Bone & Joint Research

Supplementary Material

10.1302/2046-3758.124.BJR-2022-0164.R2

Supplementary Methods. Detailed secondary thematic analysis methodology

Introduction

The Core Outcomes for Open Lower Limb Fracture (CO-OLLF) study draws on primary data collected in a study funded by the Wound management of Open Lower Limb Fractures Trial (WOLLF HTA-10/57/20), the results of which have been published separately.[1] In the primary research, a purposive sample of 25 participants between two and four years post-injury were recruited from the WOLLF Trial participants between October 2016 and April 2017 during routine clinical follow-up. Purposive sampling included a range of sex, age, mechanism of injury, the severity of open lower limb fracture, and time since injury.[1] Participants were only recruited to the WOLLF Trial if, at the end of their first debridement surgery, wound closure was not possible, necessitating additional treatment with skin or muscle flaps. This eligibility criterion ensured that all patients recruited were at the higher end of the open lower limb fracture severity spectrum (this excluded patients with Gustilo Anderson (GA) type I open lower limb fracture, whose wounds could be closed in the primary surgery). Thus, interview data reflected the patient recovery journey following a GA II or III open lower limb fracture. Ethical approval for the interviews was granted by the NHS Health Research Authority (12/WM/0001).

The deductive secondary thematic analysis presented in this study aimed to identify outcomes important to patients. It used a primary dataset that explored the lived experience of recovery from open lower limb fracture.[1] The primary study used an inductive approach to gain an understanding of the lived experience of recovery from open lower limb fracture.

Consideration of the appropriateness of secondary analysis of the WOLLF study qualitative dataset

The benefits of undertaking a secondary thematic analysis using primary data from the patient interviewsClick or tap here to enter text. are: 1) high-quality data gathered by experienced qualitative researchers in this field as part of an National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA)-funded study was used; 2) the interview data covered a broad range of experience and included up to four years post-injury; 3) open-ended questions elicited key areas for further exploration, e.g. limited mobility, challenges with intimacy, and surgical scarring disrupting self-image; and 4) the reuse of primary data reduced research and resource waste.[2,3]

Secondary thematic analysis

Study design

A thematic analysis approach was used, informed by the work of Braun and Clarke.[4,5] Epistemologically, the thematic analysis took an essentialist or realist approach. In this approach, meaning in the patient experience was theorized in an uncomplicated manner by assuming that a unidirectional relationship exists between experience, meaning, and the language the patients used. This approach is recognized in the work of Potter and Wetherel[6] and Widdicombe and Wooffitt,[7] where it is acknowledged that language reflects and enables us to articulate meaning and experience. The data were coded by the lead author (ALA), whose background includes medical training in Trauma and Orthopaedic Surgery. It was recognized that coding of the data was not possible in an epistemological vacuum, and consequently, the data were interpreted to some extent through a medical lens.

Data analysis

The first stage of the thematic analysis of the 25 interview transcripts was inductive. Immersion in the data, by reading and re-reading the anonymized interview transcripts while making notes and annotating potential outcome codes, was undertaken. Open coding was used to identify text extracts that may represent outcome codes. The second stage was deductive, and the outcome codes were grouped and organized under appropriate outcome domains in the Core Outcome Measures in Effectiveness Trials (COMET) Taxonomy of Outcomes.[8] Interpretation of the grouped outcome codes involved an iterative process of reading and re-reading the coded text extracts under each outcome domain of the COMET Taxonomy of Outcomes. This process helped to generate an understanding of the meaning and patterns behind the patient's experience to develop outcome themes. The computer software package NVivo V.12 (QSR International, UK) was used to help manage the data.

This approach enabled the following research question to be answered: 'what outcomes are important for patients within their experience of recovery from open lower limb fracture?' To facilitate reflection on the process of interpretation, a sample of five interview transcripts were coded in duplicate by two researchers (ALA, ET), before meeting to discuss and compare identified outcome codes and themes. Differing interpretations of meaning were discussed. The remaining analysis was conducted by the lead author (ALA). Rigour was demonstrated through trustworthiness.[9] Authors were engaged with the data and held regular meetings throughout the analysis, allowing for reflection and discussion over the creation and categorization of outcome codes and themes. Auditability was demonstrated through the use of quotes to illustrate outcome themes and the categorization of themes to the COMET Taxonomy of Outcomes, Outcome Domains and Core Areas. Data saturation in terms of the generation of new outcome themes was achieved; no further new outcome themes were identified following analysis of the first 15 interview transcripts. However, all 25 interview transcripts were analyzed to ensure that saturation was achieved. Outcome themes were reviewed throughout the thematic analysis and evolved in an iterative process to best reflect the underlying outcome codes.

Defining an outcome theme

Outcome themes were identified where meaning in the dataset was interpreted to represent an important patient outcome. For example, pain and discomfort:

> *I sit down for an hour and I get up, oh the pain you can't describe it, but I mean for seconds, but it's enough to… it's really, really painful.* P2

> *I feel the discomfort in that part of, in the upper, I don't know what the technical term is, in, in, in that sort of, in, in, in the bit between the foot and the ankle.* P10

> *I know they have the Hippocratic oath to try and do the best they can but sometime saving it, so it looks like a foot is far less than the ramifications of the pain of it. The disability is not the problem, it's the pain. I could hobble for the rest of my life quite easily without pain.* P13

The experience of pain and discomfort, and the lack thereof, was important to patients during their recovery and therefore this was identified as an outcome theme. Extracts of patient experience from the 25-interview transcripts analyzed where pain or discomfort was discussed were coded under the outcome theme of 'pain'. Codes were then reviewed over the whole dataset, and the theme 'pain or discomfort' was created, which best described the underlying outcome of importance in the coded patterns of patient experience, i.e. inclusion of the outcomes pain and discomfort.

The creation of outcome themes was not limited to high-prevalence codes such as 'pain or discomfort'. Researcher judgement and discussion with the research team were also used to identify relevant and important outcome codes interpreted from the data when creating outcome themes, particularly for low-prevalence outcome codes. For example, sexual function:

> *We don't have sex because every single time I move there's something you know I can't, yeah and plus you know, look at my legs you know it's just like 'no'.* P19

The above text extract was the only datum coded as 'sexual function'. Following discussion within the research team and later in discussion groups, it was felt that sexual function might be an important patient outcome following open lower limb fracture that warranted thematizing. This decision was justified by researcher judgement and a hypothesis that the area may have been under-represented in the data due to its personal nature.

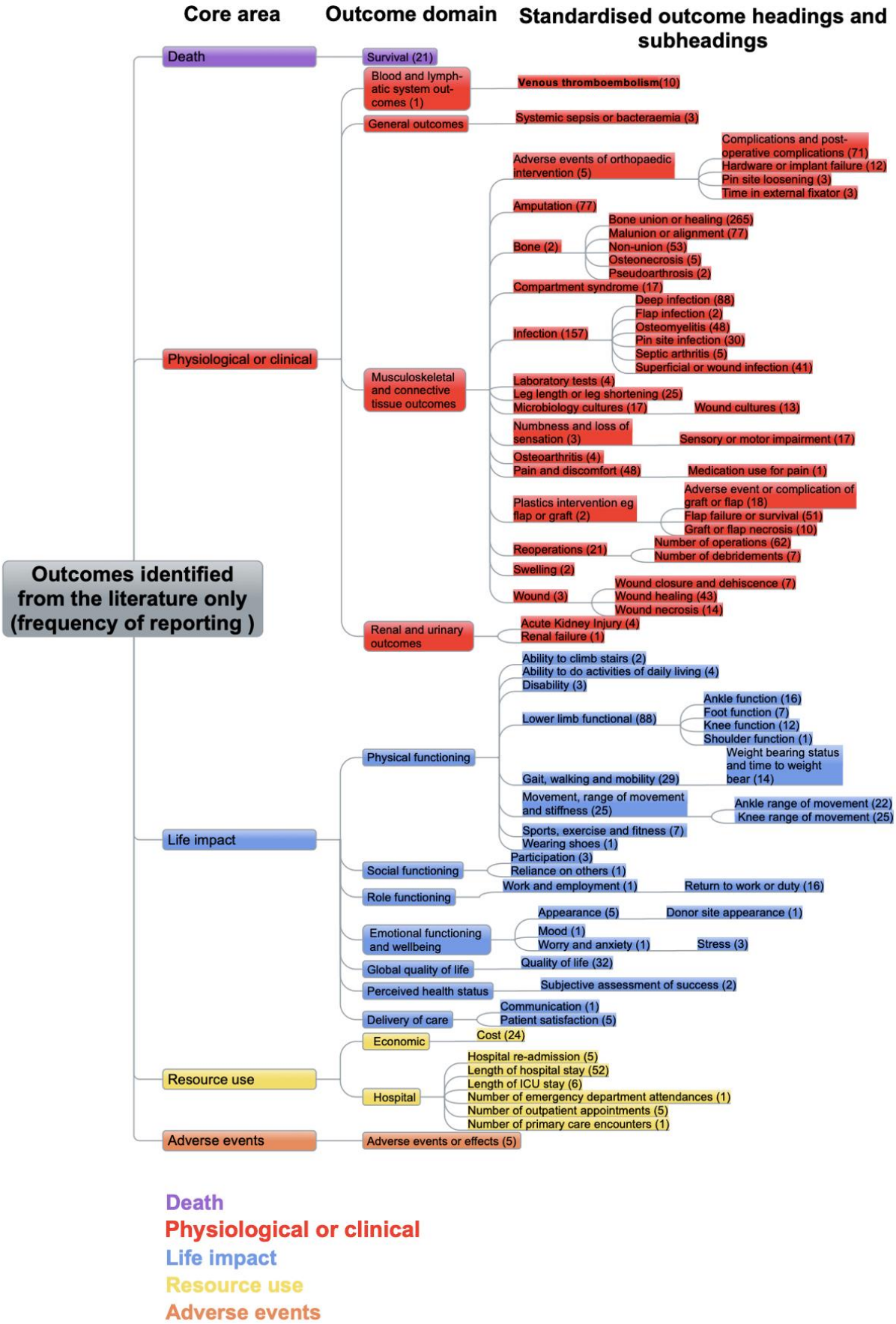


Fig a. Standardized outcome headings identified from the literature and frequency of reporting categorized using the Core Outcomes Measures in Effectiveness Trials Initiative, Taxonomy of Outcomes, Outcome Domains and Core Areas using a colour code.

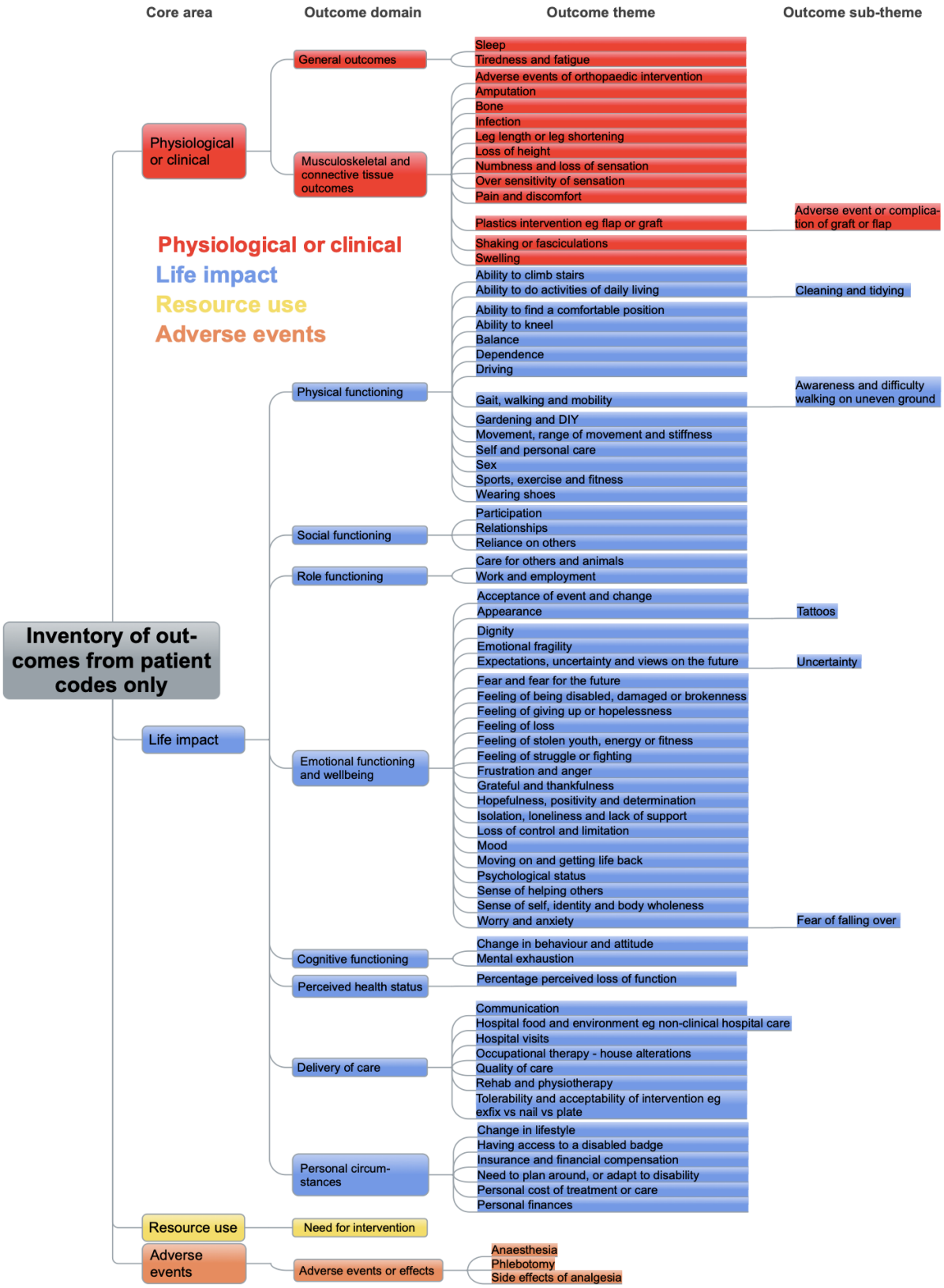


Fig b. Outcome themes interpreted from the thematic analysis categorized using the Core Outcomes Measures in Effectiveness Trials Initiative, Taxonomy of Outcomes, Outcome Domains and Core Areas using a colour code.

Table i. Progression of the inventory of outcomes through Structured Discussion Groups (SDGs) and a Study Management Group (SMG) meeting to the final list of outcomes taken to the Delphi survey.

Outcome themes categorized by the COMET Taxonomy of Outcomes core area and outcome domain (outcome domain number)	Number of systematic review codes	Primary outcome codes	Secondary outcome codes	Outcome statements presented at the healthcare professional SDG (SDG1)	Outcomes presented at the patient SDG (SDG2)	Outcomes presented to the Study Management Group (SMG)	Outcomes approved for Delphi survey round 1
1. Death							
Mortality/survival (1)							
Death	21	1	20	Death is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Death changed to Survival.*	Survival	→	Survival
2. Physiological or clinical							
Blood and lymphatic system outcomes (2)							

Venous thromboembolism	10	0	10	Diagnosis of venous thromboembolism is an important outcome to measure when recovering from open lower limb fracture.	Venous Thromboembolism (blood clots in the legs or lungs)	→	Venous thromboembolism (blood clot in legs or lungs)
General outcomes (9)							
Sleep	0	0	0	Quality of sleep is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Outcome joined with fatigue as it was felt that there was significant concept overlap.*	Sleep and fatigue *SDG2: Participants recognized sleep as important, comparing it to being worse after the injury than looking after a 2-year-old. Although they did recognize that it may not be important enough to become a core outcome.*	→	Sleep and fatigue
Systemic sepsis or bacteraemia	3	0	3	Absence of systemic infection is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Dropped due to only being reported in only 3 studies.*			Number of unplanned hospital re-admissions[1]
Tiredness and fatigue	0	0	0	Tiredness and fatigue is an important outcome to measure when recovering from open lower limb fracture.			Length of hospital stay[1]

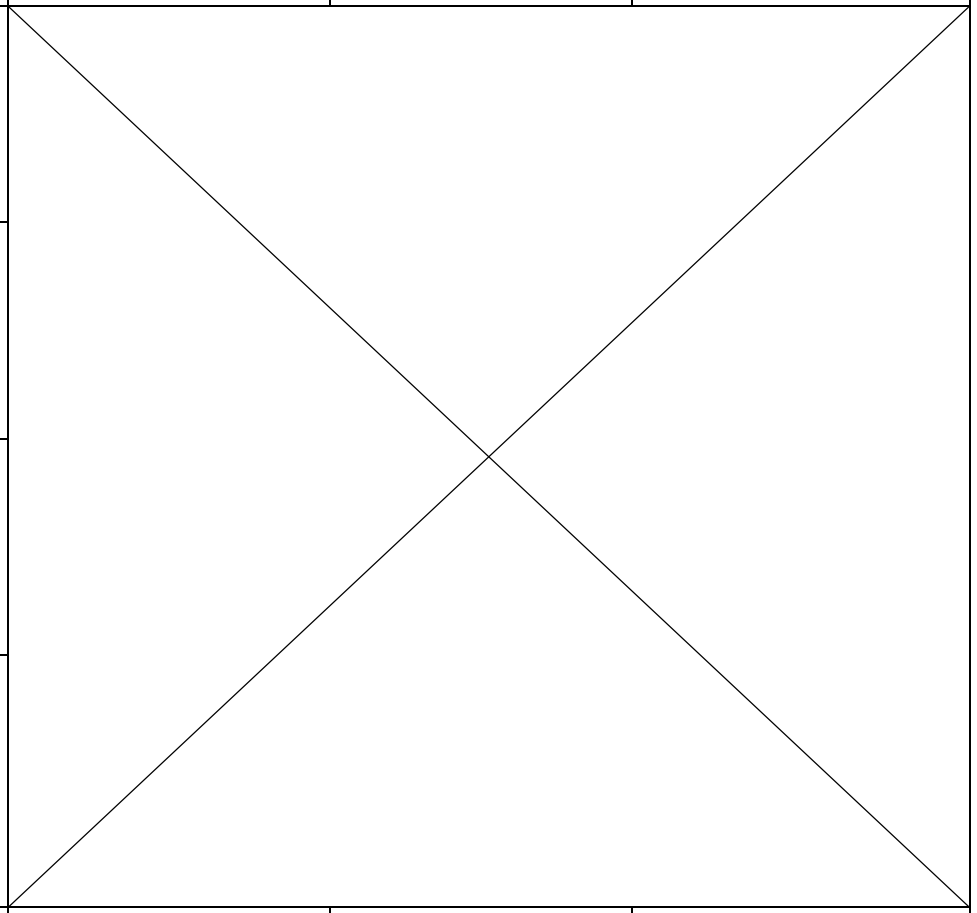
[1] Outcome previously categorized under COMET Taxonomy of Outcomes core area: Resource use, outcome domain: Hospital. Moved general outcomes domain following SMG1.

				SDG1: Combined with sleep as above.		
						Number of outpatient appointments[1]
						Number of primary care visits[1]
Musculoskeletal and connective tissue outcomes (15)						
Adverse events of orthopaedic intervention	5	2	3	*SDG1: Dropped due adverse events core area below*		
Complications and postoperative complications	71	1	70	Complications following treatment is an important outcome to measure when recovering from open lower limb fracture.	Complications	Complications *SMG1: Dropped due to overlap with 'number of adverse events' outcome below.*
				Complications resulting from muscle flaps or grafts is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Soft-tissue complication thought to be a specific and serious complication justifying inclusion as a separate outcome theme.*	Complications resulting from soft-tissue (muscle flaps or grafts)	→	Complications resulting from soft-tissue (muscle flaps or grafts)
Hardware or implant failure	12	0	12	Hardware or implant failure is an important outcome to measure when recovering from open lower limb fracture.	Metalwork failure *SDG2: Participants recognized metalwork*	→	Metalwork failure

				SDG1: Implant term dropped, feeling term could be associated with aesthetic surgery, e.g. breast implant.	*failure as important. One patient recounted his experience of needing an additional surgery for a 'snapped' piece of metalwork.*		
Pin site loosening	3	1	2	External fixator pin site loosening is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Outcome dropped due to cover of concept by 'metalwork failure outcome'*			
Time in external fixator	3	0	3	Time in an external fixator is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Dropped as felt to be too specific with sufficient coverage of concept in other outcome themes, e.g. '*Tolerability and acceptability of surgical intervention e.g. external fixator, is an important outcome to measure when recovering from open lower limb fracture'.			
Amputation	77	8	69	Amputation is an important outcome to measure when recovering from open lower limb fracture.	Amputation *SDG2: All participants agreed that amputation is a very important outcome*	→	Amputation

					theme. It was also recognized that the term amputation is very broad. There are many types of amputation which have big effects on your eventual function, e.g. below knee vs through knee vs above knee. It was also discussed that an amputation may be a good option for some people.		
Bone	2	0	2	Bone union is an important outcome to measure when recovering from open lower limb fracture. *SDG1: 'union' dropped in favour of 'healing' as felt to be more intuitive for patients.*	Bone healing	→	Bone healing
Bone union or healing	265	15	250				
Malunion or alignment	77	0	77	Malunion, alignment and rotational deformity is an important outcome to measure when recovering from open lower limb fracture.	Malunion, alignment and rotational deformity	→	Malunion, alignment and rotational deformity
Nonunion	53	2	51	Nonunion is an important outcome to measure when recovering from open lower limb fracture. *SDG1: outcome dropped as from a patient perspective bone union/healing and nonunion/non-healing are the same concept.*			

Osteonecrosis	5	1	4	Osteonecrosis is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Too specific and infrequently reported in the literature, can be covered by adverse events core area below.*			
Pseudoarthrosis	2	0	2	Pseudoarthrosis is an important outcome to measure when recovering from open lower limb fracture. *SDG1: As above.*			
Compartment syndrome	17	0	17	Compartment syndrome is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Felt that the consequences of a compartment syndrome would be picked up in other outcome themes, e.g. appearance and walking, gait and mobility.*			
Infection	157	27	130				
Deep infection	88	14	74	Deep infection is an important outcome to measure when recovering from open lower limb fracture. *SDG1: from a clinical point of view the distinction between deep and*	Deep infection	→	Deep infection

				superficial infection is important and does effect practice. So it is important to differentiate between the two rather than having a broad 'infection' outcome theme.			
Flap infection	2	0	2	Flap infection is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Covered in surface infection*			
Osteomyelitis	48	6	42	Osteomyelitis is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Covered in deep infection*			
Pin site infection	30	2	28	Pin site infection is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Covered in surface infection*			
Septic arthritis	5	4	1	Septic arthritis is an important outcome to measure when recovering from open lower limb fracture. *SDG1: dropped due to infrequency of reporting.*			
Superficial or wound infection	41	1	40	Superficial or wound infection is an important outcome to measure	Surface infection	→	Surface infection

				when recovering from open lower limb fracture. *SDG1: changed to 'surface infection', superficial infection felt to imply infection may be trivial.*			
Laboratory tests	4	0	4				
Leg length or leg shortening	25	0	25	Leg or bone shortening is an important outcome to measure when recovering from open lower limb fracture.	Leg or bone shortening	→	Leg or bone shortening
Loss of height	0	0	0				
Microbiology cultures	17	1	16	Microbiological culture results are an important outcome to measure when recovering from open lower limb fracture. *SDG1: Dropped as covered by the deep/surface infection outcome themes. Felt that the culture result is not important to the patient.*			
Wound cultures	13	1	12				
Numbness and loss of sensation	3	0	3	Sensation loss is an important outcome to measure when recovering from open lower limb fracture.	Change in sensation *SDG2: there was some debate about taking this outcome theme out. However, patients did present personal accounts of how their sensation had changed. One patient who had an amputation talked about trying to desensitize*	→	Change in sensation

					his stump using 'chilli cream'.		
Sensory or motor impairment	17	1	16	Muscle weakness is an important outcome to measure when recovering from open lower limb fracture.	Muscle weakness *SDG2: Participants felt that this is well covered in the 'walking, gait and mobility' outcome theme. However, they kept it is as they recalled personal accounts of having to build up strength in specific muscles in their injured limbs.*	→	Muscle weakness
Osteoarthritis	4	0	4	Development of post-traumatic osteoarthritis is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Dropped due to the symptoms overlapping with pain and range of movement outcome themes.*			
Over-sensitivity of sensation	0	0	0	Over-sensitivity is an important outcome to measure when recovering from open lower limb fracture. *SDG1: It was felt that this was not an intuitive outcome, difficult to*			

				define and overlapped with pain so was dropped.			
Pain or discomfort	48	1	47	Pain is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Joint pain and discomfort to create an overarching pain outcome theme, 'pain or discomfort'.*	Pain or discomfort	→	Pain or discomfort
				Ache is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Ache dropped as participants felt that ache was on the same spectrum as pain and can be described as discomfort which may be a better term to use as its more general.*			
				Postoperative pain is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt that this outcome is an important part of the treatment experience, but would be adequately covered by one outcome theme; 'pain and discomfort'. There was also a consensus opinion that postoperative pain is an expected*			

				event after an operation, making it an unnecessary standalone outcome theme for consideration in the COS.			
				Pain on walking is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Adequately covered by a pain or discomfort outcome.*			
Medication use for pain	1	0	1	Medication use for pain is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Dropped as covered later in the adverse events core area.*			
Plastics intervention, e.g. flap or graft	2	0	2	Muscle flap or skin graft failure or survival is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt this would be encompassed by adverse events core area and 'unplanned return to the operating theatre' outcome.*			
Adverse event or complication of graft or flap	18	1	17	Muscle flap or skin graft necrosis is an important outcome to measure when recovering from open lower limb fracture. *SDG1: As above.*			
Flap failure or survival	51	4	47				
Graft or flap necrosis	10	0	10				

Reoperations	21	5	16	Number or reoperations, revision surgeries or surgical procedures is an important outcome to measure when recovering from open lower limb fracture. *SDG1: encompassed by '*Unplanned return to the operating theatre' outcome.	Unplanned return to the operating theatre *SDG2: Patients identified that this was an important marker of complication during recovery and recounted their own storeys where discharge decisions had gone wrong.*	→	Unplanned return to the operating theatre
Number of debridements	7	0	7	Number of debridements is an important outcome to measure when recovering from open lower limb fracture. *SDG1: encompassed by '*Unplanned return to the operating theatre' outcome.			
Number of operations	62	1	61				
Shaking or fasciculations	0	0	0				
Swelling	2	0	2	Swelling is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt swelling would be adequately covered by functioning outcomes*			
Wound	3	0	3				
Wound closure and dehiscence	7	1	6	Type of wound closure is an important outcome to measure when recovering from open lower limb fracture.			

				SDG1: Participants did not feel this represented an outcome.	
				Wound dehiscence (reopening) is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt that this would be covered in the 'unplanned return to the operating theatre' outcome.*	
Wound healing	43	2	41		
Wound necrosis	14	1	13	Wound necrosis (skin breakdown) is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt that this would be covered in the 'number of adverse events' outcome or 'unplanned return to the operating theatre' outcome.*	
Renal and urinary outcomes (19)					
Acute kidney injury	4	2	2	Acute kidney injury is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Not a highly reported outcome for open lower limb*	

				fracture, not mentioned in patient interviews so decision to drop.			
Renal failure	1	0	1	Development of renal failure is an important outcome to measure when recovering from open lower limb fracture. *SDG1: As above.*			
3. Life impact							
Physical functioning (25)							
Ability to climb stairs	2	0	2	Ability to climb stairs is an important outcome to measure when recovering from open lower limb fracture.	Ability to climb stairs *SDG2: Participants felt it was adequately covered by activities of daily living.*	Ability to do activities of daily living	Ability to do activities of daily living
Ability to do activities of daily living	4	0	4	Ability to do activities of daily living is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt that this was an important outcome but wanted a clearer definition of what activities of daily living may include. It was discussed that if selected as a core outcome this would be identified when choosing an appropriate measurement instrument.*	Ability to do activities of daily living		
Cleaning and tidying	0	0	0				

Ability to find a comfortable position	0	0	0				
Ability to kneel	0	0	0	Ability to kneel is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Kneeling felt to be an essential part of patients functioning, e.g. builders, paramedics doing CPR, and playing with children were examples given in patient interviews.*	Ability to kneel *SDG2: Participants thought kneeling was very important.*	→	Ability to kneel
Balance	0	0	0	Ability to balance is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Balance was felt to be an important part of recovery, and this was expressed at interview.*	Ability to balance *SDG2: Participants felt balance is important as it effects walking, exercise, e.g. keeping a football up, as well as other normal life activities.*	→	Ability to balance
Dependence	0	0	0	Ability to be independent is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Recognized as an important broad reaching outcome theme that links to others around participation and emotional wellbeing.*	Ability to be independent *SDG2: Participants felt this outcome themes also related strongly to mental health.*	→	Ability to be independent
Disability	3	1	2				

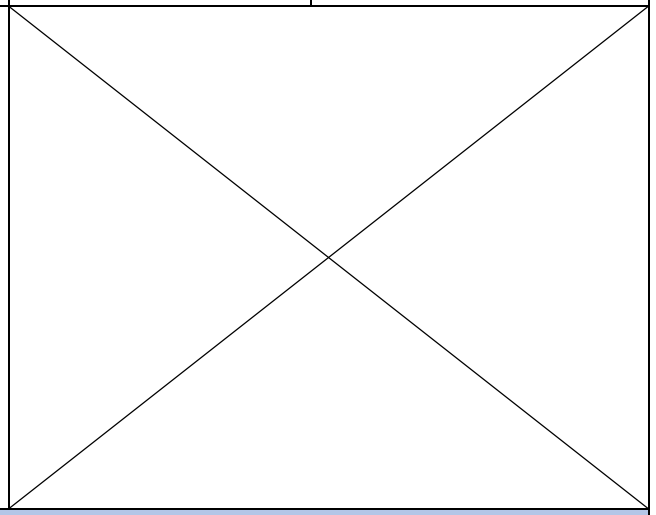
Driving	0	0	0	Ability to drive is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Driving caused some discussion about whether to keep or not. Participants agreed it should be kept after descriptions of patients valuing it as important in the interviews.*	Ability to drive *SDG2: Driving recognized as very important, not only a key part of some people's employment but also central to their independence.*	→	Ability to drive
Function - lower limb functional and general physical function	88	8	80	Lower limb function is an important outcome to measure when recovering from open lower limb fracture.	Lower limb function *SDG1: Participants decided not to distinguish between anatomical areas of the lower limb when measuring function, as the anatomical characteristics of people's open lower limb fractures are different.*	→ *SDG2: Participants happy to keep lower limb function broad and bot breaking up into anatomical areas of lower limb functioning.*	Lower limb function
Ankle function	16	0	16	Ankle function is an important outcome to measure when recovering from open lower limb fracture.			
Foot function	7	0	7	Foot function is an important outcome to measure when recovering from open lower limb fracture.			
Knee function	12	0	12	Knee function is an important outcome to measure when recovering from open lower limb fracture.			
Shoulder function	1	0	1	Shoulder function is an important outcome to measure when recovering from open lower limb fracture.			

