

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effect of nursing interventions on the incidence of delirium after open heart surgery

#### Protocol summary

##### Study aim

The effect of nursing interventions on the incidence of delirium after open heart surgery

##### Design

In this study, 60 patients were conveniently sampled and randomly allocated to the experimental and control groups. The random number table will be used for random allocation. Blinding will not be performed in this study. The CAM-ICU scale will be used for diagnosis of delirium.

##### Settings and conduct

This study will be conducted in the intensive care unit of Shahid Beheshti Hospital in Qom. Interventions will begin immediately after open heart surgery. The intervention will last for three days. Blinding will not be performed in this study. The incidence of delirium in the second and third days after surgery will be compared between the experimental and control groups.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: age over 18 years, being a candidate for Coronary Artery Bypass Graft and being alert at the time of admission (Orientation to time, place, and persons). The non-inclusion criteria: being admitted due to emergency heart surgery, isolation due to infectious disease, deterioration of the patient's condition after surgery, having a history of previous major surgery, and a lack of consent.

##### Intervention groups

In the intervention group, in addition to routine interventions, patients will receive a video tutorial, and Hospital Elder Life Program (HELP). In the control group, only routine care, including walking once a day in the second and third day of surgery, avoiding dehydration, reminding patients of the use of own glasses and hearing aids will be performed.

##### Main outcome variables

The main outcome variable in this study would be the incidence of delirium.

#### General information

##### Reason for update

Incorrect recording of inclusion and exclusion criteria

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150724023314N2**

Registration date: **2020-02-08, 1398/11/19**

Registration timing: **retrospective**

Last update: **2020-03-02, 1398/12/12**

Update count: **1**

##### Registration date

2020-02-08, 1398/11/19

##### Registrant information

###### Name

Mohammad Abbasinia

###### Name of organization / entity

Qom university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3242 4753

###### Email address

mabasiniya@muq.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-01, 1398/06/10

##### Expected recruitment end date

2019-12-30, 1398/10/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effect of nursing interventions on the incidence of delirium after open heart surgery

**Public title**

The effect of a nursing intervention on the incidence of delirium

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 years and over being candidate for Coronary Artery Bypass Graft being alert at the time of admission (Orientation to time, place, and persons).

**Exclusion criteria:**

Being admitted due to emergency heart surgery Isolation due to infectious disease Deterioration of the patient's condition after surgery

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will be assigned to intervention and control groups using a random number table.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The participants were blinded to whether they had been assigned to the intervention or control group throughout the study.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Qom University of Medical Sciences

**Street address**

Qom University of Medical Sciences, Saheli street, Qom.

**City**

Qom

**Province**

Ghoush

**Postal code**

3713649373

**Approval date**

2019-07-13, 1398/04/22

**Ethics committee reference number**

MUQ.REC.1398.136

**Health conditions studied****1****Description of health condition studied**

Delirium

**ICD-10 code**

F05

**ICD-10 code description**

Delirium, not induced by alcohol and other psychoactive substances

**Primary outcomes****1****Description**

Incidence of delirium

**Timepoint**

First, second and third day of surgery

**Method of measurement**

CAM-ICU Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the intervention group, in addition to routine interventions, patients will receive a video tutorial, and Hospital Elder Life Program (HELP).

**Category**

Prevention

**2****Description**

In the control group, only routine care, including walking once a day in the second and third day of surgery, avoiding dehydration, reminding patients of the use of own glasses and hearing aids will be performed.

**Category**

Prevention

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Shahid Beheshti Hospital of Qom

**Full name of responsible person**

Mohammad Abbasinia

**Street address**

Shahid Beheshti Hospital, Shahid Beheshti Boulevard,  
Qom

**City**

Qom

**Province**

Ghousm

**Postal code**

3719964797

**Phone**

+98 25 3612 2112

**Email**

armak1364@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ghousm University of Medical Sciences

**Full name of responsible person**

Mohammad Hosori

**Street address**

No. 83, University of Jihad Alley, Safashahr Street,  
Qom

**City**

Qom

**Province**

Ghousm

**Postal code**

9345637169

**Phone**

+98 25 3285 2720

**Email**

hozori@muq.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ghousm 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**

Ghousm University of Medical Sciences

**Full name of responsible person**

Mohammad Abbasinia

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

No. 83, University of Jihad Alley, Safashahr Street,  
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**City**

Qom

**Province**

Ghousm

**Postal code**

9345637169

**Phone**

+98 25 3285 2720

**Email**

armak1364@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ghousm University of Medical Sciences

**Full name of responsible person**

Mohammad Abbasinia

**Position**

Assistant Professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

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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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable