

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparing of the effectiveness of Written Emotional Disclosure and Bensons Relaxation on anxiety and perceived stress in the family members of ICU patients of Shahrekord Kashani hospital

Protocol summary

Study aim

Comparing of the effectiveness of Written Emotional Disclosure and Bensons Relaxation on anxiety and perceived stress in the family members of ICU patients of Shahrekord Kashani hospital

Design

Given that there are three ICU wards 1, 2 and 3 in the hospital for trauma patients hospitalization, these three ICU wards were randomly selected as intervention group for relaxation, emotional detection and control and sampling was done by easy sampling. Randomization in groups is done using Random Allocation software.

Settings and conduct

The study is carried out on first-degree family members of patients admitted to the ICU ward of Shahrekord Kashani Hospital. The objectives of the study are described to the participants. For each intervention group, training is provided on how to do it. The Spielberger Anxiety and Stress Questionnaires will be completed by the participants before and immediately after the intervention and one month after the end of each intervention.

Participants/Inclusion and exclusion criteria

blood family members of patients in the ICU of Shahrekord Kashani Hospital, Informed consent to participate in the study, 24 hours hospitalization, at least 18 years of age, literacy, lack of cognitive and mental disorders, no drug addiction, sedatives And alcohol, no record of sedation

Intervention groups

3 intervention group: Written Emotional Disclosure, Bensons Relaxation and control group

Main outcome variables

Spiel Berger questionnaire will be used to assess severity of anxiety; Cohen's perceived stress questionnaire used to measured stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190911044749N1**

Registration date: **2019-10-21, 1398/07/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-21, 1398/07/29**

Update count: **0**

Registration date

2019-10-21, 1398/07/29

Registrant information

Name

Nasrin Forozandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3334 6010

Email address

nas_for@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of the effectiveness of Written Emotional Disclosure and Bensons Relaxation on anxiety and perceived stress in the family members of ICU patients of Shahrekord Kashani hospital

Public title

the effectiveness of Written Emotional Disclosure and Bensons Relaxation on anxiety and perceived stress in the family members of ICU patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

First-degree blood relatives with patient Reading and writing skills no psychological disorders Non-use of drugs, sedatives and alcohol No record of using relaxation techniques

Exclusion criteria:

Failure to cooperate at any time of study Companions whose patients have suffered brain death

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Three ICU sections 1, 2 and 3 were randomly selected for the patients in the relaxation, emotional detection, and control groups. Samples were selected by simple sampling and randomization in groups will be done using Random Allocation software.

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 Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani

Ave., Shahrekord City

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.SKUMS.REC.1397.71

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2

Description of health condition studied

stress

ICD-10 code

F43

ICD-10 code description

Reaction to severe stress, and adjustment disorders

Primary outcomes

1

Description

Mean Perceived Stress Score of Family Members of Patients

Timepoint

at baseline, immediately and one month after intervention

Method of measurement

The Cohen's perceived stress Questionnaires

2

Description

Mean Anxiety Score of Family Members of Patients

Timepoint

at baseline, immediately and one month after intervention

Method of measurement

The Spielberger Anxiety Questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Bensons Relaxation

Category

Behavior

2

Description

Intervention group: Written Emotional Disclosure

Category

Behavior

3

Description

Control group: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Kashani Hospital

Full name of responsible person

Nasrin Forozandeh

Street address

Shahrekord Kashani Hospital, Parastar Ave.,
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+98 38 3226 4825

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Kashani@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Seyyed Kamal Solati

Street address

Shahrekord University of Medical Sciences, Kashani
Ave., Shahrekord City

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Email

pajoohesh@skums.ac.ir

Web page address

<https://skums.ac.ir/>

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahrekord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Nasrin Forozandeh

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Faculty of Nursing and Midwifery, Rahmatiyah Town,
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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Personal information will be used only in this study

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available