

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of the effect of receiving and not-receiving supportive-educational intervention on the level of stress, depression, anxiety, perceived social support, and satisfaction of the caregivers of the patients undergoing gynecological surgery; a randomized clinical trial

Protocol summary

Summary

The aim of the current study is to comparative evaluation of the effect of receiving and not-receiving supportive, educational intervention on the level of stress, depression, perceived social support, and satisfaction of the caregivers of the patients undergoing gynecological surgery. The research population is the patients' caregivers referring to Khorramabad city's training Asali hospital. The number of the subjects regarding to sample size formula is 60 caregivers in each group. The caregivers will be classified in 2 groups; control group (without supportive, educational intervention), and intervention group (with supportive, educational intervention). In intervention group, each caregiver will be undergone education and support in time of her patient's arrival to the operating theater after obtaining informed consent form and directing to the waiting room located beside the operating theater according to the predetermined supportive educational program, but control group will not receive any supportive educational intervention. Before and after the patient's surgery, the level of the stress, anxiety, and depression of the caregivers will be assessed by depression, anxiety and stress scale(DASS21), the level of satisfaction by self made questionnaire and perceived social support by the Multidimensional Scale of Perceived Social Support, respectively. The subjects and study statistician are not informed about the groups and the way of delivering intervention. The inclusion criteria are the following; lack of psychological disease, being of patient's caregiver in the hospital and in the waiting room during surgery; being literate. The exclusion criteria are the following: lack of desire to continue cooperation in each step of the study and/or the decease of the patient.

General information

Acronym

depression, anxiety and stress scale, DASS

IRCT registration information

IRCT registration number: **IRCT201604205596N5**

Registration date: **2016-07-01, 1395/04/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-01, 1395/04/11

Registrant information

Name

Nasrin Galehdar

Name of organization / entity

Lorestan University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Isfahan University of Medical Sciences and Vice chancellor for research of Lorestan University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of receiving and not-receiving supportive-educational intervention on the level of stress, depression, anxiety, perceived social support, and satisfaction of the caregivers of the patients undergoing gynecological surgery; a randomized clinical trial

Public title

Effect of supportive-educational intervention on the level of stress, depression, anxiety, perceived social support, and satisfaction of the caregivers of the patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Desire to participate in the study; ability to perceive and fill out the questionnaire; lack of psychological disease; the age between 18 to 55 years old; lack of participation in current similar study; being of patient caregiver in the hospital and waiting room in time of surgery; being literate. Exclusion criteria: Lack of desire to continue cooperation in each step of the study; decease of the patient.

AgeFrom **18 years** old to **55 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization is performed using random numbers table

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, Pardis campus, Kamalvand, Khorramabad, Lorestan

City

Khorramabad

Postal code**Approval date**

2015-04-06, 1394/01/17

Ethics committee reference number

LUMS.REC.1394.2

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

Stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

2**Description of health condition studied**

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

3**Description of health condition studied**

Depression

ICD-10 code

F32.0

ICD-10 code description

Mild depressive episode

4**Description of health condition studied**

Satisfaction

ICD-10 code

-

ICD-10 code description**5****Description of health condition studied**

Perceived social support

ICD-10 code

-

ICD-10 code description**Primary outcomes**

1

Description

The level of depression, anxiety and stress of the caregivers

Timepoint

Upon arrival of the patient to the operating room and in the first visit with caregiver and in time of patient's exit of the operating theater

Method of measurement

Depression, Anxiety and stress scale(DASS21)

Secondary outcomes

1

Description

The level of satisfaction

Timepoint

Upon arrival of the patient to the operating room and in the first visit with caregiver and in time of patient's exit of the operating theater

Method of measurement

The self made questionnaire

2

Description

Perceived social support

Timepoint

Upon arrival of the patient to the operating room and in the first visit with caregiver and in time of patient's exit of the operating theater

Method of measurement

The multidimensional scale perceived social support

Intervention groups

1

Description

The patients' caregivers being in the waiting room will be presented via supportive educational program by operating theater nurse in form of speech, question and answer, and slides by a monitor. This international program will be in 6 steps, and each step will take 10 minutes long. The educational points will be about postoperative cares; the principles and arrangements of traffic and visit; correct and effective communication. The necessary information will be presented to the patient's caregiver in educational programs intervals. Each caregiver will be visited by operating theater nurse to receive support and answers of the questions sporadically for at least 10 minutes.

Category

Other

2

Description

The control group will receive no education

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Asali Hospital of Khorramabad city

Full name of responsible person

Nasrin Galehdar

Street address

Asali khorramabad charity hospital, Palestine street, Khorramabad, Lorestan

City

Khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Dr. Morovat Taheri Kalani

Street address

Lorestan University of Medical Sciences, Academic Complex Kamalvand, kilometer 5 khorramabad road Tehran, Khorramabad, Lorestan

City

Khorramabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Lorestan University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Nemat Bakhsh

Street address

Azadi square, Hezar Jarib avenue, Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

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

Lorestan University of Medical Sciences

Full name of responsible person

Nasrin Galehdar

Position

MSc of nursing education, Faculty member

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