Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Akram Sanagoo

Name of organization / entity
Golestan University of Medical Sciences

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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
125.0

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 Scinses
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Other areas of specialty/work
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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
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