

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of using disease management Smartphone based application on perceived stress and self-efficacy of caregivers of the elderly with Parkinson's disease

Protocol summary

Study aim

Determining the effect of using disease management Smartphone based application on perceived stress and self-efficacy of caregivers of the elderly with Parkinson's disease

Design

This study will be a two-group randomized clinical trial on 60 elderly caregivers with Parkinson's disease in two groups of 30 intervention and control based on "available" sampling and randomly assigned participants to two groups using random sampling method. Block construction will be done. To prevent the publication of content between the two groups, a special code is considered for each person using the application. The intervention phase will last for one month and the results will be analyzed and reported with SPSS software.

Settings and conduct

This study will be performed on elderly caregivers with Parkinson's disease who refer to the Neurology Clinic of Ghaem Hospital, Imam Reza Neurology Clinic and the office of respected specialists of the project. Blinding and hiding the group of people will be done using envelopes and special numbers.

Participants/Inclusion and exclusion criteria

Elderly caregiver: 1. Spend the most time caring for the elderly with Parkinson's. 2. Having a smart phone 3. Age 18 to 60 years 4. Literacy 5. No history of mental disorders 6. Do not use anti-anxiety and sedative drugs
Exclusion criteria: 1. Occurrence of acute debilitating disease during the study 2. Dissatisfaction with continuing the study

Intervention groups

After training the caregivers of the application, intervention groups will be installed on mobile phones. The control group will use the training items provided in the application in the pamphlet. During the one-month intervention, research units will be contacted at least

once a week regarding application usage and potential problems.

Main outcome variables

Perceived stress levels of caregivers; Self-efficacy caregivers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210530051443N1**

Registration date: **2021-09-15, 1400/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-15, 1400/06/24**

Update count: **0**

Registration date

2021-09-15, 1400/06/24

Registrant information

Name

hossein sanaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4346 3273

Email address

sanaeih18@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-05, 1400/04/14

Expected recruitment end date

2021-10-06, 1400/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using disease management Smartphone based application on perceived stress and self-efficacy of caregivers of the elderly with Parkinson's disease

Public title

The effect of using disease management application on elderly caregivers with Parkinson's disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Elderly caregiver: Spend the most time caring for the elderly with Parkinson's Elderly caregiver: Having a smart phone Elderly caregiver: 18 to 60 years old Elderly caregiver: No history of mental disorders Elderly caregiver: literacy Elderly caregiver: Do not use anti-anxiety and sedative drugs Elderly: Age over 70 years Elderly: The definitive diagnosis of Parkinson's has been confirmed by a neurologist Elderly: Existence of moderate to high cognitive status according to MSE questionnaire Elderly: No history of stroke Elderly: No underlying mental illness

Exclusion criteria:

Caregiver exclusion criteria: Acute debilitating disease during the study Caregiver exclusion criteria: dissatisfaction with the continuation of the study Elderly Exclusion Criteria: hospitalization Elderly Exclusion Criteria: Change of the elderly caregiver Elderly Exclusion criteria: Acute problems such as heart attacks and strokes, debilitating infections, heavy bleeding, any other disease that reduces the patient's level of consciousness Elderly Exclusion Criteria: Transfer to a nursing home

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Sampling will be done randomly in the "available" type and the participants will be assigned to two groups randomly using the block randomization method. Blocking is usually done to balance the number of specific samples. One of the studied groups is used in this study, blocks are randomly selected using SPSS

software.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding is one-way blind method in which patients are first randomly assigned to two groups, and the researcher when assigning individuals to two groups will do randomly. In the data analysis stage, the groups will enter the software as A and B and the analyzer will be unaware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of the School of Nursing and Midwifery - Mashhad University of Medical Sciences

Street address

Bojmehran village, Shafa alley, Mohammad Hassan Sanaei house

City

neyshbour

Province

Razavi Khorasan

Postal code

93441-73427

Approval date

2021-03-01, 1399/12/11

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.003

Health conditions studied**1****Description of health condition studied**

Parkinson's disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes**1****Description**

Perceived stress is the body's response to a change that requires adaptation or a physical, mental, or emotional response; stress can be triggered by any stressful factor or stimulus. The caregiver's score is based on Cohen's

Perceived Stress Inventory (PSS), which has 14 questions and is used to measure perceived stress in the past month. A high score indicates high stress and a low score indicates low stress.

