

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Designing a theory based educational intervention on improving adherence to treatment in patients with hypertension in sarab city : A social networking trial

#### Protocol summary

##### Study aim

Findings of the study can provide an accurate and effective educational model with the aim of increasing drug adherence and ultimately improve the quality of life of patients with hypertension.

##### Design

This randomized controlled trial, with parallel, single-blind groups, was performed on 130 patients with hypertension. All participants complete the health action process approach questionnaire. Then the samples will be randomly divided into experimental and control groups.

##### Settings and conduct

After completing health action process approach questionnaire, the samples that were randomly selected from four sarab comprehensive health centers will be divided into two experimental and control groups. The experimental group will then receive the online training intervention. The control group will receive routine actions. The outcome evaluator did not know how to randomize the disease and examine the data related to the outcome variables, regardless of the groups of individuals.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Morbidity of primary hypertension for at least the last 6 months. Having media literacy and familiarity with and access to social networks. Age range 20 to 65 years. Criteria for non-entry: Participation in educational programs related to drug adherence. Morbidity of psychiatric disorders or addiction. Any need for medication changes in patients for any reason. Another person is responsible for giving the patient medicine.

##### Intervention groups

The experimental group receives online virtual training using social networks in three sessions. Participants in the control group perform routine activities

##### Main outcome variables

drug adherence, blood pressure control, self-efficacy, action planning, coping planning, behavioral intent, perceived risk, expectation of outcome

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200617047816N1**

Registration date: **2020-09-08, 1399/06/18**

Registration timing: **retrospective**

Last update: **2020-09-08, 1399/06/18**

Update count: **0**

##### Registration date

2020-09-08, 1399/06/18

##### Registrant information

##### Name

Vahid Farajzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 4323 7840

##### Email address

farajzadehv35@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-24, 1398/12/05

##### Expected recruitment end date

2020-03-10, 1398/12/20

##### Actual recruitment start date

2020-02-24, 1398/12/05

**Actual recruitment end date**

2020-03-10, 1398/12/20

**Trial completion date**

2020-06-09, 1399/03/20

**Scientific title**

Designing a theory based educational intervention on improving adherence to treatment in patients with hypertension in sarab city : A social networking trial

**Public title**

Designing a theory based educational intervention on improving adherence to treatment in patients with hypertension

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Morbidity of primary hypertension Having media literacy and familiarity with and access to social networks Conscious consent and voluntary participation in research Have hypertension for at least the last 6 months Age range 20 to 65 years

**Exclusion criteria:**

Participation in educational programs related to drug adherence Morbidity of psychiatric disorders or addiction and any disorders that prevents the effective and complete presence of the patient in the sessions and affects the results of the research Any need for medication changes in patients for any reason. Another person is responsible for giving the patient medicine Taking drugs that affect their consciousness.

**Age**

From **20 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **130**

Actual sample size reached: **130**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, stratified random and block method is used. The randomization unit is individual and the randomization tool is a sealed envelope. Randomization layers in this study are comprehensive health centers The present study is single-blind. The outcome assessor is unaware of how the disease is randomly assigned and will review data on outcome variables regardless of groups of individuals. After collecting the data, the groups are named in letters so that the analyzer is not informed about the intervention and control group.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The outcome evaluator did not know how to randomize the disease And examine the data related to the

outcome variables, regardless of the groups of individuals. After collecting the data, the groups are named in alphabetical order so that the analyst from the intervention and control group is not informed.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

This study is done online. Participants are trained through cyberspace.

**Secondary Ids**

empty

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

Ethics committee of Qazvin University of Medical Sciences

**Street address**

Qazvin University of Medical Sciences., Shahid Bahonar Blvd., Qazvin

**City**

Qazvin

**Province**

Qazvin

**Postal code**

34197-59811

**Approval date**

2020-04-20, 1399/02/01

**Ethics committee reference number**

IR.QUMS.REC.1399.047

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

Primary hypertension

**ICD-10 code**

I10

**ICD-10 code description**

Essential (primary) hypertension

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

Drug compliance

**Timepoint**

Before the intervention, one month , two & Six months after the intervention, the questionnaire is completed.

**Method of measurement**

The Medication Adherence Rating Scale

## 2

### **Description**

Health action process model subscale

### **Timepoint**

Before the intervention, one month , two & Six months after the intervention, the questionnaire is completed.

### **Method of measurement**

Health action process approach subscale questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Patients with hypertension receive Online group virtual training adherence to treatment consisting of three training sessions of 30 to 45 minutes, using social networks .In order to evaluate the effectiveness of the educational program, patients will be evaluated through questionnaires in three time periods, before the intervention, two and six months after the intervention.Meetings are based on behavior change techniques and include: health outcomes, importance of outcomes, volunteer empowerment, focus on past success, action planning, problem solving, and coping planning.

#### **Category**

Behavior

### 2

#### **Description**

Control group: Participants in the control group perform routine activities.(Such as: measuring blood pressure, monitoring patients, teaching a healthy lifestyle).At the end of the study, an intensive training session is held for them.

#### **Category**

Behavior

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Sarab University of Medical Sciences

##### **Full name of responsible person**

Vahid Farajzadeh

##### **Street address**

Sarab University of Medical Sciences., Imam Khomeini Blvd., Sarab

##### **City**

Sarab

##### **Province**

East Azarbaijan

##### **Postal code**

5471915931

#### **Phone**

+98 41 4322 4586

#### **Email**

farajzadehv35@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Qazvin University of Medical Sciences

##### **Full name of responsible person**

Dr. Amir Pakpur Haji Agha

##### **Street address**

Qazvin University of Medical Sciences., Shahid Bahonar Blvd., Qazvin

##### **City**

Qazvin

##### **Province**

Qazvin

##### **Postal code**

34197-59811

##### **Phone**

+98 28 3333 6001

##### **Email**

pakpour\_amir@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Qazvin 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**

Qazvin University of Medical Sciences

##### **Full name of responsible person**

Vahid Farajzadeh

##### **Position**

Staff

##### **Latest degree**

Bachelor

##### **Other areas of specialty/work**

Health Promotion

##### **Street address**

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**City**

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**Province**

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**Email**

farajzadehv35@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr, Amir Pakpur Haji Agha

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

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**Person responsible for updating data****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Vahid Farajzadeh

**Position**

Staff

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health Promotion

**Street address**

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**City**

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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**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Master's instructions will be followed.

**When the data will become available and for how long**

According to the plan of Qazvin School of Health

**To whom data/document is available**

University of Medical Sciences

**Under which criteria data/document could be used**

At the discretion of the professor

**From where data/document is obtainable**

Qazvin Medical Sciences

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

According to the protocols of Qazvin University of Medical Sciences

**Comments**

does not have