

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effect of smartphone software based Self Management Education on the quality of life in Parkinson's disease patients

Protocol summary

Study aim

main purpose: Evaluating the effect of smartphone software-based self-management training on the quality of life of people with Parkinson's Sub-objectives: 1- Evaluation of quality of life and its dimensions in patients with Parkinson before, one month, three months after intervention 2- Comparison of quality of life and its dimensions in patients with Parkinson before, one and three months after the intervention Practical goals: If the positive effect is confirmed, the smartphone software will be provided to the clients and their families.

Design

Clinical trial without control group, phase two, conducting on 77 patients.

Settings and conduct

quasi experimental study in neurologic clinics of Selected medical education Centers of Iran University of Medical sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: -People with PD with recorded medical records, able to read and write, and use smartphone software. If the patient was not able, qualified carer will be used. - are in the mild and moderate stages of the disease Exclusion criteria: - Death of the client, Hospitalization due to other diseases during the intervention - Progression of the disease according to the clinical criteria of Hohann Yaher to stage 5 (stage of absolute disability) - Reluctance of the client / caregiver to continue participating in the study

Intervention groups

Smartphone software containing self-management information was at once provided to the intervention group and follow up for 12 weeks.

Main outcome variables

Quality of life and its aspects in Parkinson's disease.

General information

Reason for update

Acronym

PDQ (parkinson disease quality of life)

IRCT registration information

IRCT registration number: **IRCT20220417054561N1**

Registration date: **2022-08-07, 1401/05/16**

Registration timing: **retrospective**

Last update: **2022-08-07, 1401/05/16**

Update count: **0**

Registration date

2022-08-07, 1401/05/16

Registrant information

Name

kosar zeighami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5592 2771

Email address

kzeighami76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

2021-07-23, 1400/05/01

Actual recruitment end date

2021-10-23, 1400/08/01

Trial completion date

2022-01-21, 1400/11/01

Scientific title

Evaluation of the effect of smartphone software based Self Management Education on the quality of life in

Parkinson's disease patients

Public title

Evaluation of the effect of smartphone software based Self Management Education on the quality of life of Parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with Parkinson's disease whose disease has been confirmed by a neurologist and recorded in their medical records. Being in the mild and moderate stage of the disease (stages 1, 2, 3 and 4). Have the ability to read and write, and use smartphone software.

Exclusion criteria:

Existence of active diseases such as cancer

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **77**

Actual sample size reached: **77**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

It is a quasi-experimental one-group study (intervention group with 77 samples) that is designed to evaluate the effect of self-management education through software.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran university of medical sciences, Ethics Committee in Biomedical Research

Street address

No.14, Building no.4, group 114, Moradi street, dolat abad, shahre-rey.

City

Tehran

Province

Tehran

Postal code

18598-35841

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.IUMS.REC.1400.132

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

quality of life in parkinson`s disease

Timepoint

assessing quality of life before, 1 and three months after onset of intervention

Method of measurement

Parkinson`s Disease Quality of life Questioner (PDQ-36)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The self-management content provided by the smartphone software was provided from up-to-date, evidence-based medical, nursing, and rehabilitation sources. The accuracy, precision, and validity of this information was confirmed by three faculty members of the School of Nursing and Midwifery of Iran University of Medical Sciences. To conduct this quasi-experimental study, there was a need for an application that could be installed on a smartphone running the Android operating system, which could be used online and offline. The main features of this software are: educational content related to 1- Familiarity with the nature of the disease and motor and non-motor symptoms (general view of the disease) 2- Treatment methods, follow-up recommendations and adherence to medical and pharmaceutical treatment, Monitoring symptoms, 3- Self-management measures in physical symptoms (imbalance, gait disturbance and freezing, brady Keynesian, stiffness and tremor, muscle cramps, dyskinesia, tremor, masked face), 4- Self-management measures in symptoms Non-physical (cardiovascular problems, sleep and fatigue, mood and cognition, memory and concentration, gastrointestinal

symptoms, nutrition management, urinary symptoms, self-efficacy, social support), 5- Talk to families (to prepare and improve home conditions , And supporting the family in using the software and accompanying the patient's family in self-management) 6- Frequently asked questions, 7- Contacting the caring nurse (researcher); This software, called "Parkin Seven", was divided into 7 parts and presented 7 recommendations in each part, was provided to the research units. All information in the software is based on scientific evidence and extracted from sites and scientific journals and authoritative books related to the subject and was provided to the clients at once by the smartphone software. Due to dyskinesia and other complications (such as tremors and visual disturbances) related to the disease and restrictions on the use of smartphones, images and text could magnify. This software is designed to inform patients and their families by providing information about the disease, symptoms, symptom management, treatment, and self-care training in the form of text and photos.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Clinic of Hazrat-e- Rasool Hospital

Full name of responsible person

Alice Khachian

Street address

faculty of nursing and midwifery of iran university of medical sciences, Yasemi street, Vali-e-asr Street

City

Tehran

Province

Tehran

Postal code

۱۹۹۶۷۱۳۸۸۳

Phone

+98 21 4365 1000

Fax

Email

alicekhachian@hotmail.com

2

Recruitment center

Name of recruitment center

Neurology Clinic of Firoozgar Hospital

Full name of responsible person

Alice Khachian

Street address

faculty of nursing and midwifery of iran university of medical sciences, Yasemi street, Vali-e-asr Street

City

Tehran

Province

Tehran

Postal code

۱۹۹۶۷۱۳۸۸۳

Phone

+98 21 4365 1000

Fax

Email

alicekhachian@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Masoomeh Kheirkhah

Street address

faculty of nursing and midwifery of iran university of medical sciences, Yasemi street, Vali-e-asr Street

City

Tehran

Province

Tehran

Postal code

۱۹۹۶۷۱۳۸۸۳

Phone

+98 21 4365 1000

Email

fnm@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

1

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

Iran University of Medical Sciences

Full name of responsible person

Kosar Zeigham

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No 6, Parhoon4 building, Bakhtiary alley,
Shirmohammadi st., Pilghoosh st., Bayat st., Shahre-
Rey

City

Tehran

Province

Tehran

Postal code

18598-35841

Phone

+98 21 5592 2771

Email

kzeighami76@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Alice Khachian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

faculty of nursing and midwifery of iran university of
medical sciences, Yasemi street, Vali-e-asr Street

City

Tehran

Province

Tehran

Postal code

۱۹۹۶۷۱۳۸۸۳

Phone

+98 21 4365 1000

Email

alicekhachian@hotmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Kosar Zeighami

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No 6, Parhoon4 building, Bakhtiary alley,
Shirmohammadi st., Pilghoosh st., Bayat st., Shahre-
Rey

City

Tehran

Province

Tehran

Postal code

18598-35841

Phone

+98 21 5592 2771

Email

kzeighami76@gmail.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

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

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

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

The statistical data are based on the Parkinson's Quality
of Life Questionnaire, which has eight dimensions. By
sharing statistical methods, the score of each dimension
of the questionnaire and the overall quality of life score
are also shared. Other characteristics, such as
demographic information, will be unrecognizable.

When the data will become available and for how long

The access period will start after the results are
published.

To whom data/document is available

Any findings from these results will be available to
everyone.

Under which criteria data/document could be used

Academic researchers will be allowed to access and
perform any analysis and use to improve the quality of
care, rehabilitation, and quality of life for patients.

From where data/document is obtainable

Interested researchers can receive them by sending an
e-mail to kzeighami76@gmail.com, stating the purposes
of accessing the documents. With the permission of the
responsible author, Dr. Khachian, the file will be sent to
them. In addition, in the publication of their research,
that have been done with the help and use of the
documents of this research, accurate reference should
be made.

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

Interested researchers can receive them by sending an
e-mail to kzeighami76@gmail.com, stating the purposes
of accessing the documents.

Comments