

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of digital storytelling on sleep quality and anxiety of patients with pituitary adenoma candidated for transsphenoidal surgery

#### Protocol summary

##### Study aim

Determining the effect of digital storytelling on sleep quality and anxiety in patients with pituitary adenoma candidates for transsphenoidal surgery

##### Design

This RCT is single blinded with 2 groups, each with a volume of 35 people, placed in groups in the form of simple random allocation through the website <http://www.jerrydallal.com/random/randomize.htm>.

##### Settings and conduct

This intervention is an educational method that includes video, images and words of treatment staff, doctors and patients with healed pituitary adenoma in about 10 to 15 mins. This training package is provided to the people of the test group before surgery and after hospitalization, and pre- and post-operative care, how to care for dressings, when to go to the clinic for a visit, and so on are involved in it. The control group will not receive this training package, they only receive the common training in the department. The effectiveness of the study will be measured through PSQI and STAI questionnaires which will be completed by the patients of both groups in the pre-surgery phase, 1 day after entering the neurosurgery department after surgery and 3 weeks later when visiting the clinic. This intervention is single blinded and statistic analyser is not informed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering from Benign pituitary adenoma and having GCS 15/15. Exclusion: Decreased GCS ( below 15) before or after surgery.

##### Intervention groups

The intervention group includes people who receive the digital storytelling training package and control group are people who only receive the common training in the department.

##### Main outcome variables

Anxiety Sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191027045257N4**

Registration date: **2023-04-09, 1402/01/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-04-09, 1402/01/20**

Update count: **0**

##### Registration date

2023-04-09, 1402/01/20

##### Registrant information

##### Name

Pegah Matourypour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6105 4126

##### Email address

matourypour@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-22, 1401/10/01

##### Expected recruitment end date

2023-04-21, 1402/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of digital storytelling on sleep quality and anxiety of patients with pituitary adenoma candidates for transsphenoidal surgery

#### Public title

Effect of digital storytelling on sleep quality and anxiety of patients with pituitary adenoma candidates for transsphenoidal surgery

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Suffering from Benign pituitary adenoma that has been confirmed through diagnostic methods and examinations by a specialist doctor. 18 to 60 aging Not suffering from intellectual disability and learning disorders

Consciousness level with Glasgow coma scale 15  
Accessing and working with social networks or e-mail, working with electronic devices and the permission of the attending physician to use them The absence of nausea in patients

##### Exclusion criteria:

Patients' loss of consciousness (GCS less than 15) during hospitalization after surgery Getting meningitis or infection after surgery patient's death The patient's unwillingness to participate in the study and continue to participate in it Occurrence of apoplexy or bleeding after surgery Nausea and severe headache for the patient

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Data analyser

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients who are eligible to enter the study are placed in two groups, control and test, by simple randomization at the individual level using the website <http://www.jerrydallal.com/random/randomize.htm>. The research environment is the same for both groups, but the sampling time will be different. It means that when a patient is hospitalised, sampling will be done and when he or she discharged, sampling of another patient will start.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Data is entered in SPSS software in the form of groups 1 and 2. The statistical analyst does not know which is the control group and which is the intervention.

#### Placebo

Not used

#### Assignment

Other

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Imam Khomeini Hospital of Tehran University of Medical Sciences

##### Street address

Tohid sq, Nosrat st

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733171

#### Approval date

2022-11-21, 1401/08/30

#### Ethics committee reference number

IR.TUMS.IKHC.REC.1401.209

## Health conditions studied

### 1

#### Description of health condition studied

Pituitary adenoma

#### ICD-10 code

D35.2

#### ICD-10 code description

Benign neoplasm of pituitary gland

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Before the surgery, one day after entering the post-surgery department and when symptoms have stabilized, three weeks later when going to the clinic for a follow-up visit.

#### Method of measurement

STAI questionnaire for anxiety

### 2

#### Description

Sleep Quality

#### Timepoint

Before the surgery, one day after entering the post-surgery department and when symptoms have stabilized, three weeks later when going to the clinic for a follow-up visit.

#### Method of measurement

PSQI questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: patients suffering from pituitary adenoma who will receive digital storytelling and use it before surgery, after surgery when they came to neurosurgery ward and during hospitalization. Digital storytelling might be given to patients when they hospitalised. Patients can watch this storytelling right before surgery and they can use it when they need help. This storytelling is composed of doctor and nurses guides like; pre op and post op readinneses, adventures of patients who cured and things like diet and excersice after surgery.

#### Category

Treatment - Other

### 2

#### Description

Control group: patients suffering from pituitary adenoma who dont receive digotal storytelling during hospitalization and just receive routin cares and training in ward from nurses and doctors working there. The cares and patient's training will be based on protocols and brochures which are used in hospital.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini hospital

##### Full name of responsible person

Hediyeh Shokraneh

##### Street address

Tohid sq. Nostrat st

##### City

Tehran

##### Province

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##### Postal code

1419733141

##### Phone

+98 21 6119 0000

##### Email

HediyehShokraneh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Pegah Matourypour

#### Street address

Tohid sq, Nosrat st

#### City

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#### Phone

+98 21 6692 7171

#### Email

Matourypour@yahoo.com

#### 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

Pegah Matourypour

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Pegah Matourypour

**Position**

PhD nursing candidate

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hediyeh Shokraneh

**Position**

MS.c Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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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**

There is no additional data

**Study Protocol**

No - There is not 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**

No - There is not 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