				SDG1: Dropped as less relevant for open lower limb fracture. Shoulder pain from using crutches is more an adverse event.			
Gait, walking, and mobility	29	3	26	Walking, gait, and mobility is an important outcome to measure when recovering from open lower limb fracture.	Walking, gait, and mobility	→	Walking, gait, and mobility
Awareness and difficulty walking on uneven ground	0	0	0				
Weightbearing	2	0	2	Ability to fully weightbear is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Dropped as encompassed by 'walking gait and mobility'.*			
Weightbearing status and time to weightbear	14	0	14				
Gardening and DIY	0	0	0	Ability to do gardening and DIY is an important outcome to measure when recovering from open lower limb fracture. *SDG1. Participants thought that this could be merged with 'activities of daily living' however they wanted to let the patients decide. A note was taken to discuss at SDG2.*	Ability to do gardening and DIY. *SDG2: Patients agreed that this outcome can be merged with 'activities of daily living'. Not an essential activity, more of a hobby.*		
Movement, range of motion, and stiffness	25	0	25	Range of motion and joint stiffness is an important outcome to	Joint stiffness		

				measure when recovering from open lower limb fracture. *SDG1: Range of motion and joint stiffness were thought to be different outcome concepts, e.g. joint stiffness is often described in patients with arthropathies while range of motion may not be as important as function for example in that context. Therefore, the two outcome concepts were split as separate themes*	*SDG2: Participants didn't feel 'joint stiffness' was important enough to justify keeping it as a standalone outcome theme. They felt it ties into 'walking, gait and mobility' as well as 'range of movement'.*		
Ankle range of motion	22	0	22	Ankle range of motion is an important outcome to measure when recovering from open lower limb fracture. *SDG1: As per the lower limb functioning outcome themes, a decision was made not to split by anatomical area.*	Range of motion	→	Range of motion
Knee range of motion	25	0	25	Knee range of motion is an important outcome to measure when recovering from open lower limb fracture. *SDG1: As above.*			
Self and personal care	0	0	0	Ability to be able to do self and personal care is an important outcome to measure when recovering from open lower limb fracture.	Ability to do self and personal care. *SDG2: Added the dressing to this outcome theme*	Ability to dress and do self and personal care.	Ability to dress and do self and personal care.

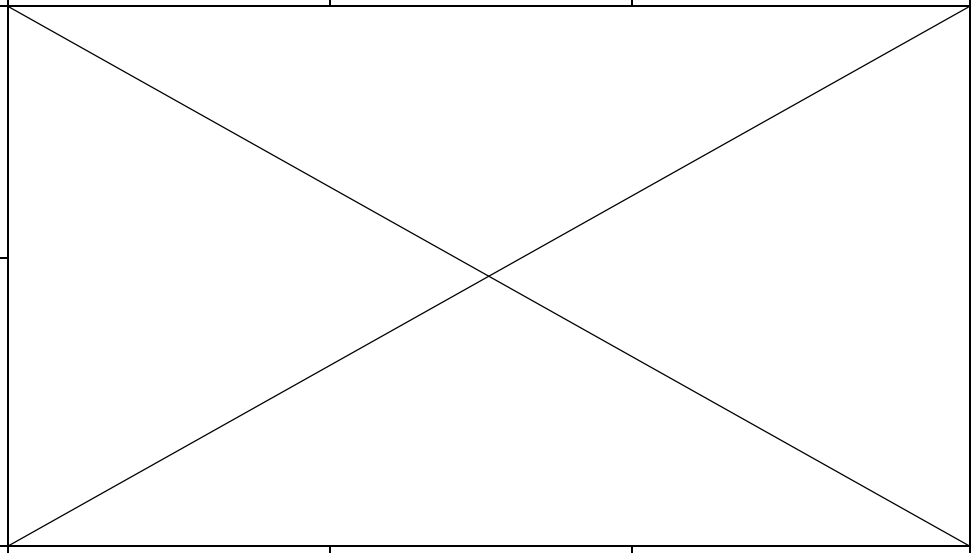
				SDG1: Participants felt that this was an important outcome theme and should be kept as it encompasses activities like toileting and washing more specifically than 'activities of daily living'.	*heading. Participants described the ability to start dressing for themselves as a key stage in their recovery representing a large step towards independent living again. This was felt to be important enough to be a standalone outcome themes and not merged with 'activities of daily living'.*		
Sex	0	0	0	Ability to enjoy sex is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Outcome term changed from sex to intimacy. Although only discussed once in the interviews, the outcome theme was kept as it may have been under-represented by patients.*	Ability to have intimate relationships. *SDG2: Participants thought that 'ability to have intimate relationships' is important. This outcome theme was also linked to the importance of being able to kneel.*	→	Ability to have intimate relationships
Sports, exercise, and fitness	7	0	7	Ability to partake in sports and exercise is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Sports dropped as it may put off older people from scoring the outcome; the term exercise*	Ability to partake in exercise. *SDG2: Wording changed to 'ability' rather than 'partake'. Made more sense to the participants.*	Ability to exercise	Ability to exercise

				represents the concept more broadly.			
Wearing shoes	1	0	1	Ability to comfortably wear shoes is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Changed to include the term 'comfortably' to indicate that the outcome is more about being able to wear shoes as a function rather than for appearance. Clothes also added to outcome theme.*	Ability to comfortably wear shoes and clothes of your choice. *SDG2: Participants discussed need to buy new trainers and not being able to wear the right clothes at work.*	→	Ability to comfortably wear shoes and clothes of your choice.
Social functioning (26)							
Participation	3	0	3	Ability to participate in social events is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants agreed that this theme heading represents an important component of social functioning.*	Ability to participate in social events. SDG2: *This was recognized as important by participants who discussed events in life they could not join in with. This related to mental wellbeing.*	→	Ability to participate in social events.
Relationships	0	0	0	Ability to maintain and develop relationships is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt it was helpful to have a broad relationship*	Ability to start, maintain, and develop relationships	→	Ability to start, maintain, and develop relationships

				outcome theme. The addition of the word 'start' was added to encompass difficulties that may be encountered making new relationships, e.g. starting intimate relationships.			
Reliance on others	1	0	1	Not having to rely on other people is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Outcome theme wording changed to encompass people who may not have been fully independent before their injuries to emphasize the importance of maintaining their level of independence pre-injury, e.g. the elderly fragility open lower limb fracture population.*	Maintaining a level of independence. *SDG2: Dropped as participants felt it overlapped with 'ability to be independent' in the physical functioning outcome domain.*		
Role functioning (27)							
Care for others and animals	0	0	0	Being able to care for other people and animals is an important outcome to measure when recovering from open lower limb fracture.	Being able to care for other people and/or animals	→	Being able to care for other people and/or animals
Work and employment	1	0	1	Being able to work or return to work is an important outcome to measure when recovering from open lower limb fracture.	Being able to work, return to work or active duty (military)	Being able to return to life roles (e.g. caring, work, military duty)	Being able to return to life roles (e.g. caring, work, military duty)

Return to work or duty	16	2	14	Return to work or active duty (military) is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt that all three role functioning outcomes could be combined but decided to only combine the two work/employment/duty outcome themes at this stage. It thought best to let the patients decide in SDG2 whether they wanted to combine all three outcome themes in the outcome theme 'return to life roles'.*	*SDG2: Participants decided to change 'return to work or active duty' to 'return to life roles' this was because they thought it would be more specific, i.e. you may return to work or the military but not in the same role as before. They also decided to keep 'being able to care for other people and animals separate, as, for example, you may not be able to return to your previous work role but can still look after your children. They identified this outcome theme as 'essential'.*		
Emotional functioning and wellbeing (28)							
Acceptance of event and change	0	0	0	Ability to accept the event and life change is an important outcome to measure when recovering from open lower limb fracture. *SDG1: It was felt that this outcome theme linked closely with depression and could therefore be covered to some extent in the 'mood' outcome theme. However, it*	Ability to accept the event and life change[5]	→	Ability to accept the event and life change[5]

				was decided not to drop it at this point.			
Appearance	5	0	5	Appearance of lower limb, e.g. scars, flaps, and swelling is an important outcome to measure when recovering from open lower limb fracture. *SDG1: This outcome theme was kept as a standalone appearance outcome theme as the direct appearance of the injured lower limb was felt be important to many patients after open lower limb fracture. It also encompasses specific appearance issues patients mentioned including swelling and flap appearance.*	Appearance of lower limb, e.g. scars, flaps, and swelling[1] *SDG2: Participants did not feel that appearance in itself was important, they felt the issue lays with feeling different and being accepted by society. However, they did concede that they were all male and a woman may feel differently, so decided to keep the appearance outcome themes.*	→	Appearance of lower limb, e.g. scars, flaps, and swelling[1]
				General appearance, e.g. putting on weight is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Outcome theme heading changed to include changing shape as well as weight gain to encompass strength or muscle loss which men are often more concerned about and weight gain which women are often more concerned about. It was also thought that 'donor site*	General appearance, e.g. changing shape or weight[1] *SDG2: As above.*	General appearance, e.g. changing shape or weight[1] *SMG: Outcome theme title changed to 'change in body shape or weight' to be more specific an outcome theme.*	Change in body shape or weight[1]

				appearance' and 'tattoos' could be dropped and represented by this outcome theme.			
Donor site appearance	1	0	1	Donor site appearance is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Dropped as encompassed by general appearance.*			
Tattoos	0	0	0	Appearance of lower limb tattoos following injury is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Dropped as encompassed by general appearance.*			
Dignity	0	0	0	Maintaining a feeling of dignity is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Dignity felt to be justified as a separate outcome to dependence and was recognized as potentially a key area of importance for older patients.*	Maintaining a feeling of dignity[6]	→	Maintaining a feeling of dignity[6]
Emotional fragility	0	0	0	Having emotional strength is an important outcome to measure when recovering from open lower limb fracture.	Having emotional strength *SDG2: Participants opted to change the outcome theme heading to include*	Emotional vulnerability, volatility, and fragility[5]	Emotional vulnerability, volatility, and fragility[5]

				SDG1: It was felt that this outcome theme is very closely linked to feelings commonly associated with depression and an argument was made on this basis to drop it. However, the feeling of inability to cope with emotions and emotional breakdowns were commonly described in narratives of recovery. On that basis it was decided to keep the outcome and change the theme heading to 'having emotional strength'.	*vulnerability, volatility and fragility which was thought to better represent the concepts the outcome is trying to capture from the lived experiences of patient dealing with emotional struggle including unexpected and unwanted extreme emotional outbursts at times during recovery. They felt that this outcome is also closely related to, and manifests as a consequence of feelings of uncertainty.*		
Expectations, uncertainty, and views on the future	0	0	0	Having clear expectations and views on the future with lack of uncertainty is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt that this outcome theme tries to capture the patient need for a clear treatment plan and good idea of what their final recovery outcome may look like.*	Having clear expectations and views on the future with lack of uncertainty[3] *SDG2: Participants related to this outcome theme.*	→	Having clear expectations and views on the future with lack of uncertainty
Uncertainty	0	0	0				

Fear and fear for the future	0	0	0	Living in fear, e.g. fear of falling or going outside and fear for the future is an important outcome to measure when recovering from open lower limb fracture. *SDG1: This outcome theme heading was changed to include 'tolerance of uncertainty' as it was felt that this was a more clearly defined psychological concept which relates to a person's emotional state including their mood, i.e. people in lower mood states do not have as much tolerance to deal with uncertainties in life.*	Tolerance of uncertainty and living in fear, e.g. fear of falling or going outside and fear for the future.[3] *SDG2: Participants also related to this outcome theme. "that's quite a good actually". One patient talked about becoming very risk adverse and scared to leave the house, which got to the point that he decided to see a clinical psychologist.*	→	Tolerance of uncertainty and living in fear, e.g. fear of falling or going outside and fear for the future.[3]
Feeling of being disabled, damaged, or brokenness	0	0	0	Feelings of disablement, being damaged or broken is an important outcome to measure when recovering from open lower limb fracture.	Feelings of disablement, being damaged or broken[2]	→	Feelings of disablement, being damaged or broken[2]
Feeling of giving up or hopelessness	0	0	0	Feelings of giving up and hopelessness is an important outcome to measure when recovering from open lower limb fracture.	Feelings of giving up and hopelessness[2] *SDG2: Participants also related this outcome to feelings of uselessness and argued they were the same thing.*	→	Feelings of giving up and hopelessness[2]
Feeling of loss	0	0	0	Feeling of loss is an important outcome to measure when recovering from open lower limb fracture.	Feeling of loss[2]	→	Feeling of loss[2]

Feeling of stolen youth, energy, or fitness	0	0	0	Feelings of struggle or fighting against the body is an important outcome to measure when recovering from open lower limb fracture.	Feelings of struggle or fighting against the body[5]	→	Feelings of struggle or fighting against the body[5]
Feeling of struggle or fighting	0	0	0				
Frustration and anger	0	0	0	Feeling of frustration and anger is an important outcome to measure when recovering from open lower limb fracture.	Feeling of frustration and anger[2] *SDG2: Participants identified with this outcome and talked about their experiences dealing with the compensation process. One patient talked about his feeling after the two people he felt were responsible for his injury won a lottery syndicate which elicited strong feeling of frustration.*	→	Feelings of frustration and anger[2]
Gratitude and thankfulness	0	0	0	Feelings of hopefulness, positivity, and determination is an important outcome to measure when recovering from open lower limb fracture.	Feelings of hopefulness, positivity, and determination[2]	→	Feelings of hopefulness, positivity, and determination[2]
Hopefulness, positivity, and determination	0	0	0				
Isolation, loneliness, and lack of support[2]	0	0	0	Isolation, loneliness, and lack of emotional support is an important outcome to measure when recovering from open lower limb fracture.	Isolation, loneliness, and lack of emotional support[2]	→	Isolation, loneliness, and lack of emotional support

Loss of control and limitation	0	0	0	Loss of control and feeling of limitation is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt the word 'confidence' should appear here as patients may more easily identify with confidence over the 'fear for the future' outcome detailed above. Patients may not consider themselves afraid but rather lacking their previous confidence doing activities such as sports etc.*	Loss of confidence or control and feeling of limitation[3]	→	Loss of confidence or control and feeling of limitation[3]
Mood	1	0	1	Low mood is an important outcome to measure when recovering from open lower limb fracture.	Low mood[2]	→	Low mood[2]
Moving on and getting life back	0	0	0	Ability to move on and feeling of getting life back is an important outcome to measure when recovering from open lower limb fracture.	Ability to move on and feeling of getting life back[2]	→	Ability to move on and feeling of getting life back[2]
Psychological status	0	0	0	Experience of flashbacks to the traumatic event is an important outcome to measure when recovering from open lower limb fracture.	Experience of flashbacks to the traumatic event[4]	→	Experience of flashbacks to the traumatic event[4]
Sense of helping others	0	0	0				

Sense of self, identity, and body wholeness	0	0	0	Feelings of self-identity and body wholeness is an important outcome to measure when recovering from open lower limb fracture.	Feelings of self-identity and body wholeness[2] *SDG2: Some participants did not identify with this outcome theme, "that's a bit deep for me". And some did. It was agreed that this theme is related to how severe the open lower limb fracture is. The more severe, the more chance that a person may feel a loss of identity and their body no longer being recognized as theirs anymore.*	→	Feelings of self-identity and body wholeness[2]
Worry and anxiety	1	0	1	Being anxious or stressed is an important outcome to measure when recovering from open lower limb fracture.	Being anxious or stressed[3]	→	Being anxious or stressed[3]
Fear of falling over	0	0	0				
Stress	3	1	2				

Emotional functioning and wellbeing outcomes subcategorization

The emotional functioning and wellbeing outcome themes were discussed at length at the professional and patient Structured Discussion Groups (SDGs), where arguments were made to keep the granularity of the different outcome themes or merge them into overarching headings recognized from a psychological perspective. A trauma psychologist attended the professional SDG. It was noted that the outcome themes could be grouped by overarching themes used in the field of clinical psychology in trauma. Going forward to patient SDG and beyond the emotional wellbeing and outcome themes were grouped as below (superscript on the above emotional functioning and wellbeing outcome themes represents the outcome groups they were subsequently categorized to).

