

# 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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1366736511

#### **Phone**

+98 21 5517 6810

#### **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

##### **Street address**

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

##### **City**

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##### **Phone**

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##### **Fax**

+98 21 6105 4170

##### **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**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Person responsible for updating data**

**Contact**

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Tehran University of Medical Sciences

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pashaeypoor.sh@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**

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**