Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of mental imagery on delirium and sleep quality of patients in the intensive care unit

Protocol summary

Study aim
The effect of mental imagery on delirium and sleep quality of patients in the intensive care unit

Design
Using four-block blocks, all possible modes for placing the letters A and B in the four-block blocks are considered, which is a total of 6 modes. The sheets are drawn randomly from outside the container and the letters are written on it respectively and the desired sheet is returned to the container. A table of random numbers is also used. Use the envelope in order to keep the information secret

Settings and conduct
In the intervention group, patients' mental imaging is performed by visual, olfactory and auditory methods and preferably for 15 to 20 minutes (nights before going to bed and in the morning after waking up for three days). In the control group, no intervention is performed. Intensive care unit of Baqiyatallah Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 40 years, no cognitive-neurological disorders, having stable hemodynamics and ability to communicate, in case of hearing loss, use of hearing aids Criteria for non-inclusion: patient and family unwillingness to cooperate, severe visual impairment due to eye injuries in the intensive care unit, severe hemodynamic disturbance during the intervention, impaired consciousness in a way that can not communicate, score with RASS (4-to5-)

Intervention groups
Mental imaging in the intervention group by visual, olfactory and auditory methods using short video clips from previous photos of the patient with the help of family, And soothing images with audio file and simultaneous use of fragrance are pleasant. In the control group, questionnaires are completed without intervention.

Main outcome variables
Delirium that is negative with the CAM-ICU tool. Quality of life, 100 with Richard Campbell tools

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200801048261N1**
Registration date: **2021-03-24, 1400/01/04**
Registration timing: **prospective**

Last update: **2021-03-24, 1400/01/04**
Update count: **0**

Registration date
2021-03-24, 1400/01/04

Registrant information

Name
Talieh Fathiniae sangachin

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8840 9345

Email address
taliehfathinia@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-09, 1400/01/20

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of mental imagery on delirium and sleep quality of patients in the intensive care unit

Public title
The effect of mental imagery on delirium and sleep quality

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 40 years No cognitive-neurological disorders Having stable hemodynamics and the ability to communicate Use a hearing aid in case of hearing loss

Exclusion criteria:
The unwillingness of the patient and the family to cooperate Severe visual impairment due to eye injuries in the intensive care unit Severe hemodynamic disturbance during the intervention Impairment of consciousness in a way that it is unable to communicate Score in the review with RSS tool (4- to 5-)

Age
From **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Quadruple blocks Limited envelope Random number table All possible states are considered for placing the letters A and B in the quadruple blocks, which include a total of 6 states. These 6 states are numbered in the quadruple blocks from 1 to 6, and each is noted in separate sheets and placed in a container. Each slice of the sheet is randomly drawn out of the container and the letters are written on it, respectively, and the desired sheet is returned to the container. Use the envelope in order to keep the information secret

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
Medical Ethics Committee (Baqiyatallah Al-Azam Hospital)

Street address
Baqiyatallah Al-Azam Hospital, corner of Sheikh Baha'i, Mulla Sadra Street, Vanak Square.

City
Tehran

Province
Tehran

Postal code
1435915371

Approval date
2021-03-02, 1399/12/12

Ethics committee reference number
IR.BMSU.BAQ.REC.1399.053

Health conditions studied

1

Description of health condition studied
The effect of mental imagery on delirium and sleep quality of patients in the intensive care unit

ICD-10 code
F05

ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
Delirium that is negative with the CAM-ICU tool.

Timepoint
Do the plan for 15 to 20 minutes, preferably (nights before going to bed and in the morning after waking up for three days). Delirium is measured and scored daily for each patient three times a day.

Method of measurement
Confusion Assessment Method For The Intensive Care Unit In Delirium Assessment.

Secondary outcomes

1

Description
Quality of life score

Timepoint
The quality of sleep is measured at the beginning of the study (before the intervention) and after the intervention, in the morning for three days.

Method of measurement
Richard Campbell Instrument in 5-Item Visual Analog Scale (Case)

Intervention groups

1

Description
Intervention group: In the intervention group, mental imaging of patients is performed by visual, olfactory and auditory methods and preferably for 15 to 20 minutes (nights before going to bed and in the morning after waking up for three days).
Category
Prevention

2

Description
Control group: There is no intervention in the control group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Talieh Fathiniaye Sangachin
Street address
Baqiyatallah Al-Azam Hospital, corner of Sheikh Baha'i, Mulla Sadra Street, Vanak Square.
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taliehfathinia@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Seyed Tayeb Moradian
Street address
Baqiyatallah Al-Azam Hospital, corner of Sheikh Baha'i, Mulla Sadra Street, Vanak Square.
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Phone
+98 21 8248 3131
Email
t.moradyan@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Seyed Tayeb Moradian
Position
Dean of the School of Nursing
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Baqiyatallah Al-Azam Hospital, corner of Sheikh Baha'i, Mulla Sadra Street, Vanak Square.
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Fakhreddin Faizi
Position
science Committee
Latest degree
Ph.D.

Other areas of specialty/work
Nursery
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Person responsible for updating data

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Name of organization / entity
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Position
Nurse - Senior Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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