

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

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Shast Kola Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Honarvar

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Web page address

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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

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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