

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The Effect of Written / Speech Expression on Depression, Anxiety and Stress in Patients After Open-Heart Surgery Amiralmomenin Kordkuy Hospital

#### Protocol summary

##### Study aim

The main objective: determining the effect of written / spoken exposition on depression, anxiety and stress. Specific purpose: comparison of anxiety and stress depression in patients immediately, one week and one month after the beginning of the study in four groups.

##### Design

100 patients are randomly assigned to quadruple blocks in four groups of 25.

##### Settings and conduct

The open heart surgery departments of Amiralmomenin Kurdoki Hospital are the place of study. Double blind study.

##### Participants/Inclusion and exclusion criteria

Research samples are open-heart hospital post-operative patients. Conditions for inclusion to study: lack of mental illness; non-use of drugs. Exclusion criteria: disclose less than three times in the emotional disclosure group or having readmission during the study.

##### Intervention groups

Intervention: four to ten minutes to expose 10-15 minutes of written / spoken emotional excitement. Study groups: two groups of Intervention and two control groups. Intervention group one: negative emotional disclosure. Intervention group Two: Positive emotional disclosure. Control group one: Neutral emotional disclosure. Control group two: no action is taken.

##### Main outcome variables

Depression; anxiety; stress

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110219005866N29**  
Registration date: **2018-10-27, 1397/08/05**

Registration timing: **retrospective**

Last update: **2018-10-27, 1397/08/05**

Update count: **0**

##### Registration date

2018-10-27, 1397/08/05

##### Registrant information

###### Name

Akram Sanagoo

###### Name of organization / entity

Golestan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 1443 0360

###### Email address

sanagoo@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-22, 1397/04/01

##### Expected recruitment end date

2018-09-21, 1397/06/30

##### Actual recruitment start date

2018-06-22, 1397/04/01

##### Actual recruitment end date

2018-09-21, 1397/06/30

##### Trial completion date

2018-09-21, 1397/06/30

##### Scientific title

The Effect of Written / Speech Expression on Depression, Anxiety and Stress in Patients After Open-Heart Surgery Amiralmomenin Kordkuy Hospital

##### Public title

Effect of Written / Speech Expression on Depression, Anxiety and Stress

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

No use of psychoactive drugs No addiction

### Exclusion criteria:

Patients for any reason continue to participate in the study at the time of study Patients with less than three exposures in the emotional exacerbation group are excluded Patients re-admitted to the study

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **100**

Actual sample size reached: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Four random block assignments were assigned to the groups

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Executable Examiner; Information Analyzer

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

##### Street address

Gorgan.Golestan University of Medical Sciences

##### City

Gorgan

##### Province

Golestan

##### Postal code

49341-74515

#### Approval date

2018-07-15, 1397/04/24

## Ethics committee reference number

IR.GOUMS.REC.1397.073

## Health conditions studied

### 1

#### Description of health condition studied

Coronary heart disease

#### ICD-10 code

I25.0

#### ICD-10 code description

Coronary heart disease

## Primary outcomes

### 1

#### Description

Depression

#### Timepoint

Come to study, one week later, one month after the study

#### Method of measurement

DASS-21 questionnaire (depression, anxiety, stress)

### 2

#### Description

stress

#### Timepoint

Come to study, one week later, one month after the study

#### Method of measurement

DASS-21 questionnaire (depression, anxiety, stress)

### 3

#### Description

Anxiety

#### Timepoint

Come to study, one week later, one month after the study

#### Method of measurement

DASS-21 questionnaire (depression, anxiety, stress)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Two intervention groups: intervention group one, negative emotional disclosure, intervention group two, positive emotional disclosure

#### Category

Behavior

## 2

### Description

Control group: two groups of control, control of neutral excitement and control group two, routine care

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Golestan University of Medical Sciences

##### Full name of responsible person

Akram Sanagoo

##### Street address

Shast Kola Road

##### City

Gorgan

##### Province

Golestan

##### Postal code

49165-568

##### Phone

+98 17 3245 1360

##### Fax

+98 17 3242 5171

##### Email

a\_sanagu@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gorgan University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Reza Honarvar

##### Street address

Shast kola

##### City

Gorgan

##### Province

Golestan

##### Postal code

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##### Phone

+98 17 3242 1660

##### Fax

+98 17 2345 6778

##### Email

honarvar@goums.ac.ir

##### Web page address

<http://goums.ac.ir/>

#### Grant name

Deputy of Research and Technology of Golestan University of Medical Sciences

#### Grant code / Reference number

#### Is the source of funding the same sponsor

#### organization/entity?

Yes

#### Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

##### Full name of responsible person

Akram sanagoo

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

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## Person responsible for scientific inquiries

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**Latest degree**

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**Street address**

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**Province**

Golestan

**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