Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative Effectiveness of Atrial Fibrillation-Specific Cognitive Behavioral Therapy (AF-CBT) and Stress Management and Resiliency Training (SMART) on Perceived Stress, Psychological Resilience, Quality of Life, and Sleep Quality in Patients with Atrial Fibrillation: A Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect and comparison of AF-CBT training and SMART training on perceived stress, psychological resilience, quality of life, and sleep quality in patients with atrial fibrillation

Design

A randomized, single-blind, three-group parallel clinical trial on 141 patients. The randomization process was performed through a random number generator.

Settings and conduct

This randomized trial included 141 atrial fibrillation patients (1:1:1) from Tehran cardiac centers. AF-CBT involved a 10-week online exposure-based program; SMART, an 8-week mind–body and coping skills training; the control group received routine nursing education. Blinding was limited to data analysis.Due to the nature of the intervention, blinding was limited to statistical analysis.

Participants/Inclusion and exclusion criteria

Age 18 years or older - Diagnosis of atrial fibrillation based on ECG- Having a CHA_2DS_2-VASc score of 1 or higher in men and 2 or higher in women; Having severe complications from current disease-Malignant disease or a diagnosis of terminal illness-Having cognitive impairment and psychiatric disorder-Receiving regular psychotherapy for a mental disorder-Participation in another study.

Intervention groups

SMART is an 8-week online group program that teaches mind-body skills, stress awareness, healthy lifestyle, and cognitive-behavioral techniques in weekly 1.5-hour sessions along with daily practice. A 10-week online CBT treatment with 5 PDF modules and weekly physical and situational exposure exercises, daily self-monitoring, behavioral activation, and therapist reporting to reduce fear and avoid symptoms of AF. The control group receives standard center training: individual training by a nurse, educational pamphlet, and ongoing follow-up by the ward nurse.

Main outcome variables

Perceived stress; Quality of life; Sleep quality; Cognitive resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240205060913N2**
Registration date: **2025-07-31, 1404/05/09**
Registration timing: **prospective**

Last update: **2025-07-31, 1404/05/09**
Update count: **0**

Registration date

2025-07-31, 1404/05/09

Registrant information

Name

Sogand Sarmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6552 4357

Email address

sogandsarmadi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-08-01, 1404/05/10
Expected recruitment end date
2025-09-01, 1404/06/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Effectiveness of Atrial Fibrillation-Specific Cognitive Behavioral Therapy (AF-CBT) and Stress Management and Resiliency Training (SMART) on Perceived Stress, Psychological Resilience, Quality of Life, and Sleep Quality in Patients with Atrial Fibrillation: A Randomized Clinical Trial

Public title
Atrial Fibrillation-Specific Cognitive Behavioral Therapy (AF-CBT) and Stress Management and Resiliency Training (SMART) in Patients with Atrial Fibrillation
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years or older. Diagnosis of atrial fibrillation based on ECG CHA_2DS_2-VASc score of 1 or greater in men and 2 or greater in women.
Exclusion criteria:
Patients with severe complications of their current disease atrial fibrillation immediately after thoracic surgery acute pulmonary embolism known hyperthyroidism malignant disease with a prognosis of survival of less than one year or a diagnosis of terminal illness cognitive impairment and psychiatric disorder receiving regular psychotherapy for a psychiatric disorder participation in another study.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **141**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients enrolled in the study will be randomly assigned in a 1:1:1 ratio to one of three groups: “Cognitive Behavioral Therapy for Atrial Fibrillation (AF-CBT)”, “Stress Management and Resilience Training (SMART)”, and the control group. The randomization process was performed through a random number generator. An independent research assistant who will not be involved in data collection will use the Research Randomizer software (http://www.randomizer.org) to generate the random number list. A total of 141 papers, 47 of which will be printed with the number 1, 47 with the number 2, and the last 47 with the number 3 (1, 2, and 3 representing the intervention and control groups, respectively), will be sealed in an envelope that will only be accessible by the research assistant at the time of randomization.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the treatment, patients and therapists were aware of the group assignment, and only the statistician would be unaware of the group assignment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculties of Pharmacy, Nursing and Midwifery - Shahid Beheshti University of Medical Sciences
Street address
Tehran, Vali Asr St., intersection of Ayat A... Hashemi Rafsanjani Highway, in front of Heart Hospital
City
Tehran
Province
Tehran
Postal code
1996835119
Approval date
2025-07-21, 1404/04/30
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1404.073

Health conditions studied

1

Description of health condition studied
Atrial fibrillation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Perceived stress: In this study, perceived stress refers to the score obtained from perceived stress.

Timepoint

Before and immediately after the intervention and 3 months after the intervention

Method of measurement

PSS-10 – Perceived Stress Scale

2

Description

Atrial fibrillation-specific quality of life: In this study, atrial fibrillation-related quality of life refers to the average score obtained from the Atrial Fibrillation Impact on Quality of Life Questionnaire.

