Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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 candidated for transsphenoidal surgery

Public title
Effect of digital storytelling on sleep quality and anxiety of patients with pituitary adenoma candidated for transesphenoidal 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 Glascow 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 recieve 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 readinesses, 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 recieve digotal storytelling during hospitalization and just recieve 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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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
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Position
PhD nursing candidate

Latest degree
Master

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Person responsible for updating data

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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