

Orthotics for knee instability (OKIS)

Submission date 21/08/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 22/05/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

People suffering from a neuromuscular disease, such as polio, or a disease of the central nervous system, often have a problem called knee instability. Knee instability is caused by weakness in the muscles of the knee. This can result in difficulties in walking and can lead to falls as the knee gives way during activities. Orthotic devices, otherwise known as braces or callipers, are used to support and give strength to the knee and also hold the leg in position. To date, there has not been any research on what types of orthotic devices are most commonly used by the NHS, how much they cost and how well they work. There is some evidence to suggest that people don't use their orthotic devices as they should, so it's important to understand patients' perceptions of how these devices affect their physical, psychological and social wellbeing, whether they are satisfied with the treatment and to learn more about their views of different aspects of their treatment. Here, we want to carry out an interview study, talking to people in both a one-to-one setting and in focus groups about their experiences using their orthotic device.

Who can participate?

People aged at least 16 with a neuromuscular disorder and whose walking has been affected by instability of the knee.

What does the study involve?

Participants are invited to take part in a one-to-one interview with a researcher, or in a focus group discussion. The interviews focus on the participants' experiences of their orthotic device, how it affects their everyday life and what they hope they will get from the treatment. They are encouraged to share their views with others during the focus group discussions. The sessions last for about an hour and a half and are recorded on a digital audio recorder. Everything discussed is confidential.

What are the possible benefits and risks of participating?

Participants do not benefit directly from taking part in the study. However, they will be helping to better understand how to improve treatment for people with neuromuscular disease and knee stability and improve future research. It is very unlikely that any harm should come to participants as a result of taking part in this study. However, if they do have any concerns about the way they have been approached or treated during this study, they will be advised to contact the Chief Investigator for the overall study.

Where is the study run from

The research is being undertaken by researchers based at the University of York. We will be recruiting patients to the study from St Georges Healthcare NHS Trust, Royal Derby Hospitals NHS Foundation Trust and Leeds Teaching Hospitals NHS Trust.

When is the study starting and how long is it expected to run for?

September 2014 to March 2015

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Catriona McDaid

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

16978

Study information

Scientific Title

Orthotic management of the knee in neuromuscular and central nervous system conditions

Acronym

OKIS

Study objectives

What are the important physical and psycho-social treatment outcomes for people who have been fitted with an orthotic device for knee instability.

Ethics approval required

Old ethics approval format

Ethics approval(s)

14/LO/1132; First MREC approval date 18/06/2014

Study design

Non-randomised; Observational; Design type: Qualitative

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Musculoskeletal disorders, Neurological disorders; Subtopic: Musculoskeletal (all Subtopics), Neurological (all Subtopics); Disease: Musculoskeletal, Neuro-muscular and Encephalitis

Interventions

Qualitative interview: Study participants will take part in a face-to-face interview with the researcher or participate in a focus group discussion.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Patient perspectives of experiences of orthoses; Timepoint(s): Participation in interview/focus group on one occasion

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/03/2015

Eligibility**Key inclusion criteria**

1. Adults (16 years and older) with a neuromuscular disorder who have impaired walking ability due primarily to instability of the knee. Neuromuscular disorder will include conditions that primarily affect the peripheral nerve, muscle and neuromuscular junction e.g. motor neurone disease, muscular dystrophy, myasthenia gravis, spinal muscular atrophy, Charcot Marie Tooth disease, polio, myopathies, inclusion body myositis. People with knee instability related to CNS conditions will also be included e.g. spinal cord injury, spina bifida, stroke.
2. People who are able to give informed consent.

3. Purposive sampling will be used to select participants for interview to reflect a range of conditions, age, sex, length of time fitted with an orthosis, high and low usage, living in different regions in England.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

Key exclusion criteria

1. People aged under 16 years.
2. People with neuromuscular disorders other than those listed in Inclusion criteria above.
3. People who are unable to give informed consent, due to cognitive impairment, or for other reasons.

Date of first enrolment

01/09/2014

Date of final enrolment

31/03/2015

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

York Trials Unit, Heslington

York

United Kingdom

YO10 5DD

Sponsor information

Organisation

University of York (UK)

ROR

<https://ror.org/04m01e293>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research Health Technology Assessment; Grant Codes: 13/30/02 (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes