Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Discharge Education with the Teach-Back Method on the anxiety of Family Caregivers of Patients Hospitalized in the Intensive Care Unit

Protocol summary

Study aim

Determining the impact of feedback-based discharge training on the anxiety of family caregivers of patients admitted to the special care units of Shahid Rahmonun Hospital in Yazd in 1403

Design

The clinical trial has two intervention and control groups with randomized parallel groups in phase 2 on 76 patients.

Settings and conduct

After the announcement of the resident doctor in the ICU based on the start of the patient discharge process and education to the family, the demographic and anxiety questionnaires will be provided to them at first. For the control group, routine training during discharge is done verbally and in writing. For the intervention group, these trainings will be done in a feedback way.In each of the two studied groups, Spielberger's anxiety questionnaire will be completed by caregivers after the third training session, and the anxiety level will be obtained

Participants/Inclusion and exclusion criteria

A) Inclusion criteria Patient: 1. Hospitalization of the patient in the intensive care unit 2. People who will be discharged with GCS less than 15

Intervention groups

For the control group, routine training during discharge is done verbally and in writing. For the intervention group, these trainings will be done in a feedback way. In each of the two studied groups, Spielberger's anxiety questionnaire will be completed by caregivers after the third training session, and the anxiety level will be obtained.

Main outcome variables

If feedback-oriented training has an effect on reducing the anxiety of caregivers, it can be suggested as an effective intervention in educational programs during the discharge of patients hospitalized in special care units of hospitals under the Ministry of Health, in order to reduce the anxiety of caregivers.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241229064205N1**
Registration date: **2025-02-06, 1403/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-06, 1403/11/18**
Update count: **0**

Registration date

2025-02-06, 1403/11/18

Registrant information

Name

maryam zeighamian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3724 9036

Email address

maryamzeighamian1375@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-29, 1403/10/09

Expected recruitment end date

2025-04-29, 1404/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Discharge Education with the Teach-Back Method on the anxiety of Family Caregivers of Patients Hospitalized in the Intensive Care Unit

Public title

The Effect of Discharge Education with the Teach-Back Method on the anxiety of Family Caregivers of Patients Hospitalized in the Intensive Care Unit

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalization of the patient in the intensive care unit
People with GCS less than 15 will be discharged

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are initially selected according to the available method based on the entry and exit criteria, and then gradually, based on the table of random numbers, they are randomly assigned to the intervention and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University - Isfahan Branch (Khorasgan)

Street address

Tehran, Quds town (west), between South Flamek and Zarafshan, Simai Iran St., Central Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th floor

City

Khorasgan

Province

Isfehan

Postal code

8916933367

Approval date

2025-01-06, 1403/10/17

Ethics committee reference number

IR.IAU.KHUISF.REC.1403.472

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

anxiety

Timepoint

Before training and after training

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Teach-Back Method:Intervention group: feedback-oriented training: training to provide regular feedback to specific individuals. This can help them identify their strengths and weaknesses and improve their skills

Category

N/A

2

Description

Control group: Training during routine hospital discharge

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Martyr Dr. Rahnamun Hospital

Full name of responsible person
رضا قادریان

Street address
Farrokhi St

City
yazd

Province
Yazd

Postal code
۸۹۱۳۸۱۴۳۹۶

Phone
+98 35 3626 0001

Email
rahnamoon@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Mohammad Mehdi Karimnejad

Street address
Yazd, Safia, Alam Square, Shohdai Anom Blvd., Islamic Azad University Complex

City
yazd

Province
Yazd

Postal code
8915813135

Phone
+98 35 3821 6781

Email
info@iauyazd.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Yazd University of Medical Sciences

Full name of responsible person
Maryam Zeighamian

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No45،Alley46،Shahid KhalilHasanBeigi Street

City
Yazd

Province
Yazd

Postal code
8916933367

Phone
+98 35 3724 9036

Fax

Email
maryamzeighamian1375@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Maryam Zeighamian

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No45،Alley46،Shahid KhalilHasanBeigi Street

City
Yazd

Province
Yazd

Postal code
8916933367

Phone
+98 35 3724 9036

Fax

Email
maryamzeighamian1375@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Maryam Zeighamian

Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No45،Alley46،Shahid KhalilHasanBeigi Street
City
Yazd
Province
Yazd
Postal code
8916933367
Phone
+98 35 3724 9036
Fax
Email
maryamzeighamian1375@gmail.com

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