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# Home-based virtual reality for help with symptoms of multiple sclerosis

**Submission date**
02/02/2022

**Recruitment status**
No longer recruiting

**Registration date**
04/02/2022

**Overall study status**
Completed

**Last Edited**
06/02/2024

**Condition category**
Nervous System Diseases

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

## Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a condition that can affect the brain and spinal cord. People with (MS often struggle as much with “hidden symptoms” of MS as with more “visible” symptoms (e.g. difficulty walking; speech difficulties). HSMS include fatigue, pain, depression, poor sleep and anxiety. Treating HSMS can be challenging. Medicines can help mood and pain, but may worsen fatigue and have side effects. Non-drug treatments including relaxation, mindfulness and exercise may be helpful but can be difficult for patients to access. There is a need for new effective strategies to help patients manage their symptoms which are engaging, effective, acceptable and accessible. Virtual reality (VR) provides an immersive escape into new environments and experiences which would not otherwise be accessible. This can help to relax and distract from unpleasant symptoms. This is an initial feasibility study to explore the home use of VR for symptom management by people with MS.

Who can participate?
Patients aged 18 years or over with progressive MS and at least one hidden symptom of MS

What does the study involve?
Participants are randomly divided into two groups of five. The first group will be provided with a simple VR headset at home. They can use it to try activities like swimming with dolphins, watching the sunrise at the beach or guided meditation and mindfulness. The second group will be provided with access to pre-recorded audio-guided meditation and relaxation sessions. Both groups will use the equipment at least three times per week for 6 weeks. Participants will be asked about their symptoms before the study starts, halfway through, at the end of 6 weeks and 1 month after the study to look for longer-lasting effects. The researchers will look at how the study was delivered, how easy it was to recruit participants, and how many dropped out. They will ask participants about their experiences and how the study could be improved. They will use their findings to design a larger trial to study the effects of VR on HSMS.

What are the possible benefits and risks of participating?
The researchers can’t promise that taking part in this study will help. It is hoped that both of the interventions may help participants to feel more relaxed and that this may help with some of the symptoms commonly seen in MS, including fatigue, pain, depression and anxiety. However, the

researchers cannot guarantee that this will happen. They are interested in finding out whether the interventions have any effect on the symptoms that can occur with MS, especially pain, and they are hoping that the results of this study will help them to go on to develop a much larger trial where they can gather more information. Particiants may find that they can't get on with the VR headset or with the MP3 player. They may find that they get bored of using them, or they don't like the programmes. Some people can find the VR headset makes them feel claustrophobic or uncomfortable, or they can feel sick (like motion sickness). Some people can find being asked about their mood or their symptoms can make them feel worse.

Where is the study run from?
University Hospitals of Derby and Burton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2019 to May 2023

Who is funding the study?
British Society of Rehabilitation Medicine (UK)

Who is the main contact?
Dr Laura Edwards
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Laura Edwards

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
272595

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 49253, IRAS 272595

# Study information

### Scientific Title
A feasibility study of virtual reality relaxation for treating hidden symptoms in people with progressive multiple sclerosis

### Acronym
IDYLL

### Study objectives
It is feasible to deliver a trial of home-based virtual reality to improve pain and other hidden symptoms in people with multiple sclerosis.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 07/06/2021, London - Surrey Research Ethics Committee (Nottingham Centre, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8372; surrey.rec@hra.nhs.uk), REC ref: 21/LO/0353

### Study design
Randomized; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Rehabilitation, Other

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Home

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

### Health condition(s) or problem(s) studied
Multiple sclerosis

## Interventions
Randomization: simple randomization via an online system

Intervention:
5 participants will attend a brief training and education session to become familiarised with the VR headset and its use (facilitated remotely if required). They will be provided with their own headset which is pre-loaded with an 8-week programme, consisting of 56 modules designed to support people with chronic pain with 56 different VR experiences to educate, relax, distract and empower them (EaseVRx). AppliedVR's headset has been specifically designed to be user-friendly, lightweight and to be used by people with restricted mobility, which is particularly appealing for our patient population.

On average, the VR experiences last for 7 minutes (range 2-15 minutes). The 8-week programme is designed to be worked through sequentially, with weekly themes including "The Mind and Pain Relief" (week 2); "Relaxation" (week 4) and "Journey to Wellness" (week 8). It is designed for one session to be delivered each day, and once one session has completed, the next session automatically appears for the user. On-demand content is also available if the user wishes to have extra sessions. It is anticipated that the different experiences may be attractive to different individuals and will explore this in our qualitative work.

Once participants (with carers if required) are confident and comfortable using the headset, they will be asked to use it at home on a daily basis (no upper limit on use) and to record when they used it. If they choose to use extra "on-demand" experiences, the researchers will ask them to record which experience they chose each time. After 8 weeks, the headset will be returned to the investigators.

