

Disability and Rehabilitation



ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/idre20

Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective

Chantel Ostler, Margaret Donovan-Hall, Alex Dickinson & Cheryl Metcalf

To cite this article: Chantel Ostler, Margaret Donovan-Hall, Alex Dickinson & Cheryl Metcalf (2022): Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective, Disability and Rehabilitation, DOI: 10.1080/09638288.2022.2138989

To link to this article: https://doi.org/10.1080/09638288.2022.2138989

9	© 2022 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group.
	Published online: 11 Nov 2022.
	Submit your article to this journal 🗗
ılıl	Article views: 415
Q	View related articles 🗷
CrossMark	View Crossmark data 🗗



ORIGINAL ARTICLE



Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective

Chantel Ostler^a, Margaret Donovan-Hall^b, Alex Dickinson^b and Chervl Metcalf^b

^aPortsmouth Enablement Centre, Portsmouth Hospitals University Trust, University of Southampton, Portsmouth, UK; ^bFaculty of Engineering, University of Southampton, Southampton, UK

ABSTRACT

Purpose: There is currently no consensus regarding what outcome domains to measure following lower limb prosthetic rehabilitation. Prosthetic users have a unique insight into important outcome domains, little is currently known about their critical viewpoint.

Materials and methods: A total of 37 participants who underwent lower limb amputation in the last five years were recruited from UK limb fitting centres and social media. Data were collected using focus groups and interviews and analysed using reflexive thematic analysis.

Results: Five themes were identified. 1) The ability to participate in important activities, 2) *how* participants were able to undertake these activities, i.e., independently, with ease, safely and with minimal equipment. 3) A comfortable, easy-to-use prosthesis, 4) the importance of managing pain and finally, 5) adjusting and accepting their new normal. These five themes, or outcome domains, did not exist in isolation, but appeared to interact with each other, contributing to, or inhibiting the participant's holistic sense of recovery.

Conclusions: Understanding important outcome domains that define what recovery means to people following amputation can help to inform domain consensus, as well as direct the focus of rehabilitation. Domain consensus would guide the selection of measurement tools that evaluate prosthetic interventions in a meaningful way.

➤ IMPLICATIONS FOR REHABILITATION

- There is currently no consensus around which outcome domains should be measured following prosthetic rehabilitation.
- Outcome domains of importance from a patient's perspective focus on participation in important activities, prosthesis comfort, pain management, and acceptance of their new normal.
- Identifying these domains can help direct the focus of rehabilitation as well as inform outcome measurement practice.
- The interrelated nature of these domains suggests the need for a physical and psychosocial multidomain approach to outcome measurement in prosthetic rehabilitation, with patient priorities at its centre.

ARTICLE HISTORY

Received 12 January 2022 Revised 4 October 2022 Accepted 9 October 2022

KEYWORDS

Outcome; measurement; prosthetic; amputation; qualitative; meaningful; experience; recovery

Introduction

As the demand for healthcare increases [1] and the cost of delivering services to an aging population spiral [2], outcome measurement has been highlighted as central to understanding the value of healthcare provision [3]. The term "outcome measurement" can be better understood by breaking it down into the outcome domain being measured and the measurement tool used for the task. An outcome domain can be defined as an element of health (i.e., pain, physical function, emotional wellbeing, and social activity) that is changed by a particular intervention [4]. A measurement tool can be defined as a standardised instrument used in research and clinical practice to capture and evaluate the change [5].

Within the field of prosthetic rehabilitation, research focusing on outcome measurement appears to centre around the

development and analysis of measurement tools [6–15]. For example, a review carried out by Heinemann and colleagues [16] identified 43 different tools for use following lower limb amputation. The wide range of tools available has led several authors to highlight an absence of consensus in the field regarding the use of measurement tools, i.e., which tools should be used to evaluate different domains [6,7]. A recent narrative review [17] suggests that this may be driven by a lack of understanding and consensus around which outcome domains characterise meaningful recovery following prosthetic rehabilitation.

The absence of consensus regarding both outcome domains and measurement tools is problematic for clinical and research settings. In clinical practice, consensus would enable routine measurement of agreed domains, using standardised tools, across prosthetic service providers nationally, and internationally. This information could inform the use of available resources to have

the greatest impact on patient's lives [3]. Such an approach could also allow benchmarking to identify services where outcomes measured against agreed domains are good and use those as exemplars to raise standards across healthcare providers; reducing variation in the system.

In research, a consensus about what outcome domains are important and should be measured would enable effective comparison and synthesis of studies that evaluate the same interventions. This could contribute to a less fragmented evidence base and reduce research waste [18]. However, consensus is not a problem unique to prosthetic rehabilitation [19,20] and has led to the development of initiatives, such as Core Outcome Measurement in Effectiveness Trials (COMET) [21], and the International Consortium of Health Outcome Measurement (ICHOM) [22]. These organisations take a step back from selecting measurement tools and first seek to develop consensus around what outcome domains to measure, in research (COMET), or clinical settings (ICHOM). Both organisations advocate for a multistakeholder approach to developing outcome domain consensus, with patients at the centre of the process, as these are the individuals for whom health and rehabilitation interventions have the most impact. Understanding this perspective not only has the potential to direct meaningful outcome measurement but can also provide insight into what domains are most valued by patients and should be the focus of rehabilitation.

Qualitative approaches are increasingly used to explore meaningful outcome domains from the patient's perspective [18]. Within the field of prosthetic rehabilitation qualitative approaches have been highlighted by Murray and Forshaw as important patient centred methodologies for informing healthcare for people with limb loss [23]. A recent editorial by Dillon et al. [24] also encouraged qualitative enquiry in the field of prosthetics, championing its use in informing clinical practice and future research.

Several authors have begun to explore what people who use a prosthetic limb feel are important outcome domains using qualitative approaches. A small body of research has explored this phenomenon within the context of the international classification of functioning (ICF) [25–28]. The ICF is a classification system developed by the World Health Organisation (WHO) to provide a universal language to describe the health and functioning of individuals [29]. It describes a dynamic interaction between many different domains, which can be characterised as body impairments, activity limitations, and participation restrictions, as well as contextual factors, such as environmental conditions and personal factors [29]. The ICF is often used to categorise functional impairment following amputation [30].

Several studies have used qualitative methods to explore the views of patients and clinicians to develop a core set of concepts from the wider ICF that describe function and disability following lower limb amputation. It has been suggested that these core concepts/domains could be used to inform rehabilitation priorities and direct which outcome domains to measure [25–27].

Although large numbers of the concepts identified by patients (92%) and clinicians (82%) in these studies were matched to ICF domains [25,26], not all the concepts aligned. Both studies highlighted that important concepts, such as "socket comfort and appearance" and "acceptance following amputation", could not be matched and were therefore not included [25,26]. In addition to this, ICF core set development uses a deductive approach that follows core set development guidance [31] including questions designed to illicit responses within the ICF domains [25]. This approach may diminish the voice of the patient by limiting the depth and richness of their personal accounts, which could lead

to further important domains specific to prosthetic users being misunderstood or overlooked. Although the ICF provides a useful foundation for understanding functioning and disability, exploring outcome domains of importance exclusively within this universal framework may restrict the depth and understanding of the experience of prosthetic limb users.

Two further studies have used more iterative qualitative designs to take a patient centred approach to understanding outcome domains of importance, such as balance, safety, independence, and adjustment to amputation [32,33]. McDonald and colleagues [32] used a qualitative focus group approach to explore domains related to physical function, that were important to five individuals with lower limb loss taking part in a trial of two different prosthetic feet. Schaffalitsky et al. [33,34] also explored the benefits of prosthetic prescription from a patient, clinician, and wider stakeholder viewpoint. Interestingly clinicians and patients often prioritised different domains. As clinicians are most likely to select what outcome domains are measured [32], it is possible that services may not be capturing what patients think are the domains that really matter.

These studies also focused on the outcome of a single intervention in the post-amputation rehabilitation pathway, i.e., the prescription of prosthetic componentry, and did not consider the outcome of a multidisciplinary approach to *rehabilitation* with that device, delivered in a holistic way through a variety of interventions, i.e., physiotherapy, counselling, occupational therapy, etc. Evidence-based guidance from a range of professional bodies involved in prosthetic rehabilitation recommend that recovery following lower limb amputation should be facilitated by a period of multidisciplinary rehabilitation that addresses the physical, psychological, and social needs of the patient, far beyond prescribing them with a prosthetic device [35–38].

