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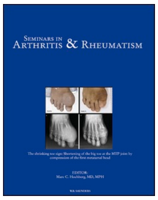

What outcomes are important to people with foot and ankle disorders in rheumatic and musculoskeletal diseases? An OMERACT qualitative interview study across four continents

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ABSTRACT

Background: The foot and ankle are frequently affected in rheumatic and musculoskeletal diseases (RMDs), yet there is a lack of high-quality evidence to determine the effectiveness of treatments. Outcomes in research are often inconsistently measured, impeding evidence synthesis. Additionally, clinical decisions are based on research outcomes, but these are not always regarded as important by people with RMDs. This study aimed to determine domains of importance to people with RMDs who have experienced foot and ankle disorders, and aid in developing a standardised core outcome set (COS) to address these issues.

Methods: Participants from four continents (Europe, Africa, Australia, North America) were recruited to semi-structured interviews through clinical departments and electronic mailing lists. Analysis was conducted using a mixed deductive/inductive approach to the framework method. Patient research partners co-produced the interview schedule and recruitment materials, and co-interpreted results.

Results: Fifty-six participants (age range 27 to 76 years; 66 % female), with foot and ankle disorders in a variety of RMDs (including inflammatory arthritis, osteoarthritis, crystal arthropathies, connective tissue diseases), were interviewed. Sixteen domains were described by participants: pain, physical function, fatigue, deformity, skin and nail health, swelling, temperature, numbness, poor circulation, cramping, activities/participation, footwear

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impact, psychological impact, sleep, healthcare utilisation and personal expenses. Most domains were considered important to participants regardless of RMD or geographic location.

Conclusions: Foot and ankle disorders have far-reaching consequences for people with RMDs. This large qualitative study provides a foundation for achieving international consensus on a core outcome set for foot and ankle disorders in RMDs, to improve the quality of evidence demonstrating effectiveness of treatments.

Key messages

What is already known about this subject?

- Integration of the perspectives of people with RMDs is fundamental when developing a core outcome set, to ensure that findings from trials are meaningful and transferrable to clinical practice.
- Foot and ankle disorders in RMD cause pain and deformity, limit physical, social and occupational function, and cause financial and emotional burden, but perspectives of people with rarer RMDs and from under-represented geographic locations are rarely incorporated.

What does this study add?

- This large, international, qualitative study, which involved semi-structured interviews with a diverse range of participants across four continents, indicates that similar domains are important to participants, regardless of their geographic location or specific RMD.
- Previously unexplored domains, including foot/ankle-specific fatigue, cognitive fatigue, and contextual factors were identified.

How might this impact on clinical practice or future developments?

- This study provides a foundation for achieving international consensus on a core outcome set for foot and ankle disorders in RMDs, to improve the quality of evidence demonstrating effectiveness of treatments.

Introduction

The foot and ankle are frequently affected in rheumatic and musculoskeletal diseases (RMDs) [1–6]. However, there is a lack of high-quality evidence to determine the effectiveness of treatments [7–11]. A major contributing factor is that outcomes in research are often inconsistently measured, impeding evidence synthesis. Additionally, clinical decisions about patient care are made on the basis of research outcomes, but these are not always regarded as important or relevant by patients.

A core outcome set (COS) is a standardised, minimum set of domains and instruments, developed through rigorous consensus methods, that should be measured and reported in all clinical trials undertaken in a specific area of health [12,13]. Implementation of a COS can improve the consistency and quality of information about effective treatments, aiding health professionals and patients in decision-making [14]. The Outcome Measures in Rheumatology (OMERACT) initiative has successfully developed COSs for many RMDs since its formation in 1992 [12]. The patient perspective is integrated at each stage of the OMERACT COS development process, ensuring core outcomes are relevant, and therefore translatable, to clinical practice [15].

The OMERACT Foot and Ankle Working Group is developing a COS for foot and ankle disorders in RMDs [16]. The intended COS scope is presented in Table 1. Candidate domains for this COS have been identified through a scoping review of clinical trials and observational studies [17], synthesis of existing qualitative studies with patients [18] and secondary analysis of a qualitative dataset [19]. Existing qualitative studies have predominantly focused on the impact of foot and ankle disorders in patients with rheumatoid arthritis (RA) and osteoarthritis (OA) within high-income countries, of White or unreported ethnicity, and whose first language is English [18]. To facilitate synthesis of all research in a specific area of health, a COS should be applicable and adopted across relevant settings and disciplines [13]. Further understanding and comparison of domain priorities among patients in different geographic locations, who have a range of RMDs, first languages and ethnicities, is needed.

Objectives

The aim of this study was to establish which domains are important to people living with RMDs who have sought advice and treatment for foot and ankle disorders, through an exploration of their experiences. The objectives were to:

- Examine the range and scope of domains experienced by patients with a variety of RMDs
- To understand and compare the importance of the identified domains across a range of RMDs, countries, and ethnicities.

Methods

This qualitative interview study utilised a pragmatic approach and was reported in-line with the Consolidated Criteria for Reporting Qualitative Studies (COREQ) framework [20] (supplemental file 1).

