Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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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

Nursery

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Person responsible for scientific inquiries

Contact
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Latest degree
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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