There is currently limited research which takes an iterative patient-centred approach to understanding outcome domains that are important to prosthetic users following lower limb amputation, particularly from a holistic rehabilitation perspective. Therefore, the aim of this study was to explore important outcome domains of recovery, from the perspective of people who have undergone prosthetic rehabilitation following lower limb amputation.

Materials and methods

Research design

This research has been developed from a critical realist world view which looks to access the knowable world, in this case, the perceptions of the most important outcome domains following lower limb amputation, within a community of prosthetic users [39]. Due to the exploratory nature of this work, and limited previous research on the topic, an experiential qualitative approach was used independent of any specific theoretical and epistemological stance, such as grounded theory or phenomenology. This open approach, using reflexive thematic analysis [40], fits well with the critical realist world view, seeking to capture the complexity, and diversity of recovery following lower limb loss [39], and will explore and interpret what domains characterise a successful outcome from the perspective of the person with lower limb loss.

Patient and public involvement and engagement (PPIE)

Patient and public involvement and engagement (PPIE) in research is defined as "research being carried out 'with' or 'by'

members of the public rather than 'to', 'about' or 'for' them"[41,42] and is vital to ensure research is focused on issues the public feel are important and is conducted in a participant centred way. As the notions of "outcome" or "domain" may be viewed as "research" or "clinically-focused" concepts, ensuring we were asking about them in a way that people with limb loss found accessible was an important part of our PPIE. We worked closely with a group of public research partners who were established prosthetic limb wearers. The group helped us to think about the language patients may use when talking about outcome domains, as well as practical issues, such as where patients would like to find out about the study and how they might like to take part. This crucial PPIE approach allowed us to co-design the study and study materials, such as the interview guide, to ensure a positive participant experience, maximise recruitment, and develop accessible language around the concept of outcome domains in partnership with patients.

Ethical review

The study was given ethical approval by the East Midlands Research Ethics Committee and the National Health Service (NHS) Health Research Authority (Ref: 8/EM/0259).

Participants

Participants were invited to take part in the study if they were over the age of 18 and had undergone a major lower limb amputation (i.e., an amputation occurring at or proximal to the ankle, due to the extent of the functional impact associated with higher levels of amputation [43]) within the last five years. This was to ensure the clarity with which they were able to recall their rehabilitation experiences. The inclusion criteria also stated that participants must have completed rehabilitation with a prosthetic limb, allowing them to reflect on their own recovery.

A number of recruitment approaches were used to generate a sample with a range of rehabilitation and limb loss experiences relevant to UK practice. Clinical teams (i.e., Physiotherapists, Prosthetists, and Rehabilitation Consultants) working in four English NHS prosthetic rehabilitation centres introduced the study to eligible participants as they completed their outpatient rehabilitation, or returned for follow-up reviews with their prosthetist or multidisciplinary team. Adverts were also posted on social media platforms and invitation letters were sent to limb supporting charitable organisations with loss to share their members.

Sampling was undertaken using a two-staged process using both convenience and purposive sampling that was informed by a demographic questionnaire. This approach was undertaken to build a sample with a diverse range of characteristics, views, and experiences, which are representative of people who undergo prosthetic rehabilitation. The questionnaire collated self-reported information from participants on a variety of characteristics which may influence outcome following lower limb amputation, such as age, level of amputation, presence of co-morbidities, functional status, and social support [44,45]. Convenience sampling was used in stage one and the characteristics of the sample were monitored throughout. This approach led to fewer older transfemoral participants included in the sample than are described in the UK limb loss population [46–48]. The final six participants in the study were recruited purposively. Stage two purposive sampling involved clinical teams approaching participants with the

required characteristics (65 years of age or older, and a transfemoral amputation) which were verified prior to consent using the demographic questionnaire.

Procedure

As the aim of the study was to explore and understand the views and experiences of participants, focus groups and semi-structured interviews were used to collect data as these approaches enable follow up questions and contextualisation of answers [39]. The selection of both of these methods was on the advice of our PPIE group, to enable and promote participation in a way that individuals found most acceptable and comfortable. As we were talking about life after amputation, which is a complex and life-changing experience, it was anticipated that the choice of how to be involved would allow people to feel more at ease when sharing their experiences.

Participants self-selected how they would like to take part, and the focus groups and interviews were completed independently of each other and in parallel. This multiple-method approach allowed data source triangulation, providing different views of the same phenomenon, gathered using different methods to enhance credibility [49].

Focus groups took place in a quiet room in each of the four recruiting limb centres and lasted no more than an hour and a half. Interviews were undertaken either over the telephone or in a location of the participant's choosing and lasted up to one hour. Written informed consent was collected from all participants prior to their involvement in the study.

A semi-structured interview guide was co-produced with our PPIE group (Figure 1) and was used to collect data during both interviews and focus groups. Data were audio recorded and then transcribed verbatim to capture all verbal utterances. Transcripts were fully anonymised to remove any identifiable information and pseudonyms were used throughout to ensure the confidentiality of participants. Written consent was also obtained for using verbatim quotations.

Research team and reflexivity

Contextual information about the research team has been presented here to enable readers to assess any influence our background and experience may have had on the research [50]. All of the interviews and two of the four focus groups in the study were undertaken by the first author (CO). CO is a consultant clinical academic physiotherapist at one of the recruiting limb centres. She has over 15 years' experience in prosthetic rehabilitation clinical practice, and 10 years of experience in research. This study is being undertaken as part of CO's Ph.D., but she has undertaken several qualitative research enquiries prior to the study described here. The second author (MDH) is one of CO's Ph.D. supervisors, a health psychologist and associate professor. She has over 20 years of experience undertaking qualitative research with people following limb loss, and complimentary areas of rehabilitation. MDH conducted the other two focus groups as some of the participants were known to CO. Both CO and MDH undertook aspects of the data analysis, described below in Table 1. Involvement of a second researcher helped to refine ideas, enhance the reflexive process, and by viewing the phenomenon through a different lens, provide more comprehensive interwithin the findings, therefore pretive depth credibility [40].

(1) Introductions and story sharing

(2) Visual timeline of rehab journey-

Imagine we are going to take you back in time to the point where you had finished your rehabilitation (Rehabilitation phase). What had you hoped you would achieve by this point?

What would you have liked to achieve in order to be happy with the outcome?

Discuss what 'kind' of walking did you want to be able to do?

At what point did you think 'I'm OK'

(3) Word cards

How would you describe this achievement?

What words would you use?

Here are some words used by other people what do you think?

FREEDOM
INDEPENDENCE
COMFORT
ADJUSTED
PAIN FREE
MANAGABLE

What do you think success is for you?

Figure 1. Semi-structured interview guide.

Table 1. Description of reflexive thematic analysis process.

Phase	Description of process
(1) Familiarisation with the data	Audio-recordings of both focus groups and interviews were transcribed verbatim. Transcripts were read and re-read and initial noticing's recorded in a research journal by CO.
(2) Coding	Complete coding of the focus group and interview data sets was performed separately, by CO. With a subsection competed by MDH. Extracts of text were coded in as many ways as needed, including both data-derived and research-derived codes. Coding decisions were discussed and a reflective journal was completed by CO throughout the analysis process to reflect on the different researcher lenses, and the researchers own views and assumptions.
(3) Generating initial themes	For each analysis, the codes and coded data were examined. Similarities and overlap were identified between codes and potential patterns relevant to the research question were created by CO and MDH.
(4) Reviewing and developing themes	Separate visual maps of initial themes from the interview and focus groups analyses were created and compared by CO. All transcripts were re-read and the fit of initial themes reviewed in relation to the full data set and coded data by CO.
(5) Refining, defining, and naming themes	The full set of themes from both analyses was then reviewed, refined, and integrated by CO and MDH. Themes were collapsed or expanded in order to present coherent patterns within the data. The wider research team (AD, CM), reviewed refined themes to ensure they captured important meaning in relation to the research question, and assisted reflection on researcher assumptions. A person-centred approach was taken by CO to name the themes in order to capture the voice of participants.
(6) Writing up	Writing the report also acted as part of the process of refining and defining themes. Appropriate examples of extracts from the full data set were selected to represent each theme by CO. Analysis was linked to the research question and literature, and a final report was produced by CO, MDH, AD, and CM.

A reflexive diary was kept by CO throughout and discussed regularly with the rest of the research team (MDH, AD, and CM), in order to reflect on the impact of different perspectives and assumptions influencing the study design, data collection, and data analysis.