Participants and recruitment

Adults ($\geq$ age 18) with RMDs (inflammatory arthritis, osteoarthritis (OA), crystal arthropathies, connective tissue diseases (CTDs), and musculoskeletal (MSK) conditions in the absence of systemic disease) who were receiving or had previously received treatment for foot and ankle disorders were eligible to participate, in accordance with the predetermined scope of the intended COS [16]. Inclusion and exclusion criteria are presented in Table 2. Patients were recruited through clinical departments via local facilitators (clinicians and researchers) in the UK, Australia and Egypt, and through OMERACT electronic mailing lists reaching multiple countries. A purposive sample was recruited, based on RMD type and duration, geographic location and a broad range of demographic characteristics (age, sex, first language, ethnicity).

Data collection

Data were collected through individual semi-structured interviews, held online (Microsoft Teams or Zoom), by telephone, or face-to-face (UK only, within a hospital setting), depending on patient preference.

Table 1
Proposed COS scope.

Population	Adults ($\geq$ 18 years) with foot and ankle disorders inflammatory arthritis, osteoarthritis, spondyloarthropathies, connective tissue diseases, crystal arthropathies and musculoskeletal disorders (e.g. plantar heel pain and tendinopathies affecting the foot and ankle in the absence of systemic disease).
Intervention	Pharmacological, conservative and surgical interventions
Study type	Randomised controlled trials, controlled clinical trials, observational studies

Interviews were conducted between October 2022 and March 2024. Interviews with patients in Egypt were conducted in Arabic by one of two researchers (ES, female, or AM, male, both rheumatologists/MD). All other interviews were conducted in English by LSC (female, research fellow trained in qualitative interviewing, podiatrist by clinical background, MSc); attendance of an independent interpreter was offered to participants whose first language was not English to aid participation. Participants were unknown to the interviewers. The three interviewers met before interviews in Egypt commenced to discuss and practise an open-ended approach to questioning. Prior to the interview, the interviewers explained their clinical and research interests and reasons for conducting the study. An interview schedule (supplemental file 2) was developed based on existing literature, input from patient research partners, and discussions with multidisciplinary health professionals and researchers. The interview schedule, participant information sheet and consent form were discussed with members of the research team based in Egypt (ES, AM) prior to written translation into Arabic, to ensure cultural sensitivity. The interview guide was iteratively modified throughout data collection, as any new concepts raised by participants were identified. The interview duration ranged from 16 to 75 mins. Field notes were made after each interview. Interviews were audio recorded; English audio recordings were transcribed verbatim by a third-party transcription service, and checked and approved by LSC. Arabic audio recordings were simultaneously translated and transcribed verbatim by third party translators with bilingual competence and medical expertise, independently back-translated to check for consistency and accuracy, and checked and approved by ES and AM.

Data analysis

Interview data were organised using NVivo (Lumivero, USA) and analysed using a mixed deductive (bottom-up, theory-driven) and inductive (top-down, data-driven) approach to the framework method [21]. The deductive approach involved coding transcripts according to a predetermined categorisation matrix, developed from previous relevant literature [17–19] and patient research partner input, and arranged by core areas according to the OMERACT conceptual framework for domains (OMERACT 2.1 Filter): manifestations (signs, symptoms, biomarkers), life impact, longevity and societal/resource use [22]. Domains were coded and categorised as "broad domains" (a domain of interest to be measured) and "target domains" (a structure or process within a broad domain), according to OMERACT definitions [12]. The broad domain of activity and participation was categorised into three target domains (Table 3) [23]. An inductive approach was undertaken where new codes were identified, and new domains identified from these codes were added to the categorisation matrix. One researcher (LSC) led the analysis, supported by a senior qualitative researcher (CF) and an experienced patient research partner (PR) through ongoing peer debriefing. Two other analysts (LM, CJ, both podiatrists with experience in RMDs), neither of whom were involved with OMERACT, independently coded six transcripts using a fully inductive approach. Coding and domain categorisation decisions were then compared and discussed by the three researchers until consensus was reached. Examples of domain categorisation decisions are presented in supplemental file 3.

Table 3
Activities and participation domain definitions.

Type of activity [23]	Definition
Obligatory	Activities required for survival and self-sufficiency, including hygiene and self-care, walking and driving.
Committed	Activities associated with principal productive social roles, including paid work, household responsibilities and caring responsibilities.
Discretionary	Participating in religious and spiritual activities, socialising, exercise, engaging in leisure time activities and pastimes, and pursuing hobbies.

Patient research partner involvement

Two patient research partners (PR and CH, UK- and Canada-based, respectively) with lived experience of foot and ankle disorders and RMDs provided input into the design of this study, co-produced and piloted the interview schedule and categorisation matrix, and contributed to interpretation of the findings, including domain categorisation decisions.

Results

Fifty-six patients from eight countries, across four continents, participated in an interview. There were no dropouts. Participant characteristics are summarised in Table 4. Patients who had more than one RMD affecting the foot/ankle were asked about each RMD in turn. Forty-four interviews were held fully in English, two were held in English and aided by an interpreter, and 10 were held in Arabic. Sixteen domains were described by participants; the domain categorisation matrix is presented in Table 5. Findings are presented according to broad domains for each OMERACT core area [12], with a narrative overview of participants' descriptions and experiences of each domain. Participants did not rank individual domains in order of importance, although domains are presented in order of reported frequency within each core area. Verbatim quotes supporting each domain are presented in Tables 6-8.

