

Participant Information Sheet

Orthotic management of instability of the knee in neuromuscular disease

I would like to invite you to take part in this study. Before you decide whether to do so it is important for you to understand why it is being done and what it will involve. Please read the following information carefully and discuss it with others if you wish.

What is the purpose of this study?

This study will compile information about the types of orthotic devices that are currently being used within the NHS for the management of knee instability due to neuromuscular disease and central nervous system disorders. We are trying to find out what orthotic devices are being used for patients with different conditions, the frequency of their use and the resources required to provide them to patients. This information will be used to inform a survey which we intend to send out to orthotists and physiotherapists who fit orthotic devices

Who is doing the study?

The study, commissioned by the National Institute of Health Research, is being led by Dr Catriona McDaid, a senior researcher at the Department of Health Sciences at the University of York. This focus group and the subsequent survey of health care professionals are being undertaken by Joanne O'Connor, a researcher at the Centre for Reviews and Dissemination at the University of York. A second researcher, experienced in facilitating focus groups will also be involved to assist with the work.

Why have I been asked to participate?

You have been invited to participate in this focus group because you are a health care professional who fits or is involved with fitting orthotic devices.

Do I have to take part?

The decision to take part in this study is entirely voluntary. You do not have to take part if you do not want to.

What will be involved if I take part in this study?

If you confirm you would like to take part in the study, and you are able to attend on the date and time given, you will be asked to confirm your name, preferred method of contact (email/telephone/post) and to give some brief details about your area of professional expertise. When you attend for the focus group discussion, there will be 5 to 7 other people present and two facilitators. A digital audio recording will be taken of the group discussion for later transcription. The session will last no longer than 90 minutes.

What are the advantages and disadvantages of taking part?

By taking part in the study you will be helping us to understand more about the use of orthotics devices within the NHS. We will use that information to inform the survey of health care professionals as well as inform our study's report on use of orthotic devices within the NHS, and what further research is required.

Participation will involve attending a focus group and giving up approximately 90 minutes of your time.

We will cover reasonable travel expenses and refreshments will be provided.

Can I withdraw from the study at any time?

You are free to withdraw from the study at any time without giving a reason. If you choose to withdraw from the study during the focus group, any information you have already provided during the discussion would still be used.

Will the information I give be kept confidential?

The information that you give us and anything you say in the focus group will be treated in the strictest confidence. Only the research team will have access to your personal data (this will be limited to your name, contact details, your special area of expertise or interest and the focus group you are in).

The focus group transcripts will be stored securely and will not include any of your personal details. With your permission the focus groups will be digitally audio recorded so that they can be accurately transcribed. In the focus group transcripts you will be given a pseudonym so you cannot be identified; any other potentially identifying features will be removed. The digital recordings will be permanently erased once they have been transcribed and the transcripts will be stored securely for five years after which time they will be destroyed.

All data will be stored in a secure and locked location in accordance with data protection requirements and all information collected about you during the study will be stored securely in a locked office and on a password protected computer. The information will be destroyed after five years.

What will happen to the results of the study?

The results of the focus groups will be used to inform the questions asked within a survey of health professionals. The results may be reported in the final report which will be submitted to the funders. The results may also be reported in academic journals and during conference proceedings. No individual will be able to be identified from details in any reports, papers or presentations that come out of the study.

Who has reviewed this study?

This study has been reviewed and approved by the Department of Health Sciences Research Governance Committee (HSRGC), University of York, 19th May 2014.

If you agree to take part, would like more information or have any questions or concerns about the study please contact me;

Researcher contact details

Thank you for taking the time to read this information sheet.