

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of scheduled Visitation on the components of mental health of the families whose patients have undergone open heart surgery

Protocol summary

Study aim

Determining the effect of scheduled visit on family mental health components of patients undergoing open heart surgery

Design

Eligible samples are assigned to two groups based on the random assignment method of permutation blocks. These permutation blocks are constructed using a random number table. Then, different consecutive weeks are assigned to the test and control groups based on this random allocation method. The sample size based on PASS software version 15 about 33 people in each group were considered.

Settings and conduct

First, after receiving the code of ethics and the letter of introduction, the research method is explained to the patient and the family. In order to observe the etiquette for the family members of the visiting candidate (intervention), a training class of 10-15 minutes is formed only on the first day. It takes place at 3 pm (the first two days of the meeting) and 11 am (the third day of the meeting) in the presence of the researcher at post-icu. In both groups, the questionnaires are filled in on the first and last day.

Participants/Inclusion and exclusion criteria

1. Having a relative relationship with the patient
2. Do not suffer from major mental disorders
3. No history of using drugs, alcohol and psychotropic drugs
4. Be literate
5. No family problems

Intervention groups

In the intervention group, the appointment starts from the time the patient enters the PACU from the ICU for 30 minutes 3 times a week (3 consecutive days) at 3 pm (the first two days of the appointment) and 11 am (the third day of the appointment) in the presence of the researcher. However, the control group visits their patients according to the ward policy.

Main outcome variables

Reduce anxiety Reduce depression Reducing stress

Increase perceived social support Increase satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220216054043N1**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **retrospective**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Hadis Assadollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3322 7077

Email address

h.assadollahi72@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-02, 1399/12/12

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

2021-03-02, 1399/12/12

Actual recruitment end date

2021-09-21, 1400/06/30

Trial completion date

2021-09-21, 1400/06/30

Scientific title

The effect of scheduled Visitation on the components of mental health of the families whose patients have undergone open heart surgery

Public title

The effect of scheduled Visitation on the components of mental health of the families

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1. Having a relative relationship with the patient 2. Do not suffer from major mental disorders (depression, schizophrenia, anxiety) according to self-expression 3. No history of using drugs, alcohol and psychotropic drugs 4. Be literate 5. No family problems during the last 6 months (death of loved ones, divorce)

Exclusion criteria:

1. Death of the patient 2. Withdrawal from attending the study 3. Absence from all sessions until the end of the intervention 4. Non-compliance with the research protocol (especially in the control group)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 66

Actual sample size reached: 66

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible samples are assigned to two groups based on the random assignment method of permutation blocks. These permutation blocks are constructed using a random number table. Then, different consecutive weeks are assigned to the test and control groups based on this random allocation method. Thus, the second week may be randomly assigned to the control group and the third week to the control group, the fourth week to the experimental group and so on. The sampling method of the patient's family will be unlikely to be sequential. That is, we continue sampling in the order of hospitalization time in POST-ICU and according to the entry and exit criteria to complete the required sample size.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

No.18,pardeesan7,

City

Khorramabad

Province

Lorestan

Postal code

6816845933

Approval date

2021-02-20, 1399/12/02

Ethics committee reference number

IR.LUMS.REC.1399.335

Health conditions studied

1

Description of health condition studied

Scheduled Visitation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score, Depression score, Stress score, Satisfaction score, Perceived social support score

Timepoint

On the first day before the intervention On the third day after the intervention

Method of measurement

. Depression Anxiety Stress Scale 21, Family Satisfaction in the Intensive Care Unit questionnaire ,. Multidimensional Scale of Perceived Social Support

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The appointment starts from the time the patient enters the PACU from the ICU for 30 minutes 3 times a week (3 consecutive days) at 3 pm (the first two days of the appointment) and 11 am (the third day

of the appointment) in the presence of the researcher.

Category

Other

2

Description

Control group: According to the routine section

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Dr. Nasrin Galedar

Street address

Khorramabad, East Goldasht, next to Social Security Hospital, School of Paramedical Sciences

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h.assadollahi72@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr.Nasrin galedar

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr.Nasrin galedar

Position

Educational Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Ph.D.

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data can be published. Personal data remains confidential. Data are among the results of the study and statistical analysis before publication.

When the data will become available and for how long

After completing the research

To whom data/document is available

Employed researchers or academic institutions

Under which criteria data/document could be used

To be used for other research work

From where data/document is obtainable

Hadis Asadollahi executor of plan Dr. Nasrin Galedar responsible person

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

by Email

Comments