

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of the effect of using a reminder application and medication reminder box on the adherence of patients with heart failure to the medication regimen: a randomized controlled trial

#### Protocol summary

##### Study aim

Comparison of the effect of using a reminder application and medication reminder box on the adherence of patients with heart failure to the medication regimen

##### Design

Single-blind randomized controlled trial with control group, sample size of 189 people, computer random number table was used for randomization.

##### Settings and conduct

This study was a single-blind randomized controlled trial with the aim of investigating the effect of using web-based SMS reminder application and drug reminder box in comparison with the control group on adherence to the drug regimen in three groups (one control group and two intervention groups) in patients with failure. Cardiologist referred to the Cardiovascular Clinic of Tabriz University of Medical Sciences. To hide the allocation of envelopes opaque sealed the same will be used and numbered the envelopes from 1 to 189 is performed and the type of intervention based on a random sequence assignment written on paper and package the order will be placed and all of these steps by the Non-research will be done.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: heart failure patients with at least 18 years old; ability to read and write. Non-entry conditions: patients with cognitive problems.

##### Intervention groups

Patients in the can control group for storing monthly medications, patients in the first intervention group will receive 4 medicine boxes for storing drugs for one month, and patients in the second intervention group will receive SMS reminders personalized by a reminder application on the web.

##### Main outcome variables

Adherence to medication regimen after intervention in study groups

#### General information

##### Reason for update

Changing the mental status questionnaire from MMSE to AMTS

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160110025937N6**  
Registration date: **2021-01-16, 1399/10/27**  
Registration timing: **prospective**

Last update: **2022-08-13, 1401/05/22**

Update count: **2**

##### Registration date

2021-01-16, 1399/10/27

##### Registrant information

##### Name

Aefeh Allahbakhshian

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3479 6770

##### Email address

allahbakhshiana@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-01, 1400/05/10

##### Expected recruitment end date

2021-09-21, 1400/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of using a reminder application and medication reminder box on the adherence of patients with heart failure to the medication regimen: a randomized controlled trial

**Public title**  
Comparison of the effect of using a reminder application and medication reminder box on the adherence of patients with heart failure to the medication regimen

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Minimum age 18 years Ability to read and write in Persian Early diagnosis of chronic heart failure confirmed by a cardiologist No cognitive problems based on the Cognitive Level Status Questionnaire ATMS (Abbreviated Mental Test Score) Mobile phone availability and ability to use it Class 2 and 3 heart failure based on the New York Cardiac Function Scale for 3 months or more based on the physician  
**Exclusion criteria:**  
Having cognitive impairment Inability to read short messages Lack of access to mobile phones

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **189**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, based on the inclusion criteria of heart failure patients from the Cardiovascular Clinic of Shahid Madani Hospital in Tabriz in 1400 will be selected by available methods and by stating the objectives of the research, their consent and consent will be obtained to participate in the study. Participants in the study randomly using RAS software with blocks of sizes 6 and 9 and 1: 1: 1 allocation ratio in three control groups and the first intervention group (drug reminder box) and the second intervention group (web SMS reminder system) ) will be placed. To hide the allocation, opaque, closed and identical envelopes will be used and the envelopes will be numbered from 1 to 189 and the type of intervention will be written on paper based on a random allocation sequence and placed inside the envelopes, respectively. Production of the allocation sequence and preparation of the envelopes based on it will be done by a person not involved in the research. In order to control age as a

confounding factor, stratification will be done in terms of age. According to the proportion of patients with heart failure aged 18-45 years and 46 years and above, one-fifth of the envelopes will be allocated to the first age group and the rest to the second age group.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is a single-blind controlled trial that includes the control group (no intervention) and the first intervention group (receiving a medicine box) and the second intervention group (receiving a reminder SMS). In this intervention, to prevent possible bias in the study results, all samples will be examined by a cardiologist who is not aware of how the samples are placed in the intervention and control groups, and their cardiac function status is based on the performance status classification scale. The New York Heart (NYHA) will be examined at the beginning of the study. Also, data related to adherence to the drug regimen will be collected by a researcher who is not aware of how the samples are placed in the intervention and control groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

**Street address**

3rd floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht St.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665931

**Approval date**

2020-12-12, 1399/09/22

**Ethics committee reference number**

IR.TBZMED.REC.1399.837

**Health conditions studied**

**1**

**Description of health condition studied**

Heart failure

**ICD-10 code**

**ICD-10 code description**

Heart failure

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

Medication Adherence

**Timepoint**

Before the intervention, at the end of the first, second and third months after the intervention

**Method of measurement**

Medication Adherence Rating Scale Questionnaire and use the medicine box

**Secondary outcomes****1****Description**

Hospitalization

**Timepoint**

After the end of the intervention

**Method of measurement**

Self-report of patients

**Intervention groups****1****Description**

First intervention group: patients of the first intervention group 4 medicine boxes for storing medicines for one month, each of which is the medicine needed for a week in the morning, noon, evening and night meals prepared by the researcher for the group participants. The first intervention is prepared to receive. Then drugs for heart failure in 5 classes of drugs (diuretics, angiotensin receptor blockers, angiotensin converting enzyme inhibitors, beta-blockers and digital) will be placed in medicine boxes for 4 weeks by the researcher. The first intervention group will then be instructed on how to use the medicine box and then will be given feedback on the ability to use the device in practice. Participants will use this device for 3 months. The researcher will also be provided with the researcher's phone number to contact him or her if needed. At the end of 4 weeks, the researcher will contact the participant and ask the participants to count the amount of pills left by the researcher and place the pills for the second month, as well as to complete the medication compliance questionnaire and the checklist of cognitive levels. Record the use of drugs by the researcher to go to the clinic again and the amount of drug compliance will be calculated by dividing the amount of pills received according to the form completed by patients and counting the remaining pills by the researcher to the number of pills prescribed for all groups. The same will be done for the second and third months.