Manifestations (signs, symptoms and biomarkers)

Pain

All participants reported foot and/or ankle pain (Q1, Q2). Severity of pain varied, with severe pain described as "unbearable", "like torture" and "the most excruciating pain ever". Participants described different types of pain, including "a throbbing, sharp, stabbing pain", "like walking on knives", "shooting pain", "like a bruising", "a burning hot pain", "like somebody's sticking pins in the ends of your toes", "like [a] toothache in your foot". Pain was experienced at different times, including during or after weightbearing, at rest, on movement of the foot or ankle, on pressure, in the morning and at night. For most participants, resolution or reduction of foot/ankle pain mattered most, compared to other treatment outcomes. Most participants with systemic diseases deemed their foot or ankle the area of their body most affected by pain or their "biggest problem", and it was often the first area to have been

Table 2
Participant inclusion and exclusion criteria.

Inclusion criteria
Aged 18 or over
Diagnosis of a RMD and have received treatment (conservative, pharmacological or surgical) for a foot and/or ankle disorder within the last 12 months
Able to give informed consent
Exclusion criteria
Acute trauma or injury to the foot/ankle (e.g. fracture, rupture, sprain), or a sports injury
Comorbidities affecting the foot/ankle (e.g. diabetes, primary neurological conditions, or peripheral arterial disease)
Lacking capacity to give informed consent

Table 4
Participant characteristics.

Gender	Women (37) Men (19)
Age (years)	Median: 56.5 IQR: 22.5
Geographic location	Europe: United Kingdom (27), Republic of Ireland (1), Serbia (1), Malta (1) Africa: Egypt (10) Australia: Australia (8) North America: United States (6), Canada (2)
Race/Ethnicity	White British (18), Egyptian (10), White American (8), White Australian (8), Chinese (2), White Canadian (2), White Irish (1), Maltese (1), Arab (1), Bangladeshi (1), Indian (1), Black African (1), Other African (1), Mixed (1),
First language	English (38), Arabic (11), Mandarin (2), Malayalam (1), Farsi (1), Portuguese (1), Turkish (1), Maltese (1)
RMD	RA (18) SpA: Ankylosing spondylitis (4), psoriatic arthritis (5), enteropathic arthritis (3), reactive arthritis (1) JIA: Juvenile-onset RA (2), juvenile-onset psoriatic arthritis (1) OA (8) CTDs: Systemic sclerosis (5), systemic lupus erythematosus (2) mixed/undifferentiated CTD (3), dermatomyositis (1) Secondary Sjogren’s syndrome (2), secondary Raynaud’s phenomenon (12) Crystal arthropathies: Gout (1), pseudogout (1) MSK disorders with no systemic condition: Plantar heel pain (2), Achilles tendinopathy (3), peroneal subluxation (1), toe deformities (1), flatfoot (1)
Self-reported duration of foot/ ankle symptoms (years)	Median: 12 IQR: 20

RMD rheumatic and musculoskeletal disease, RA rheumatoid arthritis, JIA juvenile idiopathic arthritis, SpA spondyloarthropathy, OA osteoarthritis, CTD connective tissue disease, MSK musculoskeletal.

affected.

Physical function

Most participants described limitations in physical function, regardless of RMD, ethnicity or geographic location. Participants conveyed limitations in movement in their foot/ankle, describing a loss of flexibility. Some participants perceived that range of movement was as important or more important than pain, contributing to “feeling disabled”, although one participant described it as “something that creeps up slowly, so you get used to it”. Stiffness in the foot/ankle was also frequently reported by participants, described as “locking” and “gelling” of the joints, and the feeling that “a little rod of steel is running through my big toe”. Limited range of movement and stiffness were closely linked, with some participants considering these to be the same concept, although others felt that stiffness was less impactful in comparison (Q7-Q10).

Participants also experienced weakness and joint instability in their foot/ankle, reporting experiences of “a sudden twist”, “giving way”, and “feeling like my ankle could turn very easily”. Some participants perceived that muscle weakness led to balance issues (Q11, Q12); participants reported being more conscious of their feet, and being more conscious of the ground when walking, as a result.

Changes in gait were reported by participants, including a reduction in walking speed and stride length (Q13), “limping”, “waddling”,” hobbling”, “hopping about”, “walking on the outside of my feet” and being “unable to walk in a straight line”. Altered gait was linked to pain when weightbearing. Some participants felt their foot/ankle disorders impacted on other joints, particularly the knees and hips, as a result of altered gait patterns (Q14).

Fatigue

Participants reported experiencing physical fatigue as a result of their foot/ankle problems (Q4), describing “getting tired so easily”, feeling “completely strung out”, “exhausted” and “weary”, “like the whole body doesn’t want to move”. Foot/ankle problems could result in both overall fatigue and fatigue localised to the foot and ankle (Q5), described as “aching” and “tired” feet, and participants reported that their overall fatigue worsened in-line with declining foot/ankle symptoms. Foot/ankle pain was perceived to be the primary cause of fatigue for most participants, although muscle weakness was also implicated. Foot/ankle-specific fatigue often occurred as a result of activities and participation, whilst some participants perceived that being unable to exercise due to foot/ankle problems was the cause of overall fatigue. Participants also reported experiencing cognitive fatigue, described as “a heavy weight or burden that I’m carrying around” and feeling “emotionally and mentally drained” as a result of foot/ankle problems, particularly pain and associated worry. Cognitive fatigue affected concentration (Q6). Fatigue was reported by participants with all RMD types, but was more frequently reported in those with systemic conditions.

Deformity

Participants discussed a range of deformities in their foot/ankle, including hammer and retracted toes, overlapping toes, bunions, and flatfoot. They described “crooked and squished”, “bent” and “distended” toes, feet “growing sausagey (*sic*)” and “going over to one side”, and ankles “falling inward”. Appearance of deformity was less important to some participants than pain (Q17). Deformity contributed to stiffness and reduced range of movement, skin and nail issues, and altered gait. Deformity was reported among participants with all RMD types, but was deemed less severe among those with non-systemic, localised MSK disorders compared to other RMDs.

Skin and nail health

Participants reported skin and nail problems, including callosities, blisters, dry skin, cracking skin, ingrowing, breaking, and thickened nails. Skin and nail issues were linked to deformity and attributed to footwear and orthotics, and were problematic irrespective of RMD, ethnicity or geographic location. These issues often resulted in pain (Q18), but many participants perceived they were “easily treated”. Most participants with skin and nail problems were unconcerned by their appearance. Some participants also experienced colour changes in their feet and described their experiences of foot ulceration and infection (Q19, Q20); in CTDs, wound healing was often a priority due to the severity of pain that digital ulcers caused.

Swelling

Of participants who reported swelling in their foot/ankle (Q15, Q16), some described a feeling of “tightness” or “imminent explosion”. Swelling could occur at rest or after weightbearing. Swelling was reported in all RMD types, but was often deemed more important when it caused pain, particularly in crystal arthropathies.

Temperature changes

A minority of participants described temperature changes in their foot/ankle, which could be painful, particularly in Raynaud’s phenomenon.

Numbness

A minority of participants experienced episodes of numbness, which could occur at the same time as pain (Q3).

Poor circulation

Some participants, with RA, SpA and CTDs, described poor circulation, with one participant with a CTD stating that circulation was the biggest problem affecting their feet.

Table 5
Categorisation of domains.

OMERACT core area	Broad domain	No. (%) of participants reporting domain	Continent representation	RMD representation	Target domains
Manifestations (signs, symptoms, biomarkers)	Pain	56 (100 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Pain severity Pain during weightbearing Pain after weightbearing Pain at rest Pain on movement Morning pain Pain on pressure Pain at rest Pain at night
	Physical function	50 (89 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Reduced range of movement Stiffness Muscle weakness, instability and balance Altered gait/walking
	Fatigue	34 (61 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Overall fatigue Foot/ankle-specific fatigue[*] Cognitive fatigue[*]
	Deformity	32 (57 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Deformity
	Skin and nail health	31 (55 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Skin condition Nail condition Ulceration Colour changes Infection
	Swelling	26 (46 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Swelling at rest Swelling after weightbearing[*]
	Temperature	11 (20 %)	Europe; Africa; North America	RA; SpA; CTD; MSK disorder	Temperature
	Numbness	8 (14 %)	Europe; Africa; North America; Australia	SpA; OA; CTD; MSK disorder	Numbness
	Poor circulation	7 (13 %)	Europe; North America	RA; SpA; CTD	Poor circulation
	Cramping	5 (9 %)	Europe; North America	RA; SpA; OA; CTD	Cramping during weightbearing Cramping at rest Cramping at night
Life impact	Activities/ participation	56 (100 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Obligatory activities Committed activities Discretionary activities
	Footwear impact	52 (93 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Footwear comfort Footwear aesthetics Footwear choice Impact on clothing
	Psychological impact	50 (89 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Changes in mood Fear of falling Perception of appearance Self-confidence
	Sleep	17 (30 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; CTD; MSK disorder	Sleep
Longevity[**]					
Resource/societal use	Healthcare utilisation	56 (100 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Appointments/ consultations Hospitalisation Medication use
	Personal expenses	47 (84 %)	Europe; Africa; North America; Australia	RA; JIA; SpA; OA; crystal arthropathy; CTD; MSK disorder	Appointments/ consultations Medication use Work impact Transport costs Device costs

RMD rheumatic and musculoskeletal disease, RA rheumatoid arthritis, JIA juvenile idiopathic arthritis, SpA spondyloarthropathy, OA osteoarthritis, CTD connective tissue disease, MSK musculoskeletal.

[*] Domain identified inductively and not in initial coding framework.

[**] No domains related to the OMERACT core area of longevity.

Cramping

A minority of participants reported cramping in their feet, resulting in pain. Cramping was described as “locking”, “a horrible feeling” and “unpredictable”, and could occur during weightbearing, at rest and at night.

Life impact

Activities and participation

All participants acknowledged the impact of foot/ankle disorders on activities and participation. This impact varied; some participants were severely restricted, whilst others felt they could do their usual activities

Table 6
Verbatim quotes for manifestations/abnormalities target domains.

Target domain	Quote no.	Verbatim quote	Gender	RMD	Continent
Pain when weightbearing	Q1	A lot, all the time, I cry because of pain when I try to stand on them. I cannot sleep without the treatment. I cannot walk or go anywhere.	Man	RA	Africa
Pain severity	Q2	The pain is too much. I can't do anything. It's stressful.	Man	MSK disorder	Europe
Numbness	Q3	It feels like, on the bottom of both feet, right in the pad of your foot, it feels like a wasp sting that's maybe an hour old. So it's numb and achy and hurts all at the same time.	Woman	SpA	North America
Overall fatigue	Q4	The more pain I'm in, the more fatigue I have. The pain will go away but the fatigue will still be there because I'm just completely strung out by the amount of pain that I've pushed through.	Man	JIA	Australia
Foot fatigue	Q5	At [a] certain point I just have to collapse and have to put my feet up and have to rest […] it definitely causes a lot of extra fatigue on top of just what comes with having the disease in general.	Woman	RA	North America
Cognitive fatigue	Q6	The discomfort becomes a distraction to everything, it overrides everything […] it affects your concentration because you just […] can't be bothered, I just want to sit down.	Woman	MSK disorder	Australia
Range of movement	Q7	Ideally I would like to be able to move my ankle better. I feel like, at this point, I can put up with the pain and I would rather just not be limited in functionality more so.	Woman	MSK disorder	North America
	Q8	If you're driving you need your ankles to move, so driving becomes difficult, climbing stairs, bending about, anything that you do in a regular world becomes more difficult.	Man	CTD	Europe
Stiffness	Q9	Stiffness for me is a heavy feeling with mild pain. My foot feels tired, I walk slowly, like I've already been walking for hours and hours. It takes more energy to move.	Man	RA	Europe
	Q10	If I had a choice between a tablet for pain and a tablet for stiffness, I'd take pain any day.	Man	OA	Australia
Muscle weakness, instability and balance	Q11	The whole foot feels very unstable because quite a lot of the time, if I'm just walking normally, even in flat shoes across the car park at work, if I'm on the slope I don't feel steady.	Woman	MSK disorder	Europe
	Q12	I have this weakness in my feet so I don't feel as steady, I'm afraid. I feel my balance is not that steady anymore.	Woman	RA	Europe
Altered gait	Q13	I've almost got to the point where I'm making little short paces […] from side to side because I can't stride out normally.	Woman	MSK disorder	Europe
	Q14	If you limp, then your knees will go bad, then your hips will go on you.	Woman	SpA	Australia
Swelling	Q15	Even when I wear the flat shoes, the ones I wear mostly out of everything, my foot throbs because it feels like it's going to explode with the swelling.	Woman	OA	Europe
	Q16	There's been occasions where my feet, my ankles especially, [they've] really swollen up … it sort of bursts your footwear off. You tie your laces and it's extremely painful, and when you take your shoe off it looks like – I can only describe it like an elephant's foot.	Man	Crystal arthropathy	Europe
Deformity	Q17	I don't care what they [my feet] look like. I'd have all my toes off. I say sometimes, oh, I just wish I could have my feet taken off, have a transplant if they did foot transplants. But it's not about how they look, it's how they feel … it's the pain.	Woman	CTD	Europe
Skin condition	Q18	I don't like having that dry skin … because it's painful, to be honest, because actually it cracks and then goes deeper inside.	Woman	SpA	Europe
Ulceration	Q19	The ulcers are so painful, so painful. I wouldn't wish it on nobody, even my worst enemy.	Woman	CTD	Europe
Infection	Q20	The thing that concerns me most is that the skin between my toes dries up and breaks. It bleeds and there is pus.	Woman	CTD	Africa

but for less time, or by making adaptations, pushing through pain or accepting they would be in pain afterwards.

Obligatory activities

Most participants reported that foot/ankle disorders impacted on walking (Q21). For many, being able to walk was a priority. Participants described reducing the quantity and distance of walks due to pain when weightbearing, and difficulties walking up and downhill up and down stairs and on uneven surfaces, linking to reduced range of movement, muscle weakness, instability and fear of falling. Swelling, temperature changes, numbness, and skin and nail problems also contributed to reduced walking ability. Some participants required walking aids or to hold onto something or someone to be able to walk. Foot/ankle disorders affected driving (Q22); participants described changing to an automatic car and limiting driving duration as a result of pain, cramping and numbness. Personal care was also affected (Q23).

Committed activities

Participants described giving up work (Q24), modifying their roles at work or changing jobs, making adjustments (e.g. needing to take breaks at work, change shoes, and stand less), reducing their hours, and taking time off work (Q25). In most cases, participants in jobs that involved weightbearing were affected, although pain at rest and cognitive fatigue could also affect non-weightbearing work. Work disruption caused psychological distress and had financial implications. Foot/ankle disorders also impacted on participants' family roles (Q26), leading to reliance on others and loss of independence, and affected household responsibilities, including shopping, cooking, cleaning and ironing.

Discretionary activities

Participation in religious activities was also affected by foot/ankle disorders. Participants of, for example, an Islamic cultural background, in Egypt and the UK, described modification of Muslim prayer movements, such as sitting in a chair to pray, and praying at home rather than at a mosque, due to pain when weightbearing and limited range of movement in the foot/ankle (Q27). These restrictions led to psychological impact for some participants. Many participants reported a decline in socialising due to their foot/ankle disorders, avoiding leaving the house, and cancelling or rescheduling plans, which affected relationships with friends and family (Q28). Reduced social activities were usually a direct result of pain, but was influenced by temperature changes, instability, balance and fear of falling, or foot ulceration. Multiple sports, hobbies and activities for relaxation and pleasure were affected (Q29, Q30). Participants also discussed the impact of their foot/ankle disorders on holidays and special occasions, which were particularly affected by activity limitations and footwear impact.

