

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

An investigation of the drug management application effect on drug adherence and consequences in older adults

Protocol summary

Study aim

This study aims to determine the effect of drug management application on drug adherence and consequences in older adults

Design

A randomized controlled trial of 192 people will be used at randomization at <https://www.Randomization.com>

Settings and conduct

This study will be performed on the elderly with inclusion criteria referred to Ziaian Hospital. The drug management application will be installed on their phone with the aim of improving the process of drug use. The Morisky questionnaire will be used to evaluate the effectiveness of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age between 60-74 years old 2. Conscious consent to enter the study 3. Taking more than five types of medication during day 3. Writing and reading literacy 4. Having a smart mobile phone and the ability to use it 5. The ability to communicate and not having dementia 6. Having any diseases of hypertension, diabetes, chronic obstructive pulmonary disease (COPD) 7. Use only Tab in the medication regime. Exclusion criteria: 1. Reluctance to continue attending the study 2. Hospitalization or death of the elderly 3. Use of rare, expensive, and special drugs 4. Use of injectable drugs (such as insulin in diabetes)

Intervention groups

The drug application is installed on the intervention group's mobile phone, and reminders about when to take the drugs will be set. In the meantime, the control group receives the usual care of the center and no intervention is made for them. But at the end of the study, in order to observe the research ethics and if the application is effective on the drug adherence of the intervention group, this program will be installed on their smartphone and the method of using it will be taught.

Main outcome variables

Drug adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191231045966N1**

Registration date: **2021-07-18, 1400/04/27**

Registration timing: **prospective**

Last update: **2021-07-18, 1400/04/27**

Update count: **0**

Registration date

2021-07-18, 1400/04/27

Registrant information

Name

Hossein Poorcheraghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 1111 1111

Email address

hossein75.poorcheraghi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An investigation of the drug management application effect on drug adherence and consequences in older adults

Public title

Effect of mobile application on drug use in older adults

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 60-74 years old
Conscious consent to enter the study
Taking more than five types of medication during the day
Reading and writing literacy
Having a smart phone and the ability to use it
Ability to communicate and not having dementia
Having any of the following diseases: hypertension, diabetes, chronic obstructive pulmonary disease (COPD)
Use only the drug form of the tablet (Tab) in the drug program

Exclusion criteria:

Reluctance to continue participating in the study
Hospitalization or death of the participants
Use of rare, expensive and special drugs
Use of injectable drugs (such as insulin in diabetes)

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **192**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a randomized clinical trial that will be conducted to determine the effect of drug management application on drug adherence and consequences in older adults. The study population is all community older adults who take five or more drugs in their daily medication regimen and were referred to the elderly clinic in Ziaian Hospital. The method is: after obtaining permission to conduct research from the Ethics Committee of the School of Nursing and Midwifery and Rehabilitation with IR.TUMS.FNM.REC.1400.068 ID, the researcher will choose among the elderly who referred to this center and meet the inclusion criteria, then the samples are randomly assigned to the experimental and control groups by random blocking method. To perform randomization, 192 samples are selected by the available sampling method, and using the random blocking method, they are assigned in two groups of control and intervention. Depending on the sample size, 48 blocks of 4 (or 32 blocks of 6) are required for random block allocation. The intervention group will be displayed with A and the control group with B. The website <https://www.Randomization.com> will be used for random

blocking method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to blinding random allocation from the researcher, a dark envelope sample size is prepared and each of created random groups will be written on a card and put inside the envelope. At the beginning of the registration of individuals, according to the order of arrival of the samples, one of the envelopes is opened in order and the assigned group of that sample is specified.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

Street address

School of Nursing and Midwifery & Rehabilitation, Doctor Mirkhani (Eastern Nosrat), Tohid square, District, Tehran provenance

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2021-07-17, 1400/04/26

Ethics committee reference number

IR.TUMS.FNM.REC.1400.068

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Drug adherence

Timepoint

In the present study, Morisky Adherence Questionnaire (MAQ) will be completed by both control and intervention groups before the start of the study and after 8 weeks from the beginning of the study.

Method of measurement

Morisky Adherence Questionnaire (MAQ)

Secondary outcomes

1

Description

Drug consequences

Timepoint

In the present study, a researcher-made questionnaire on drug consequences before and 8 weeks after the intervention will be completed by the control and intervention groups.

Method of measurement

researcher-made drug consequences questionnaire

Intervention groups

1

Description

Intervention group: The drug application is installed on the intervention group's mobile phone, and reminders about when to take the drugs will be set.

Category

Lifestyle

2

Description

Control group: Control group receives the usual care of the center and no intervention is made for them. But at the end of the study, in order to observe the research ethics and if the application is effective on the drug adherence of the intervention group, this program will be installed on their smartphone and the method of using it will be taught.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ziaeian Hospital

Full name of responsible person

Hamidreza Hekmat

Street address

Ziaeian Hospital, Aboozar square, Qazvin Ave, Tehran

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Province

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1366736511

Phone

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Email

ziaeian@tums.ac.ir

Web page address

<https://ziaeian.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahnaz Geranmay

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School of Nursing Midwifery ,Tehran University of Medical Sciences Nosrat st. Tohid sq. Tehran

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Email

nursing_intl@tums.ac.ir

Web page address

<http://www.fnm.tums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shahzad Pashaeypoor

Position

Associate Professor of Nursing

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

Contact

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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

In this study, all the information obtained after
completing the Morisky Drug Adherence Questionnaire
and the researcher-made Drug Consequences
Questionnaire can be shared after identifying individuals.

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

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

All researchers working in academic and scientific
institutes can use the results of this study without any
preconditions.

From where data/document is obtainable

Shahzad Pashaeypoor Associate Professor of Nursing
Department of Community Health and Geriatric Nursing,
School of Nursing & Midwifery Tehran University of
Medical Sciences 00989124913843
Pashaeypoor.sh@gmail.com Zipcode: 1419733171

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

Without providing any specific documentation, the
information will be available to them as soon as possible
in the form of the specified instructions.

Comments