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Quality of life following a lower limb reconstructive procedure

Submission date
30/01/2020

Recruitment status
No longer recruiting

Registration date
28/02/2020

Overall study status
Completed

Last Edited
28/03/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Patient reported outcome measures (PROMs) are designed and developed to assess patients' health outcomes from their perspective (Black 2013; Bredart et al., 2014). Patients are best placed to identify which health outcomes are most relevant to them (Paterson, 2004; Trujols et al., 2013). Therefore, to ensure that patients' perspectives are fully captured in a manner that is relevant and understandable to them, it is vital that they are central to the development of PROMs (McKenna, 2011; Paterson, 2004). Despite increased awareness of the need to include patients in the development of PROMS, patients are still being underused (Wiering, de Boer, Delnoij, 2017) and there is concern over the extent to which existing PROMS used with patients who are requiring, undergoing or who have undergone reconstructive surgery for a lower limb condition, are fit for the purpose of accurately capturing important patient experiences.

Aim: To explore what is most important to patients requiring, undergoing or who have undergone reconstructive surgery for a lower limb condition with regards to quality of life, important outcomes and measurable impacts.

Who can participate?
Participant are patients and staff.
The patient participants will be adults (16+) requiring, undergoing or undergone reconstructive surgery for a lower limb condition (leg, ankle or foot) which may be as a result of a congenital or acquired condition, from trauma, infection, nonunion or malunion.
Conditions may include:
• Infection - A fracture fixation which becomes infected
• Nonunion - A fracture which does not heal
• Malunion / Deformity - A fracture which does not heal in correct position.
• Any acquired or congenital condition leading to bone deformity.
• Leg length discrepancy or bone loss
• Congenital lower limb deformities
• Joint contracture
• Lower limb injuries where further limb reconstruction is required.
• Poly-trauma patients (as long as one of the above criteria are met).

The staff participants will be orthopaedic clinicians and physiotherapists who treat patients meeting the above inclusion criteria and who work at one of the five participating sites.

What does the study involve?
In order to explore important outcomes to patients after a lower limb condition, patients will be invited to take part in a semi-structured interview or a focus group and staff will be invited to take part in a semi-structured interview. Patients: Interviews and focus groups will be undertaken with patients who are requiring, undergoing or who have undergone reconstructive surgery for a lower limb condition, and will have received care through the NHS at one of the participating sites. Patient interviews will explore key health-related quality of life factors and other relevant factors to patients who have experienced a lower limb condition that requires or required reconstructive surgery. Important factors may include physical, social and psychological well-being as well as job and lifestyle related factors. Staff: Interviews will be undertaken with Orthopaedic staff (clinicians and physiotherapists) at each site. The staff will be asked to discuss, from their perspective, what they believe to be important outcomes and goals for patients.

What are the possible benefits and risks of participating?
Participants may not benefit from taking part in this research. However what they tell us may help us to understand what patients go through during a lower limb condition and reconstruction and its consequences. There are no physical risks to participating and we anticipate that the interviews/focus groups will not cause distress. However participants will be made aware that they can refuse to answer any questions which they feel uncomfortable with and can stop the interview at any time.

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
May 2020 to August 2021

Who is funding the study?
Hull University Teaching Hospitals NHS Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269088

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 269088

Study information

Scientific Title
A qualitative approach to exploring what is important to patients with regards to quality of life when requiring, undergoing or after undergoing reconstructive surgery for a lower limb condition.

Acronym
PROLLIT

Study objectives
The principle research objective is to explore what is most important to patients who are requiring, undergoing or who have undergone reconstructive surgery for a lower limb condition, with regards to quality of life, important outcomes and measurable impacts. This information will be used to determine whether patient priorities in terms of outcomes are currently being met by existing patient reported outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/06/2020, South Central - Berkshire Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; nrescommittee.southcentral-berkshire@nhs.net), ref: 20/SC/0114.

Study design

Qualitative study design using interviews and focus groups

Primary study design
Other

Secondary study design

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Lower limb conditions which require or required reconstructive surgery.

Interventions
Interviews and focus groups will be undertaken with patients and staff.
Patients:
Patients will be identified and invited to participate in the research by orthopaedic clinicians, physiotherapists or research nurses at participating NHS hospitals in the first instance. Interviews will be at the hospital or over the telephone. Participants will be provided with an information sheet before consent is obtained. We will ensure that participants have read the information sheet and have a full understanding of the study before consent is obtained. Participants will not be pressured to take part and will be reminded of their right to withdraw at any time. Verbal consent will be obtained on an on-going basis during interviews. Patient interviews will explore key health-related quality of life factors and other relevant factors to patients who have experienced a lower limb condition that requires or required reconstructive surgery. Important factors may include physical, social and psychological well-being as well as job and lifestyle related factors. Topic guides will be used to guide the conversation. The interview will last between 30 minutes to 1 hour and the focus groups will last between 1-2 hours. Interviews will be audio recorded and transcribed verbatim. Participants will be informed that quotations may be used and published, but that all identifiable information will be removed. All participants will be provided with a unique ID to maintain their anonymity.

Staff:
Staff (orthopaedic clinicians or physiotherapists) will be invited to participate in the study by either direct contact from the researcher if they meet the clinician when visiting the hospital for patient interviews or through the lead contact at each site. Participants will be provided with an information sheet before consent is obtained. We will ensure that participants have read the information sheet and have a full understanding of the study before consent is obtained. Participants will not be pressurised to take part and will be reminded of their right to withdraw at any time. Verbal consent will be obtained on an on-going basis during interviews. The interview will be guided by a topic guide and staff will be asked to discuss, from their perspective, what they perceive to be important outcomes and goals for patients. The interview will last between 30 minutes to 1 hour. Interviews will be audio recorded and transcribed verbatim. Participants will be informed that quotations may be used and published, but that all

identifiable information will be removed. All participants will be provided with a unique ID to maintain their anonymity.

Sampling quotas will not be applied but, in order to obtain a wide range of views, recruitment will aim to target a range of participants with regards to age, gender, different lower limb conditions, condition severity, treatment received and stage of reconstructive treatment. A sampling frame will be developed to streamline this process. The sampling frame will be developed through collaboration with lead clinicians from the participating sites. Recruitment will continue until the interviews provide no new information. We anticipate this to be around 50-75 patient participants (10-15 from each site) and around 10 (2 from each site) staff interviews.

The topic guides will be developed from a literature review of the area and reviewed by experts in the field and our patient, public involvement and engagement group. A systematic review on the same topic is currently being undertaken and if appropriate may also inform the topic guides. The topic guides will be used to guide the conversation, to ensure that it stays on track and to provide prompts to facilitate discussion.

Concept elicitation will be undertaken in the interview/focus group by asking the participants questions which explore their thoughts, attitudes and beliefs surrounding important goals and outcomes what is important to them with regards to quality of life in relation to requiring, undergoing or after reconstructive surgery for a lower limb condition.

Intervention Type
Other

Primary outcome measure
Qualitative methods will be used to explore what is important to patients who are requiring, undergoing or who have undergone reconstructive surgery for a lower limb condition, with regards to quality of life, important outcomes and measurable impacts

Secondary outcome measures
N/A

Overall study start date
01/06/2019

Completion date
01/08/2021

Eligibility

Key inclusion criteria
Patient:
1. Adults (16+) requiring, undergoing or have undergone reconstructive surgery for a lower limb condition (leg, ankle or foot) which may be as a result of a congenital or acquired condition, from trauma, infection, nonunion or malunion. Conditions may include:
1.1. Infection - A fracture fixation which becomes infected
1.2. Nonunion - A fracture which does not heal
1.3. Malunion / Deformity - A fracture which does not heal in correct position. Any acquired or congenital condition leading to bone deformity.

1.4. Leg length discrepancy or bone loss
1.5. Congenital lower limb deformities
1.6. Joint contracture
1.7. Lower limb injuries where further limb reconstruction is required
1.8. Poly-trauma patients (as long as one of the above criteria are met)

Staff:
2. Staff participants will be orthopaedic clinicians and physiotherapists who treat patients meeting the above inclusion criteria and who work at one of the five participating sites

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
85

Key exclusion criteria
Patients will be excluded if they have experienced a condition in a part of the body that is not a lower limb, they have had a lower limb amputation and if they are under the age of 16.

Staff will be excluded if they do not have direct contact/involvement with the care of patients who are requiring, undergoing or who have undergone reconstructive surgery for a lower limb condition.

Date of first enrolment
04/11/2020

Date of final enrolment
01/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull Royal Infirmary
Hull and East Yorkshire Hospital NHS Trust.
Anlaby Road

Hull
United Kingdom
HU3 2JZ

Study participating centre
Leeds General Infirmary
Leeds Teaching Hospitals NHS Trust
Great George St
Leeds
United Kingdom
LS1 3EX

Study participating centre
James Cook University Hospital
South Tees Hospital NHS Foundation Trust
Martin Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
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United Kingdom
SE5 9RS

Study participating centre
Royal Liverpool University Hospital
Prescot Street
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L7 8XP

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Sponsor type
University/education

Website
https://www.york.ac.uk/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hull University Teaching Hospitals NHS trust

Results and Publications

Publication and dissemination plan
We aim to publish the systematic review protocol and qualitative study protocol in a peer-reviewed scientific journal. We also intend to publish the systematic review findings and the findings from the qualitative study in a peer-reviewed journal in 2020. All members of the research team will be involved in manuscript preparation and revisions. The advisory panel will also be invited to contribute to papers where appropriate. The advisory panel will be acknowledged in papers. We also anticipate the attendance of the research team members at any relevant conferences over the course of the project.

Intention to publish date
01/01/2022

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/12/2020	28/03/2023	Yes	No
HRA research summary			28/06/2023	No	No