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Developing a core outcome set for foot and ankle disorders in rheumatic and musculoskeletal diseases: A scoping review and report from the OMERACT 2022 foot and ankle special interest group session

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ABSTRACT

Objectives: Foot and ankle involvement is common in rheumatic and musculoskeletal diseases, yet high-quality evidence assessing the effectiveness of treatments for these disorders is lacking. The Outcome Measures in Rheumatology (OMERACT) Foot and Ankle Working Group is developing a core outcome set for use in clinical trials and longitudinal observational studies in this area.

Methods: A scoping review was performed to identify outcome domains in the existing literature. Clinical trials and observational studies comparing pharmacological, conservative or surgical interventions involving adult participants with any foot or ankle disorder in the following rheumatic and musculoskeletal diseases (RMDs) were eligible for inclusion: rheumatoid arthritis (RA), osteoarthritis (OA), spondyloarthropathies, crystal arthropathies and connective tissue diseases. Outcome domains were categorised according to the OMERACT Filter 2.1.

Results: Outcome domains were extracted from 150 eligible studies. Most studies included participants with foot/ankle OA (63% of studies) or foot/ankle involvement in RA (29% of studies). Foot/ankle pain was the outcome domain most commonly measured (78% of studies), being the most frequently specified outcome domain across all RMDs. There was considerable heterogeneity in the other outcome domains measured, across core areas of manifestations (signs, symptoms, biomarkers), life impact, and societal/resource use. The group's progress to date, including findings from the scoping review, was presented and discussed during a virtual OMERACT Special Interest Group (SIG) in October 2022. During this meeting, feedback was sought amongst delegates regarding the scope of the core outcome set, and feedback was received on the next steps of the project, including focus group and Delphi methods.

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Conclusion: Findings from the scoping review and feedback from the SIG will contribute to the development of a core outcome set for foot and ankle disorders in RMDs. The next steps are to determine which outcome domains are important to patients, followed by a Delphi exercise with key stakeholders to prioritise outcome domains.

Background

Foot and ankle disorders frequently occur in rheumatic and musculoskeletal diseases (RMDs) [1–6]. Foot and ankle problems lead to a substantial reduction in quality of life and are often highlighted explicitly by patients [7–11]. However, there is a paucity of high-quality evidence assessing the effectiveness of treatments for these disorders and translation of existing research evidence into practice is typically poor [12]. Inconsistency in outcome measurement contributes to these issues [13,14].

The Outcome Measures in Rheumatology (OMERACT) Foot and Ankle Working Group aims to address these issues through the development of a core outcome set (COS) using an established framework [15]. Briefly, this process will involve determining what outcome domains should be measured (core domain set) through a scoping review of the existing literature, qualitative research, a modified Delphi study and final consensus meeting, followed by a systematic review and feasibility evaluation of candidate outcome measurement instruments for each core domain [16,17]. This paper reports two phases towards the development of an initial core domain set: (i) a scoping review of outcome domains in existing clinical trials and LOS for foot and ankle disorders in RMDs, and (ii) the OMERACT 2022 virtual Special Interest Group (SIG) feedback exercise focussing on the scope of the COS and focus group and Delphi methods.

Phase 1 – scoping review

A scoping review of existing literature was conducted to establish the scope and frequency of outcome domains that are potentially important to researchers and clinicians and should be considered for inclusion in a future core domain set.

Methods

Search strategy

A search strategy was developed with input from the wider multidisciplinary and multi-stakeholder OMERACT Foot and Ankle Working Group, which includes four patient research partners. The following databases were searched from 1980 to August 2020: Ovid MEDLINE, Ovid Embase, Cumulative Index of Nursing and Allied Health (CINAHL), Cochrane Library (Cochrane Central Register of Controlled Trials (CENTRAL) and Cochrane Database of Systematic Reviews), Physiotherapy Evidence Database (PEDro). Additionally, three trial registries (ClinicalTrials.gov, ISRCTN registry, ANZCTR) were searched from 2015-August 2020. Examples of search terms are provided in Supplementary Table 1.

