Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Effects of Immersive Virtual Reality on patient anxiety during surgery under regional anesthesia: A randomized clinical trial

Protocol summary

Study aim
This study aimed to examine the effect of immersive virtual reality on the anxiety of patients undergoing regional anesthetic surgery.

Design
parallel group, randomized, single-blind clinical trial

Settings and conduct
The anxiety levels of all patients were measured 4 times: 1. Baseline data were measured 1 day before the scheduled elective surgery in the inpatient ward. 2. During the pre-operation in the pre-operation room. 3. Thirty minutes after the intervention 4. After the surgical procedure was completed The surgeons who reported their satisfaction scores were blinded to the group assignment because the patient was covered by surgical drape. Outcome assessors also blinded to group assignment because anxiety level assessed when the head mounted device has removed from patient.

Participants/Inclusion and exclusion criteria
A total of 30 participants referred to dr Kariadi General Hospital (Indonesia) from October 2021 to December 2021 were enrolled in this randomized, single-blind clinical trial. The patients were divided into VR and control groups (n = 15 in each group). The control group received midazolam (0.02 mg/kg) as premedication. The intervention group received an immersive virtual reality intervention without premedication. The data of anxiety scores were assessed using the Spielberger state-trait anxiety inventory 6.

Intervention groups
Once the regional anesthetic induction was completed, the intervention group received an immersive virtual reality (IVR) intervention using Oculus Quest VR via a head-mounted device and earphones. During the IVR intervention, patients saw meditative 3D videos from Real VR Fishing software and listened to soothing nature sounds for 30 minutes. Every 30 minutes, the patient was given a break for 5 minutes before being given another IVR intervention until the procedure was completed.

Main outcome variables
anxiety score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230219057451N1**
Registration date: **2023-02-21, 1401/12/02**
Registration timing: **retrospective**

Last update: **2023-02-21, 1401/12/02**
Update count: **0**

Registration date
2023-02-21, 1401/12/02

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-14, 1400/07/22

Expected recruitment end date
2022-01-30, 1400/11/10

Actual recruitment start date
2021-10-15, 1400/07/23

Actual recruitment end date
2021-12-30, 1400/10/09
Trial completion date
2021-12-31, 1400/10/10

Scientific title
Effects of Immersive Virtual Reality on patient anxiety during surgery under regional anesthesia: A randomized clinical trial

Public title
Effects of Immersive Virtual Reality on patient anxiety during surgery : A randomized clinical trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Male and female aged 18-50 years Graduated from high school/equivalent American Society of Anesthesiologists (ASA) physical status I-II Patients who are going to have lower abdominal or lower extremity surgery under regional anesthesia combined with spinal epidural neuraxial block No previous surgery history No history of epilepsy, psychiatric disorders, or claustrophobia and having visual acuity > 6/60 Patients with moderate to severe anxiety scores (Spielberger state-trait anxiety inventory [STAI] score > 38)
Exclusion criteria:
Patients with shock or other major anesthetic or surgical complications during the procedure Patients who refused to participate in the study Regional anesthetic needle insertion >2 times VR device (Oculus Quest VR) that is damaged or error during the surgery process Patients who dropped out of this study
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of randomization that we used was simple random sampling procedure. The randomization process was performed using numbers randomized by an internet-based computer program (www.randomization.com). The numbers were placed in a sealed envelope. The sealed envelope was opened when the patient arrived at the pre-operation room; then, the patient asked to take one of the papers containing a number. The intervention was given to the subjects selected through randomization based on number in the sealed envelope. Odd numbers were the intervention group, even numbers were the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
This was single blind clinical trial. The surgeons who reported their satisfaction scores were blinded to the group assignment because the patient was covered with surgical drape. Outcome assessors also blinded to group assignment because anxiety level assessed after the intervention was over, the head mounted device has already removed from patient. So, the outcome assessor didn’t know which one is the intervention group or control group
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Health Research Ethic Committee RSUP dr. Kariadi Semarang
Street address
No. 16, dr Sutomo Street
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Semarang
Postal code
50244
Approval date
2021-10-14, 1400/07/22
Ethics committee reference number
No. 929/EC/KEPK-RSDK/2021

Health conditions studied

1

Description of health condition studied
Healthy Subject
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety score
Timepoint
Before intervention, after intervention, after surgery
Method of measurement
Patient's anxiety measured using Spielberger State-Trait Anxiety Inventory 6 (STAI-6), which is a shortened

version of the original STAI (known as the Indonesian version of STAI)

Secondary outcomes

1

Description
Blood Pressure, Heart Rate, Patient and Surgeon Satisfaction
Timepoint
Blood Pressure and heart rate measured every 10 minutes during the surgical procedure . Patient and Surgeon satisfaction measured after the surgery ended.
Method of measurement
Blood pressure measured using automated sphygmomonometer. Heart rate measured using electrocardiograph. Patient and Surgeon satisfaction measured using questionnaire based on likert scale 1 - 10

Intervention groups

1

Description
Intervention group:
Category
Treatment - Devices

2

Description
Control group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
RSUP dr Kariadi General Hospital
Full name of responsible person
Chandra Hermawan Manapa
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Sponsors / Funding sources

1

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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
Diponegoro University
Proportion provided by this source
100
Public or private sector
Private
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
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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 further information

Study Protocol
No - There is not 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
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