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Orthotics for knee instability (OKIS)

Submission date
21/08/2014

Recruitment status
No longer recruiting

Registration date
22/10/2014

Overall study status
Completed

Last Edited
22/05/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 dont use their orthotic devices as they should, so its 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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Study website
http://kneeorthotics.blogspot.co.uk

Contact information

Type(s)
Scientific

Contact name
Dr Catriona McDaid

Contact details
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York
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YO10 5DD
-
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2014

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

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50;

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
England

United Kingdom

Study participating centre
York Trials Unit, Heslington
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

Sponsor details
Department of Health Sciences
York Trials Unit
Area 4
Sebohm Rowntree Building, Heslington
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United Kingdom
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Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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