

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

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Street address

Ahmad Abad St, Daneshgah Blvd, Isfahan

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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

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

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Full name of responsible person

Mina sadeghi

Position

Master student of nursing

Other areas of specialty/work

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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