Data analysis

Data were analysed iteratively using reflexive thematic analysis, described by Braun and Clarke [39,40,51], as it provides a flexible approach which sets out a way of systematically grouping and

identifying meaning within the data. NVIVO software (QSR International, Melbourne, Australia) was used to manage the data. Initially, interviews and focus groups were analysed separately. Verbatim transcripts were coded in as many ways as needed, allowing lines of text to be coded more than once in order to consider different interpretation and meaning. A second researcher coded a subsection of the transcripts. Similarities and overlaps were identified between codes and potential patterns relevant to the research question were created. Visual maps of initial themes from the interview and focus group analyses were created independently of each other to compare and contrast. The full set of themes from both analyses was then reviewed, refined and integrated, in order to present coherent patterns within the data. Table 1 describes the stages of thematic analysis and by whom they were undertaken.

The characteristics of the sample were also analysed using data collected from the demographic questionnaire. Means and percentages were used to describe the full sample. To explore the potential relationship within themes, participant's characteristics were linked to all the quotations within the subthemes. Although this process of synthesis helped contextualise the findings, it was carried out cautiously as the sample was small and this was not the key aim of this qualitative approach.

Data saturation was not sought as reflexive thematic analysis does not presume that the themes emerge from the data but are interpreted during the researcher's analytical process, and on this basis further interpretations are always possible [52]. In addition, experiences following lower limb amputation can be diverse, depending on characteristics, such as age or cause of amputation, and it is unlikely any one study design would be able to capture them all [52]. Data collection was completed when close to 40 participants were recruited as this was deemed a pragmatic sample size based on the time and resources available to the research team [53].

Synthesised member checking [54] was undertaken following data analysis to offer participants the opportunity to reflect and feedback on the themes. This process enabled further triangulation of the knowledge gathered around the phenomenon of outcome domains of importance following prosthetic rehabilitation. Member checking allowed participants to assess the trustworthiness of the findings, ensuring they resonated with their experiences so the results may be credible with the wider limb loss population.

An accessible synthesised summary of the results, with space for written feedback, was sent by post to participants with an accompanying return envelope. It was not possible to send all participants a summary. Three participants had not provided an address, one participant had moved, and one participant had died. Seven summaries were returned (19%). All of the returned summaries confirmed the study findings and none of the themes were altered following feedback. Written responses were added to the data set and cross referenced with existing codes, as described in Table 1.

Results

Sample characteristics

Forty-two participants were approached during the recruitment phase of the study. One participant was ineligible, three participants dropped out due to health reasons and one participant's audio recording malfunctioned. This resulted in 37 participants' views and experiences being included in the study. Eighteen participants took part in interviews (14 via telephone and four face to

Table 2 Sample characteristics

Characteristic	N = 37 (%)	N = 37 (%)		
Age	Mean 59 years (range 33–88	years)		
Gender	Male	23 (62)		
	Female	14 (38)		
Level of amputation	Transtibial	20 (54)		
	Knee disarticulation	4 (11)		
	Transfemoral	8 (21)		
	Bilateral transtibial	4 (11)		
	Hip disarticulation	1 (3)		
Time since amputation	Mean 2.2 years (range 6 months	 5 years) 		
Cause of amputation	Diabetes	10 (27)		
	Trauma	9 (24)		
	Cancer	2 (5)		
	Peripheral vascular disease	8 (22)		
	Infection	4 (11)		
	Other	4 (11)		
Number of co-morbidities	None	9 (24)		
	1	9 (24)		
	2	7 (19)		
	3	4 (11)		
	4	2 (6)		
	5	6 (16)		
Social situation	Living alone	8 (22)		
	Living with partner	19 (51)		
	Living with family	10 (27)		
Independencewith ADLs	Independent	12 (33)		
	Family supporting	19 (51)		
	Package of care	6 (16)		
Employment status	Employed	9 (24)		
	Unemployed	10 (27)		
	Retired	15 (41)		
	Volunteer	3 (8)		
Use of walking aids	None/occasional use	12 (32)		
	Sticks/crutches	21 (57)		
	Walking frame	4 (11)		
Community ambulatory	Yes	34 (92)		
	No	3 (8)		
Walking distance	50 m or less	11 (30)		
	51–500 m	10 (27)		
	501 m — 1 km	3 (8)		
	More than 1 km	11 (30)		
	Unsure	2 (5)		

face) and 19 participants took part in four focus groups comprising of a group of 7, a group of 5, a group of 4, and a group of 3.

The sample characteristics were varied and included participants between 33 and 88 years of age, with a variety of different levels of amputation, including both knee and hip disarticulation. Time since amputation ranged between 6 months and 5 years and the cause of amputation included diabetes, peripheral vascular disease, trauma, cancer, and infection. The participants also had varied social situations, employment, self-reported level of independence with activities of daily living, and functional status. Table 2 further summarises the sample characteristics.

Themes

Five themes, with associated subthemes, were identified, which illustrate what participants felt were the important outcome domains that characterise successful prosthetic rehabilitation. The themes are summarised in Table 3 and will be explored below alongside quotes from study participants. Pseudonyms are used throughout and quotes have been contextualised with information about the participant's age and level of amputation.

Theme 1 - I am able to participate in my important activities

This theme describes outcome domains of prosthetic rehabilitation related to participation in important activities.

Table 3. Summary of study themes and related subthemes.

Themes and subthemes

Theme 1. I am able to participate in my important activities Subthemes:

- (1.1) Walking again
- (1.2) Important activities at home
- (1.3) Important activities in my community

Theme 2. I can participate in my important activities in the way I want to Subthemes:

- (2.1) Doing my activities independently
- (2.2) Doing my activities easily
- (2.3) Doing my activities without falling over
- (2.4) Doing my activities with as little equipment as possible

Theme 3. My prosthesis is comfortable and easy to use

Theme 4. If I have pain, I am able to manage it

Theme 5. I am able to accept my new normal Subthemes:

- (5.1) Chasing normality
- (5.2) Adjusting to limb loss
- (5.3) Sense of achievement

Subtheme 1.1 – walking again

The participants in this study highlighted the importance of being able to walk again following their amputation. This was often the first thing they talked about when describing a successful recovery. The ability to walk was spoken of as a "wonderful" experience which helped participants regain their sense of wellbeing and was intimately linked with feeling "normal" again.

she said I'd like to try to get you on your feet now. I looked at her as though she was mad. You know and as soon as I got on my feet, I was OK. It was wonderful. I never thought I'd ever walk again.

(David, 74 years, TTA)

Being able to walk again was an important outcome; it was also described here as a skill, which when attained enabled people to participate in their important activities. It was this participation that was highly valued. The different activities participants wanted to do were often referred to on a continuum. Activities progressed from indoor household activities discussed mainly by older less mobile participants, to activities within wider community.

Subtheme 1.2 - important activities at home

Being able to walk enabled participants to carry out basic but essential household tasks, such as personal care or making and carrying their own cup of tea. Doing these important tasks while standing was also described as significant and appeared to be linked to feelings of normality, sense of self and achievement.

I was able to achieve what I wanted, I wanted to be able to stand up in my kitchen and cook and things erm like that and walk a little bit and things. Not unaided because I needed to use a stick but to me that was really good. (Gill, 67 years, TTA)

Despite the importance of household tasks, it was clear that being limited to the home environment exclusively would be a frustrating and unsatisfactory experience. Participants described a strong desire to function outside of their homes and within their communities. Even being able to get out of the house and into the garden was identified as something that could ease this frustration, particularly for people who were only able to walk short distances, i.e., less than 50 m.

Well I only just walk up and down really because I have a gardener. I: So just being able to go outside? FP: Yes. Yes, I suppose that is freedom isn't it, because at the moment I'm stuck in the house. (Rita, 81years, TFA)

Subtheme 1.3 - important activities in my community

Being able to participate in important activities outside the house was described as a vital part of recovery. The activities discussed varied from person to person and reflected the wide range of meaningful things people do in their day to day lives. Some of the activities described included; being able to go shopping, drive a car, go on holiday, and return to work, hobbies, socialising, and sport.

my husband and I used to do quite adventurous holidays, so I wanted to get back to that sort of stuff. We'd had to knock that on the head for a couple of years prior to em prior to my amputation. (Samantha,

I know for me I set myself a goal, I left here in October and I said by December I want to be driving so I just got in the car and that was it. (Lucy, 44 years, HD)

In order to venture outside of the house, several key skills seemed important for people to attain, in addition to being able to walk. For example, the ability to manage stairs, slopes, and uneven ground were viewed as essential skills, which then enabled the valued outcome of being able to participate in important activities. Steps and slope skills enabled participants to sleep upstairs again or visit other people's homes to socialise. Being able to traverse different surfaces was identified as a vital skill to function in the outside world.

what are you like on different surfaces um because because that is what pushes you from that technical ability to walking into a functional ability to walk. because it's knowing that if you can walk a mile but you can't walk on any uneven or non-level ground then it doesn't matter how far you can walk really because within that distance you are always going to encounter um some some some sort of uneven ground. (Darren, 47 years, KD)

Theme 2 - I can participate in my important activities in the way I want to

The participants in the study described success as more than whether or not they were able to participate in their important activities, they also talked about "how" they were able to participate.

Subtheme 2.1 – doing my activities independently

Participants discussed that the degree of independence they achieved following their amputation influenced how successful they felt their recovery was. The impact that independence, and conversely dependence, appeared to have on their wellbeing was significant. Lost independence led participants to talk about losing their dignity and sense of self-worth.

I wee in a bottle, I mess in a bucket. My wife has to work full time and comes home at the end of the day and she has to empty my mess out of a bucket. That isn't life. They've just finally given me planning permission and I'm trying to get somebody to come and start the building and all I've been told is next year. So that's going to be another year. Life ain't fun anymore. (Don, 64 years, TTA)

Without independence, participants were reliant on other people to help with personal care and getting out of the house. They described this reliance as frustrating and debilitating and spoke of feeling like a burden.

Yes because then even the simplest thing like going to the supermarket you know its having to say to people oh can you pass me that, can you get me that. You can do things. I mean I'm not having I can get up and get something without having to say to somebody can you do that. and I mean it means if I want to go out in the car I don't have to have the wheelchair loaded and struggle on and have my wife



there with me, I can just go on and jump in the car and go off to where I have to go to. (Adam, 38 years, TTA)

Almost all the participants who spoke about the importance of being independent and not having to rely on others lived with a spouse or with their family.

Subtheme 2.2 - doing my activities easily

As participants described their recovery following amputation, they discussed how their aims shifted over time from being able to do an activity, to doing the activity easily and with less conscious effort. They talked about the importance of mastering tasks to make them less effortful or in need of less planning. Being unable to master a task could result in not doing it at all.

I have on occasion walked to the bus stop, got on the bus and gone to a restaurant, got out walked to the restaurant, der der der so I can do that. But I still wouldn't choose to do that if that makes sense. So whilst I can do it, it's still too hard to be a routine thing sort of thing. (Darren, 47 years, KD)

I actually get on with the washing or I get on with things without having to think oh hang on a minute I just have to make sure I've got this there to be able to do then that and then that. It becomes part of you and I think for me that's I think, yes, that's when I thought actually I'm OK here. (Erica, 39 years, TTA)

Mastering activities appeared to increase participation, which seemed to be underpinned by feelings of confidence in their own ability and the capacity to adapt to new situations.

If you go out you go out sometimes you might go out of your comfort zone but you can soon slot um into being aware of what's required. (Gill, 67 years, TTA)

Subtheme 2.3 – doing my activities without falling over

Falling was a common experience amongst the participants, especially those who described themselves as community ambulators, and was frequently attributed to poor balance with the prosthetic leg. Being able to undertake important activities without falling over was described as a priority, as participants raised concerns over injury or not being able to get up from the floor. This appeared to make them feel vulnerable and increased their reliance on others.

You get them with a pushchair and they're coming straight at you. My sticks go like that. And I will put them in the path of anybody that walks in front of me because they don't realise but you have to realise if you go on that floor and you've got a prosthetic leg on it can break any part of your body because you can fall with that, you can break that. You can break your arm. So then you are in more difficulty than what they think you're in. (Steve, 83 years, TTA)

My wife is 8 stone. If I fall on the floor she cannot move me. I had to wait for my son, he's a builder, he's got arms like you, and I had to wait for him to come and help me off the floor because I cannot move. (Don. 64 years, TTA)

The consequence of these concerns for participants was a significant fear of falling, especially in community-based situations. Fear of falling appeared to reduce confidence and increased conscious effort when walking. This in turn led to reduced participation in important activities.

Well it does make me very wary afterwards for a little while. erm you know you just think oh, em er you just think you know oh I kind of get up and then the next day I'm thinking oh I've got to be very, I'm probably very tentative and looking at everything on the ground. (Elaine, 64 years, TFA).

Subtheme 2.4 - completing my activities with as little equipment as possible

Although many participants described using walking aids to improve their balance and confidence, there appeared to be a complex relationship with the equipment that was part of their lives. Being able to cease using equipment, such as wheelchairs, commodes, or walking aids, was described by many participants as a successful recovery and indicated a return to normality. Those who lived with their spouse or families often discussed the importance of parting with equipment.

So the wife summed it up the other day because I put the wheelchair in the garage because I wasn't using it much, I put it in the garage and covered it up. Oh it's lovely the house, it's getting back to normal. cos the bed was in the living room from January till December and somebody brought it back up for us in December. So that was the bed out of the living room so the living room was back to a living room. So it's changing the house. Yeah the wife said it's lovely. When that wheelchair went in the hall is clear now, I said oh it's lovely to get the house back to normal. It's like getting back to a normal life. (Jim, 66

Despite this goal, if equipment was critical to enabling important activities, participants appeared more able to accept it.

So, if I really want to do that then I might have to use the wheelchair to go the long distance to get there but then at least I can walk around whilst I'm there. (Emma, 41 years, TTA)

Theme 3 - My prosthesis is comfortable and easy to use

When considering the role of the prosthetic limb in recovery, socket comfort appeared to be the most important factor and was discussed frequently. A comfortable socket was described as enabling engagement in meaningful activity. Conversely, discomfort meant that people were not able to wear their prosthesis for as long as they needed to. This was often raised by those describing themselves as community ambulators, who reported being able to walk longer distances. In some cases, discomfort or skin breakdown was attributed to preventing limb use. This made participation in important activities very challenging.

Socket comfort is pretty, is just so important. So important. Socket comfort because I've had sockets before where I've had them for work and my leg is literally screaming at the end. and then if it rubs, then you've got a blister, then you are back in the wheelchair. (Ruth, 50 years, TTA)

Participants also talked about the impact socket comfort had on their adjustment to amputation. Participants described struggling to cope with pain and discomfort from the prosthesis, as well as the frustration of not being able to do important activities. This appeared to make it harder to accept the changes limb loss had brought to their lives.

it makes you unhappy because you think OK why is it doing this now and you know every single step you took was ... [pause] painful. There was rubbing, there was pinching and if you haven't got that right you don't want to wear it so you think oh God and you get upset and then you get down and reality kicks in again, that I'm an amputee. (Harry, 33

Participants highlighted that successful limb use was also about how usable their prosthesis was. They described the challenges of managing the fit of their prosthesis throughout the day as their residual limb volume fluctuated. The burden of having to add socks was described as frustrating and tiring.

During the course of the day if I'm doing a lot and I'm heavily sweating I have have to change them so I go about two or three sets of socks so I have to have a lot of socks with me. and em it's just very, that that in itself is very tiring and trying because you can see that and then when my sleeve starts sliding down I have to stop otherwise my leg is going to fall off. and and then it gets really, like I say it gets really uncomfortable. So by the time I'm finished I'm glad to take my leg off and feel much better. (Adam, 38 years, TTA)

Theme 4 - if I have pain, I am able to manage it

The group of participants who shared their views in this study described a range of experiences with pain. Some spoke of phantom pain and others of significant residual limb pain. Some talked about frequent and intense pain, whilst others reported that they had no pain at all. Participants who did experience pain compared the impact to that of socket discomfort, in that it affected their ability to walk again, their participation in important activities and roles, and subsequently their mental health.

if I do have this pain then I'm going to have to think about another career, another job, and and I'm going to have to think that this is for life. (Ruth, 50 years, TTA)

The ability to manage pain was an important outcome domain for the people in this study. Some participants talked about medication or limb wearing as useful management approaches. Despite these techniques, several participants discussed the need to accept that pain is now part of their lives to some degree, and there was no choice but to learn to manage it.

I think pain management because I don't think pain free is the expectation. Well it's an expectation but to achieve that I think at the end of the day you've had your leg chopped off. It's not going to operate like a normal leg would do so I think you learning to cope and deal with the pain is the important bit. (Jamie, 42 years, TTA)

Theme 5 - I am able to accept my new normal

Theme 5 is divided into three subthemes that describe psychosocial outcome domains of importance. Interestingly, all these subthemes tended to be discussed by participants who were more than 2 years post amputation, suggesting important domains may evolve over time.

Subtheme 5.1 – chasing normality

Returning to a sense of normality seemed to be the aim of recovery for participants. This sense of normality appeared to be supported by wearing a prosthesis but was often challenged in situations where the participant's new reality did not align with their life before the amputation, and differences in the "new normal" were highlighted.

When I'm on my leg I feel totally comfortable even though there's pain. But when I em when I take my leg off at night and sleep and then have to scoot on a cushion to the toilet which is only next door I feel uncomfortable and when I'm in a wheelchair I feel uncomfortable because I haven't got my leg on. (Ruth, 50 years, TTA)

Subtheme 5.2 – adjusting to limb loss

Success within this theme was often described as being able to adjust to, and accept, the new normal. Coming to terms with the changes that amputation had brought to people's lives was described as a process of psychological adjustment that individuals, and often their family members, needed to undertake following limb loss. This process was described as a difficult one, as participants tried to come to terms with the loss of important activities, unmet expectations and changing roles.

It's really hard to be honest. Umm(sigh) There's a whole array of feelings really, so from feeling a bit silly for even thinking that I'd be able to do that erm to kind of yes but anger, sadness, just kind of getting bit down about it. You know I think I've kind of got to a stage now where there's a degree of acceptance of what I can and can't do. (Darren, 47 years, KD)

Being able to adjust to an altered appearance was also highlighted. Participants described trying to adjust to their altered sense of self, as well as how others perceived them, and spoke of using the prosthesis to control their appearance and support their adjustment.

actually realistically one leg what do we want to achieve? We want to be able to walk along the street without people pointing and staring and thinking oh look at that poor bastard. That pity effect. You want to be able to walk along quite proud and quite happy with what we're doing and what we achieved without being tapped on the back, oh aren't you doing well So for me it was very important that I could wear trousers and nobody know I was an amputee. (Jamie, 42 years, TTA)

Ultimately, despite the challenge of adjusting to the amputation, success was described as being able to accept and learn to live with the new normal. This seemed to be facilitated by understanding personal limitations and managing them in a satisfactory way, as well as focusing on what could be accomplished.

but coming to terms with the things that you actually can't do. I think that's the key to being happy afterwards. I can't walk in the woods and feel the leaves among my feet as I kick them out of the way. I can't cycle and I have had an allotment and I can't use that. But it doesn't matter, I can do other things. (Angus, 88 years, TTA)

Subtheme 5.3 - sense of achievement

Many participants felt very proud of what they had achieved since their amputation, especially when they reflected on how they had progressed over time, and this motivated them to do more. Achievement and motivation were commonly associated with goal setting and many participants identified the setting and achieving of their own goals as an important success following prosthetic rehabilitation.

So this year on my 40th birthday we climbed Mount Snowden together as a family so that was my first goal of climbing different mountains. So it's that sort of keeping going isn't it. (Erica, 39 years, TTA)

Achieving goals increased people's confidence and helped give their recovery purpose. Many people talked about continuing to set new goals for themselves in the future, this was highlighted as an important part of normal human behaviour.

Goals are important throughout our lives, amputee or not. (Samantha, 54 years, TT, Member checking summary)

Discussion

The findings from this analysis offer an in-depth patient-centred view into what people who have undergone rehabilitation with a prosthetic limb feel are important outcome domains of recovery. The iterative qualitative approach used here gives voice to the experiences of prosthetic users, allowing them to reflect on what recovery means to them in the context of their own rehabilitation experience and their life with limb loss. To our knowledge, no other study has explored this phenomenon with such a large, diverse sample and with a focus solely on the views and experiences of prosthetic users. This group of participants had a mean age of 59, with almost half losing their limb due to diabetic dysvascular reasons. Other causes of amputation, such as trauma, cancer, and infection, were also represented and participants with a range of different levels of amputation were included. Our purposive sampling approach sought to ensure this variation so that a wide range of views and experiences could be included. The representation of these characteristics within the sample appears comparable to the UK limb loss population [46-48].

Outcome domains of importance were summarised into five themes that describe a successful recovery following prosthetic rehabilitation from a patient's perspective. The themes highlight the participant's desire to be able undertake their individually valued activities again, in the way they wanted, i.e., easily, independently, without falling over and with minimal equipment. They discussed how important a comfortable easy-to-use prosthesis is, and that if they have pain, they want to be able to accept and manage it. Finally, they talked about wanting to adjust and accept their new normal following amputation. The domains of pain management, socket comfort, independence, participation in work and social activities, and psychological recovery were also described in a proposed medium term (within 2 years of amputation) core outcome set for use following lower limb amputation due to dysvascular causes [55]. This initiative combined patient and clinician views and focused on outcomes of a single cause of limb loss. Our study corroborates the importance of these domains, as well as highlighting other domains, such as falling, and deepens our understanding of their importance solely from the perspective of prosthetic users.

The participants in this study identified being able to walk again as a key aspect of recovery, which contributed to a muchdesired sense of normalcy. However, it appeared to be only the beginning of a successful outcome. Walking was often viewed as an essential skill, alongside climbing stairs, and descending slopes, etc. that enabled the important domain of participation in valued activities. A meta-synthesis of qualitative research exploring the experiences of people following amputation [23] found several articles reporting that it is the involvement in valued activities that is profoundly significant to people following limb loss. When people spoke of "how well" they were getting on this often related to whether or not they were able to undertake these activities.

The concomitant nature of activity and participation described here is clearly depicted within the ICF, which articulates how the ability to perform skills such as walking underpins the person's ability to participate in their life activities [29]. Although participants articulated the importance of skills such as walking, the outcome domain of importance to participants appeared to be participation in valued activities. Yet many of the outcome measures developed for use following lower limb amputation focus on measuring the underlying domain of mobility. A systematic review by Xu et al. identified outcome domains captured following lower limb amputation in published clinical studies using outcome measures and mapped them against the ICF. Xu et al. found that of the 130 different ICF categories these domains linked to - the most frequently represented concepts, almost a quarter (22%), could be attributed to a single domain, mobility [10]. This suggests that the outcome measures commonly used in prosthetic research and clinical practice, such as the 6-min walk test, the 2min walk test, the timed up and go, the L-Test, and the 10-m walk test [56-59], as well as several patient-reported measures (PROMs) that seek to assess mobility from the patient's perspective, such as the PLUS-M and the Locomotor Capabilities Index [57,58], may not be fully capturing domains that are important to patients.

Measuring the domain of mobility as an important outcome domain following prosthetic rehabilitation may assume that the acquisition of mobility skills, such as walking or stair skills, etc., indicates that the individual will be able to participate in their valued activities. However, other factors may prevent this important transition, such as the domains identified in this study, i.e., socket comfort, fear of falling, or difficulty accepting limb loss. Measuring mobility alone may only capture the start of a successful recovery following prosthetic rehabilitation. Capturing true success, as identified by patients themselves, may lie in understanding the extent to which a person can use their regained mobility to participate in important activities.

In addition to informing outcome measurement in clinical settings, these findings suggest that in order for clinical teams to support meaningful recovery during prosthetic rehabilitation, they need to focus on more than just attainment of mobility skills. To enable meaningful participation that is highly valued by patients, the focus of rehabilitation should also involve the contextualisation of mobility skills within different environments and activities.

Our study also highlighted that important outcome domains appear to be about more than whether someone was able to participate in an activity or not, but "how" they were able to do it. Being able to master activities and do them without falling over, or fear of falling over, was described as building confidence and increasing participation. A recent systematic review by Steinberg et al. reported an annual falls rate of 50% in people with a lower limb amputation [60] and falls injuries were reported in 40-60% of incidents [61], highlighting the frequency of this experience in this population. Balance and safety were also identified as important outcome domains in two qualitative studies exploring meaningful outcomes, from a patient's perspective, following the prescription of prosthetic componentry [32,33]. Both studies reported that greater balance and stability was thought to reduce the risk of falling and this promoted confidence and increased participation in community activities. Several participants also spoke of how this helped them feel more like themselves again [32].

Our findings showed that being able to do activities independently with as little equipment as possible was also key to a successful recovery and appeared to increase our participant's selfworth and feelings of returning to "normality". Independence was identified as an important outcome domain in Schaffalitsky et al.'s qualitative study, including both prosthetic users and clinicians [33]. Interestingly clinicians in their study described independence as a functional achievement, whereas prosthetic users appeared to focus on the psychological benefit of independence, highlighting the increased self-efficacy and self-esteem they experienced, as well as the benefit of not having to rely on others. The authors discussed that although the outcome domain identified was the same, the meaning was different between the groups, and this unique perspective illustrates the need to consider both physical and psychosocial outcomes of rehabilitation [33,34].

The concept of how patients are able to participate also provides useful insights to inform the delivery of rehabilitation, which often focuses on achieving a basic level of competence, such as can a patient do a task or not? Independence, mastery, balance and confidence, and the need for less equipment all develop over time, and are activity and environment dependent. This may suggest the need for longer-term community-based approaches to rehabilitation focusing on activities of importance within the patient's own environment.

Another outcome domain which was described as an enabler of participation and a factor which dictated "how" participants were able to engage, was the comfort and usability of the prosthesis. Inadequate socket comfort is the commonest problem reported during visits to prosthetic clinics [62]. Despite this significant clinical burden, and the importance of a comfortable socket to prosthetic users as described in this study, no studies have yet been published exploring the experience of socket comfort from a patients perspective, and very few outcome measures exist to capture this domain [62,63]. Socket comfort was also one of the concepts that does not fit well within the domains of the ICF [25].

The literature that does exist focuses on assessing satisfaction with the prosthesis, but numerous definitions have been used to operationalise "satisfaction" making comparison between studies challenging [64]. Our study indicates that comfort may be a key element contributing to satisfaction with the prosthesis from a patient perspective. More research is required to understand socket comfort from this viewpoint to inform the design, fitting and use of prosthetic limbs in clinical practice, as well as for measuring the effectiveness of this process.

Linked to the domain of prosthetic comfort was the outcome domain of pain. The pain experiences of participants in this study were highly varied, in terms of both the nature of pain and its prevalence. This variation is also seen in the wider literature [65]. Many studies measure the domain of pain following amputation and focus on capturing pain intensity, frequency, and interference [65–68], but only two outcome measures used in these studies capture pain specific to the experience of people following amputation. The Prosthesis Evaluation Questionnaire (PEQ) [69] and the Trinity Amputation and Prosthesis Evaluation Scale (TAPES) [70] both include subscales that measure pain with prosthetic users. The subscales include questions about residual limb pain, phantom pain and back pain, and capture pain intensity, frequency, and interference.

However, the outcome domain of importance identified by participants in this study was that they were able to manage their pain. This can be described as pain self-efficacy, which is defined as beliefs about one's ability to control pain [71]. In the wider chronic pain literature self-efficacy has been linked to improved treatment outcomes and participation in important activities [71]. A study by Gupta and Leung found that poor self-efficacy was associated with poorer quality of life in patients with post-amputation pain and was linked to increased medication use [72]. This mismatch in how we measure pain following amputation and how patients are experiencing and coping with pain suggests that even within different domains we may not be measuring the aspect of that domain that is meaningful to prosthetic users.

The themes examined so far have predominantly focused on physical recovery. However, "feeling" normal again was discussed throughout the findings and many of the themes included examples of when problems in "physical" domains affected the mental health of participants. This clearly demonstrates an interwoven psychosocial recovery. The impact amputation can have on an individual's mental health has been previously documented in the literature with feelings of sadness, shock, anger, and despondency described [23], and depression, social discomfort, and body image anxiety found to be common experiences [73].

Gallagher and MacLachlan describe physical, psychological, and social challenges following amputation [74], which are discussed here in an entwined way by these participants. The psychological recovery following amputation appeared to be impacted by all of the themes described in this study and characterised by the emergence of a new normal following lower limb amputation. This new normal has been described previously in the literature as the forging of new identities within the constraints of prosthetic use [23]. Our findings illustrate that participants valued the ability to adjust to amputation and to be able to accept their limitations regarding participation, as well as appearance. This acceptance was also described in Murray and Foreshaw's qualitative synthesis, where several articles reported that the key task identified by participants was being able to accept their limb loss [23]. Interestingly, the themes exploring psychosocial adjustment tended to be discussed by participants who had undergone amputation more than 2 years ago. This

may indicate that outcome domains of importance evolve overtime as the reality of limb loss, and the impact and permanence of the associated disability, is more fully experienced. This phenomenon has also been described in research exploring outcome domains of importance to young people with chronic pain, who described "turning points" in their treatment where outcomes important to them changed [75]. This finding may also affect prosthetic clinical practice as the patient's focus and goals might alter as they progress through rehabilitation and beyond. Perhaps suggesting a need for evolving MDT input and care planning throughout the prosthetic life course to support changing priorities. Further research on how outcome domains of importance to people following amputation change over time would be useful to inform both clinical practice and outcome measurement initiatives, especially considering the lifelong management of this population.

Demographic data was collected as part of this study and was synthesised with the thematic analysis to explore any patterns within the themes. The findings appeared to show that the outcome domains identified were valued by a wide variety of individuals. As a subgroup analysis was not the aim of the current research, future research could explore whether outcome domains of importance vary between different types of patients, i.e., transtibial vs. transfemoral, or high activity vs. lower activity. This would deepen our understanding of what outcome domains to measure and when, as well as inform the focus of rehabilitation for different types of patients.

The apparent interconnected nature of the physical and psychosocial recovery described by these participants also highlights that outcome domains of importance do not exist in isolation for participants. Difficulties experienced by participants in one domain/theme appeared to also impact other themes. This cascade of impact, for example, socket comfort limiting participation which then affects mental health, suggests an interdependent relationship between outcome domains of importance. For a prosthetic user, a successful outcome appears to be a holistic one, which combines meaningful recovery in each of these outcome domains. The interconnected nature of these themes is visualised in Figure 2.

This finding is reflective of frameworks such as the ICF, which describe a holistic, interconnected, biopsychosocial model of disability, functioning, and health [76]. The ICF demonstrates how different elements of functioning, such as the themes and subthemes described here, are influenced by each other, as well as environmental and personal factors, to build a picture of the individuals overall health. This interdependency is also seen within the quantitative prosthetic evidence base, where many studies have demonstrated statistical relationships between the outcome domains of importance raised in this article. For example, the association among pain, activity level, prosthesis satisfaction, and psychosocial adjustment [65] or quality of life, mobility, and falls mitigation [77].

Within clinical practice, despite recommendations for a holistic patient-centred approach to rehabilitation [36,37], outcome measurement often focuses on capturing outcome domains in isolation. This also appears to be the case in the development of core outcome sets [18]. The findings presented here indicate the need for a physical and psychosocial multi-domain approach to outcome measurement in prosthetic rehabilitation, with patient priorities at its centre, which is able to capture the different impacts of prosthetic rehabilitation on more than just the patient's mobility, but around the whole person.



Figure 2. Model of holistic view of outcomes of importance following lower limb prosthetic rehabilitation.

Limitations

The sampling approaches used in this study, i.e., self-selection via convenience sampling, followed by practitioner selection of those individuals with purposively identified characteristics, may have led to potential bias. Participants who self-select may be more open and more confident to talk about their experiences [78]. This may be the case for participants who had a more positive experience of recovering from amputation, or who are happier with their outcome. Participants selected by clinicians may also have led to greater inclusion of those who are deemed successful, well-adjusted, or more open.

As this study was co-produced with our public research partners we included both interviews and focus groups, allowing participants to choose how they would like to take part. These data collection methods can produce different data, i.e., in-depth accounts vs. group sense making [79] which allowed us to triangulate these methods. We were able to collect large amounts of data through each technique, which provided richness and depth. Nonetheless care needs to be taken that this approach does not imply credibility by assuming that weaknesses in one method will be compensated by the other, rather it suggests a comprehensive process to exploring the phenomenon of interest [80]. Our accessible approach may also have contributed to the excellent engagement we experienced during recruitment and data collection. Being able to choose how to take part may have enabled participants to fit the research into their daily lives and allowed them to choose a forum where they felt most comfortable to be open and share their experiences.

