

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The Effectiveness of Solution-focused Therapy on Mental Health, Life orientation and Meaningfulness in People with Cardiovascular Disease

Protocol summary

Study aim

Determining the Effectiveness of Solution-focused Therapy on Mental Health, Life orientation and Meaningfulness in People with Cardiovascular Disease

Design

Controlled clinical trial, with parallel groups, single blind, randomized design, on 80 patients. Randomization is done in a simple way using a table of random numbers.

Settings and conduct

The place of this study is in the Cardiovascular research center of Isfahan University of Medical Sciences. The study is double blind in which neither the subjects nor the analysts have any information about the individuals in the intervention and control groups, the statistics consultant is not aware of the manner and name of the interventions performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with coronary heart disease include stable angina pectoris (SA), unstable angina pectoris (USA) and myocardial infarction (MI) and according to angiography, at least one of the coronary arteries is involved in more than 70% or so-called angio-positive; One month has passed since the acute phase of the disease; Maximum 80 years of age; Having at least reading-writing literacy. Non-inclusion criteria: they are in the acute inflammatory phase; Having acute diseases, autoimmunity, serious psychiatric disorders and in need of immediate treatment

Intervention groups

Intervention group: In this group, Solution-focused Therapy will be performed in 8 90-minute sessions.
Control group: Control group will not receive any treatment during the study period

Main outcome variables

Mental Health; Life orientation; Meaningfulness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200302046668N1**
Registration date: **2020-08-21, 1399/05/31**
Registration timing: **retrospective**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

Sayed Mostafa Abdellahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3434 2826

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sm.abdellahi@iaukishint.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Solution-focused Therapy on Mental Health, Life orientation and Meaningfulness in People with Cardiovascular Disease

Public title

Effect of Solution-focused Therapy in People with Cardiovascular Disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients diagnosed with coronary heart disease include stable angina pectoris (SA), unstable angina pectoris (USA) and myocardial infarction (MI) According to angiography, at least one of the coronary arteries is involved more than 70% (angio-positive) One month has passed since the acute phase of the disease Maximum age of 80 years old Having at least reading and writing ability Ability to hear normally Personal and conscious satisfaction to participate in the research

Exclusion criteria:

Being in the acute inflammatory phase Affected by acute diseases, autoimmunity, serious psychiatric disorders and in need of immediate treatment

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random allocation is performed using a table of random numbers. The names of the people are written as codes on paper and are placed in the sealed envelopes so that randomization can be done completely blind.

Blinding (investigator's opinion)

Single blinded

Blinding description

Evaluators and statistical consultant will be unaware of the type of intervention. In this clinical trial the analysts have no information about the individuals in the study 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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar jarib street

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Isfahan

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Postal code

8174673461

Approval date

2020-04-29, 1399/02/10

Ethics committee reference number

IR.MUI.MED.REC.1399.093

Health conditions studied**1****Description of health condition studied**

Cardiovascular Disease

ICD-10 code

I51.9

ICD-10 code description

Heart disease, unspecified

Primary outcomes**1****Description**

Mental Health

Timepoint

Before intervention, after intervention, after 2 months

Method of measurement

General health questionnaire

Secondary outcomes**1****Description**

life orientation

Timepoint

Before intervention, after intervention, after 2 months

Method of measurement

life orientation test

2**Description**

meaning in life

Timepoint

Before intervention, after intervention, after 2 months

Method of measurement

meaning in life questionnaire

Intervention groups

1

Description

Intervention group: In this group Solution-focused Therapy is performed for patients. This treatment is a type of psychotherapy that helps patients achieve the thoughts and feelings that affect their behavior. This course of treatment is performed for at least 8 sessions of 90 minutes for these patients, during which the subjects will be taught various solution-oriented techniques for cardiovascular patients.

Category

Other

2

Description

Control group: Control group will not receive any treatment during the study period, However for this group, after the end of the research, the intervention will be done free of charge if it is effective.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiovascular Research Center of Isfahan University of Medical Sciences

Full name of responsible person

Mostafa Abdollahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo Javanmard

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Grant name

Grant code / Reference number

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

No

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mostafa Abdollahi

Position

psychologist

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mostafa Abdollahi

Position

psychologist

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Not applicable

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

Not applicable