Eligibility criteria

Participants

Studies involving adult participants (18 years and over) with any foot or ankle disorders in the following RMDs were eligible for inclusion: rheumatoid arthritis (RA), osteoarthritis (OA) (including conditions typically classed under the foot osteoarthritis umbrella, such as hallux limitus and hallux rigidus [18]), spondyloarthropathies, systemic autoimmune diseases (specifically systemic sclerosis and systemic lupus erythematosus), crystal arthropathies and connective tissue diseases. Studies involving participants with foot and ankle disorders in the absence of systemic rheumatic diseases, acute trauma (e.g., fractures, ruptures or sprains) to the foot or ankle, sports-related injuries, hypermobility disorders, stress fractures or foot and ankle disorders caused by diabetes or primary neurological conditions were excluded.

Interventions

Studies comparing pharmacological, conservative (prevention, treatment) or surgical interventions with other pharmacological, conservative, or surgical interventions, placebo, sham, current care, active monitoring, or no treatment, were eligible for inclusion. Non-interventional studies, and interventional studies with no comparator, were excluded.

Outcomes

There were no restrictions on outcome domains or outcome measurement instruments.

Types of studies

Randomised controlled trials (RCTs), controlled clinical trials (CCTs), controlled before-after studies, longitudinal observational studies, cross-sectional observational studies, cohort studies, and case-control studies specifically focussing on foot and ankle disorders in RMDs, and including at least one intervention group and one comparator group, were eligible for inclusion. Published protocols and trial registry entries with clear descriptions of the intended outcome domains and outcome measurement instruments were also eligible for inclusion. There were no restrictions on setting or geographical location. Case studies, case series, editorials, commentaries, review articles and any studies not in the English language were excluded. Qualitative studies were also excluded from this scoping review but will be explored in a separate review aiming to identify outcome domains important to patients. Systematic reviews were initially screened for eligibility, and full-text articles were screened for additional eligible original studies that may have been missed by the searches. Systematic reviews were then excluded. One author (LSC) also screened the references of all included articles to identify any articles that the searches may have been missed.

Study selection

Titles and abstracts were imported into EndNote X9.3.3 (Clarivate, Philadelphia, PA) and screened independently by two review authors (LSC and JJ) against the agreed eligibility criteria following removal of duplicates. Full-text articles were retrieved when initial screening of the title or abstract suggested the study was eligible or when there was insufficient information in the title or abstract to assess study eligibility. Full-text articles were then independently assessed for eligibility by two review authors (LSC and JJ). Disagreements on study eligibility were resolved through discussion or adjudication by two other review authors (HJS, PSH).

Data extraction

The following data were extracted from full-text articles into a standardised Microsoft Excel data collection spreadsheet: lead author, publication year, RMD diagnosis, study design, study setting, duration of follow-up, geographic location, sample size, intervention (pharmacological, conservative, surgical), comparator, outcome domains and outcome measurement instruments.

Quality appraisal

A quality assessment of the included studies was not relevant for this scoping review, which primarily aimed to identify the scope and frequency of outcome domains. Therefore, no risk of bias assessment was undertaken. A separate quality assessment of studies assessing the measurement properties of outcome measurement instruments identified in this review will be undertaken during a later phase of the OMERACT process when addressing the COS development.

Synthesis of results

A Preferred Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram was developed to present the number of studies included and excluded, with reasons provided for exclusion [19]. One author (LSC) extracted and categorised outcome domains into core areas as defined by the OMERACT Filter 2.1 [20]: pathophysiological manifestations/abnormalities (further categorised into signs, symptoms, or biomarkers), life impact, societal/resource use and death. Additionally, studies capturing adverse events and treatment satisfaction were also tabulated. Outcome domains specified by study authors (as stated in the Methods section) were amalgamated and renamed where appropriate, for example 'pain when walking', 'pain when standing' and 'pain during activity' were combined in the target domain 'pain during weightbearing'. Categorisation and amalgamation of outcome domains into core areas was by the OMERACT Foot and Ankle Working Group Steering Committee, through group discussions until consensus was reached. The frequency of each reported outcome domain was tabulated, and a narrative synthesis was undertaken to summarise the characteristics and findings of included studies. Outcome domains per intervention type and RMD were summarised in separate tables for each core area of the OMERACT Filter 2.1.

In studies where outcome domains were not specified, outcomes were categorised according to the broad theme the relevant outcome measurement instrument proposed to measure. For example, the AOFAS Ankle-Hindfoot Scale proposes to measure the broad outcome domains pain, function and alignment [21], thus studies specifying AOFAS as the outcome measurement instrument without detailing any outcome domains were tabulated under all three domains. In cases where participants had more than one eligible RMD, but the intervention was centred on a clear primary issue, studies were tabulated according to this primary issue (e.g., studies comparing surgical interventions for ankle OA

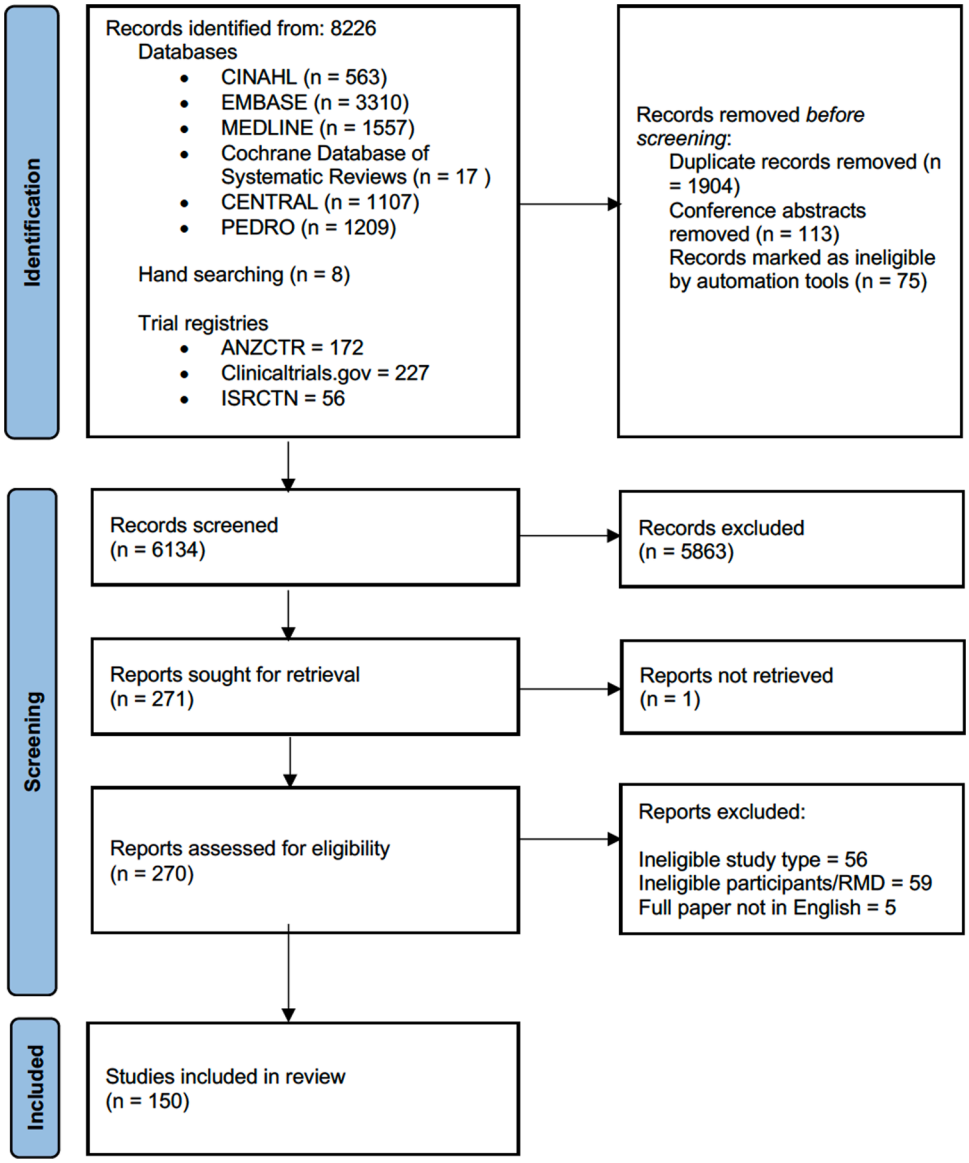

Fig. 1. PRISMA flow diagram

in which some of the participants also had RA).

Results

Study selection

The searches yielded 8234 records, of which 270 were retrieved for full-text screening. Of these, 150 studies [27–177] were eligible and included. The full selection process is presented in Fig. 1. A full overview of all extracted data is provided in Supplementary Table 2.

Characteristics of studies

Studies were conducted in 26 countries and study sample sizes ranged from 7 to 550. Over half of included studies were randomised trials ($n = 83$, 55%), whilst 30 (20%) were non-randomised prospective comparative trials, 24 (16%) were retrospective comparative studies, and 13 (9%) were controlled clinical trials. Of the 150 studies, seven studies were published protocols and 12 studies were trial registrations. Seventy-five studies (50%) investigated surgical interventions, whilst 55 studies (37%) investigated conservative interventions and 20 studies (13%) investigated pharmacological interventions.

Characteristics of participants

Of the 150 included studies, participants in 94 studies (63%) had OA, whilst 43 studies (29%) involved participants with RA, five (3%) involved participants with gout, four (3%) involved participants with spondyloarthropathies, and two (1%) involved participants with systemic autoimmune diseases (lupus and systemic sclerosis). The remaining two studies involved participants with different RMDs (one study involved some participants with RA and some with OA, and the other involved some participants with RA and some with spondyloarthropathies). Studies involving participants with two different RMDs were tabulated under both (e.g., the study including participants with RA and participants with OA was tabulated under both RA and OA).

Of the 95 studies including participants with OA, 64 (67%) investigated surgical interventions, 17 (18%) investigated conservative interventions, and 14 studies (15%) investigated pharmacological interventions. Thirty-three (73%) of the 45 studies including participants with RA investigated conservative interventions, whereas nine studies (20%) investigated surgical interventions and three studies including participants with RA (6%) investigated pharmacological interventions. Five (83%) of the six studies including participants with spondyloarthropathies investigated pharmacological interventions, whilst one (17%) investigated conservative interventions; none investigated surgical interventions. Of the five gout studies, three (60%) investigated conservative interventions and two (40%) investigated surgical interventions; none investigated pharmacological interventions. Both connective tissue disease studies investigated conservative interventions only.

Domains mapped to core areas of OMERACT Filter 2.1

Table 1 presents an overview of all outcome domains. Studies of outcome domains per core area of the OMERACT Filter 2.1, organised by RMD, are displayed in the Supplementary Material.

Manifestations/abnormalities

Outcome domains within this core area were sub-categorised into signs (Supplementary Table 3), symptoms (Supplementary Table 4) and biomarkers (Supplementary Table 5).

Table 1
Outcome domains specified in foot and ankle studies ($n = 150$).

Manifestations/ abnormalities	Life impact	Death	Societal/ resource use
Signs:	***Impact of manifestations/ abnormalities on:***	Survival [1]	Healthcare utilisation [28]
Joint range of motion [30]	Foot/ankle function or disability [102]		Direct/indirect costs [11]
Alignment [24]	Global function or disability [50]		
Global disease activity/assessment of overall condition by clinician [16]	Overall quality of life/health status [37]		
Joint swelling [8]	Social function [12]		
Foot/ankle disease activity [6]	Emotional status [10]		
Presence of deformity [5]	Sports participation [8]		
Presence of callosities [5]	Footwear requirements [7]		
Pain upon palpation [4]	Foot/ankle related quality of life/health status [5]		
Joint tenderness [4]	Pain interference [1]		
Pressure-pain threshold [2]			
Muscle strength [2]			
Joint stability [2]			
Muscle activity [1]			
Joint girth [1]			
Joint temperature [1]			
Clinician-assessment of gait [1]			
Symptoms:			
Foot/ankle pain [118]			
General pain [21]			
Joint stiffness [10]			
Fatigue [8]			
Patient global change in foot/ankle symptoms [6]			
Joint catching [4]			
Joint grinding [4]			
Patient-reported disease severity/assessment of overall condition by patient [2]			
Biomarkers:			
Disease progression/deformity on imaging [51]			
Gait [39]			
Disease activity on imaging [9]			
Disease activity on laboratory markers [6]			

Signs

Outcome domains mapped to signs (Supplementary Table 3) were joint range of motion (30 studies), alignment (24 studies), global disease activity/assessment of overall condition by clinician (16 studies), joint swelling (eight studies), foot/ankle disease activity (six studies), presence of deformity (five studies), presence of callosities (five studies), pain upon palpation (four studies), joint tenderness (four studies), pressure-pain threshold (two studies), muscle strength (two studies), joint stability (two studies), muscle activity (one study), joint girth (one study), joint temperature (one study), and clinician-assessment of gait (one study).

Symptoms

Outcome domains mapped to symptoms (Supplementary Table 4) were foot/ankle pain (118 studies), general pain (21 studies), stiffness (ten studies), fatigue (eight studies), patient global change in foot/ankle symptoms (six studies), joint catching (four studies), joint grinding (four studies), patient-reported disease severity/assessment of overall condition by patient (two studies).

The broad outcome domain foot/ankle pain was further categorised into the following target domains: pain during weightbearing (14

studies), pain during non-weightbearing (nine studies), pain severity/intensity (seven studies), pain at night (four studies), and pain on provocation (four studies). Additionally, the broad outcome domain stiffness was further categorised into the following target domains: stiffness after rest (seven studies), and stiffness during weightbearing (five studies).

Biomarkers

Outcomes mapped to biomarkers (Supplementary Table 5) were disease progression or deformity on imaging (51 studies), gait (39 studies), disease activity on imaging (nine studies), and disease activity on laboratory markers (six studies). The broad domain of gait was further categorised into target domains of plantar pressure (23 studies), temporospatial parameters (21 studies), kinematics (18 studies), and kinetics (12 studies).

Life impact

Supplementary Table 6 shows outcome domains within the core area of life impact (mapped to impact of manifestations/abnormalities). These were: foot/ankle function or disability (102 studies), global function or disability (50 studies), overall quality of life/health status (37 studies), social function (12 studies), emotional status (ten studies), sports participation (eight studies), footwear requirements (seven studies), foot/ankle related quality of life/health status (five studies), and pain interference (one study).

Societal/resource use

Outcome domains within the recommended area of societal/resource use (Supplementary Table 7) direct/indirect costs (11 studies), and healthcare utilisation (28 studies).

Death

Only one study had outcome domains mapped to the core area of death (Supplementary Table 8).

Adverse events

Of the 150 included studies, 98 specified outcome domains mapped to side effects of treatment (Supplementary Table 9).

Treatment satisfaction

Thirty-six studies mapped to treatment satisfaction (Supplementary Table 10).

