

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### The effect of nursing consultation on Anxiety and depression of Tracheostomy patient's families

#### Protocol summary

##### Summary

This study is a randomized control trial to determine the effect of nursing consultation on Anxiety and depression of Tracheostomy patient's families. All of the Tracheostomy patient's families admitted in Shahid-rajaei Hospital in Shiraz city were our statistical research community. Of them, 60 patients were selected based on inclusion criteria included: The main caregiver of the patient in the hospital and at home, the ability to speak and understand the Persian language and not having a history of psychological problems and they were randomly divided into two experimental and control groups using table of random numbers. The intervention group received In-person and telephone counseling, In-person and telephone Education and in-person answering. Patient companions filled out Beck Depression Inventory and Spiel Berger Anxiety Inventory before and after the intervention

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017072535292N1**

Registration date: **2017-07-28, 1396/05/06**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-07-28, 1396/05/06

##### Registrant information

###### Name

Mina Sadeghi

###### Name of organization / entity

Islamic Azad University Isfahan (Khorasgan) Branch

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3844 3313

###### Email address

mina.sadeghi@khuif.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Islamic Azad University Isfahan (Khorasgan) Branch

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2017-08-21, 1396/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of nursing consultation on Anxiety and depression of Tracheostomy patient's families

##### Public title

The effect of nursing consultation on Anxiety and depression

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Ability and willingness to communicate effectively with researcher; Main role of supporting the patient in the hospital and after discharge; ability to speak and understand Persian language; lack of history of psychological problems or known anxiety disorders based on history and self-declaration;. Exclusion criteria: withdrawal to continue cooperation; receive any Consultation from other nurses and patient's death.

##### Age

No age limit

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 60

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
Table of random numbers was used For randomization

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Islamic Azad University Isfahan (Khorasgan) Branch

##### Street address

Ahmad Abad St, Daneshgah Blvd, Isfahan

##### City

Isfahan

##### Postal code

8155139998

#### Approval date

2017-07-23, 1396/05/01

#### Ethics committee reference number

23810403922008

## Health conditions studied

### 1

#### Description of health condition studied

Tracheostomy

#### ICD-10 code

Z93.0

#### ICD-10 code description

Tracheostomy status

## Primary outcomes

### 1

#### Description

Depression

**Timepoint**  
before and one month after intervention

**Method of measurement**  
Beck Depression Inventory

### 2

#### Description

Anxiety

#### Timepoint

before and one month after intervention

#### Method of measurement

Eshpel Burgers' anxiety questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group received In-person and telephone counseling, In-person and telephone Education and in-person answering

#### Category

Rehabilitation

### 2

#### Description

Control group: There was no intervention

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Rajaei Hospital

##### Full name of responsible person

mina Sadeghi

##### Street address

Ahmad Abad St, Daneshgah Blvd, Isfahan

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Islamic Azad University Isfahan (Khorasgan) Branch

##### Full name of responsible person

Mina Sadeghi

##### Street address

Ahmad Abad St, Daneshgah Blvd, Isfahan

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Islamic Azad University  
Isfahan (Khorasgan) Branch

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University Isfahan (Khorasgan) Branch

**Full name of responsible person**

Mina sadeghi

**Position**

Master student of nursing

**Other areas of specialty/work**

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PhD of Educational management

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Master student of nursing

**Other areas of specialty/work**

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**Postal code**

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**Fax**

**Email**

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**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*