The reflexive process undertaken by CO also highlighted that the perspective of a physiotherapist in clinical practice gave a unique insight into the creation of themes that could be accessible to clinical practice. However, it was acknowledged that this perspective may tend towards a focus on more physical outcome domains. The involvement of MDH (a health psychologist) in the analysis and interpretation of the findings helped strengthen the rigor and credibility of our approach by identifying and understanding this perspective. This process is advocated by Braun and Clarke who suggest that researchers should have insight into, and articulate, their generative roles in research [40]. The wider team of authors was also active in reviewing the analysis and verifying the findings.

The use of an iterative qualitative style using a robust and rigorous approach has provided an in depth understanding of outcome domains of importance following prosthetic rehabilitation for these participants. The findings offer a useful insight but due to the nature of qualitative research, the complexity of this life-changing event, and the variability within the limb loss population, they may not reflect outcome domains of importance to all patients following prosthetic rehabilitation. Future research could use quantitative approaches to establish the extent to which the wider population values these domains. This study may also provide a useful foundation for future consensus work aimed at developing core outcome sets for use in research and clinical practice.

Conclusion

Outcome domains of importance following prosthetic rehabilitation appear to extend far beyond a return to walking. They encompass the what and how of participation, comfort, selfmanagement of pain, and acceptance of a post-amputation new normal. Each of these outcome domains is not viewed separately in the experiences of prosthetic limb wearers, and as such their interrelated nature needs to be captured in both clinical practice and the development of future outcome domain consensus initiatives. This will ensure prosthetic services are providing patient-centred rehabilitation and measuring outcome in a holistic way, with a focus on domains that are meaningful to patient recovery.

Acknowledgements

The authors thank the public research partners and all participants of the research for sharing their experiences. The authors also acknowledge and thank the project funders the British Association of Chartered Physiotherapist in Limb Absence Rehabilitation (BACPAR), the Institute for Life Sciences at the University of Southampton, the Engineering and Physical Sciences Research Council (EPSRC)/National Institute for Health Research (NIHR) Global Challenges Research Fund [grant EP/R014213/1], and the Royal Academy of Engineering [RAEng grant RF/130].

Disclosure statement

CO has nothing to disclose. MDH has nothing to disclose. AD reports grants from Engineering and Physical Sciences Research Council, grants from Royal Academy of Engineering, during the conduct of the study. CM has nothing to disclose.

Funding

This work was supported by British Association of Chartered Physiotherapist in Limb Absence Rehabilitation (BACPAR), the Institute for Life Sciences at the University of Southampton, the Engineering and Physical Sciences Research Council (EPSRC)/ National Institute for Health Research (NIHR) Global Challenges Research Fund [grant EP/R014213/1], and the Royal Academy of Engineering.

References

- [1] Gray M. Value based healthcare. BMJ. 2017;356:j437-2.
- [2] Value of Health Initiative. The Value of health: Improving outcomes final report. European Alliance for Value in Health; 2018.
- [3] Hurst L, Mahtani K, Pluddemann A, et al. Defining Value-based Healthcare in the NHS: CEBM report May 2019.
- [4] Clarke S, Taal E, Hewlett S, et al. OMERACT. The OMERACT glossary. OMERACT [Internet]. 2021 [Cited Oct 2021]. Available from www.omeract.org/glossary/
- [5] Robinson C, Fatone S. You've heard about outcome measures, so how do you use them? Integrating clinically relevant outcome measures in orthotic management of stroke. Prosthet Orthot Int. 2013;37(1):30–42.
- [6] Rommers GM, Vos LD, Groothoff JW, et al. Mobility of people with lower limb amputations: Scales and questionnaires: a review. Clin Rehabil. 2001;15(1):92–102.
- [7] Condie E, Scott H, Treweek S. Lower limb prosthetic outcome measures: a review of the literature 1995 to 2005. J Prosthetics Orthot. 2006;18:13–45.
- [8] Deathe AB, Wolfe DL, Devlin M, et al. Selection of outcome measures in lower extremity amputation rehabilitation: ICF activities. Disabil Rehabil. 2009;31(18):1455–1473.
- [9] Hebert JS, Wolfe DL, Miller WC, et al. Outcome measures in amputation rehabilitation: ICF body functions. Disabil Rehabil. 2009;31(19):1541–1554.
- [10] Xu J, Kohler F, Dickson H. Systematic review of concepts measured in individuals with lower limb amputation using

- the international classification of functioning, disability and health as a reference. Prosthet Orthot Int. 2011;35(3): 262–268.
- [11] Heinemann AW, Ehrlich-Jones L, Connelly L, et al. Enhancing quality of prosthetic services with process and outcome information. Prosthet Orthot Int. 2017;41(2): 164–170.
- [12] Hawkins EJ, Riddick W. Reliability, validity, and responsiveness of clinical performance–based outcome measures of walking for individuals with lower limb amputations: a systematic review. Phys Ther. 2018;98(12):1037–1045.
- [13] Scopes J. Outcome measures of physical function in adult unilateral lower limb amputees during prosthetic rehabilitation: use in clinical practice and psychometric properties [dissertation]. Glasgow: Queen Marys University; 2016.
- [14] Resnik L, Borgia M, Silver B. Measuring community integration in persons with limb trauma and amputation: a systematic review. Arch Phys Med Rehabil. 2017;98(3): 561–580.e8.
- [15] Balk EM, Gazula A, Markozannes G, et al. Psychometric properties of functional, ambulatory, and quality of life instruments in lower limb amputees: a systematic review. Arch Phys Med Rehabil. 2019;100(12):2354–2370.
- [16] Heinemann AW, Connelly L, Ehrlich-Jones L, et al. Outcome instruments for prosthetics: clinical applications. Phys Med Rehabil Clin N Am. 2014;25(1):179–198.
- [17] Ostler C, Scott H, Sedki I, et al. From outcome measurement to improving health outcomes following lower limb amputation A narrative review exploring outcome measurement from a clinical practice perspective. Prosthet Orthot Int. 2022;46(4):e341–e350. 1
- [18] Williamson PR, Altman DG, Bagley H, et al. The COMET handbook: version 1.0. Trials. 2017;18(S3):1–50.
- [19] Tugwell P, Boers M, Brooks P, et al. OMERACT: an international initiative to improve outcome measurement in rheumatology. Trials. 2007;8:38–36.
- [20] Khan K, Chief Editors of journals participating in the CROWN Initiative. The CROWN initiative: journal editors invite researchers to develop core outcomes in women's health. J Ovarian Res. 2015;8:6–12.
- [21] COMET Intitative. Core outcomes in effectiveness trials. [Internet]. Liverpool: COMET Intitative; 2022. www.comet-initiative.org
- [22] Kelley TA. International consortium for health outcomes measurement (ICHOM). Trials. 2015;16(S3):2015.
- [23] Murray CD, Forshaw MJ. The experience of amputation and prosthesis use for adults: a metasynthesis. Disabil Rehabil. 2013;35(14):1133–1142.
- [24] Dillon MP, Fatone S, Ramstrand N, et al. Prosthetics and orthotics international welcomes qualitative research submissions. Prosthet Orthot Int. 2019;43(4):366–368.
- [25] Radhakrishnan S, Kohler F, Gutenbrunner C, et al. Mobility in persons with lower extremity amputations and influencing factors: Using the international classification of functioning, disability and health to quantify expert views. Prosthet Orthot Int. 2019;43(1):88–94.
- [26] Radhakrishnan S, Kohler F, Gutenbrunner C, et al. The use of the international classification of functioning, disability and health to classify the factors influencing mobility reported by persons with an amputation: an international study. Prosthet Orthot Int. 2017;41(4):412–419.
- [27] Xu J. A Core set for people following lower limb amputation based on the international classification of functioning,

