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The effect of virtual reality on pain and anxiety during treatments for chronic lower back pain

Submission date
09/05/2024

Recruitment status
No longer recruiting

Registration date
21/05/2024

Overall study status
Completed

Last Edited
20/05/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
One of the most common types of pain that people experience worldwide is chronic low back pain (CLBP). Chronic pain patients often turn to procedural pain management despite using all pharmaceutical pain relief options. The impact of virtual reality (VR) on pain and anxiety reduction is controversial. Some studies indicate that using VR significantly reduces these symptoms when compared to regular sedatives. Thus, this study aims to assess and compare the effects of VR distraction technologies versus anesthesia (midazolam)-based sedation among patients with CLBP undergoing painful intervention on pain and anxiety levels.

Who can participate?
Patients aged between 18 and 80 years old who are referred to the pain clinic because they are suffering from non-specific low back pain persisting for more than three months at the Intervention Unit of King Fahad University Hospital in Khobar

What does the study involve?
Patients with CLBP who meet the inclusion criteria will be randomly allocated to either sedation or VR groups. Patients in the sedation group will be given sedative medication (midazolam) while the other group will be given VR glasses to wear during the procedure. Pain, anxiety, comfort, and satisfaction scores will be measured. Hemodynamics will be monitored throughout.

What are the possible benefits and risks of participating?
Participants in the VR group will benefit from not having sedative medications that have known side effects, and instead, they will be distracted from the procedure by wearing VR glasses and watching 3D video clips.

There are minor hazards of using VR glasses including headache, and nausea.

Where is the study run from?
King Fahad University Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
January 2022 to May 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Impact of virtual reality on procedural pain and anxiety in chronic low back pain patients: a quasi-experimental study

Study objectives
The null hypothesis is that VR has no impact on distracting patients and reducing chronic low back pain. The alternative hypothesis: VR has a positive impact on distracting patients and reducing chronic low back pain.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/04/2022, Imam Abdulrahman Bin Faisal University Institutional Review Board (Kingdom of Saudi Arabia, Khobar, 34212, Saudi Arabia; +966559420142; irb@iau.edu.sa), ref: RB-PGS-2022-01-188

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Chronic low back pain

Interventions
This quasi-experimental study design will be conducted at the Intervention Unit of King Fahad University Hospital in Khobar, Saudi Arabia. Between May 2022 and May 2023, chronic low back pain (CLBP) patients meeting the inclusion criteria will enrol in the study. All patients will be randomly allocated to either the sedation (SD) group or the virtual reality (VR) intervention group. A sealed envelope was used for randomization, containing odd and even numbers from 1 to 10. The assigned nurse opened the envelope; odd numbers were set for the VR group and even numbers for the SD group. The nurse then prepared both groups of patients accordingly.

Patients in the SD group will be given sedative medication (2-3 mg intravenous midazolam), while the other group will receive VR glasses. Pain, anxiety, comfort, satisfaction scores, and hemodynamics will be measured in both groups.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
(HTC)-VIVE Flow® glasses

Primary outcome measure
1. Periprocedural pain intensity score measured using the numeric pain scale (with 0 denoting no pain and 10 denoting worst possible pain) before and after the procedure
2. Anxiety measured using the State-Trait Anxiety Inventory (STAI) scale before and after the procedure

Secondary outcome measures
The secondary outcome measures included:
1. Patient comfort measured using a five-point Gloucester Comfort scale, with 1 being the most comfortable and 5 being the most uncomfortable, immediately after the procedure
2. Patient satisfaction measured using a 5-point Likert scale (1 referred to dissatisfied; 2 to less satisfied; 3 to satisfied; 4 for very satisfied; and 5 for completely satisfied) once fully alert patients reach the recovery room after the procedure
3. Hemodynamic parameters: systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), and oxygen saturation (SPO2), measured using by GE Aisys CS2® anesthesia machine throughout the procedure

Overall study start date
23/01/2022

Completion date
25/05/2023

Eligibility

Key inclusion criteria
1. Both males and females were included in the study
2. Patients who had been referred to the pain clinic because they had been suffering from non-specific low back pain persisting for more than three months
3. Patients older than 18 years old
4. American Society of Anesthesiologists (ASA) physical status classification I-III
The ASA physical status classification system is a pre-operative tool that helps anticipate a patient's risks. On a scale of I to VI: I represents healthy patients with minimal risks and VI represents patients who are brain dead and whose organs tend to be donated upon approval.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
30

Total final enrolment
29

Key exclusion criteria
1. Patients aged 17 years old and under
2. Patients who have visual or hearing impairments, dementia, and/or have been diagnosed with epilepsy or balance disorders.

Date of first enrolment
16/04/2022

Date of final enrolment
25/05/2023

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Fahad University Hospital (KFUH)
Khobar city, Saudi Arabia
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Sponsor type
University/education

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ROR
https://ror.org/038cy8j79

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/11/2024

Individual participant data (IPD) sharing plan
The datasets generated during the current study are not expected to be made available due to the privacy of the patients

IPD sharing plan summary
Not expected to be made available