**Category**

Rehabilitation

**2****Description**

Second intervention group: management and SMS sending software was designed for the patients of the second intervention group. This software is specially implemented for managing SMS recipients with the possibility of sending SMS in groups or individually. In setting the content of the SMS for the recipients, using the combination of the details of the recipient of the SMS, including the name and the selected text, makes the recipient familiar with the main content of the SMS. Basic information management is done in the form of contact information management, contact grouping, determining the specific and general text of the SMS in this software. After preparing the text of the text messages and the desired settings, the text messages are sent on the telecommunication platform through a dedicated modem that can use the telecommunication SIM card. The possibility of using panels and web telecommunication services to send text messages is also provided in this software. In this group, during the meeting, arranged on how to use SMS, which can be managed by this web-based software with the ability to manage patients' identity cards and medication regimens, and the possibility of sending the desired information at specified intervals to the SMS system. The Internet will be trained to send personalized SMS reminders that will be sent to patients several times a day at specific times according to the medication regimen, and feedback will be practically taken from the learning. And the drugs prescribed by the doctor, which should be taken by patients in this group within a month, will be poured into a can, and at the end of 30 days, the researcher will contact the participant and ask the participants to count the number of pills. Remaining by the researcher and completing the MARS Medication Adherence Questionnaire and the Cognitive Level Status Questionnaire and the Checklist for Registering Drug Use by the researcher and placing the next month's pills in the box, return to the clinic. You will also be asked questions and notes during a telephone call to the hospital during the past month due to this illness or other causes. The researcher's phone number will be provided to the participants to contact the researcher if they need help. The same will be done for the second and third months. It should be noted that all the outcomes in the mentioned times in hospitalized patients will be examined and the analysis will be done in groups with and without considering them and in case of differences in the significance of both results will be reported. Meanwhile, the length of each text message and the number of words are short and the messages will be understandable and simple for the participants, and the text messages sent in standard format will be received and used by all phones that can be used in the country's mobile network. The text of the SMS will be as follows: Mr. / Madam ---- Please take the medicine ---- in a dose of ---- at ---- hour. Finally, at the end of each intervention month, the degree of adherence to the medication

regimen in this group will be determined by filling out an MARS Medication Adherence Questionnaire.

**Category**

Rehabilitation

**3****Description**

Control group: the control group of drugs prescribed by a doctor that should be taken by patients in this group during a month will be placed in a can by the researcher and at the end of each month the participants in this group will be contacted and asked. To count the number of remaining pills in each drug group and to complete the Drug Adherence Questionnaire and the Cognitive Level Status Questionnaire and the Drug Registration Checklist and to put the pills in the box next month, go to the clinic again and so on for the second and third months. Will be acted upon.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Atefeh Allahbakhshian

**Street address**

Tabriz, Golghast St., Tabriz University of Medical Sciences

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138947977

**Phone**

+98 41 3479 6770

**Email**

allahbakhshiana@tbzmed.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Mohammadreza Rashidi

**Street address**

Tabriz University of Medical Sciences, Golghast St.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138947977

**Phone**

+98 41 3479 6770

**Email**

allahbakhshiana@tbzmed.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Atefeh Allahbakhshian

**Position**

PhD of nursing education

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Tabriz School of Nursing and Midwifery, Southern Shariati St., Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138947977

**Phone**

+98 41 3479 6770

**Email**

allahbakhshiana@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Other areas of specialty/work**

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Shariati St., Tabriz**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138947977

**Phone**

+98 41 3479 6770

**Email**

allahbakhshiana@tbzmedn.ac.ir

allahbakhshiana@tbzmed.ac.ir

**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**Requested data will be provided to researchers for  
statistical analysis of the submitted proposal (meta-  
analysis).**When the data will become available and for how long**

starting access immediately after publication

**To whom data/document is available**Data will be available to researchers as well as to  
journals.**Under which criteria data/document could be used**The data will be available to researchers upon request  
and submission of a proposal to perform meta-analysis  
using IPD data after being unidentified. Also, in  
exceptional cases, data will be made available to  
journals for checking.**From where data/document is obtainable**Refer to the email address  
(allahbakhshiana@tbzmed.ac.ir).**What processes are involved for a request to access data/document**The requests will be sent by email and data will be  
available within a week.**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Atefeh Allahbakhshian

**Position**

PhD of nursing education

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**Tabriz School of Nursing and Midwifery, Southern  
Shariati St., Tabriz**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

516566593198

**Phone**

+98 41 3479 6770

**Email**