

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The Effect of Benson's Relaxation Technique on Anxiety, Depression and Pain in Patients Undergoing Brain Tumor Surgery Admitted to the Intensive Care Unit

Protocol summary

Study aim

Determining the Effect of Benson's Relaxation Technique on Anxiety, Depression and Pain in Patients Undergoing Brain Tumor Surgery Admitted to the Intensive Care Unit

Design

a clinical trial, with a control group, with a single intervention group, non blinded, simple randomization through even or odd random numbers placed in a sealed envelope, on 74 patients who are candidates for brain tumor surgery

Settings and conduct

The studied population are conscious patients admitted to the Neurosurgery Intensive Care Unit, who are candidates for craniotomy to remove a brain tumor in a non-emergency manner at Hazrat Rasool Akram Hospital in Tehran. Questionnaires, which include demographic characteristics of the patient, Hospital Anxiety and Depression Scale, and Visual Analogue Scale for pain, are completed in three times in the control and intervention groups (20 minutes after relaxation): 1. the evening of the day before the operation 2. Half an hour before the operation 3. 24 hours after the operation

Participants/Inclusion and exclusion criteria

The participants include full conscious patients over the age of 18 who are candidates for elective brain tumor surgery and have the ability to perform relaxation exercises. The non-entry criteria include sensory and motor disorders and a history of anxiety and mental illness.

Intervention groups

In this study, there are two control and intervention groups, the control group receives routine care in the ICU after brain tumor surgery. In the intervention group, in addition to routine care, the Benson's Relaxation Technique is performed in the evening before the operation, one hour before the operation and 24 hours after the operation.

Main outcome variables

Anxiety; Depression; Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240211060957N1**

Registration date: **2024-02-26, 1402/12/07**

Registration timing: **prospective**

Last update: **2024-02-26, 1402/12/07**

Update count: **0**

Registration date

2024-02-26, 1402/12/07

Registrant information

Name

Nayereh Habibi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4475 2664

Email address

nayereh.habibi@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-20, 1403/01/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Benson's Relaxation Technique on Anxiety, Depression and Pain in Patients Undergoing Brain Tumor Surgery Admitted to the Intensive Care Unit

Public title
The Effect of Benson's Relaxation Technique on Anxiety, Depression and Pain in Patients Undergoing Brain Tumor Surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
All brain tumor patients without a history of chemotherapy or radiotherapy who undergo brain tumor surgery for the first time Having the ability to perform relaxation exercises (not having neurological dysfunction in the form of numbness and immobility of organs) Full consciousness (score 15 according to the Glasgow Coma Scale) Not having a tracheal tube Stable vital signs Informed and voluntary consent of the patient
Exclusion criteria:
Having uncontrolled diabetes Having a history of anxiety and psychiatric diseases and taking psychiatric and anti-anxiety drugs Drug addiction

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are placed in the control or test group by a simple random method through even or odd random numbers placed in a sealed envelope.

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
Research Ethics Committees of Shahed University
Street address
Shahed University, facing the holy shrine of Imam Khomeini, Persian Gulf Highway
City
Tehran
Province
Tehran
Postal code
3319118651
Approval date
2024-02-05, 1402/11/16
Ethics committee reference number
IR.SHAHED.REC.1402.116

Health conditions studied

1

Description of health condition studied
Anxiety, Depression, Pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety score in Hospital Anxiety and Depression Scale
Timepoint
The evening of the day before the operation, half an hour before the operation, 24 hours after the operation
Method of measurement
Hospital Anxiety and Depression Scale

2

Description
Depression score in Hospital Anxiety and Depression Scale
Timepoint
The evening of the day before the operation, half an hour before the operation, 24 hours after the operation
Method of measurement
Hospital Anxiety and Depression Scale

3

Description
Pain score on Visual Analog Scale
Timepoint
The evening of the day before the operation, half an hour before the operation, 24 hours after the operation
Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group, in addition to the routine care in the ICU, perform the Benson's Relaxation Technique for 15 minutes in the evening of the day before the operation, one hour before the operation and 24 hours after the operation, under the supervision of the researcher. Benson's Relaxation Technique is taught to the patient as follows: 1- To be placed in a comfortable position in bed. 2- close the eyes slowly. 3- Focus on gradually relaxing the muscles, starting from the soles of the feet and progressing to the face, and keep them relaxed. 4- Inhale through the nose and exhale slowly through the mouth. 5- When he exhales, he should say a pleasant word that calms him down, such as "God" and continue to breathe naturally and easily. 6- Continue these exercises for 15 minutes. 7- After finishing work, sit quietly on the bed for a few minutes with eyes closed and then with eyes open. 8- Do not worry about whether you are successful in achieving a deep level of relaxation or not. Maintain a positive attitude and allow relaxation to occur at its own pace. When intrusive thoughts occur, try to ignore them and return to repeating "God".

Category

Rehabilitation

2

Description

Control group: Patients receive routine care in the ICU and no intervention is performed for the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasool Akram Hospital

Full name of responsible person

Mohsen Nabiuni

Street address

Hazrate Rasool Akram Hospital, Maziar Mansoori Ave., Satar Khan Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shahed University

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

Shahed University

Full name of responsible person

Nayereh HABIBI

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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4th floor, No.12, Behzadi Alley, Yas Town, Koohak Avenue, Golestan Town

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Dissertation and article

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Health researchers

Under which criteria data/document could be used

For doing researches

From where data/document is obtainable

Researcher

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

Sending e-mail documents showing activity in the field of health.

Comments

After collecting the data and analyzing the findings, the publication of the findings will be done by writing a thesis and an article.