- disability and health [dissertation]. Sydney, Australia: University of New South Wales; 2019.
- [28] Burger H. Functioning of persons following lower limb amputation-patients' perspective. Med. 2012;48:471–479.
- [29] World Health Organization. The ICF: an overview. Geneva, Switzerland: World Health Organization; 2001.
- [30] Kohler F, Xu J, Silva-Withmory C, et al. Feasibility of using a checklist based on the international classification of functioning, disability and health as an outcome measure in individuals following lower limb amputation. Prosthet Orthot Int. 2011;35(3):294-301.
- [31] Selb M, Escorpizo R, Kostanjsek N, et al. A guide on how to develop an international classification of. Eur J Phys Rehabil Med. 2015;51(1):105-117.
- [32] McDonald CL, Cheever SM, Morgan SJ, et al. Prosthetic limb user experiences with crossover feet: a pilot focus group study to explore outcomes that matter. J Prosthetics Orthot. 2019:31:133-139.
- Schaffalitzky E, Gallagher P, MacLachlan M, et al. [33] Understanding the benefits of prosthetic prescription: exploring the experiences of practitioners and lower limb prosthetic users. Disabil Rehabil. 2011;33(15-16):1314-1323.
- Schaffalitzky E, Gallagher P, MacLachlan M, et al. [34] Developing consensus on important factors associated with lower limb prosthetic prescription and use. Disabil Rehabil. 2012;34(24):2085-2094.
- [35] College of Occupational Therapists. Occupational therapy with people who have had lower limb amputations. Evidence-based guidelines. College of Occupational therapists. 2011.
- [36] British Society of Rehabilitation Medicine. Amputee and prosthetic Rehabilitation-Standards and guidelines. 3rd ed. London: British Society of Rehabilitation Medicine; 2018.
- Broomhead P, Clark K, Dawes D, et al. Evidence based clin-[37] ical guidelines for the physiotherapy management of adults with lower limb prostheses. BACPAR. 2012;03:1-68.
- [38] British Association of Prosthetists and Orthotists (BAPO). Service provision guidance for prosthetic & orthotic services. Seedhill, Paisley: BAPO; 2021.
- [39] Clarke V, Braun V. Successful qualitative research: a practical guide for beginners. 1st ed. London: Sage; 2013.
- [40] Clarke V, Braun V. Successful qualitative research: a practical guide for beginners. London: Sage: 2013.
- [41] Partnership UPISD. UK standards for public involvement. England: NIHR; 2019.
- [42] INVOLVE. Briefing notes for researchers: involving the public in NHS, public health and social care research. Eastleigh: INVOLVE; 2012.
- [43] Jupiter D, LaFontaine J, Barshes N, et al. Transmetatarsal and minor amputation versus major leg amputation: 30-Day readmissions, reamputations, and complications. J Foot Ankle Surg. 2020;59(3):484-490.
- [44] Taylor SM, Kalbaugh CA, Blackhurst DW, et al. Preoperative clinical factors predict postoperative functional outcomes after major lower limb amputation: an analysis of 553 consecutive patients. J Vasc Surg. 2005;42(2):227-235.
- Darter BJ, Hawley CE, Armstrong AJ, et al. Factors influencing functional outcomes and return-to-Work after amputation: a review of the literature. J Occup Rehabil. 2018;28(4): 656-665.
- [46] Twiste M. Limbless statistics. 2021. www.limbless-statistics.

- Davie-Smith F, Hebenton J, Scott H. A survey of the lower [47] amputee population in Scotland. Physiotherapy Amputee Research Group. 2020.
- [48] Moxey PW, Hofman D, Hinchliffe RJ, et al. Epidemiological study of lower limb amputation in England between 2003 and 2008. Br J Surg. 2010;97(9):1348-1353.
- Lambert SD, Loiselle CG. Combining individual interviews and focus groups to enhance data richness. J Adv Nurs. 2008:62(2):228-237.
- [50] Yardley L. Demonstrating validity in qualitative psychology. In: Smith J, editor. Qualitative psychology: a practical guide to research methods. 3rd ed. London: Sage Publications Limited; 2015. p. 257-272.
- [51] Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77-101.
- [52] Braun V, Clarke V. To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales. Qual Res Sport Exerc Heal. 2021;13(2):201-216.
- [53] Green J, Thorogood N. Qualitative methods for health research. London: SAGE Publications Inc; 2004.
- [54] Birt L, Scott S, Cavers D, et al. Member checking: a tool to enhance trustworthiness or merely a nod to validation? Oual Health Res. 2016;26(13):1802-1811.
- [55] Ambler GK, Brookes-Howell L, Jones JAR, et al. Development of core outcome sets for people undergoing major lower limb amputation for complications of peripheral vascular disease. Eur J Vasc Endovasc Surg. 2020;60(5):730-738.
- [56] NHS Clinical England. Commissionina Policv: Microprocessor controlled prosthetic knees. England: NHS England: 2016.
- [57] NHS England. Complex disability equipment - prosthetic specialised services for people of all ages with limb loss. England: NHS England; 2015.
- Scopes J, Tisdale L, Cole M-J, et al. The BACPAR outcome [58] measures toolbox: a step towards standardising outcome measures for physiotherapists working with lower limb amputees. Physiotherapy. 2015:101:e1357-e1358.
- [59] Gailey RS. Predictive outcome measures versus fucntional outcome measures in the lower limb amputee. J Prosthetics Orthot. 2006;18:51-60.
- Steinberg N, Gottlieb A, Siev-Ner I, et al. Fall incidence and associated risk factors among people with a lower limb amputation during various stages of recovery-a systematic review. Disabil Rehabil. 2019;41(15):1778-1787.
- [61] Hunter SW, Batchelor F, Hill KD, et al. Risk factors for falls in people with a lower limb amputation: a systematic review. Pm R. 2017;9(2):170-180.e1.
- [62] Hanspal RS, Fisher K, Nieveen R. Prosthetic socket fit comfort score. Disabil Rehabil. 2003;25(22):1278-1280.
- [63] Gailey R, Kristal A, Lucarevic J, et al. The development and internal consistency of the comprehensive lower limb amputee socket survey in active lower limb amputees. Prosthet Orthot Int. 2019;43(1):80-87.
- [64] Baars EC, Schrier E, Dijkstra PU, et al. Prosthesis satisfaction in lower limb amputees. Medicine. 2018;97(39):e12296.
- [65] Desmond D, Gallagher P, Henderson-Slater D, et al. Pain and psychosocial adjustment to lower limb amputation amongst prosthesis users. Prosthet Orthot Int. 2008;32(2):244-252.
- [66] Ehde DM, Czerniecki JM, Smith DG, et al. Chronic phantom sensations, phantom pain, residual limb pain, and other regional pain after lower limb amputation. Arch Phys Med Rehabil. 2000;81(8):1039-1044.

- [67] Morgan SJ, Friedly JL, Amtmann D, et al. Cross-Sectional assessment of factors related to pain intensity and pain interference in lower limb prosthesis users. Arch Phys Med Rehabil. 2017;98(1):105–113.
- [68] Skeat J, Perry A. Factors influencing the use of outcome measures for patients with low back pain: a survey of New Zealand physical therapists. Int J Lang Commun Disord. 2008;43(2):110–125.
- [69] Legro MW, Reiber GD, Smith DG, et al. Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. Arch Phys Med Rehabil. 1998;79(8):931–938.
- [70] Gallagher P, MacLachlan M. Development and psychometric evaluation of the Trinity amputation and prosthesis experience scales (TAPES). Rehabil Psychol. 2000;45(2):130–154.
- [71] Miles CL, Pincus T, Carnes D, et al. Measuring pain self-efficacy. Clin J Pain. 2011;27(5):461–470.
- [72] Gupta N, Leung C. The effect of post-amputation pain on health-related quality of life in lower limb amputees. Disabil Rehabil. 2020;0:1–7.
- [73] Horgan O, MacLachlan M. Psychosocial adjustment to lower-limb amputation: a review. Disabil Rehabil. 2004; 26(14–15):837–850.

- [74] Gallagher P, MacLachlan M. Psychological adjustment and coping in adults with prosthetic limbs. Behav Med. 1999; 25(3):117–124.
- [75] Joslin R, Donovan-Hall M, Roberts L. Exploring the outcomes that matter most to young people treated for chronic pain: a qualitative study. Children. 2021;8(12): 1170.
- [76] Ustun T, Chatterji S, Bickenbach J, et al. The international classification of functioning disability and health: a new tool for understanding disability and health. Disabil Rehabil. 2003;25(11–12):565–571.
- [77] Stevens PM. Prioritizing primary outcomes in prosthetic rehabilitation: Observations from recent evidence. J Prosthetics Orthot. 2021;33:82–87.
- [78] Robinson OC. Sampling in interview-based qualitative research: a theoretical and practical guide. Qual Res Psychol. 2014;11(1):25–41.
- [79] Guest G, Namey E, Taylor J, et al. Comparing focus groups and individual interviews: findings from a randomized study. Int J Soc Res Methodol. 2017;20(6):693–708.
- [80] Mays N, Pope C. Assessing quality in qualitative research. BMJ. 2000;320(7226):50–52.