

# 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 Zarafashan & 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

##### City

Tehran

##### Province

Tehran

##### Postal code

141973317

##### Phone

+98 21 6691 4368

##### 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

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Tehran University of Medical Sciences,16th St, North Amirabad

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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

**Position**

Master student of Internal Surgery Nursing

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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**