Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of neurocognitive rehabilitation after coronary artery bypass graft surgery in improving quality of life: A randomized controlled trial

Protocol summary

Study aim

The aim of this study is to assess the efficacy of Computerized Cognitive Rehabilitation Therapy (CCRT) as a supplementary treatment to Routine Cardiac Rehabilitation (RCR) after Coronary Artery Bypass Graft (CABG) surgery in improving Quality of Life (QoL).

Design

The study is a randomized, single blind and parallel-group controlled trial with CCRT, active control and control groups in which 75 outpatients are going to be randomized by enrollment date.

Settings and conduct

This study will be carried out in Tehran Heart Center. At the beginning, general assessment of patients (demographic and clinical data) will be recorded and subjects complete the QoL questionnaire (SF-36), then baseline assessment of cognitive functions will be done.The computerized cognitive training program applied in this study is Maghzineh®.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Male or female outpatients. Aged between 40 and 80. Capable of perception of the research nature. Able to give informed consent before any study is written. Capable to speak in Persian with study personnel. Able to read and write and work with computer. Participation in concurrent standard routine rehabilitation during the trial; Exclusion Criteria:Dependency on alcohol or drugs. Has any mental disorders that might interfere with the exact assessment or accuracy of treatment. Has any clinical conditions that cause the usage of prescribed drugs that could have any effect on the Attention.

Intervention groups

Patients in CCRT group will receive CCRT plus RCR. CCRT is going to be conducted individually in 24, 20-minute sessions within 8 weeks; Patients in the active control group will receive a sham version of CCRT plus RCR; Patients in the control group will receive RCR without any cognitive intervention for 2 months.

Main outcome variables

cognitive functions; Quality o Life

General information

Reason for update

Acronym

CABG; CCRT; RCR; QoL

IRCT registration information

IRCT registration number: **IRCT2017022132704N1**
Registration date: **2017-10-28, 1396/08/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-23, 1397/09/02**
Update count: **2**

Registration date

2017-10-28, 1396/08/06

Registrant information

Name
Simin Sadat Ajtahed
Name of organization / entity
Shahidbeheshti medical university
Country
Iran (Islamic Republic of)
Phone
+98 31 5533 9289
Email address
s.ajtahed@gmail.com

Recruitment status

Recruitment complete

Funding source

This study was founded by personal financial sources by researcher and Cognitive Sciences and Technologies Council.

Expected recruitment start date

2017-10-17, 1396/07/25

Expected recruitment end date

2018-01-15, 1396/10/25

Actual recruitment start date

2017-10-21, 1396/07/29

Actual recruitment end date

2018-01-20, 1396/10/30

Trial completion date

2018-09-15, 1397/06/24

Scientific title

Efficacy of neurocognitive rehabilitation after coronary artery bypass graft surgery in improving quality of life: A randomized controlled trial

Public title

Efficacy of neurocognitive rehabilitation after CABG surgery in improving quality of life

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female outpatients. Aged between 40 and 80. Capable of perception of the research nature. Able to give informed consent before any study is written. Capable to speak in Persian with study personnel. Able to read and write and work with computer. Participation in concurrent standard routine rehabilitation during the trial.

Exclusion criteria:

Dependency on alcohol or drugs. Has any mental disorders that might interfere with the exact assessment or accuracy of treatment. Has any clinical conditions that cause the usage of prescribed drugs that could have any effect on the Attention.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data and Safety Monitoring Board

Sample size

Target sample size: **75**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a randomized controlled trial with pre-, post- and follow-up assessments that is going to be conducted in CCRT, active control and control groups. 75 outpatients will be selected by convenience sampling among patients after CABG surgery. Randomization will be carried out by the patients enrollment date in Tehran Heart Center(first month= CCRT group, second month= active control group, third month= control group).

