Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Group-Based In-Person and Mobile Phone–Based Education on Treatment Adherence and Self-Care Behaviors in Patients with Atrial Fibrillation: A Controlled Clinical Trial

Protocol summary

Study aim

Assessment of the Effectiveness of Patient Education Using Two Methods—“In-Person Group Training” and “Mobile Phone-Based Training via Social Media Platforms”—on Medication Adherence and Self-Care Behaviors in Patients with Atrial Fibrillation

Design

Randomized block design method with blocks of 4 and 6, two groups of 72 people, intervention in three stages before, three months and six months after the start of the intervention, SPSS software, Repeated measures test.

Settings and conduct

Tehran Heart Center, the first part in three stages: educational needs assessment, designing the educational package, and validating the educational package and examining its effectiveness in the next part.

Participants/Inclusion and exclusion criteria

Individuals over 18 years of age with a diagnosis of atrial fibrillation, who are literate, mobile phone literate, have access to the Internet and one of the devices such as a smartphone, are willing to participate in the study, and are not simultaneously participating in another educational intervention.

Intervention groups

Intervention in two groups: in-person group training and mobile phone-based training. In the in-person group training group, content was presented in the form of interactive methods. In the mobile phone-based training group, educational materials were sent to individuals' personal social media at specific intervals 3 times a week.

Main outcome variables

Medication and Non-Medication Adherence and Self-Care Behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250130064570N1**
Registration date: **2025-07-26, 1404/05/04**
Registration timing: **retrospective**

Last update: **2025-07-26, 1404/05/04**
Update count: **0**

Registration date

2025-07-26, 1404/05/04

Registrant information

Name

Morteza Dadvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3211 8664

Email address

ah-sarkardeh@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

2024-01-23, 1402/11/03

Actual recruitment end date

2024-02-22, 1402/12/03

Trial completion date

2024-02-22, 1402/12/03

Scientific title
Comparison of Group-Based In-Person and Mobile Phone–Based Education on Treatment Adherence and Self-Care Behaviors in Patients with Atrial Fibrillation: A Controlled Clinical Trial

Public title
Comparison of Group-Based In-Person and Mobile Phone–Based Education on Treatment Adherence and Self-Care Behaviors in Patients with Atrial Fibrillation: A Controlled Clinical Trial

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
People over 18 years of age with a diagnosis of atrial fibrillation Being able to read and write Being literate in using a mobile phone Internet access Access to one of the devices such as tablet, smartphone, and computer People's willingness to participate in the study

Exclusion criteria:
Lack of concurrent participation in another educational intervention related to this heart disease

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **144**
Actual sample size reached: **144**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
All participants completed the informed consent form prior to the start of the intervention. The initial questionnaire was completed by the research facilitator, after which each individual was given an envelope containing their assigned order of entry into the study, indicating to which educational group they belonged. Subsequently, the specific information for that group—including session schedules and the method of receiving educational materials—was provided to the patient.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کارگروه/کمیته اخلاق در پژوهش دانشکده بهداشت و پیراپزشکی- دانشگاه علوم پزشکی تهران

Street address
Blvd., North Tabarsi 13- No. 18

City
Mashhad

Province
Razavi Khorasan

Postal code
9156766614

Approval date
2022-12-24, 1401/10/03

Ethics committee reference number
IR.TUMS.SPH.REC.1401.202

Health conditions studied

1

Description of health condition studied
Atrial fibrillation

ICD-10 code
I48.2

ICD-10 code description
Chronic atrial fibrillation

Primary outcomes

1

Description
Medication Adherence Score in Patients with Atrial Fibrillation

Timepoint
At baseline, three months, and six months after the start of the intervention

Method of measurement
Researcher-designed questionnaire assessing treatment adherence and self-care behaviors among patients with atrial fibrillation.

2

Description
Non-Pharmacological Treatment Adherence Score in Patients with Atrial Fibrillation

Timepoint
At baseline, three months, and six months after the start of the intervention

Method of measurement
Researcher-designed questionnaire assessing treatment adherence and self-care behaviors among patients with atrial fibrillation.

3

Description
Self-Care Behavior Adherence Score in Patients with Atrial Fibrillation
Timepoint
At baseline, three months, and six months after the start of the intervention
Method of measurement
Researcher-designed questionnaire assessing treatment adherence and self-care behaviors among patients with atrial fibrillation.

Secondary outcomes

1

Description
The number of visits to the emergency department of Tehran Heart Hospital in the past six months.
Timepoint
Before the start of the intervention and six months after the start of the intervention
Method of measurement
One question about whether you have visited the emergency department of the heart hospital in the past six months, one question about the number of visits to the emergency department of the heart hospital during the past six months, and one question about the duration of your stay in the emergency department of the hospital

2

Description
The number of hospital admissions to Tehran Heart Hospital in the past six months.
Timepoint
Before the start of the intervention and six months after the start of the intervention.
Method of measurement
One question about whether you have been admitted to the heart hospital in the past six months, one question about how many times you have been admitted to the heart hospital, and one question about the duration of your stay at the heart hospital during the past six months.

Intervention groups

1

Description
Intervention group: The face-to-face group training was conducted using interactive methods such as Q&A sessions, group discussions, lectures, podcasts, and short film screenings. The sessions took place in the auditorium of Tehran Heart Center, with 8 to 10 participants attending each session. The intervention in the face-to-face training group lasted approximately one month.
Category
Behavior

2

Description
Intervention group: Mobile phone–based training was delivered through social media platforms, with content sent to participants' personal social media accounts three times a week at regular intervals. Feedback from participants on each session's content was collected within two days after the material was sent. Responses to the messages were considered as confirmation of content receipt by the user. The materials sent included images, podcasts, and short video clips.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Motahare Hatami
Street address
Tehran Heart Center, Corner of Jalal Al Ahmad Highway, North Kargar Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
9156766614
Phone
+98 21 8802 9600
Fax
Email
mdadvar77@gmail.com
Web page address
https://thc.tums.ac.ir/contactus

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahnaz Ashoorkhani
Street address
School of Public Health, Pour Sina Street, Ghods Street, Enghelab Avenue, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3333
Fax

Email
sph@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran Heart Center
Proportion provided by this source
50
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
Mahnaz Ashoorkhani
Position
Associate Professor of Health Education and Health Promotion
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
School of Public Health, Pour Sina Street, Ghods Street, Enghelab Avenue, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3333
Email
ashoorkhani@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahnaz Ashoorkhani
Position
Associate Professor of Health Education and Health Promotion
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
School of Public Health, Pour Sina Street, Ghods Street, Enghelab Avenue, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3333
Email
ashoorkhani@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Morteza
Position
PhD in Health Education and Health Promotion
Latest degree
Master
Other areas of specialty/work
Health Promotion
Street address
No. 18, North Tabarsi 13th Street, Mashhad, Khorasan Razavi, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9156766614
Phone
+98 51 3211 8664
Email
mdadvar77@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to

make this available	
Data Dictionary	Undecided - It is not yet known if there will be a plan to make this available