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Virtual reality for chronic low back pain: a mixed-methods feasibility study in the Kingdom of Saudi Arabia

Submission date
09/05/2023

Recruitment status
No longer recruiting

Registration date
11/05/2023

Overall study status
Completed

Last Edited
19/08/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Chronic low back pain (CLBP) is persistent pain in the lower back that lasts more than 12 weeks and has been the leading cause of functional disability for over three decades. Recently, there is growing interest in managing pain using fully immersive virtual reality (VR) technology. The study aims to assess the possibility of delivering fully immersive VR to patients with CLBP, measure its outcomes, investigate its safety, and gather opinions of patients and staff regarding the intervention.

Who can participate?
People with CLBP and healthcare providers

What does the study involve?
The study will be done in two phases. In the first phase, fully immersive VR will be delivered to the participants, and their feedback will be collected using questionnaires. The second phase will involve follow-up interviews with patients and physiotherapists to understand their thoughts on the fully immersive VR treatment. The interviews will be recorded, transcribed, and analyzed using computer software.

What are the possible benefits and risks of participating?
The possible benefits of participating include reducing pain, disability and fear of movement and improving the quality of life resulting from the fully immersive VR treatment. There is minimal risk of experiencing discomfort from wearing the VR goggles or participating in the study, but all necessary precautions will be taken to ensure participant safety.

Where is the study run from?
King Abdulaziz Specialist Hospital (Saudi Arabia)

When is the study starting, and how long is it expected to run for?
October 2021 to September 2023

Who is funding the study?
Taif University (Saudi Arabia)

Who is the main contact?
Fahad Alotibi, fsotibi@tu.edu.sa

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Delivering fully immersive virtual reality as a rehabilitation tool to adult patients with chronic low back pain in the context of the Kingdom of Saudi Arabia: a mixed-methods feasibility study

Study objectives
This research aims to investigate the feasibility, safety, and acceptability of using fully immersive virtual reality (VR) as a rehabilitation intervention for adult patients with chronic low back pain (CLBP), in the Kingdom of Saudi Arabia (KSA). The objectives are to evaluate the feasibility of delivering fully immersive VR interventions to CLBP patients in the KSA context as follows, assess recruitment, retention, and dropout rates, assess treatment compliance and fidelity, assess the completeness of questionnaire data, evaluate the tolerability of fully immersive VR, evaluate the acceptability of delivering fully immersive VR interventions in a population with CLBP and healthcare providers (HCPs) in the KSA context, and identify facilitators and barriers to delivering fully immersive VR intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 28/04/2023, Research Ethics Committee at the Faculty of Medicine and Health Sciences at University of Nottingham (Faculty of Medicine & Health Sciences, Research Ethics Committee c/o Faculty Hub E41, E Floor (nr School of Life Sciences Reception), Medical School, QMC Campus, Nottingham University Hospitals, NG7 2UH, UK; +44 (0)115 951 5559; fmhs-researchethics@nottingham.ac.uk), ref: FMHS 2310-0323

2. Approved 15/03/2023, Local Research and Studies Department at the Directorate of Health Affairs Taif (Al Khalediah, Qurwa, Taif 26521, KSA; +966 (0)12 736 6200; rs-taif@moh.gov.sa), ref: 801

Study design
Mixed-methods explanatory sequential design in a multi-centre uncontrolled pre-intervention post-intervention feasibility trial

Primary study design
Interventional

Study type(s)
Other

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

Interventions
The study will be done in two phases. In the first phase, fully immersive VR using a head-mounted display will be delivered to the 30 participants, and their feedback will be collected using questionnaires. The second phase will involve 12 follow-up interviews with nine patients and three physiotherapists to understand their thoughts on the fully immersive VR treatment. The interviews will be recorded, transcribed, and analyzed using computer software.

