

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of pre-operative provision of information with Peer method on anxiety of patients undergoing thyroidectomy surgery

Protocol summary

Study aim

Assessing the effect of peer awareness on preoperative anxiety of a candidate for thyroidectomy

Design

A clinical trial with a control group with parallel groups, without blinding, randomized on 78 patients, the blocking method was used for randomization.

Settings and conduct

This study is performed in Imam Khomeini Hospital of Tehran. First, the background and demographic information of the patients were collected. before awareness Patients complete Spielberger Manifest Anxiety Questionnaire and the saliva sample taken. then, in the intervention group, awareness is performed and the next day saliva samples taken and Patients complete Questionnaire again. The control group receives the information according to the previous routine of the ward.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 18 to 70; First surgical experience; Lack of family relationship with other participants in the study; No family history of thyroidectomy; No membership in the treatment team; Lack of speech and hearing problems; No dementia and cognitive impairment; Do not take medications that reduce or increase cortisol (such as corticosteroids, anticonvulsants, insulin). Exclusion criteria: Any severe changes and worsening of the disease during the study; Any invasive treatment during the study; Any patient dissatisfaction during the project.

Intervention groups

In the intervention group, guidance including patient health and surgery information and postoperative care, thyroidectomy complications and other information is provided to the patients in the intervention group in a 30 minute session.

Main outcome variables

Anxiety before thyroidectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201206049623N1**

Registration date: **2021-02-12, 1399/11/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-12, 1399/11/24**

Update count: **0**

Registration date

2021-02-12, 1399/11/24

Registrant information

Name

atefe asadpurasl

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3235 1775

Email address

a-asadpurasl@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-04, 1399/10/15

Expected recruitment end date

2021-09-06, 1400/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pre-operative provision of information with Peer method on anxiety of patients undergoing thyroidectomy surgery

Public title

Effect of pre-operative provision of information with Peer method on anxiety of patients before thyroidectomy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 18 to 70 First surgical experience Lack of family relationship with other participants in the study No family history of Thyroidectomy Not be part of the medical staff Lack of speech and hearing problems No dementia and cognitive impairment Do not take medications that reduce or increase Cortisol (such as Corticosteroids, Anticonvulsants, Insulin)

Exclusion criteria:

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling in this research is done in two stages. In the first step, the samples are selected by the Convenience Sampling method. In the second stage, the allocation of samples to the two groups of intervention and control is done randomly and by blocking method; The letter A is considered for the intervention group and the letter B for the control group. Then we write all the combinations of the letters A, A, and B ,B, which are 6 different combinations, on 6 cards: 1. AABB 2. ABBA 3. ABAB 4. BAAB 5. BABA 6. BBAA Then, from digits 1 to 6, a digit is randomly selected(With the help of a table of random numbers or patient number one is asked to choose a card at random.) For example, if the digit 2 is selected This means that the first person is in the intervention group and the next two people are in the control group and the fourth person is in the intervention group and This Process continues until the sample size reaches the quorum.

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

School of Nursing and Midwifery and School of Rehabilitation, Tehran University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1417935840

Approval date

2020-11-30, 1399/09/10

Ethics committee reference number

IR.TUMS.FNM.REC.1399.146

Health conditions studied

1

Description of health condition studied

thyroidectomy surgery

ICD-10 code

E00-E90

ICD-10 code description

Endocrine, nutritional and metabolic diseases

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety score in Spielberger's overt anxiety questionnaire

Timepoint

Completion of the questionnaire before the intervention and after informing

Method of measurement

Spielberger Obvious Anxiety Questionnaire

2

Description

Measuring anxiety with salivary cortisol levels

Timepoint

Before the intervention and one day after provision of

information

Method of measurement

Saliva sample in the amount of 3 to 5 cc

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, guidance including patient health and surgery information and postoperative care, thyroidectomy complications and other information is provided to the patients in the intervention group in a 30-minute session. It should be noted that the peer groups in this study are those who have recently undergone surgery and have a drain and dressing in the neck area. To reduce errors due to peer diversity, peers are taught by the researcher about postoperative complications, symptoms of calcium loss, swallowing and voice changes, cervical drainage, and psychological support. At the end of the training, a checklist is prepared that And its reliability has been pre-measured and evaluated by the researcher. The answers to the clients' questions are also done by the researcher.

Category

Other

2

Description

Control group: The control group receives routine ward training by nurse.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital complex, Tehran

Full name of responsible person

Atefe Asadpurasl

Street address

Imam Khomeini hospital complex, Tohid Squire, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733114

Phone

+98 21 6119 2370

Email

imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mojde Navidhamidi

Street address

School of Nursing Midwifery, Tehran University of Medical Sciences Nosrat st. Tohid sq. Tehran. IRAN

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141973317

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Email

fnm-researchdeputy@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Atefe Asadpurasl

Position

Master student of Internal Surgery Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Tehran Medical Sciences Alley,16th Street, Amirabad North

City

Tehran

Province

Tehran

Postal code

1869676759

Phone

+98 21 8822 3165

Email

Atefeaspour72@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Atefe Asadpurasl

Position

Master student of Internal Surgery Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Atefeasadpourasl

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Will be published.

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

For all

Under which criteria data/document could be used

To increase knowledge in this field

From where data/document is obtainable

atefeasadpour72@gmail.com

What processes are involved for a request to access data/document

It will be done as soon as possible after requesting by email.

Comments