

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Determine effective training program for improving relationship between patient and assistant in managing unpleasant consequences

Protocol summary

Summary

The purpose of study is to determine the appropriate educational program for improving communication skills, controlling and managing stress by emergency medical assistants. This study will be done in Rasoul-e-Akram Hospital in 2016. Initially, communication skills and information transmission by the assistance using the SPIKES tool will examine. The study population were emergency medical assistant of Iran University of Medical Sciences, 64 students will be randomly assigned to training groups, in a training program group GRIEV_ING and the other group Belgian interuniversity curriculum communication skills training (BIC-CST) presented until evaluate the effectiveness of each program in managing and transmitting bad news. Assessment of assistant's skills were after-training, two and four weeks after the training. In addition, the director of the research team will monitor how to transmit bad news by the assistants and the behavioral characteristics, expression of the contents and the amount of stress they will monitor.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102228342N2**

Registration date: **2017-10-25, 1396/08/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-25, 1396/08/03

Registrant information

Name

Mohammad Hosseini Kasnavieh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6653 9233

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-09-28, 1396/07/06

Expected recruitment end date

2018-03-12, 1396/12/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determine effective training program for improving relationship between patient and assistant in managing unpleasant consequences

Public title

Determine effective training program for improving relationship between patient and assistant

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All emergency medical assistants will be included in the study That training at Iran University of Medical Sciences Exclusion criteria: Exclusion criteria are not considered due to the importance of stress management and communication skills

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Postal code**Approval date**

2017-09-13, 1396/06/22

Ethics committee reference number

IR.IUMS.REC 1396.31261

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

problems related to primary support group, including family circumstances

ICD-10 code

Z63

ICD-10 code description

Z63.4, Z63.7, Z63, Z63.8

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

Managing bad news transfer

Timepoint

Before starting the study and after-training, two and four weeks after the training

Method of measurement

SPIKES questionnaire

Secondary outcomes**1****Description**

Setting interview

Timepoint

Before starting the study and after-training, two and four weeks after the training

Method of measurement

SPIKES Questionnaire

2**Description**

Strategy

Timepoint

Before starting the study and after-training, two and four weeks after the training

Method of measurement

SPIKES Questionnaire

3**Description**

Planning

Timepoint

Before starting the study and after-training, two and four weeks after the training

Method of measurement

SPIKES Questionnaire

4**Description**

Professionalism

Timepoint

Before starting the study and after-training, two and four weeks after the training

Method of measurement

SPIKES Questionnaire

5**Description**

Empathy

Timepoint

Before starting the study and after the intervention

Method of measurement

SPIKES Questionnaire

6**Description**

Knowledge

Timepoint

Before starting the study and after-training, two and four

weeks after the training
Method of measurement
SPIKES Questionnaire

7

Description

Invitation

Timepoint

Before starting the study and after-training, two and four weeks after the training

Method of measurement

SPIKES Questionnaire

Intervention groups

1

Description

The GRIEVING training group is in five sessions two hours (10 hours) at once a week. The program of communication skills, control and management stress will also be held for 10 hours.

Category

Behavior

2

Description

The BIC-CST training program for 30 hours includes communication skills (10 sessions of three hours once week) and 10 hours are of control and management stress

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-e Akram Hospital

Full name of responsible person

Mohammad Hosseini Kasnavieh

Street address

Niyayesh St, Sattar Khan St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Kazem Malakouti

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

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, Iran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Hosseini Kasnavieh

Position

Assistant

Other areas of specialty/work

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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