1 - Appearance outcomes

2 - Depression outcomes

3 - Anxiety outcomes ***4 - Post-traumatic stress outcomes*** ***5 - Resilience and acceptance outcomes*** ***6 - Satisfaction with care outcomes***							
Cognitive functioning (29)							
Change in behaviour and attitude	0	0	0	Change in outlook, behaviour, and attitude towards life is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants agreed to merge this outcome with mental exhaustion below to better encompass cognitive function.*	Lack of concentration and focus	→	Lack of concentration and focus
Mental exhaustion	0	0	0	Being mentally exhausted is an important outcome to measure when recovering from open lower limb fracture. *SDG1: As above merged to 'lack of concentration and focus'. This outcome better represents mental agility and speed of thinking or lack thereof.*			
Global quality of life (30)							

Quality of life	32	0	32	Quality of life is an important outcome to measure when recovering from open lower limb fracture. *SDG1: All agreed quality of life is an important outcome theme.*	Quality of life	→	Quality of life
Perceived health status (31)							
Percentage perceived loss of function	0	0	0	Percentage of perceived loss of function is an important outcome to measure when recovering from open lower limb fracture.	Percentage of perceived loss of function	Percentage of perceived loss of function *SMG: Decided to drop the term 'percentage' in favour of 'degree' to be more intuitive. It was felt that perceived health status would be better suited to general health rather than also being included specifically for lower limb function.*	Degree of perceived loss of general health and wellbeing
Subjective assessment of success	2	0	2	A subjective assessment of success of intervention is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants suggested changing wording to 'general health and wellbeing' to better*	Degree of perceived loss of general health and wellbeing	Degree of perceived loss of general health and wellbeing *SMG: As above.*	

				capture the concept loss of other elements of health not directly related to the injured limb.			
Delivery of care (32)							
Communication	1	0	1	Communication of healthcare professionals to patients is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants didn't entirely agree this should be an outcome, but felt that it should be discussed with the patients.*	Quality of communication of healthcare professionals to patients *SDG2: Patients felt that this outcome theme is important enough from their experiences to be kept in for the Delphi survey.*	→	Quality of communication of healthcare professionals to patients
Hospital food and environment, e.g. non-clinical hospital care	0	0	0	The non-clinical hospital experience, e.g. food, ward environment, is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants didn't feel that this represented an outcome in of itself, more a standard of care. It was recognized that this would overlap with patient satisfaction.*			
Hospital visits	0	0	0				
Occupational therapy - house alterations	0	0	0	Help adapting to the home environment, e.g. occupational therapy interventions is an important outcome to measure			

				when recovering from open lower limb fracture. *SDG1: As above.*			
Patient satisfaction	5	0	5	Satisfaction with care received is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt that this was an important outcome and potentially covers many of the outcome themes in the delivery of care domain.*	Satisfaction with care *SDG2: Participants felt that this outcome theme was perhaps too broad but decided to retain it for the Delphi survey. Patients expressed strong feelings of satisfaction around input from their trauma nurse specialists.*	→	Satisfaction with care
Quality of care	0	0	0				
Rehab and physio	0	0	0	Delivery of physiotherapy and rehabilitation is an important outcome to measure when recovering from open lower limb fracture. *SDG1: As per 'Hospital food and environment outcome'*			
Tolerability and acceptability of intervention, e.g. external fixator vs nail vs plate	0	0	0	Tolerability and acceptability of surgical intervention, e.g. external fixator, is an important outcome to measure when recovering from open lower limb fracture. *SDG1: It was felt that this should be kept at this stage as the 'time in external fixator' outcome theme*	Tolerability and acceptability of surgical intervention, e.g. external fixator	→	Tolerability and acceptability of surgical intervention, e.g. external fixator

				was dropped. There was a discussion around not dropping to many outcome themes at this stage in the research as there is more validity in dropping themes as the Delphi Stage due to a wider audience.			
Personal circumstances (33)							
Change in lifestyle	0	0	0	Change in lifestyle is an important outcome to measure when recovering from open lower limb fracture. *SDG1: There was a feeling that 'change in lifestyle' could encompass the below three outcome themes. However, at this stage in the project it was decided to keep them as separate outcome themes*	Change in lifestyle	→	Change in lifestyle
Having access to a disabled badge	0	0	0	Being able to use disabled facilities, e.g. disabled parking is an important outcome to measure when recovering from open lower limb fracture.	Being able to use disabled facilities, e.g. disabled parking. *SDG2: Participants did not feel that this was an essential outcome to measure in their recovery.*		
Insurance and financial compensation	0	0	0	Being compensated financially for injury is an important outcome to measure when recovering from open lower limb fracture.	Being compensated financially for injury	→	Being compensated financially for injury

				SDG1: This outcome theme was contentious as it is something that would be difficult to measure in a trial. However, many patients described getting through the compensation litigation process as a key element of moving forward with life and gaining a level of acceptance.			
Need to plan around, or adapt to disability	0	0	0				
Personal cost of treatment and care	0	0	0	Personal cost of treatment and care following injury is an important outcome to measure when recovering from open lower limb fracture. *SDG1: this was recognized as being important to patients and so kept for SDG2 discussion.*	Personal cost of treatment and care following injury	→	Personal cost of treatment and care following injury
Personal finances	0	0	0	Effect of injury on personal finances is an important outcome to measure when recovering from open lower limb fracture. *SDG1: As above.*	Effect of injury on personal finances	→	Effect of injury on personal finances
4. Resource use							
Economic (34)							

Cost	24	8	16	Cost to healthcare provider is an important outcome to measure when recovering from open lower limb fracture.	Cost to healthcare provider	Cost to healthcare provider *SMG: This was decided as out of scope for the aims of this core outcome set project.*	
Hospital (35)							
Hospital re-admission	5	0	5	Number of hospital re-admissions is an important outcome to measure when recovering from open lower limb fracture.	Number of unplanned hospital re-admissions	Number of unplanned hospital re-admissions[2]	*See general outcomes*
Length of hospital stay	52	0	52	Length of hospital stay is an important outcome to measure when recovering from open lower limb fracture.	Length of hospital stay	Length of hospital stay[2]	*See general outcomes*
Length of intensive care unit (ICU) stay	6	0	6	Length of ICU stay is an important outcome to measure when recovering from open lower limb fracture. *SDG1: Participants felt that this wasn't a useful measure in the context of long-term recovery from open lower limb fracture.*			
Number of Emergency Department attendances	1	0	1	Number of Emergency Department attendances is an important outcome to measure when			

[2] Outcome moved to general outcome domain following SMG meeting.

				recovering from open lower limb fracture. *SDG1: Participants could drop this as it would be better captured by the outcome theme 'hospital re-admission' and 'unplanned return to the operating theatre'.*			
Number of outpatient appointments	5	0	5	Number of outpatient appointments is an important outcome to measure when recovering from open lower limb fracture.	Number of outpatient appointments	Number of outpatient appointments[2]	*See general outcomes*
Number of primary care encounters	1	0	1	Number of primary care visits is an important outcome to measure when recovering from open lower limb fracture.	Number of primary care appointments	Number of primary care visits[2]	*See general outcomes*
Need for intervention (36)							
No outcome themes identified in this outcome domain.							
Social or career burden (37)							
No outcome themes identified in this outcome domain.							
5. Adverse events							
Adverse effects (38)							
Adverse events	5	0	5	Number of adverse events is an important outcome to measure when recovering from open lower limb fracture. SDG1: Decided to retain this outcome theme, but expected that	Number of adverse events	→	Number of adverse events

				this will need further defining if accepted as a core outcome.			
Anaesthesia	0	0	0	Poor experience during anaesthesia is an important outcome to measure when recovering from open lower limb fracture.	Poor experience during anaesthesia	→	Poor experience during anaesthesia
Phlebotomy	0	0	0	Discomfort from blood-taking and cannula insertion is an important outcome to measure when recovering from open lower limb fracture. *SDG1: This was removed as it was not felt be a useful outcome theme as phlebotomy is essential for the practice of modern medicine.*			
Side effects of analgesia	0	0	0	Side effects of pain medication is an important outcome to measure when recovering from open lower limb fracture.	Side effects of medication	→	Side effects of medication
Number of outcome statements/themes	**150**			**121**	**77**	**71**	**68**

Table ii. Percentage of stakeholder groups scoring 7 to 9 (critical) for outcomes in Delphi survey rounds 1 and 2.