Control:
5 participants will attend a training and education session led by a Clinical Neuropsychologist in relaxation techniques (facilitated remotely if required). They will be provided with an MP3 player containing 40 pre-recorded audio relaxation guides, around 10 minutes duration each. Participants will be asked to use the relaxation programmes daily for the next 8 weeks (more frequently if preferred) and to record when they used the programmes. After 8 weeks, the MP3 player will be returned to the investigators.

The choice of control was based upon the provision of relaxation/distraction but without the immersive 3D nature of VR. The researchers felt it was important to have a control which "delivered" an intervention, could be self-directed, and could be delivered in the form of a gadget or technology.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
-

## Primary outcome measure
Feasibility:
1. Recruitment assessed by meeting the recruitment target of 10 participants at 10 weeks from

study recruitment opening
2. Retention: rates of drop-out assessed by simple counting at 4, 8 and 12 weeks from randomisation.
3. Study delivery: provision of sufficient reliably-working headsets which are easy for PwMS to don, doff and use, based on participant/carer report at each timepoint and by participant-generated feedback in-between timepoints as required.
4. Reliability of use: assessed using the frequency of use recorded by the VR headset and participant reports, and compliance assessed with participant interviews at 4, 8 and 12 weeks

The feasibility of conducting an incremental cost-effectiveness analysis alongside a full RCT of the home-based VR intervention over and above the control, assessed by collecting basic health service utilisation data from patients with respect to contacts with primary and secondary health care and social services at 4, 8 and 12 weeks.

## Secondary outcome measures

MS-related outcomes:
Participants will complete questionnaires/intervention details as at baseline at the end of weeks 3 and 6 (see below for details of questionnaires). There will be a further set of follow-up questionnaires 1 month after the intervention period ends. Questionnaires can be completed by the participant, by the participant and carer together, or by the participant (with or without carer) with the investigator via telephone, online or in person to try to minimise drop-out and non-completion due to questionnaire burden.
1. Pain measured using the Wong-Baker FACES Pain Rating Scale
2. Quality of life measured using the Leeds MS QoL
3. Fatigue measured using the Fatigue Severity Scale (FSS)
4. Well-being measured using Coop/Woncacharts
5. Sleep measured using the Athens Insomnia Scale
6. Overall MS symptoms measured using the Multiple Sclerosis Impact Scale (MSIS-29)
7. Health status measured using EQ-5D-5L for informing health economics analysis

Qualitative outcomes:
Participants in each arm will be invited to take part in a more in-depth user experience study at the beginning of the study. This will include real-time user observation of the VR/relaxation programme with opportunistic questioning and in-depth qualitative interviews to explore the experience of using the interventions, barriers or facilitators to use, and any changes that they would recommend for future work.
If participants have partners/carers/family members who are willing to participate, the researchers will ask about their experiences of the study and intervention. There are many facets of wellbeing and QoL in MS that will not map onto the selected questionnaires. The researchers will therefore examine issues identified and described by our participants as being important to their experiences. They will seek participant feedback regarding outcome measures.

Health economics outcomes:
The feasibility of conducting an incremental cost-effectiveness analysis alongside a full RCT of the home-based VR intervention over and above the control, assessed by collecting basic health service utilisation data from patients with respect to contacts with primary and secondary health care and social services

## Overall study start date

03/09/2019

### Completion date
31/05/2023

# Eligibility

### Key inclusion criteria
1. Progressive multiple sclerosis (PMS) (primary or secondary) (OR friend/relative/carer of a person with PMS)
2. Aged 18 years or over
3. Capable of giving informed consent
4. Participant able to don and doff headset and/or indicate wish for headset to be donned and doffed
5. At least one hidden symptom of MS (HSMS)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 10; UK Sample Size: 10

### Total final enrolment
10

### Key exclusion criteria
1. Psychotic symptoms (delusions/hallucinations)
2. History of seizures/motion sickness
3. Unable to wear headset
4. Unable to complete outcome measures (including with assistance)
5. Unable to view VR
6. Unable to hear relaxation recordings
7. Recurrent ear infections or blockages (may make use of headphones with MP3 player uncomfortable or difficult)

### Date of first enrolment
04/10/2021

### Date of final enrolment
30/09/2022

# Locations

### Countries of recruitment
United Kingdom

### Study participating centre
**Florence Nightingale Community Hospital**
London Road
Derby
United Kingdom
DE1 2QY

## Sponsor information

### Organisation
University Hospitals of Derby and Burton NHS Foundation Trust

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### Sponsor type
Hospital/treatment centre

### Website
https://www.uhdb.nhs.uk/

### ROR
https://ror.org/04w8sxm43

## Funder(s)

### Funder type
Charity

### Funder Name
British Society of Rehabilitation Medicine

# Results and Publications

## Publication and dissemination plan
Data will be presented at the British Society for Rehabilitation Medicine annual meeting. Planned publication in a peer-reviewed journal.

## Intention to publish date
05/08/2023

## Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary
Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Basic results | | 06/02/2024 | 06/02/2024 | No | No |