ISRCTN46681140 https://doi.org/10.1186/ISRCTN46681140

Investigating virtual immersive experiences in the management of chronic pain – the VIPA study

Submission date
10/02/2021

Recruitment status
No longer recruiting

Registration date
22/02/2021

Overall study status
Completed

Last Edited
25/04/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic pain is very common, affecting between 33-50% of the UK population (just under 28 million adults). Despite this, there are not many options for patients to manage their symptoms. Morphine-like drugs are commonly prescribed, but these can cause a range of unwanted side effects, contributing to a lower quality of life. In conditions such as Fibromyalgia Syndrome (FMS), we know that these drugs are not very effective. Non-drug treatments such as graded exercise and psychological therapies are instead recommended. However, the availability of these treatments is varied throughout the UK. It is therefore important to develop accessible non-drug treatments that provide relief from the suffering caused by chronic pain.

Virtual reality (VR) is a modern technology in which a person becomes fully immersed within a 360-degree, computer-generated, three-dimensional, 'virtual' environment. This is achieved through a VR head-mounted display (HMD) and headphones. When a person moves their head, they can see different aspects of the 360-degree environment. The user can also interact with the use of hand controllers. The multisensory, immersive experience created by VR has shown promising results for reducing acute pain and anxiety, but its use is still understudied in chronic pain. At this early stage in the study of this technology, it is important to find the optimum characteristics of the technology when using it for specific chronic pain conditions.

Electroencephalography (EEG) is a technique used to investigate the electrical activity of the brain over time. Studies using EEG have found specific patterns in individuals suffering from chronic pain conditions such as FMS. Additionally, EEG has been used to investigate changes in brain activity during and after VR interventions. EEG can also be used as a tool for neurofeedback, where the user is taught to control elements of their brain's electrical signals (brainwaves). When this is used alongside VR, the user can visualise changes in their electrical signals after seeing various actions presented on screen. This novel technology is called a 'Brain-Computer Interface' (BCI) and has shown promising results when used for rehabilitation.

The VIPA study aims to determine the best characteristics of a VR treatment for patients with chronic pain. The study will specifically look at chronic pain due to FMS or following total knee

replacement surgery. The study team will conduct multiple experiments in two groups of individuals with chronic pain. The experiments will investigate the acceptability and influence on symptoms of different VR technologies, virtual environments, activities, and the use of brain-computer interface. EEG will be used to investigate changes in brain characteristics with VR. The project will use commercially available VR technologies and a VR program that has been co-developed alongside a local digital health company for use in this research.

Who can participate?
Patients aged 18 years or older with a diagnosis of Fibromyalgia Syndrome (FMS) or chronic pain following a total knee replacement (TKR).

What does the study involve?
Four sessions, each focusing on a different aspect of the VR technology will be offered to participants. Individuals can choose to participate in as many of the sessions as they choose. In their first session, participants will be asked to complete a number of questionnaires to provide information about themselves, including their medication and symptoms. Participants will also be asked about their experience of pain and how acceptable they find the VR technology before and after each session.

During session 1, participants will compare their experiences of using four different commercially available VR technologies whilst completing the same interactive activity. The aim of this session is to determine how the different VR technologies influence symptoms of chronic pain and how acceptable participants find the different VR technologies.

During session 2, participants will compare their experiences of two different virtual environments whilst completing the same interactive activity. Data related to the participant's brain activity will be recorded using electroencephalography (EEG) before, during, and after the VR session. The aim of this session is to determine the acceptability, influence on symptoms, and changes in brain activity induced by different virtual environments.

During session 3, participants will compare their experiences of four different interactive activities in VR. EEG data will be recorded before, during, and after the VR session. The aim of this session is to determine the acceptability, influence on symptoms, and changes in brain activity following different interactive VR experiences.

During session 4, participants will complete a VR-based task using a brain-computer interface (BCI) to control actions within the task. EEG will be used as a tool for the BCI and will simultaneously collect data before, during, and after the intervention. The aim of this session is to determine the acceptability, influence on symptoms, and changes in brain activity following a VR-based BCI.

What are the possible benefits and risks of participating?
Other research studies have shown a positive influence on pain with VR, however, the researchers cannot guarantee that taking part in the VIPA study will bring any direct benefits to symptoms.

The risks of VR and EEG are mild overall. The use of VR inherently contributes to a lack of awareness of physical surroundings, which introduces the risk for injury. Participants will remain seated during VR interventions. There is a small risk of VR-induced discomfort including symptoms of sickness, headache, and eyestrain. These effects are usually mild and alleviated quickly following the removal of the VR headset. The use of EEG can occasionally cause minor discomfort due to skin irritation.

Where is the study run from?
The Norwich Medical School based at the University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
From July 2018 to September 2021 (updated 10/05/2021, previously: June 2021)

Who is funding the study?
British Society of Rheumatology (BSR), Action Arthritis Charity (UK), Orbital Media (UK), and Norwich Academic Training Office (UK)

Who is the main contact?
Dr Jordan Tsigarides, j.tsigarides@uea.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
271209

Central Portfolio Management System (CPMS)
45066

Study information

Scientific Title
Investigating Virtual Immersive experiences in the management of chronic widespread PAin – the VIPA study

Acronym

VIPA

Study objectives
1. To determine the optimal characteristics of a VR intervention in two cohorts of patients with chronic pain
2. To determine how feasible it would be to conduct a larger clinical trial in the future by investigating acceptability and influence on symptoms of the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/06/2020, South West – Cornwall & Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)207 104 8019; cornwallandplymouth.rec@hra.nhs.uk), ref: 20/SW/0050

Primary study design
Interventional

Study design
Non-randomized interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fibromyalgia syndrome, chronic widespread pain

Interventions
Currently, there are few studies investigating the use of virtual reality (VR) in a chronic pain setting. The studies that have been published include participants with a range of different chronic pain conditions, all with different types of pain and mechanisms underlying. Because of this, there are no 'gold standard' guidelines for the development of a VR program, and the types of programs used in the current literature are vastly different from each other.

The study team has co-developed a new VR program alongside a digital health company (Orbital Media) to be used in people with chronic pain. This new VR program has not previously been used in a research or commercial setting and has not previously been studied in people with Fibromyalgia Syndrome (FMS). Similarly, to the best knowledge of the study team, this research will be one of the first to investigate the use of a brain-computer interface (BCI) for this group of patients.

When creating innovative solutions like these for use in clinical practice, it is important that firstly an iterative process of development is followed. This should be informed by extensive feasibility and pilot data to address the acceptability and influence on pain of the different VR characteristics, including the technologies, environments, activities, and controller mechanism. Only following this, can a thorough process of well-designed, robust, large-scale clinical trials be conducted to determine the intervention's efficacy and utility in everyday practice.

The virtual reality (VR) lab will be at the University of East Anglia and participants will be recruited directly from rheumatology and pain management clinics at the Norfolk & Norwich

University Hospital and Addenbrookes University Hospital. Clinicians will be informed about this feasibility study and will identify patients with a diagnosis of Fibromyalgia Syndrome (FMS). These individuals will be given an invitation letter and participant information sheet (PIS). The PIS will contain comprehensive information on the study and will state the inclusion/exclusion criteria clearly. Individuals will declare interest in participation by returning the completed reply slip located at the bottom of the invitation letter. This reply slip will ask the individual for their name and contact details so that the research team can contact them to inform them of dates /times of experiments that would be suitable. The reply slip will also ask the individuals to select which of the four experiments they would be interested in attending. Upon receipt of an interested individual's reply slip, a member of the research team will contact the individual using the contact details provided. At this point, the research team will answer any questions that the individual has regarding the study and will confirm their interest in participation. The research team will also confirm that the potential participant satisfies the inclusion/exclusion criteria and confirm which of the four experiments they would like to participate in. They may participate in each of the experiments only once, but may participate in all four of the experiments should they wish. If choosing to be involved in experiments 2-4 (with qEEG), participants will be sent an information document on how to prepare for these experiments. Individuals that confirm their interest and satisfy the inclusion/exclusion criteria for participation will be offered dates/times to attend the experiment(s) that they are interested in. PICs will not be involved in directly collecting data or gaining consent.

All of the experiments will be conducted at the VR lab. At the beginning of the first experiment that participants attend, they will be asked to complete and sign a consent form. This will be witnessed and countersigned by one of the research team who will also answer any questions and provide access to the PIS if requested. Participants will then be asked to complete a baseline questionnaire. The intention of this questionnaire is to collect data on the participants to confirm their eligibility for the experiments and to provide relevant data to inform the subsequent data analysis. Completed baseline questionnaires will be screened by the research team to ensure the satisfaction of the inclusion/exclusion criteria prior to the intervention. Following this, participants will be asked to complete the following questionnaires:

1. McGill Pain Questionnaire (Short Form)
2. Pain Visual Analogue Scale (VAS
3. Widespread Pain Index (WPI)
4. Symptom Severity Scale (SSS)
5. Revised Fibromyalgia Impact Questionnaire (FIQR)
6. The Patient Health Questionnaire 9 (PHQ-9)
7. The Generalised Anxiety Disorder Assessment (GAD-7)

Additionally, at the beginning of each experimental session, participants will receive a safety briefing and an explanation/tutorial for each of the pieces of equipment being used in the experiment.

Experiment 1 will be used to investigate the acceptability of the different VR technologies. Participants will use four different types of VR technology (Samsung Gear VR, Oculus Go, Oculus Quest, and Oculus Rift) to complete the same cognitive task. Following the use of each piece of VR technology, participants will be asked to complete a short questionnaire about their experiences of using the technology. Additionally, after using all of the pieces of technology, participants will be asked to complete a final questionnaire asking them to compare them.

Experiment 2 will be used to investigate the influence of different VR environments on pain and acceptability. Participants will use the same piece of VR technology to complete the same cognitive task in two different VR environments. Participants will also wear an electroencephalography system (EEG) with data being collected before, during and after using

the VR technology. Participants will be asked to complete multiple pain VAS scores at different stages of the experiment. They will also be asked to complete a small number of questions whilst using the VR technology (between environments), as well as a questionnaire about their experience of each environment.

Experiment 3 will be used to investigate the influence of different cognitive tasks completed in VR on pain and acceptability. Participants will use the same piece of VR technology to complete four different cognitive tasks. These cognitive tasks will be completed in the same VR environment. Similar to Experiment 2, EEG data will also be collected before, during, and after using the VR technology. Multiple pain VAS scores will be completed at different points throughout the experiment. They will also be asked to complete a small number of questions between tasks, followed by a questionnaire about their experiences at the end of the experiment.

Experiment 4 will be used to investigate the influence of a Brain Computer Interface (BCI) on pain and acceptability. Participants will use the same piece of VR technology to complete one cognitive task using the BCI system. Initially, participants will be receive a 'training period' where they will have the opportunity to practice using their 'brain-waves' to control elements of a computer program. They will then use the VR/BCI system to complete one of the cognitive tasks using their 'brain-waves' to trigger actions in the task (instead of using the physical trigger on a handheld controller). EEG data will be collected before, during and after using the VR technology. At the end of the experiment, participants will complete a questionnaire to share their experiences of using the BCI/VR system.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
VR program

Primary outcome(s)
Acceptability measured using post-intervention subjective experience questionnaires including the simulator sickness questionnaire post-intervention within each experiment

Key secondary outcome(s)
1. Pain measured using the visual analogue score (VAS) and McGill Pain Questionnaire Short Form (MPQ-SF) at baseline and post-intervention within each experiment
2. Electroencephalogram (EEG) characteristics measured using EEG immediately pre-intervention (2 minutes resting-state eyes closed, 2 minutes resting-state eyes open), during the VR activity, after each VR activity (2 minutes resting state), and immediately post-intervention (2 minutes resting-state eyes closed, 2 minutes resting-state eyes open) within experiments 2, 3 and 4

Completion date
01/09/2021

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Ability to communicate using conversational English and has the capacity to consent
3. Confirmed diagnosis of Fibromyalgia Syndrome (FMS) or chronic pain following a total knee replacement
4. Current chronic widespread pain for ≥3 months preceding recruitment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Any co-morbid condition that is exacerbated by exposure to flashing lights or screens
2. Diagnosis of cognitive impairment
3. Current visual or hearing impairment that would prevent the participant from using the technology included in the experiments

Date of first enrolment
01/10/2020

Date of final enrolment
01/06/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of East Anglia
Norwich Medical School
University Drive
Norwich

United Kingdom
NR4 7TJ

Sponsor information

Organisation
University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
British Society for Rheumatology

Alternative Name(s)
BSR

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
Orbital Media And Advertising Limited

Funder Name
Action Arthritis

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/01/2025	25/04/2025	Yes	No
HRA research summary			28/06/2023	No	No