Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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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.

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East Azarbaijan

Postal code

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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

I50

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work
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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
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