Fully Immersive Virtual reality via head-mounted display equipment (Meta Quest 2) with two connected touch controllers (Oculus, Facebook Technologies, LCC, Menlo Park, USA) will be used in this study. The intervention will involve games that may encourage patients with chronic low back pain to perform exercises and stay active. The intervention will be delivered over three 6-minute sessions over 1 week.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 19/09/2023:

1. The recruitment rate is recorded as the rate at which participants will be recruited to participate in 12 weeks
2. The retention rate is assessed by the rate at which participants will complete the outcome assessment within 14 weeks
3. The dropout rate is assessed as the rate for participants who do not follow up resulting in an inability to record outcome measures by 14 weeks
4. Completeness of questionnaire data is recorded as the completion rate of secondary outcomes data up to 14 weeks
5. Treatment compliance is assessed as the rate of participants completing treatment by 13 weeks
6. Treatment fidelity is assessed as the rate for sessions adhered to the fitting standard operating procedure designed for this study by 13 weeks
7. Adverse events are recorded as the participants will be asked to report any adverse events throughout the study
8. The acceptability will be explored with qualitative interviews

9. The facilitators and barriers to implementing fully immersive VR will be explored with qualitative interviews

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Previous primary outcome measure:

1. The recruitment rate is recorded as the rate at which participants will be recruited to participate in 10 weeks
2. The retention rate is assessed by the rate at which participants will complete the outcome assessment within 10 weeks
3. The dropout rate is assessed as the rate for participants who do not follow up resulting in an inability to record outcome measures by 10 weeks
4. Completeness of questionnaire data is recorded as the completion rate of secondary outcomes data up to 11 weeks
5. Treatment compliance is assessed as the rate of participants completing treatment by 10 weeks
6. Treatment fidelity is assessed as the rate for sessions adhered to the fitting standard operating procedure designed for this study by 10 weeks
7. Adverse events are recorded as the participants will be asked to report any adverse events throughout the study
8. The acceptability will be explored with qualitative interviews on weeks 11-12
9. The facilitators and barriers to implementing fully immersive VR will be explored with qualitative interviews in weeks 11-12

Key secondary outcome(s))
The questionnaire completion rate will be tested if they are feasible to be collected, which are as follows:
1. Pain measured using the Numerical Pain Rating Scale (11-NPRS) at baseline and 3-5 days post-intervention
2. Disability measured using the Oswestry Disability Index (ODI) at baseline and 3-5 days post-intervention
3. Kinesiophobia measured using the 17-item Tampa Scale of Kinesiophobia (17-item TSK) at baseline and 3-5 days post-intervention
4. Quality of life measured using the 36-item Short Form Health Survey (SF-36) at baseline and 3-5 days post-intervention

Completion date
22/09/2023

Eligibility

Key inclusion criteria
The inclusion criteria for patients are as follows:
1. Adults with CLBP for more than 12 consecutive weeks
2. Attending physiotherapy clinic for their CLBP
3. Be able to read, write, communicate in Arabic or English, and give consent

The inclusion criteria for HCPs are as follows:
1. Qualified physiotherapists with a minimum of 2 years of experience
2. Worked with patients with CLBP for the past 12 months
3. Be able to communicate in Arabic or English and give consent

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
36

Key exclusion criteria
The exclusion criteria for patients are as follows:
1. Evidence of severe pathological conditions, including neurological, cardiovascular, or musculoskeletal disorders, such as cauda equina, tumours, fractures, and spondyloarthropathies
2. Health conditions that prevent safe participation include but are not limited to seizures, vertigo, blindness, and disorders affecting balance
3. History of spinal or hip surgery
4. Pregnancy
5. Wearing medical devices containing magnets or components emitting radio waves, such as cardiac pacemakers, hearing aids, and defibrillators

Date of first enrolment
29/05/2023

Date of final enrolment
28/08/2023

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Abdulaziz Specialist Hospital
Qurwa
Taif
Saudi Arabia
26521

Study participating centre
King Faisal Medical Complex
Shihar road
Alhadaek
Taif
Saudi Arabia
26514

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
Taif University through the Saudi Arabian Cultural Bureau in London

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The de-anonymised data will be available upon reasonable request from Fahad Alotibi (fahad.alotibi@nottingham.ac.uk). Consent will be obtained from participants for data sharing. The data will be shared 12 months after the PhD thesis submission and will be available for 7 years after the award date of the degree. Data requestors need to sign a data access agreement to access data. Upon publication, the datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes