SPIN-VR Participant Information Sheet (PIS)

SHORT TITLE: Sensor-based physiotherapy intervention with virtual reality (SPIN-VR)

FULL TITLE: A randomised feasibility study to evaluate the home-based personalised virtual reality physiotherapy rehabilitation compared to usual care in the treatment of pain for people with knee osteoarthritis.

Chief Investigator: Dr Mohammad Al-Amri, Cardiff University

Introduction

We would like to invite you to take part in a research study. Joining the study is your choice. We want you to understand why the research is being done and what it involves before you decide. We want you to have all the information you need to help you decide whether you would like to take part, and to answer any questions you may have.

Please read the following information. If you want, you can discuss this with friends and family and ask any questions you have.

The information sheet explains the purpose of the research study and what will happen if you decide to take part. You will have time to decide whether you want to take part and, if you choose to take part, you will be invited to a research clinic where you will be asked to sign a consent form, and complete some assessments.

If you choose to take part, we will ask you to sign a consent form. By signing the consent form, you are telling us that you:

- Understand what you have read
- Consent to take part in the study
- Consent to the use of your data as described.

Thank you for reading this.

What is the purpose of this research study?

Osteoarthritis (OA) is a common problem that causes pain and trouble moving in the knees and hips. Patients are often encouraged to do physiotherapy exercises to help manage their knee pain and other symptoms. Studies show that doing these exercises at home can be as helpful as doing them in a clinic. Using new technology like virtual reality (VR) could be a way of helping people carry out their physiotherapy exercises at home. Virtual reality can include technologies such as movement sensors which are worn on a person's body that move an animated character on a computer screen so that the character follows the person's body movements.

We want to see if using virtual reality technology helps people with knee osteoarthritis to do their physiotherapy exercises in their own home, and to compare this to standard physiotherapy without virtual reality. We want to know whether people do the exercises better and more often with the help of a virtual reality system. To do this, we first need to carry out this initial small study to find out whether a full study will be possible.

The home-based virtual reality system

The virtual reality system connects to a laptop and the laptop can be connected to your TV if you wish. Painless sensors are then placed on your arms and legs (using straps on top of your clothing). The laptop detects the sensors and you will see an animated character on the TV or laptop screen. When you move your arms and legs, the animated character will also move on the screen. We will show you exactly how to set up and use the virtual reality system.

You will play games using the virtual reality system where you control a character on the screen by moving your arms and legs. The exercises you carry out using the virtual reality system will mimic the types of usual exercises you will have been asked to do by a physiotherapist. At the end of the game, you get a score based on how well you did. The better you do at the game, the harder the game will get.

Why have I been invited to take part in this research study?

You have been invited to take part in this study because you have pain in your knees due to osteoarthritis and your physiotherapist thinks you are suitable for the study. Other participants in this study will all have knee osteoarthritis like you.

Do I have to take part?

You can choose to join the study or not. If you do, you'll get this sheet to keep and we'll ask you to sign a consent form. You can leave the study any time, without giving an explanation. We will keep any data we have collected up until you decided to leave. If you do not want to take part, that's okay, it will not change your care in any way.

What will taking part involve?

Before your treatment

We will invite you to a Cardiff University research clinic at the Heath Park Campus (near the University Hospital of Wales) where a researcher will ask you to sign a consent form. They will take some basic details from you and conduct some tests. These tests will assess your osteoarthritis symptoms and how functional your knees are. There will also be some questionnaires that you will be asked to complete. These will ask how you're feeling emotionally and physically, as well as ask you about how well you function in day-to-day life.

We will put you into one of two groups. To do this, the researcher will take some details from you (which are not possible to identify you with). They will use these to run a computer programme that will put you into one of the two groups by random chance. Like flipping a coin.

1) Half of the participants will be given some standard physiotherapy exercises to do at home for 12 weeks.
2) Half of the participants will be given the home-based virtual reality system to set up at home. They will then use the system for 12 weeks.

We will assign you to a group by chance. Neither you nor the researcher can choose which group you will be in. You will have an equal chance of receiving the possible advantages or disadvantages of each group.

During your treatment

If you are allocated to the standard physiotherapy group…

you will learn some exercises and a daily routine from a physiotherapist (either remotely or in a face to face clinic). They will give you some resources on performing these exercises. Then, you will do the exercises at home for 12 weeks. You will attend the physiotherapy clinics another 4 times over the 12 weeks to review your progress (either remotely or in a face to face clinic).

If you are allocated to the virtual reality group…

a researcher from our team will guide you through the process of using the virtual reality system. You will be provided with a laptop and sensors, and any additional kit required to set up the virtual reality system. We will show you how to attach the sensors to your arms and legs using straps that go over your clothing. We will show you how to connect the sensors to the laptop and start the virtual reality games on the laptop. If you prefer, you have the choice to connect the laptop to your TV and enjoy the games on a larger screen. However this is optional, and the games can be played on the laptop. The laptop will need to connect to the internet. If you do not have internet at home, we will provide you with a stick that plugs into the laptop and can provide internet. When you are comfortable using the equipment, you will be given this equipment in a bag to take home.

You will play the exercise games on the virtual reality system **3 days of the week, for 12 weeks**. If you have any problems setting up the equipment at home, there will be a number you can call to speak with a researcher. They will be able to help you with the setting up of the equipment. As you complete the virtual reality games, your progress will be sent to a researcher to review. Over the 12 weeks, you will have two opportunities to attend a clinic with a physiotherapist to discuss how your treatment is going.

After your treatment

At the end of the 12 weeks of treatment, we will invite you back to the research clinic. We will perform the same tests and give you the same questionnaires that you did at the first visit. If you were in the virtual reality group, we will ask you to bring the equipment back.

24 weeks after you finish the treatment, we will invite you back to another research clinic. Here we will perform the same tests as before along with the same questionnaires.

Patient interviews

We will be asking patients that were part of the home-based virtual reality group if they would be happy to be interviewed by a researcher, after they have completed their treatment. The interview will ask you questions about how you felt about using the virtual reality, and your involvement in this research study. This interview is optional, and you can do the rest of the study without also doing an interview. We will ask you when you consent to the rest of the study if you're happy to also do an interview. We will also ask if we can anonymously quote what you say ('word for word'/verbatim) during the interview in any publications. The interview will be done remotely over a video call on the internet with a Cardiff University researcher. Your video image will not be retained after the interview, nor will it be shared with anyone outside Cardiff University. You can choose to turn your camera off if you would prefer not to be video-recorded during the interview. We will record the audio of the interview, and it will be sent to an approved company to be transcribed. You will not be identified by name in the recording. Once the audio has been transcribed, it will be deleted by the approved transcription company's database. A copy of the interview audio and the transcription will be stored securely and anonymously on Cardiff University servers. At the end of the study, the audio recordings will be deleted, and the transcriptions will be archived with the rest of the study.

What are the risks of taking part in the research study?

There is little risk of taking part in this research study. The exercises we will ask you to perform in both groups are standard exercises. Physiotherapists use them already in standard knee osteoarthritis treatment.

We will ask you some personal questions about how you are feeling and ask you to complete some questionnaires that you may find inconvenient, but they should not be distressing.

There is a chance that you won't like or be able to use the virtual reality system at home. This is not a problem, and we want to know how acceptable you find it as it is an important part of this study. We will give you as much support as you need.

What are the possible benefits of taking part in the research study?

We hope that participants in both groups will benefit from the physiotherapy exercises. We currently don't know if there is any benefit to using the virtual reality system. The information collected in the research study will help researchers decide if a larger study is possible. A larger study will gather evidence to find out if the virtual reality system works to help participants do their physiotherapy exercises.

You will also receive vouchers for completing the study. You will receive a £20 voucher for each of the assessments you complete (baseline, 12-week, and 24-week). You will also receive a £20 voucher for completing the treatment, regardless of which treatment you are given. If you complete the entire study, you will receive a total of £80 in vouchers. Additionally, you will receive a £25 voucher if you decide to be interviewed.

What if something goes wrong?

If you wish to make a complaint, or have grounds for concerns about any aspect of the manner in which you have been approached or treated during the course of this research, please contact the Research team via phone +44 (029)20 68 7115 or e-mail Al-AmriM@cardiff.ac.uk. If your complaint is not managed to your satisfaction, please contact Jennifer Davies at daviesj@cardiff.ac.uk. When contacting, please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make.

You can also seek independent advice about anything from Cardiff & Vale University Health Board's Patient Advice and Liaison Service (PALS).

Email: concerns@wales.nhs.uk

Telephone: 029 2074 4095 / 029 2074 3301

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action, but you may have to pay for it.

Will my taking part in this research project be kept confidential?

All information collected from or about you during the research project will be kept strictly confidential and any personal information you provide will be managed in accordance with data protection legislation. If you consent to take part in the research study, your medical records may be inspected by researchers from

CEDAR (Cardiff & Vale University Health Board), the Sponsor organisation (Cardiff University), or by people from regulatory authorities, to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site.

Information collected about you may be shared with other researchers in the future to support further research, but we will make sure that it does not contain any information which can be used to identify you. It is intended that the results of this study will be presented at medical conferences and published in medical journals. Any information which is made public will be completely anonymous and you will not be identified.

With your permission, we will contact your GP to inform them of any unforeseen medical issues or findings relevant to your ongoing health and treatment, which may be discovered during the course of the research.

How will we use information about you?

We will need to use information from you and from your medical records for this research project. This information will include your:

- Name;
- Initials;
- NHS number;
- Contact details;
- Information relating to your health, osteoarthritis diagnosis and treatment.

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- by asking one of the research team
- by viewing the Cardiff University Data Protection Policy: www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection
- by contacting the University's Data Protection Officer by email: inforequest@cardiff.ac.uk or in writing to: Data Protection Officer, Compliance and Risk, University Secretary's Office, Cardiff University, McKenzie House, 30-36 Newport Road, Cardiff CF24 0DE

Who is organising and funding the research?

The money to enable this research is coming from a charity called Versus Arthritis. They will not be able to find out who took part in the study. It is being organised and Sponsored by Cardiff University. The study is being managed by CEDAR (Centre for Healthcare Evaluation, Device Assessment and Research), an NHS department in Cardiff & Vale University Health Board.

What happens to the data at the end of the research study?

All the research data will be stored on Cardiff University password protected servers for 15 years from the end of the study. All electronic data will be stored on secure University IT systems with password protected documents backed up after each participant entry. All electronic data will be entered onto a University Drive which is a secured server only accessible by named individuals and password protected. Regular backups of the electronic data will be performed after each entry. We will write a report which shows the findings of the workshop, and we will publish this.

What will happen to the results of the research study?

The information that we collect from people taking part in this research study (without any personal information which could be used to identify you) will be used to decide whether it is possible to carry out a larger study on VR-based home physiotherapy compared to usual physiotherapy for people with knee OA. We will write a report which shows the findings of the study, and it is our intention to publish the results of this study in academic journals and present findings at conferences. Participants will not be identified in any report, publication, or presentation. We will also put a summary of the results on the CEDAR website (http://www.cedar.wales.nhs.uk/) and the SPIN Research Group webpage (The Sensor Physiotherapy Intervention (SPIN) Research Group - Research - Cardiff University).

We will also produce lay summaries to disseminate findings to all participants. If you would like a copy of the findings, please contact the Chief Investigator, Dr Mohammad Al-Amri (Al-AmriM@cardiff.ac.uk), who will be happy to send you these.

Who has reviewed this research study?

All research in the NHS is reviewed by an independent committee called an NHS Research Ethics Committee. This research project has been reviewed and given a favourable opinion by Wales REC 3.

Further information and contact details

Should you have any questions, comments or problems relating to this research study, please feel free to contact the individuals below.

Advice as to whether you should participate in the research study:

If you wish, please feel free to discuss your possible involvement with your GP, family members and friends or any person you feel would give you impartial advice and support.

Who to approach with any questions about this research study:

If you have any questions or concerns about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions:

Chief investigator:	**Dr Mohammad Al-Amri** Senior Research Fellow, Cardiff University **Telephone**: 02920 687 115 **Email**: al-amrim@cardiff.ac.uk
Other Investigators:	**Dr Judith White** Principal Researcher, CEDAR **Telephone**: 02921 841 599 **Email**: Judith.White3@wales.nhs.uk **Samuel Bird** Senior Researcher, CEDAR **Telephone**: 02921 848 692 **Email**: Samuel.Bird2@wales.nhs.uk **Dr Kate Button** Head of Research and Innovation, School of Healthcare Sciences, Cardiff University **Telephone**: 02920 687 734 **Email**: ButtonK@cardiff.ac.uk
CEDAR Office:	**CEDAR** Cardiff & Vale University Health Board, Cardiff Medicentre, Heath Park, Cardiff, CF14 4UJ **Email:** uhw.Cedar@wales.nhs.uk **Tel:** 02921 844771 **Website:** www.cedar.nhs.wales

You will be given a copy of this Information Sheet and your signed consent form to keep.

Thank you for considering taking part and taking the time to read this participant information sheet.