Timepoint

This variable will be measured first and then one month after the start of the study.

Method of measurement

Perceived Stress Scale

2

Description

Self-efficacy is a degree of a person's sense of mastery over the ability to perform the desired actions. Practical definition: The score obtained by the self-efficacy questionnaire with 35 questions and the higher the score, the higher the self-efficacy indicator is considered. This questionnaire has five dimensions. These include caregiver self-efficacy in gathering information about treatment, symptoms and health care, gaining support, responding to problem behaviors, managing home, personal and medical care, and controlling distressing thoughts about care.

Timepoint

This variable will be measured first and then one month after the start of the study.

Method of measurement

Revised Caregiving Self-Efficacy Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the application is prepared. Application capabilities include teaching various items such as name, mode of action, how to better use drugs, drug interactions, doses, side effects, management and non-drug therapies, proper exercise, disease risk symptoms, proper nutrition and food, medication reminders Reminders to see a doctor, the ability to communicate with the treatment team, etc. are important cases for the next visit to the doctor. Then a meeting will be held with research units to teach how to use the application, which will be held in accordance with the opinions of caregivers in the faculty or clinic. After learning how to use, the application will be installed on their mobile phones. The researcher gives his / her phone to the research units so that if he / she has any questions, he / she can answer them. Also, during the research, the research units will be contacted at least once a week regarding the use of the application and possible problems. In order to prevent the publication of content between the two groups, a special code has been considered for each person using the application, so that the caretaker will not be able to install this application on other devices without prior notice.

Category

Behavior

2

Description

Control group: The trainings are routinely provided based on the contents of the application. The researcher gives his / her phone to the research units so that he / she can answer any questions. Also, during the research, at least once a week, the research units will be contacted regarding the use of educational items and possible problems.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Najmeh Valizadeh Zare

Street address

Imam Reza Research and Treatment Center, Imam Reza (AS) Hospital Square, Ibn Sina St., Mashhad

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Razavi Khorasan

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IRH.CRU@mums.ac.ir

2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Najmeh Valizadeh Zare

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Ghaem Hospital, Ahmadabad St., Mashhad

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Province

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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

Najmeh Valizadeh Zare

Street address

Danesh va Salamat Town , between Shahid Javan and
Al-Shahidi Squares, Shahid Fakoori Boulevard,
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presidentoffice@mums.ac.ir

Web page address**Grant name**

The Vice Chancellor for Research Department at
Mashhad University of Medical Sciences

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

Hossein Sanaei

Position

Msc student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Danesh va Salamat Town, between Shahid Javan and
Shahid Square, Shahid Fakuri Boulevard, Mashhad

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Najmeh Valizadeh Zare

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Hossein Sanaei

Position

MSC student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Phone

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Email

sanaeih18@yahoo.com

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

Undecided - It is not yet known if there will be 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

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

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

Caregiver questionnaires can be shared after deleting the names at the end of the study.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Only people who work in universities and should be doing research related work.

Under which criteria data/document could be used

Analyzes have no limits. Researchers must make a written commitment that the information will not be published anywhere and that the results of the analysis will be published with the permission of the principal investigator. The researcher must also provide evidence of his or her involvement in ongoing research.

From where data/document is obtainable

In order to receive information, the request must be sent in writing to the email address ValizadehN@mums.ac.ir.

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

After receiving the request in the mentioned e-mail, MIT.and information will be provided to her after one month.

Comments