Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Examination of the effect of using smartphone application on drug self-efficacy and drug adherence in elderly polypharmacy

Protocol summary

Study aim
Evaluating the effect of using smartphone application on drug self-efficacy and drug adherence in elderly polypharmacy

Design
Clinical trial with the control group, with parallel groups, without blinding, randomized on 60 elderly subjects, randomized with random blocks of randomization site

Settings and conduct
This two-group clinical-randomized trial study will be performed on the elderly who refer to the Danesh Amuz Health Center and Sadaf Health Center and have the inclusion criteria. Sixty elderly people will be randomly divided into control and intervention groups. In the first session, the researcher will introduce the plan for both groups in a different session, and after the session, individuals will fill in the questionnaires of demographic information, drug self-efficacy, drug adherence, and the list of drugs used. In the second session, which is dedicated to the intervention group, the application will be installed on mobile phones. During this period, the researcher will respond to the problems of the intervention group, and this process will continue for eight weeks. The control group will receive the same routine medication training by the health center personnel. Both groups' self-efficacy and drug adherence questionnaires will be measured at the beginning of the study and at the end of the intervention.

Participants/Inclusion and exclusion criteria
Admission: polypharmacy and the ability to use smartphones. Exclusion: elderly people who get a high drug self-efficacy score and a high drug adherence score at the beginning

Intervention groups
The intervention group will receive the drug application and the control group will receive the routine drug training of the treatment centers.

Main outcome variables
Increasing the rate of drug self-efficacy and adherence to the drug in the elderly of polypharmacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210704051777N1**
Registration date: **2021-09-15, 1400/06/24**
Registration timing: **retrospective**

Last update: **2021-09-15, 1400/06/24**
Update count: **0**

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

Registrant information

Name
Shokoufeh Shafiee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2676 5506

Email address
shafiees971@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-01, 1400/04/10

Expected recruitment end date
2021-09-01, 1400/06/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Examination of the effect of using smartphone application on drug self-efficacy and drug adherence in elderly polypharmacy

Public title
Evaluation of the effect of drug application in polypharmacy elderly

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Elderly people who take more than three drugs a day. Elderly who have the ability to use smartphones

Exclusion criteria:
Elderly people who get a drug self-efficacy score of ۲۹ or higher at the beginning of the study. Elderly people who get a high drug adherence score of zero at the beginning of the study. Elderly who have cognitive impairment

Age
From **60 years** old to **100 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
Using the permutation block method, they were divided into control and intervention groups. The permutation block method is one of the random allocation methods in which each block is selected according to the number of groups studied. In this study, there are two blocks, AB and BA. One of the blocks was randomly selected. If the first block, AB, was selected, the first person was assigned to group A and the second person to group B. And this process continued until all the samples were assigned. The characteristic of this method was that the two study groups had equal numbers. All steps were performed using Random Allocation software.

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
Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2021-02-02, 1399/11/14

Ethics committee reference number
IR.MUMS.NURSE.REC.1400.019

Health conditions studied

1

Description of health condition studied
Poly pharmacy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Increase in morriski drug adherence score

Timepoint
8 weeks after installing the drug application

Method of measurement
Drug Adherence Questionnaire Moriski

Secondary outcomes

1

Description
Drug self-efficacy

Timepoint
8 weeks after installing the drug application

Method of measurement
Seams Drug Self-Efficacy Questionnaire

Intervention groups

1

Description
Intervention group:they receive a drug application ;the content of this application has been prepared and edited by a geriatric master's degree student and under the supervision of professors of Mashhad University of Medical Sciences. The elderly can use this application to access all their common drugs and increase their information about drugs. All drug descriptions in this

application are simple and fluent and can be understood by all ages .This application has visual and textual content about how the drugs function in the elderly body, ways to take medicine, pharmaceutical forms and safe dosage of the drug in the elderly.This application has educational videos about insulin injection, how to use inhalation spray and eye drops, ear and nose.The researcher gives complete training to the elderly to use the application.Then installs the application on the elderly phone and encourages the elderly to use the application with continuous follow-up. This process will continue for 8 weeks.During this period, the elderly can raise their possible problems or any medical questions through the communication link in the application with the researcher, to which the researcher will respond and take appropriate action.At the end of the study, the questionnaire of drug self-efficacy and medication adherence will be filled out again by the elderly.

Category

Treatment - Drugs

2

Description

Control group:They will receive routine medication training by health center staff

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Danesh Amuz Health Center

Full name of responsible person

Simin Gazani

Street address

Danesh Amuz Square

City

Mashhad

Province

Razavi Khorasan

Postal code

1981634547

Phone

+98 51 3893 2322

Email

Drgazani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hasan Jahed Tehrani

Street address

Daneshgah street

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9138813944

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Email

Jahedh@mums.ac.ir

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

Najme Valizade

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be 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
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
Part of the information about the main outcome

When the data will become available and for how long
6 months after the results are published

To whom data/document is available
Nurses

Under which criteria data/document could be used
In research on the elderly

From where data/document is obtainable
Shokoufehshafiee, shafiees971@mums.ir

What processes are involved for a request to access data/document
Review in terms of type of research

Comments