Timepoint

Before and immediately after the intervention and 3 months after the intervention

Method of measurement

AFEQT – Atrial Fibrillation Effect on Quality-of-Life

3

Description

Sleep Quality

Timepoint

Before and immediately after the intervention and 3 months after the intervention

Method of measurement

PSQI – Pittsburgh Sleep Quality Index

4

Description

Psychological resilience

Timepoint

Before and immediately after the intervention and 3 months after the intervention

Method of measurement

CD-RISC – Connor-Davidson Resilience Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Atrial fibrillation (AF)-specific exposure-based cognitive behavioral therapy will be delivered entirely over the Internet using a secure, personalized web-based platform. The intervention will be therapist-led, will last 10 weeks, and will consist of 5 interactive modules with weekly assignments to be completed in the first 5 weeks. The modules will be downloadable as PDF files. After completing the fifth module, participants will continue to work with the treatment content for the remaining 5 weeks and will submit weekly reports of their exposure exercises to the therapist. Participants will be asked to spend approximately 30–60 min per day studying and practicing the treatment content. The treatment will primarily address two processes that perpetuate disability in atrial fibrillation (30, 41): hypervigilance and fear of AF symptoms, and avoidance of physical and social activities. Treatment interventions will include: education about atrial fibrillation (pathophysiology and drug therapy) and heightened attention to symptoms; self-monitoring practice (awareness of current cardiac symptoms, thoughts, feelings, and behavioral motivations) to reduce the negative value of symptoms; exposure to physical sensations similar to AF symptoms by performing a series of physical exercises, such as walking up and down stairs to increase heart rate or inducing dizziness or shortness of breath with hyperventilation, to reduce fear and hypervigilance of symptoms; exposure to real-life situations with conditions or activities that are usually avoided (such as participating in a social activity while experiencing cardiac symptoms); reduction or elimination of behaviors such as delaying pulse checking that would be used to control symptoms. Behavioral activation, which is encouraging patients to take action toward important life goals that are disrupted by AF; focus on preventing relapse and managing potential progression.

Category

N/A

2

Description

Intervention group 2: The SMART program is a structured psycho-educational intervention that teaches participants a variety of skills to cope more effectively with stress and reduce its negative effects on health. The program includes training in mind-body skills (meditation techniques, brief relaxations, mindfulness, and yoga), stress awareness tools, healthy lifestyle behaviors (sleep, exercise, nutrition, and social support), and cognitive restructuring and adaptive coping skills (modeled after cognitive-behavioral therapy, acceptance and commitment therapy, and positive psychology). The program will meet once a week for 1.5 hours for eight weeks and will include lecture segments, experiential exercises, and small group activities. As part of the program, participants will receive a workbook and audio-guided meditation files and will be encouraged to practice for 10–20 minutes daily and keep a daily journal of their practices (37). Although many of the tools learned in the program are designed to be integrated into daily life, participants are asked to use one of the program's brief relaxations if they experience cardiac symptoms (such as palpitations) as a way to reduce automatic dissonance and associated anxiety. All SMART group sessions will be held online via a secure, approved videoconferencing platform that allows for encrypted transmission of audio and video, and will be led by a faculty member experienced in leading these groups. Sessions will be held in the evenings on weekdays. The study's research coordinator will assist each participant in installing the required software and familiarizing them with how to connect and use the virtual environment prior to the first session.

Category

N/A

3

Description
Control group: The control group will receive the same routine training as each center, which includes patient education by nurses, educational pamphlets, and educational follow-ups by the ward nurse.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Cardiac Departments of Selected Hospitals and Heart Clinics in Tehran

Full name of responsible person
Sogand Sarmadi

Street address
No 291, East 10 and 11 Ave., Donyamali Blvd ., Andishe Town

City
Tehran

Province
Tehran

Postal code
3354383423

Phone
+98 21 6562 4357

Email
sogand.sarmadi@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
Tehran - Shahid Chamran Highway - Yemen Street - Arabi Street, Shahid Beheshti University of Medical Sciences and Healthcare Services - building number two of the university headquarters - sixth floor

City
Tehran

Province
Tehran

Postal code
19395-4631

Phone
+98 21 2387 2206

Email
urm@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Neda Sanaie

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Valiasr St., Niayesh Insersection, Nursing and Midwifery Faculty

City
Tehran

Province
Tehran

Postal code
1996835119

Phone
+98 21 8865 5366

Email
nedasanaie@ymail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Neda Sanaie

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Tehran, Vali Asr St., intersection of Ayat A... Hashemi Rafsanjani Highway, in front of Heart Hospital

City

Tehran

Province
Tehran

Postal code
1996835119

Phone
+98 21 8865 5366

Email
nedasanaie@ymail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Neda Sanaie

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Tehran, Vali Asr St., intersection of Ayat A... Hashemi Rafsanjani Highway, in front of Heart Hospital

City
Tehran

Province
Tehran

Postal code
1996835119

Phone
+98 21 8865 5366

Email
nedasanaie@ymail.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