

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Evaluating the effects of self management interventions on life style and complications in patients with Atrial Fibrillation

#### Protocol summary

##### Summary

Main aim: Evaluating the effects of self management interventions on life style and complications in patients with Atrial Fibrillation. Inclusion criteria: All patients should be with chronic AF on the following basis: Sustained AF being treated with long-term pharmacological therapy with the intention of establishing optimal ventricular rate control and/or minimization of thrombotic risk, Recurrent paroxysmal or sustained AF being treated with pharmacological or electrical cardio-version with long-term pharmacotherapy to prevent recurrent AF and/or minimize thrombotic risk, Recurrent paroxysmal AF being treated with long term pharmacological therapy to minimize thrombotic risk; All patients should be more than 18; should not participate in any other study simultaneously; should be eager to participate in study and fill informed consent. Exclusion Criteria: Patients with C.V.A, cancer and liver failure; absence for more than two Sessions; suffering from psychological problems; not participating in study for any reason. Method: randomized controlled trial. Study population: all patients with atrial fibrillation in Fasa. Sample size:72 cases. Intervention: patients in intervention group will receive teaching in six sessions during three week period. Then we will call the patients fore three times (after the fourth, eighth, and twelfth week of intervention). Walker questionnaire and check lists will be completed for all cases in three times: before intervention, four weeks after intervention and twelve weeks after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015082023606N3**

Registration date: **2015-11-10, 1394/08/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-11-10, 1394/08/19

##### Registrant information

###### Name

Farzaneh Kazemi Ara

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 4254 7375

###### Email address

stud2392002274@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-Chancellor for Research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2015-05-22, 1394/03/01

##### Expected recruitment end date

2015-06-20, 1394/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effects of self management interventions on life style and complications in patients with Atrial Fibrillation

##### Public title

The effects of self management interventions on life style and complications in patients with Atrial Fibrillation

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion Criteria: Sustained AF being treated with long-term pharmacological therapy with the intention of establishing optimal ventricular rate control and/or minimization of thrombotic risk; Recurrent paroxysmal or sustained AF being treated with pharmacological or electrical cardio-version with long-term pharmacotherapy to prevent recurrent AF and/or minimize thrombotic risk; Recurrent paroxysmal AF being treated with long term pharmacological therapy to minimize thrombotic risk; All patients should be more than 18; should not participate in any other study simultaneously; should be able to comprehend Persian and communicate; should be eager to participate in study and fill informed consent.

Exclusion Criteria: Patients with C.V.A, cancer and liver failure; absence for more than two Sessions; suffering from psychological problems; not participating in study for any reason.

## Age

From **18 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **72**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

##### Street address

7th floor, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

##### City

Shiraz

##### Postal code

1978-71345

## Approval date

2010-09-23, 1389/07/01

## Ethics committee reference number

ct-9377-7347

## Health conditions studied

### 1

#### Description of health condition studied

Atrial Fibrillation

#### ICD-10 code

I48

#### ICD-10 code description

Atrial Fibrillation and flutter

## Primary outcomes

### 1

#### Description

Life style

#### Timepoint

before education, four weeks after education, at the end of twelfth week

#### Method of measurement

Walker Questionnaire

## Secondary outcomes

### 1

#### Description

Atrial Fibrillation Complications

#### Timepoint

before education, four weeks and twelve weeks after education

#### Method of measurement

Check list

## Intervention groups

### 1

#### Description

Patients in intervention group will receive education in six sessions during three weeks and telephone follows up after fourth week, eighth week and twelfth week of intervention.

#### Category

Lifestyle

### 2

#### Description

control group will receive usual care.

#### Category

Lifestyle

## Recruitment centers

1

#### Recruitment center

**Name of recruitment center**

Fasa Vali-e-Asr Hospital

**Full name of responsible person**

Hojat-o-Ilah Najafi

**Street address**

Vali-e-Asr Hospital, Avesena sq., Shahid Rajayi blvd.,  
Fasa, Fars, Iran

**City**

Shiraz

#### Sponsors / Funding sources

1

#### Sponsor

**Name of organization / entity**

Vice chancellery for research affairs

**Full name of responsible person**

Dr. Gholamreza Haatam

**Street address**

7th floor, Shiraz University of Medical Sciences, Zand  
Blvd., Shiraz, Iran

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellery for research affairs

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

#### Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Shiraz Medical University

**Full name of responsible person**

Mahnaz Rakhshan

**Position**

Ph.D.n

**Other areas of specialty/work**

**Street address**

School of Nursing and Midwifery, Namazi  
Square, Shiraz, Iran

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#### Person responsible for scientific inquiries

#### Contact

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#### Person responsible for updating data

#### Contact

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**Full name of responsible person**

Hojat-o-Ilah Najafi

**Position**

B.A

**Other areas of specialty/work**

**Street address**

Vali-e-Asr Hospital, Avesena sq., Shahid Rajayi blvd.,  
Fasa, Fars, Iran

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Fasa

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7461747377

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**Web page address**

www.fums.ac.ir

#### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*