Outcomes	Delphi Round 1				Delphi Round 2			
	Patients	Healthcare professionals	Researchers	All	Patients	Healthcare professionals	Researchers	All
Outcomes reaching 'consensus-in' at Delphi survey round 1								
Outcomes reaching 'consensus-in' at Delphi survey round 2	**n = 74**	**n = 102**	**n = 11**	**n = 187**	**n = 55**	**n = 73**	**n = 8**	**n = 136**
Physical functioning 1. Ability to do activities of daily living	88	95	10	92	91	99	10	96
2. Ability to kneel	55	14	30	31	41	4	13	19
3. Ability to balance	75	46	60	58	96	26	38	44
4. Ability to be independent	85	87	86	86	89	92	10	91
5. Ability to drive	63	31	20	44	57	14	25	32
6. Walking, gait, and mobility	86	80	80	83	91	79	63	83
7. Ability to dress and do self and personal care	88	75	10	82	91	83	88	87
8. Ability to have intimate relationships	51	46	40	47	37	18	0	25
9. Ability to exercise	71	31	50	48	63	14	13	34
10. Ability to comfortably wear shoes and clothes of your choice	56	24	40	38	44	8	25	24
11. Lower limb function	84	53	80	67	83	54	88	68
12. Range of motion	71	33	50	49	57	14	25	32
Social functioning 13. Ability to participate in social events	59	49	70	54	48	29	38	37
14. Ability to start, maintain, and develop relationships	59	52	70	56	46	33	50	40
Role functioning 15. Being able to care for other people and/or animals	52	24	50	36	49	7	13	24
16. Being able to return to life roles (e.g. caring, work, military duty)	74	69	70	71	75	72	75	74
Emotional functioning and wellbeing 17. Appearance of lower limb, e.g. scars, flaps, and swelling	38	23	40	30	26	6	13	14
18. Change in body shape or weight	35	18	30	25	24	3	0	11
19. Feelings of self-identity and body wholeness	38	30	30	34	30	14	13	20
20. Feelings of disablement, being damaged or broken	36	36	30	35	26	14	13	19
21. Feelings of giving up and hopelessness	47	52	60	50	38	31	38	34

Outcomes	Delphi Round 1				Delphi Round 2			
Outcomes reaching 'consensus-in' at Delphi survey round 1	Patients	Healthcare professionals	Researchers	All	Patients	Healthcare professionals	Researchers	All
Outcomes reaching 'consensus-in' at Delphi survey round 2	**n = 74**	**n = 102**	**n = 11**	**n = 187**	**n = 55**	**n = 73**	**n = 8**	**n = 136**
22. Feeling of loss	40	32	40	36	28	11	13	18
23. Feelings of frustration and anger	49	34	40	40	30	8	13	17
24. Feelings of hopefulness, positivity, and determination	68	44	50	54	63	24	38	41
25. Isolation, loneliness, and lack of emotional support	49	45	40	46	45	30	13	35
26. Low mood	43	43	60	44	35	21	38	27
27. Ability to move on and feeling of getting life back	78	51	78	63	81	44	63	60
28. Having clear expectations and views on the future with lack of uncertainty	55	39	56	47	58	18	25	35
29. Tolerance of uncertainty and living in fear, e.g. fear of falling or going outside and fear for the future	47	34	50	40	32	11	13	20
30. Being anxious or stressed	47	32	60	40	35	14	25	23
31. Loss of confidence or control and feeling of limitation	50	33	50	41	42	11	13	24
32. Experience of flashbacks to the traumatic event	43	36	40	39	36	11	13	21
33. Emotional vulnerability, volatility, and fragility	44	31	60	38	35	8	25	20
34. Ability to accept the event and life change	60	42	50	50	47	21	25	32
35. Feelings of struggle or fighting against the body	48	20	33	32	33	3	0	15
36. Maintaining a feeling of dignity	55	49	60	52	58	41	38	48
Cognitive functioning 37. Lack of concentration and focus	48	37	50	42	37	13	13	22
Blood and lymphatic system outcomes 38. Venous thromboembolism (blood clot in legs or lungs)	67	49	67	57	71	39	57	52
General outcomes 39. Sleep and fatigue	54	41	80	48	49	27	25	36
40. Number of unplanned hospital re-admissions	38	49	40	44	24	28	13	25
41. Length of hospital stay	36	34	20	34	13	14	13	14
42. Number of outpatient appointments	36	27	20	31	17	4	0	9
43. Number of primary care visits	32	25	30	28	12	6	0	8

Outcomes	Delphi Round 1				Delphi Round 2			
	Patients	Healthcare professionals	Researchers	All	Patients	Healthcare professionals	Researchers	All
Outcomes reaching 'consensus-in' at Delphi survey round 1								
Outcomes reaching 'consensus-in' at Delphi survey round 2	**n = 74**	**n = 102**	**n = 11**	**n = 187**	**n = 55**	**n = 73**	**n = 8**	**n = 136**
Musculoskeletal and connective tissue outcomes 44. Metalwork failure	63	57	67	60	63	44	63	53
45. Complications resulting from soft-tissue (muscle flaps or grafts)	75	60	67	66	69	54	50	60
46. Amputation	86	86	70	85	88	89	88	88
47. Bone healing	85	76	89	80	87	74	71	79
48. Malunion, alignment, and rotational deformity	72	54	56	61	65	44	14	51
49. Deep infection	88	86	80	86	88	84	86	86
50. Surface infection	68	37	30	49	52	23	0	33
51. Leg or bone shortening	64	41	50	50	59	27	13	39
52. Change in sensation	51	33	20	39	36	11	0	21
53. Muscle weakness	60	39	40	48	45	13	13	26
54. Pain or discomfort	67	77	90	74	70	82	88	77
55. Unplanned return to the operating theatre	57	51	50	53	50	44	25	45
Global quality of life 56. Quality of life	88	91	90	90	91	99	10	95
Perceived health status 57. Degree of perceived loss of general health and wellbeing	52	52	40	51	40	21	0	27
Delivery of care 58. Quality of communication of healthcare professionals to patients	69	58	60	63	62	39	38	48
59. Satisfaction with care	59	52	60	55	49	25	50	36
60. Tolerability and acceptability of surgical intervention e.g. external fixator	60	41	40	48	43	13	13	24
Personal circumstances 61. Change in lifestyle	59	46	50	51	55	32	25	41
62. Being compensated financially for injury	45	26	50	35	29	8	25	18
63. Personal cost of treatment and care following injury	51	34	40	41	34	13	13	21

Outcomes	Delphi Round 1				Delphi Round 2			
Outcomes reaching 'consensus-in' at Delphi survey round 1	Patients	Healthcare professionals	Researchers	All	Patients	Healthcare professionals	Researchers	All
Outcomes reaching 'consensus-in' at Delphi survey round 2	**n = 74**	**n = 102**	**n = 11**	**n = 187**	**n = 55**	**n = 73**	**n = 8**	**n = 136**
64. Effect of injury on personal finances	58	42	60	49	46	23	25	32
Adverse events and effects 65. Number of adverse events	45	51	70	50	32	30	38	31
66. Side effects of medication	39	27	40	32	21	4	0	11
67. Poor experience during anaesthesia	41	28	30	33	27	4	13	13
Mortality 68. Survival	83	94	67	88	90	93	10	92
Outcomes added after Delphi survey round 1								
Musculoskeletal and connective tissue outcomes 69. Chronic pain	-	-	-	-	58	70	50	64
General outcomes 70. Length of stay (Super Spell)	-	-	-	-	20	19	13	18

Table iii. Outcomes suggested in Delphi survey round 1 and justification for inclusion or exclusion in round 2.

No.	Outcomes suggested in Delphi survey round 1	Included in Delphi round 2	Justification of Study management Group decision
1	Ability to jog and run	No	Covered by outcomes 4 and 9
2	Duration of treatment/recovery	No	Difficult to define. Duration of treatment loosely covered by outcomes 41, 42, 43, and 70
3	Return to work if working	No	Covered by outcome 16
4	Cost to NHS	No	Not in scope
5	Ability to return recreations	No	Covered by outcomes 9 and 13
6	Being prepared by the healthcare staff honestly about future abilities	No	Covered by outcomes 58 and 59
7	Ability to heal due to diabetes type 1	No	Covered by outcomes 45 and 50
8	Satisfaction with prosthetic service	No	Covered by outcome 59
9	Access to prosthetic services	No	Covered by outcome 59
10	Chronic pain	Yes	Chronic pain could be argued to be considered separately to outcome 54
11	Home plan	No	Covered by outcomes 58 and 59
12	Burden on the family, e.g. partner and children	No	Covered by outcomes 13 and 14
13	Length of stay (Super Spell – to include other health/social care settings)	Yes	Included as an encompassing outcome to include social care interactions as well as healthcare interactions
No.	**Suggested outcomes from core outcome set (COS) consensus meeting session 1 participants**	**Included in session 2**	**Justification of Study management Group decision**
1	Number and length of health encounters	Yes	Included as it is a broad outcome that also combines outcomes 40, 41, 42, and 43
2	Injury characteristics and surgical outcomes	Yes	Included as it intended to combine all objective clinical outcomes, e.g. outcomes 44, 46, 47, and 48 under one unifying outcome

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