Footwear impact

Most participants described limitations in footwear choice (Q34),

Table 7
Verbatim quotes for life impact target domains.

Target domain	Quote no.	Verbatim quote		RMD	Continent
Obligatory activities	Q21	I find that my foot gets swollen and very hot and the area round my ankle gets also hot and swollen and I cannot walk. I have to sit and put my foot up. I used to like walking a lot, but now if I walk halfway to the bus station, my foot swells.	Man	RA	Africa
	Q22	For me, it's about maintaining the ability to walk independently and being able to drive as well. They are what I would call my priorities. I want to be able to maintain movement in the joints – I don't like the idea of not being able to bend them, but for me it's about maintaining independence and mobility.	Man	JIA	Europe
	Q23	Your feet are the most important thing and if you can't stand on them, you can't walk. You can't even do the fundamentals of going to the toilet or using a bath or shower.	Man	SpA	Europe
Committed activities	Q24	I had to give up teaching actually because of my feet and that was my life.	Woman	OA	Australia
	Q25	At times, my feet are so bad I can't move so I can't go to work.	Man	CTD	Africa
	Q26	I can't take them out, the little ones. I can't take them out for a walk 'cause I can't walk anywhere. It makes you miserable.	Woman	MSK disorder	Australia
Discretionary activities	Q27	I like praying and performing soujoud and kneeling, but I can't now. I pray sitting on a chair. At times I cannot even lift my foot to do the ablution, so I just wet it by hand, but I do wash it properly for the dawn prayer. But for the rest of the prayers, I just pass my wet hand over it because it is very painful.	Man	RA	Africa
	Q28	You go to parties and you have to stand around, walk around … when you go to restaurants in the basement, you have to go down into the basement down these ugly, little steep stairs to find the washroom … And so it just snowballs, you end up with mostly your family and close friends, and even they fall off.	Woman	RA	North America
	Q29	I used to play football regularly. I don't go anymore. Now the people who go, they're not texting me anymore because every time they text me, I say no Sometimes they say, 'oh, come on, just sit with us.' And I said, 'it makes me more upset. I'd rather sit at home. Not to be there, to watch you all because I want to join, I want to be jumping and playing.'	Man	SpA	Europe
	Q30	I used to have a hobby. I liked fishing … last time I went was a few years ago, I stayed there a short time and my foot became so swollen, almost like a football. My children asked me, why am I doing this to myself? … I have fishing gear at home and I look at it every so often and smile.	Man	RA	Africa
Changes in mood	Q31	It's depressing, and very anxiety	Woman	RA	North America

(continued on next page)

Table 7 (*continued*)

Target domain	Quote no.	Verbatim quote		RMD	Continent
		inducing too, because it's like, you know, is it going to be like this forever, is it going to get worse, and just the uncertainty.			
	Q32	I used to jog myself to get that rush feeling, the good feeling that, you know, the heartbeats. That's what I miss the most … I'd go off to gym, so I'd become more addicted to it. One day if I don't go to gym, it was like something missing in my life. Now it seems like I've lost it completely … I need to clear my head, so I'm going to walk on my hand?	Man	SpA	Europe
Sleep	Q33	If it's not the pain, it's the stiffness. I have to get up and move for a while. Go for a walk around the house, then go back to bed. I can't lie still for more than three or four hours.	Man	OA	Australia
Footwear choice	Q34	I can't wear what I want. Impossible.	Woman	RA	Europe
Footwear comfort	Q35	I'm just not able to walk as well in certain types of shoes, so I definitely prioritise the comfort aspect.	Woman	MSK disorder	North America
Footwear aesthetics	Q36	Trying to get shoes is a nightmare … everything I have now is not pretty, they do not make shoes to be pretty for our health issues.	Woman	RA	Europe
Impact on clothing	Q37	If you put a dress on, well then you've got to have shoes to suit your dress. But if you've got a dress and you've got clumpy shoes on, it doesn't look too appealing.	Woman	OA	Europe
Treatment experience	Q38	I have taken five different kinds of tablets and injections, and I still have foot pain.	Man	RA	Africa
	Q39	I've complained considerably to my rheumatologist, and he seems to think there's nothing we can do about that. There's an attitude among the medical profession referring to my rheumatologist and my GP, everyone gets it [foot OA], anyone who's older gets it and there's nothing we can do so shut up and go home.	Man	OA	Australia
	Q40	Where is the support? You can't find evidence, you can't find encouragement, you can't find professionals who know the ins and outs of footcare and how to remain functional, how to maintain the function of your foot through a disease that's going to last you a whole lifetime.	Woman	RA	North America
	Q41	I'm a very strong advocate for my own care and if I need somebody to look at something and they won't do it, then I'll go and find somebody that will.	Man	JIA	Australia

