

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of care program based on smartphone application on the burden and quality of life in family caregivers of patients with major depression

Protocol summary

Study aim

Determining the effect of care program based on smartphone application on care burden and quality of life of family caregivers of patients with major depression

Design

An experimental study with a control group, with parallel groups, without blinding, randomized by simple blocking method, on about 60 caregivers. SPSS software was used for randomization.

Settings and conduct

To collect data, the researcher will refer to Ibn Sina Hospital in Mashhad, the patient's training nursing clinic, and after identifying the research units, will place them in two simple groups by simple blocking method: control and smartphone using the software.

Participants/Inclusion and exclusion criteria

Family caregivers of patients diagnosed with major depression

Intervention groups

it is an educational application intervention. The application was launched under Android Studio for use in Android version 5 smartphones. The application includes various features such as multimedia care content (audio, video, and photo), notebook, reminders to provide care, the possibility of two-way communication (with the researcher). Each of the content chapters is segmented with the associated icon. In addition to the written content of each section, the content is supported by audio and read-aloud. The reminder section has the ability to add medications by the caregiver to alert the caregiver at the time of receiving the medication. In a section called Communication Support, the caregiver can communicate with the researcher and ask him or her any possible questions. Content chapters of the application include nutrition and diet, medication, sleep and rest, activity and exercise, recognizing the disease and its symptoms, behavioral strategies to improve relationships

with the patient, shock therapy and care, treatment follow-up.

Main outcome variables

burden quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210202050222N1**

Registration date: **2022-02-05, 1400/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-05, 1400/11/16**

Update count: **0**

Registration date

2022-02-05, 1400/11/16

Registrant information

Name

somaye minaei moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3846 9453

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sminaei.moghadam95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-19, 1400/10/29

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of care program based on smartphone application on the burden and quality of life in family caregivers of patients with major depression

Public title
The effect of care program based on smartphone application for caregivers of patients with major depression

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 60 With a diagnosis of at least 6 months of major depression Lack of physical disability leading to activity limitation
Exclusion criteria:
Existence of illness associated with depression such as anxiety disorder Existence of mania episode

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random sequence was prepared before the study by the simple block method. There are 7 blocks with 10 samples. The sequence of each block is determined based on SPSS software. Each block is in a sealed envelope and the researcher does not know its sequence.

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

School of Nursing and Midwifery, Ibn Sina St.University St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2021-02-09, 1399/11/21

Ethics committee reference number

R.MUMS.NURSE.REC.1399.097

Health conditions studied

1

Description of health condition studied

major Depressive disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

burden

Timepoint

At the beginning of the study (before the intervention) and immediately after the intervention

Method of measurement

caregivers burden inventory-CBI

2

Description

QUALITY OF LIFE

Timepoint

At the beginning of the study (before the intervention) and immediately after the intervention

Method of measurement

WHOQOL-BREF questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group includes family caregivers of depressed patients who are discharging their patients. The application will be installed in a 30-minute session for caregivers and then explanations for using the application will be given to

caregivers, and once a week after installing the application, contact the caregivers. The ability and efficiency of the application will be examined and possible questions will be answered. If there are problems such as the inability to use the application and problems with the operating system and its structure, the researcher will try to solve them. Application content includes patient nutrition and diet, medication diet, sleep and rest, activity and exercise, recognizing the disease and its symptoms, behavioral strategies to improve relationships with the patient, shock therapy and care, treatment follow-up, and periodic monitoring. The Fortinash Psychiatric Nursing Care Plans, the American Depression and Anxiety Association, and the British Columbia-Canada Mood Disorders Association book were used to collect the necessary points and were narrated by three Nursing School professors and a psychiatrist and psychiatrist. After the narration, it has become a mobile application. This application is an educational type that includes text, photos, and videos about the mentioned care topics. In addition, the possibility of communicating with the nurse in the form of chat has been included in the application in order to answer their questions privately.

Category
N/A

2

Description

Control group: The control group is under routine training that has been provided by health workers (nurses, doctors, etc.) at the time of discharge. At Ibn Sina Hospital in Mashhad, due to the limitations of following a corona pandemic, family education about patient care is provided only at the time of discharge. During discharge, a nurse instructs the patient in a 10 to 15 minute session on the patient's subsequent monitoring and how to take medications according to the physician's instructions using a face-to-face method and the use of pamphlets.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ebne-Sina hospital
Full name of responsible person
Saeed Vaghee
Street address
Ebne-Sina Hospital, Horre ameli avenue, Boo Ali square, Mashhad
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Razavi Khorasan
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Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
DR.majid Ghayour mobarhan
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Ghorashi Building-Deputy of Research and Technology, Daneshgah St - next to Hoveyzeh Cinema, Mashhad, Iran
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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
Somaye Minaeimoghadam
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the caregivers' demographic information can be shared after identifying individuals. All of the quality of life and burden assessment information can be shared with caregivers after unidentified individuals.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Project partners

Under which criteria data/document could be used

People who do similar research

From where data/document is obtainable

It will be done by email with the person in charge of the project.

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

Data is made available to individuals via email.

Comments