionnaires for blinding.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Mehrdad Farzandipour
Street address
Pezeshk Blvd
City
Kashan
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Isfehan
Postal code
8115187159
Phone
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Email
farzandipour_m@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafsheh
Street address
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8715988141

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Email
banafsheh_h@kaums.ac.ir

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
Mehrdad Farzandipour

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
Kashan University of Medical Sciences

Full name of responsible person
Seyed Ali Masoud

Position
Professor

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Specialist

Other areas of specialty/work
Neurology

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Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Hamidreza Tadayon

Position
Ph.D. Candidate

Latest degree
Master

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 request for access to data for academic analysis

From where data/document is obtainable

Kashan university of medical sciences, paramedical school, Hamidreza Tadayon or Hossein Akbari

What processes are involved for a request to access data/document

Request must be sent to school by post or sent to follow email: tadayonh1@nums.ac.ir

Comments