

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Investigating the effect of nursing interventions based on self-regulation theory on self-care of patients with coronary artery disorders

#### Protocol summary

##### Study aim

Determining the effect of nursing interventions based on self-regulation theory on self-care of patients with coronary artery disorders

##### Design

This study will be a clinical trial with a control group, single-blinded (statistician), and with a randomized distribution. Participants will be 100 patients. Block random distribution method will be used for randomization.

##### Settings and conduct

Sampling will be done in the heart units of the largest public-educational hospital in Zanjan (Ayatollah Mousavi Hospital). Before the intervention, the demographic and self-care information of the patients will be determined by questionnaires. In addition to routine interventions, patients in the experimental group will receive self-care interventions based on self-regulation theory. The control group will receive only regular interventions. The data will be collected once at the beginning of the research and before the intervention, the second time at the end of the sixth week of the intervention, and the third time in the twelfth week of the intervention. The statistical analyst will not know about the groups by anonymizing the questionnaires and using a code for each questionnaire.

##### Participants/Inclusion and exclusion criteria

1. Definitive diagnosis of coronary artery disease by the cardiologist of the center
2. Consent to participate in research
3. Not having a history of severe mental disorders and underlying diseases that cause early fatigue in patients
4. Physical and mental ability required to complete the questionnaires
5. Not having vision, hearing, and Learning problems
6. Over 30 years of age

##### Intervention groups

In addition to receiving routine care and treatment, patients in the intervention group will undergo self-care training based on the self-regulation theory by the researcher.

#### Main outcome variables

Self-care

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140427017454N7**

Registration date: **2022-12-10, 1401/09/19**

Registration timing: **prospective**

Last update: **2022-12-10, 1401/09/19**

Update count: **0**

##### Registration date

2022-12-10, 1401/09/19

##### Registrant information

##### Name

kourosh Amini

##### Name of organization / entity

Zanjan university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 243377251314

##### Email address

korosh@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-22, 1401/10/01

##### Expected recruitment end date

2023-03-21, 1402/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of nursing interventions based on self-regulation theory on self-care of patients with coronary artery disorders

**Public title**  
Investigating the effect of nursing interventions based on self-regulation theory on self-care of patients with coronary artery disorders

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Definitive diagnosis of coronary artery disease by the cardiologist of the center Willingness to participate in research Physical and mental abilities required to complete the questionnaires Having over 30 years of age  
**Exclusion criteria:**  
Having a history of severe mental disorders and underlying diseases that cause early fatigue in patients Having vision, hearing, and learning problems Having under 30 years of age

**Age**  
From **30 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Data analyser

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Using the random block method, we will distribute the patients into two intervention groups: (A) and control (B). We plan to have six blocks of different combinations of A and B. Therefore, first, we will determine all possible shapes of blocks with the equal presence of both groups (A & B). We will put these six-state blocks into separate envelopes. The envelopes will be numbered. The project manager will select the envelopes randomly based on their numbers. In this way, the placement order of each patient in groups A or B will be announced to the researcher implementing the intervention by the project manager. for example, there may be a block in the form of AAABBB inside the selected envelope. This means that the first, second, and third eligible patients in the intervention group and the three last patients in the control group should be included.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The data collection tools in the study will be identified only by code and will not contain any information that the statistician can know about their grouping.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

##### Street address

Central Office of Zanjan University of Medical Sciences, Azadi Sq., Zanjan, Iran.