including the inability to wear off-the-shelf or "normal" shoes, being limited to trainers and giving up wearing "decent shoes". Many prioritised comfort, as uncomfortable shoes led to pain when weightbearing (Q35). Whilst pain and deformity were major factors affecting choice of footwear, limitations also occurred as a result of swelling, foot/ankle instability and reduced balance. Circulation issues and temperature changes could also limit footwear choice, particularly in winter and in colder locations. Many participants highlighted issues with footwear aesthetics, particularly females and/or those with RA, SpA and JIA who wore orthopaedic shoes due to severe foot deformity (Q36). These were described as looking "weird", "clumpy", "frumpy", "ugly" and "heavy". Footwear limitations impacted on clothing choices (Q37). Some participants acknowledged that they cared what their feet and shoes looked like when they were younger, but no longer did, highlighting the influence of age on priorities. Footwear limitations impacted on activities

Table 8

Verbatim quotes for societal/resource use.

Target domain	Quote no.	Verbatim quote		RMD	Continent
Device costs	Q42	I'd hate to think how much money I've spent on orthotics over the years. Shoes, mainly sports shoes, mainly those that give me that cushion effect and rock forward, yeah I'm still in those sort of shoes all the time these days. Probably every four to five months it's another $220.	Woman	OA	Australia
Medication use	Q43	My doctor prescribed me an injection, but the price increased, it used to sell for 50 Egyptian pounds, so I stopped buying it. I bought the generic, but it made me worse, so I stopped it completely. I only take painkillers now.	Woman	CTD	Africa
Work impact	Q44	When I had problems with my foot, I couldn't stand anymore. My job required me to stand all day … I gave up. I have been unemployed for nine or ten years now … I am in receipt of social security payments. It affected my psyche.	Man	RA	Africa

and participation, gait and psychological health, leading some participants to identify footwear impact as a priority, irrespective of ethnicity or geographic location.

Psychological impact

Foot/ankle disorders affected mood; participants described multiple emotions, including anxiety, depression (Q31), frustration, feeling "fed up", "miserable", "down" and "wanting to be alone". Some participants described an inability to cope. Foot/ankle pain was the primary symptom that affected participants' moods, but mood changes were also attributed to overall, foot/ankle-specific and cognitive fatigue. Participants expressed worries about swelling, numbness and discoloration, paranoia about their feet changing shape and looking different, and anxiety regarding causing foot or ankle damage by doing certain activities. Other participants expressed frustration and misery in having to restrict activities and participation, which affected their independence, morale and self-confidence. The benefits of exercise for mental health, pain and fatigue, and subsequent negative impact of not being able to exercise due to foot/ankle problems, were also emphasised by participants (Q32). For some participants, particularly those with RA, spondyloarthropathies (SpA) and juvenile idiopathic arthritis (JIA), appearance of deformity and the subsequent footwear impact also had a negative psychological impact, whilst other participants were unconcerned by deformity, prioritising pain, activities and participation. Some participants described a fear of falling, linking to muscle weakness, instability and balance issues, and also expressed fears relating to the future, ending up in a wheelchair. Emotions were particularly affected by uncertainties around prognosis and treatment, especially when participants perceived that treatments had failed, there was no plan in place, or treatment options had been exhausted. Other participants recalled being affected emotionally when they first experienced foot/ankle problems, but described getting used to these over time, highlighting the potential influence of RMD duration on this domain. Psychological impact was important to participants regardless of ethnicity or geographic location.

Sleep

Foot/ankle disorders affected participants' sleep (Q33). Sleep was primarily affected by pain at rest or at night, but other contributors included temperature changes and stiffness. Some participants reported that they were unable to sleep without painkillers for their foot/ankle pain, and lack of sleep was perceived to cause fatigue.

Societal/resource use

Healthcare utilisation and personal expenses

Healthcare utilisation and personal expenses were influenced by geographic location and subsequent healthcare systems, and overlapped in some cases. Participants described needing multiple consultations with different health professionals and undergoing surgery. Participants with foot ulceration required ongoing wound management and dressings. In some cases, foot/ankle infection had resulted in, or lengthened, time in hospital. Participants identified extra personal expenses because of their foot/ankle disorders, including those for footwear and orthoses (Q42), highlighting that only certain brands were comfortable and that shoes wore down quickly due to deformity. Participants, particularly those outside of Europe, emphasised the cost of medications and devices for their foot/ankle disorders (Q43), either directly or through insurance plans. Multiple consultations with different health professionals, particularly podiatrists and physiotherapists, also impacted on personal expenses. In many cases, participants felt that costly consultations and treatments had not been successful. Giving up work, reducing hours or changing job role had financial implications for participants (Q44), as did the need for public and private transport as a result of reduced walk. RMD type had no influence on healthcare utilisation or personal expenses.

Discussion

This study has identified 16 domains that are important to people with foot and ankle disorders across a range of RMDs and geographic locations, of diverse ethnicities. Findings provide rich insight into the experiences underpinning priorities to inform the development of a standardised COS for future foot and ankle studies. This COS could also supplement existing disease-specific COSs by adding domains specifically relevant to patients who explicitly report foot and ankle issues. Most broad domains identified in the current study overlap with those included in existing OMERACT core outcome sets [24–26] and could potentially be measured with the same instruments, minimising burden for trialists. Findings corroborate previous qualitative studies exploring patient perspectives, indicating the extensive impact of foot and ankle pain, deformity and physical function domains on activities and participation, psychological health, footwear needs and personal finances [18,19,27,28]. The current study explored the full scope of physical function in more depth, indicating that stiffness, limited range of movement, joint instability and altered gait patterns could also affect participants across multiple life impact domains. New domains of importance to patients were also identified; whilst the contribution of foot and ankle pain to overall physical fatigue is well established [18], the current study highlights the impact of foot/ankle-specific fatigue, and the influence of foot and ankle disorders on cognitive fatigue.

Whilst many domains identified from the qualitative interviews were common across all conditions, the importance of some domains differed depending on the RMD. Notably, deformity was an important domain among most participants with RA, SpA and JIA, but was less of an issue for most participants who had MSK disorders affecting the foot and ankle in the absence of any systemic condition. Additionally, skin health (including callosities, foot ulceration and infection) was particularly important to participants with CTDs. In addition to domains, this study has identified contextual factors, defined as variables that are not outcomes of a study but need to be recognised and measured to understand the study's results [29]. Contextual factors can be categorised as personal, disease-related and environmental factors [30]; findings from the qualitative interviews indicate that age, sex, ethnicity, disease duration, geographic location, treatment experiences and healthcare system could influence the results of foot and ankle studies and should be considered in future work.

This study is the first to consider the perspectives of people with foot and ankle disorders in less common RMDs, including JIA, ankylosing spondylitis, enteropathic arthritis, mixed CTDs and pseudogout, where interventional studies are particularly lacking [17]. The inclusion of ethnically and culturally diverse participants, from multiple countries representing different healthcare systems, and the large overall sample size are strengths of this study [31]. The small number of participants within some RMD categories could be considered a limitation, and some RMD subtypes (e.g. limited cutaneous systemic sclerosis versus diffuse cutaneous systemic sclerosis) were not part of the purposive sampling criteria. Similarly, RMD/foot and ankle disorder severity was not recorded in this study, and duration was self-reported by participants. Therefore, findings from this study may not represent the priorities or experiences of other patients with foot and ankle disorders in RMDs. Notwithstanding, findings relating to the impact of foot and ankle disorders in RMDs provide a grounding for future studies in under-researched areas. A further potential limitation is that the interviews were conducted by clinicians; we acknowledge that clinician-patient power dynamics may have influenced data collection. Additionally, interviews conducted in English with participants whose first language was not English, and translation of interviews conducted in Arabic, may have led to the loss of nuances and cultural references. For example, certain concepts can lack direct language equivalents, resulting in ambiguity and hindering understanding of the context and depth of responses [32]. Nevertheless, all participants provided valuable accounts of their experiences of living with foot and ankle disorders and the potential for interpretation bias was offset by robust translation and transcription processes.

The variation in experiences of seeking and receiving foot and ankle advice and treatments demonstrated in this study highlights a case for measuring health resource use in future research. Experiences of treatment uncertainty and unresolved symptoms reflect the critical need for future and definitive randomised controlled trials to determine their clinical effectiveness. Findings from this study will inform a future, multi-stakeholder Delphi consensus study aiming to prioritise domains for inclusion in a COS. Qualitative findings will ensure the domains presented in the first round of the Delphi reflect what is important to a diverse range of patients. Additionally, interview data will inform plain language definitions of domains, improving study accessibility, which may enhance patient recruitment and retention. Participants' choice of words when describing domains can also be used to inform the measurement of domains in future work. By providing a comprehensive overview of the priorities of patients with foot and ankle disorders in multiple RMDs, findings are also directly relevant to clinical practice, helping to guide the content of clinical appointments, particularly in the management of patients with RMDs where foot and ankle involvement has previously been overlooked.

Conclusion

This large qualitative study has identified 16 domains that are important to people living with foot and ankle disorders in RMDs. It provides a foundation for achieving international consensus on a COS for foot and ankle disorders in RMDs, to improve the quality of evidence demonstrating effectiveness of treatments.

Author contribution statement

LSC, HJS, CF, PR and ACR conceived the study and developed the protocol. LSC, ES and AM collected the data, supported by CF, PR and HJS. LSC, LM and CJ conducted the analysis and interpreted the results, supported by CF, PR and HJS. All authors critically revised the manuscript for important intellectual content and approved the final version of the manuscript. LSC obtained funding. LSC and HJS are the guarantors.

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Disclaimer

The funders had no role in the study design, data collection, data analysis, data interpretation or writing of the report.

Patient and public involvement

Patient research partners were involved in the design, conduct, reporting and dissemination plans of this research. Further details are presented within the Methods section of the manuscript.

Patient consent for publication

Not required.

Ethics approval

This study obtained Health Research Authority ethical approval from North East - Tyne & Wear South Research Ethics Committee (reference 22/NE/0226), University of Leeds School of Medicine Research Ethics Committee (reference MREC 22–071), Alexandria University Faculty of Medicine (reference 0,306,245), and the University of South Australia Human Research Ethics Committee (reference 205,659). The study was carried out in accordance with the Declaration of Helsinki. All participants provided written informed consent for publication.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability statement

The data supporting the findings of this study are not publicly available due to ethical restrictions; they contain information that could compromise the privacy of research participants.

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