Blinding (investigator's opinion)

Single blinded

Blinding description

The randomization of volunteer patients for participation in the study will be carried out by the patients enrollment date in Tehran Heart Center (first month= CCRT group, second month= active control group, third month= control group). clinical personnel are not aware of randomization according to enrollment date. Scores of computerized training are going to be recorded online and after the accomplishment of intervention, the data will be received from related corporation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

16 Azar Ave., Enqelab Square-

City

Tehran

Province

Tehran

Postal code

021-66491399

Approval date

2017-10-16, 1396/07/24

Ethics committee reference number

IR.ut.Rec.1395029

Health conditions studied

1

Description of health condition studied

cognitive deficit

ICD-10 code

R41.84

ICD-10 code description

Other specified cognitive deficit

Primary outcomes

1

Description

Selective attention

Timepoint

pre-intervention, post-intervention, 6-month follow-up.

Method of measurement

Flanker test

2

Description
Sustained attention
Timepoint
pre-intervention, post-intervention, 6-month follow-up.
Method of measurement
Continuous Performance test

3

Description
Divided attention
Timepoint
pre-intervention, post-intervention, 6-month follow-up.
Method of measurement
Useful Field of View

4

Description
Working memory
Timepoint
pre-intervention, post-intervention, 6-month follow-up.
Method of measurement
Digit Span test (Forward and Backward)

Secondary outcomes

1

Description
Quality of life
Timepoint
pre-intervention, post-intervention, 6-month follow-up.
Method of measurement
Quality of Life Short Form (SF-36) questionnaire

Intervention groups

1

Description
CCRT Group:This group of patients is going to receive CCRT plus RCR to activate different cognitive functions including attention, working memory and inhibition.The computerized cognitive training program applied in this study is Maghzineh®. This package has 24 exercise steps that the difficulty of exercises gradually increases according to the subject's performance. CCRT will be conducted individually in 24, 20-minute sessions within 8 weeks.
Category
Rehabilitation

2

Description
Active cotrol Group: This group patients is going to receive a sham version of CCRT plus RCR. The sham version involves the same training program without adaptivity and the difficulty level remains constant across the entire intervention. Sham version of CCRT will be conducted individually in 24, 20-minute sessions within 8 weeks.
Category
Placebo

3

Description
Control Group:Patients in this group is going to receive RCR without any cognitive intervention for 2 months.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center Hospital
Full name of responsible person
Dr. Soraya Etemadi
Street address
North Kargar Street
City
Tehran
Province
Tehran
Postal code
009821-88029731
Phone
+98 21 8833 6782
Email
etemadi1382@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cognitive Sciences and Technologies Council
Full name of responsible person
Committee of Technology Research and Infrastructure
Street address
No. 35, Alvand St., Argentine Square
City
Tehran
Province
Tehran
Postal code
00982188194954
Phone
+98 21 8819 4956
Email
research@cogc.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
1

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
College of Farabi, University of Tehran

Full name of responsible person
Simin Sadat Ajtahed

Position
Student/Master

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
6 Cheshmeh Alley., 18 Sialk Alley., Amirkabir Ave

City
kashan

Province
Isfehan

Postal code
8716900000

Phone
+98 31 5534 1046

Fax

Email
s.ajtahed@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Hamed Ekhtiari

Position
Associate professor

Latest degree
Medical doctor

Other areas of specialty/work
Neuroscience

Street address
4th Phase of Pardis, Edalat square, Cognitive Science Blvd

City
Tehran

Province
Tehran

Postal code
3718117469

Phone
+98 21 7629 1130

Fax
+98 21 7629 1140

Email
H.ekhtiari@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
collage of Farabi, University of Tehran

Full name of responsible person
Simin Sadat Ajtahed

Position
Student/ Master

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
6th Cheshme Alley., 18 Sialk Alley., Amir Kabir Ave

City
Kashan

Province
Isfehan

Postal code
8719636955

Phone
+98 31 5534 1046

Fax

Email
s.ajtahed@gmail.com

Web page address

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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

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
all data can be shared after removing the possibility of knowing individuals including: 1. demographic data; 2. data of cognitive performance and quality of life in pre-, post- and follow-up assessments.

When the data will become available and for how long

data will be available before publishing results

To whom data/document is available

no limitation

Under which criteria data/document could be used

publishing any result based on this research data is not allowed

From where data/document is obtainable

1. send request to s.ajtahed@gmail.com 2. search on OSF.io website

What processes are involved for a request to access data/document

data is accessible in the mentioned website.

Comments