

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

Taufan Pramadika

Name of organization / entity

Diponegoro University

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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

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No. 16, dr Sutomo Street

City

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Postal code

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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 sphygmomanometer. 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

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

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

Diponegoro University

Full name of responsible person

Taufan Pramadika

Position

Student

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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