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956113

#### Approval date

2022-11-22, 1401/09/01

#### Ethics committee reference number

IR.ZUMS.REC.1401.261

## Health conditions studied

### 1

#### Description of health condition studied

Coronary artery disease

#### ICD-10 code

I25.1

#### ICD-10 code description

Atherosclerotic heart disease of native coronary artery

## Primary outcomes

### 1

#### Description

The self-care score based on the Coronary Artery Disease Self-Care Inventory

#### Timepoint

At the beginning of the study (before the intervention) and six weeks after the start of the intervention, and twelve weeks after the start of the study

#### Method of measurement

The Coronary Artery Disease Self-Care Inventory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Based on the theory of self-regulation and the concept of "threat perception," first, the level of familiarity and perspective of patients with the nature of coronary artery disease, the level of risk, the complications caused by the disease, the effect of lifestyle and adherence to the treatment on the control of complications will be evaluated. Then training on the above will be provided by a trained researcher. In the next step and corresponding to the concept of "dealing with the threat" of self-regulation theory, an introduction will be given regarding self-care behaviors. At the same time, teaching the positive results of self-care will be provided. In this part of the intervention, the evaluation of the patient's views on the nature of the disease, the ongoing interventions, the results of the disease, the duration of hospitalization, and the methods of controlling and treating the disease will be done. Individual goals will be determined based on an initial needs assessment using the Self Care-Coronary Artery Disease Inventory. Recommendations will then be made on how to correct problematic behaviors. According to the patient's condition, if the patient needs it, this intervention can be continued for up to three sessions. In addition, considering the positive role of others in changing people's behavior, we will try to conduct interventions in the presence of relatives. Corresponding to the concept of "intervention evaluation," emphasized in self-regulation theory, we will ask patients about the impact of interventions. The problems and obstacles to using healthy behaviors for each patient will be examined. Patients will be verbally encouraged if they move toward the goals. The acquisition of knowledge and skills by patients will be strengthened. Patients will be asked to raise their questions and concerns. This part of the intervention will be carried out during phone calls that will last 10 to 45 minutes (depending on the needs of the patients). The evaluation will be done in the first, third, and sixth weeks after the intervention. In addition, access to the researcher will be emphasized to clear the ambiguities and answer the questions. Data collection will be once at the beginning of the research (before the intervention), the second time at the end of the sixth week, and the third and last time in the twelfth week after the start of the research. In the last stage, the data will be statistically analyzed and compared, and the results will be reported.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mousavi Hospital, Zanzan

##### Full name of responsible person

Dr. Mustafa Azizi

#### Street address

Mousavi hospital, Dr Sobouti (Gavazang) Blvd,  
Zanzan, Iran.

#### City

Zanzan

#### Province

Zanzan

#### Postal code

4513956183

#### Phone

+98 24 3313 1199

#### Fax

+98 24 3313 1203

#### Email

mousavi@zums.ac.ir

#### Web page address

<https://mousavi.zums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanzan University of Medical Sciences

##### Full name of responsible person

Dr. Samad Nedri

##### Street address

Central Office of Zanzan University of Medical  
Sciences, Azadi Sq., Zanzan, Iran.

##### City

Zanzan

##### Province

Zanzan

##### Postal code

4515613191

##### Phone

+98 24 3342 4770

##### Email

Research@zums.ac.ir

##### Web page address

<https://research.zums.ac.ir>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Zanzan 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Kourosh Amini

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery, Central Campus of Zanjan University of Medical Science, Dr Sobouti (Gavazang) Blvd, Zanjan, Iran.

**City**

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**Province**

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4513956113

**Phone**

+98 24 3314 8318

**Email**

korosh@zums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Kourosh Amini

**Position**

Associate professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

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**Position**

Associate professor

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**Email**

korosh@zums.ac.ir

## 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data will be shared after the de-identification of study participants and publication of results.

**When the data will become available and for how long**

The data availability period will start immediately after the results are published.

**To whom data/document is available**

Only researchers working in academic and scientific research centers and nurses working in hospitals can access the data of this study.

**Under which criteria data/document could be used**

If the purpose of accessing the data is to develop research projects in the future or improve services to patients. The condition of access to the data will be a written and reasonable request of the applicant.

**From where data/document is obtainable**

Those who are interested in receiving the data can send an email to the project manager at Korosh@zums.ac.ir.

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

The applicant can receive the data through an email while introducing himself and the purpose of accessing

the data. The maximum response time to the requester will be one week.

**Comments**