Domains mapped to specific RMDs

Rheumatoid arthritis

Of the 45 studies comparing treatments for foot and ankle disorders in RA, the most frequently specified outcome domains mapped to the foot/ankle pain (38 studies), foot/ankle function/disability (27 studies), and global function (17 studies). No RA studies mapped to the core area of death. Additionally, no RA studies comparing surgical or pharmacological interventions mapped to the core area of societal/resource use, and no RA studies comparing pharmacological interventions mapped to signs within the core area of manifestations/abnormalities.

Spondyloarthropathies

Of the six studies comparing treatments for foot and ankle disorders in spondyloarthropathies, the most frequently specified outcome domains mapped to disease activity (imaging) (six studies), and foot/ankle pain (five studies). No spondyloarthropathy studies mapped to the core area of death or societal/resource use.

Osteoarthritis

Of the 96 studies comparing treatments for foot and ankle disorders in OA, the most frequently specified outcome domains mapped to foot/ankle pain (68 studies), foot/ankle function/disability (67 studies), and global function/disability (50 studies).

Gout

Of the five studies comparing treatments for foot and ankle disorders in gout, the most frequently specified outcome domains mapped to foot/ankle function/disability (four studies), foot/ankle pain (three studies) and global function/disability (three studies). None of the gout studies mapped to the core areas of death or societal/resource use.

Systemic autoimmune diseases

The two studies investigating interventions for systemic autoimmune diseases mapped to the core areas of manifestations/abnormalities (symptoms: foot/ankle pain), and life impact (foot/ankle function/disability). Neither systemic autoimmune disease study mapped to the core areas of death or societal/resource use.

Phase 2 – OMERACT Foot and Ankle Virtual SIG

The OMERACT Foot and Ankle Virtual SIG took place on Wednesday 12th October 2022 on an internet-based videoconference. The aim of this exercise was to obtain feedback on the scope of the COS and to clarify how best to conduct focus groups and a Delphi consensus exercise.

Methods

Invitations to participate in the SIG were sent via email to all members of the OMERACT Foot and Ankle Working Group and the wider OMERACT community. The SIG was also promoted on social media, through OMERACT and via members of the OMERACT Foot and Ankle Working Group. The SIG commenced with an overview of the OMERACT Foot and Ankle Working Group (introduction to the Steering Committee, proposed research plan, timelines), and was followed by a discussion between two patient research partners regarding their experiences of living with foot and ankle disorders. The methods and results of Phase 1 (scoping review), and from a qualitative review (to be reported on separately) were presented to delegates, and three separate 40 minute breakout groups then conducted. Each breakout group focussed on generating discussion around one distinct main question, with additional questions asked as discussion prompts. All delegates then reconvened in the main SIG and a summary from each breakout group was fed back. To conclude the SIG, delegates were asked to vote on whether or not they felt that the development of a single core domain set for foot and ankle disorders across multiple RMDs was feasible.

Results

Fifty-two delegates attended the virtual 90 min SIG. Most delegates (n = 41, 79%) were researchers, health professionals, or both. The remaining 11 delegates (21%) were patients or representatives from patient organisations. Amongst delegates with a health professional background, most were podiatrists ($n = 14$), rheumatologists/medics ($n = 13$) or physiotherapists ($n = 7$). Delegates were split between breakout groups to ensure equal weighting of stakeholder type and familiarity with OMERACT. Table 2 presents an overview of breakout group

Table 2
Overview of SIG breakout group structure.

Breakout Group	Facilitators	Main question	Follow-up prompts
1	OMERACT Executive: PT Content experts: HBM, ACR Rapporteur: JBA	Can we have a single core outcome set for foot and ankle disorders across multiple RMDs?	• Do you think our scope of RMDs is too wide? • How do you differentiate between the foot and ankle? • When do you think it would be appropriate to have a separate core outcome set?
2	OMERACT Executive: LJM Content expert: CAF Rapporteur: LSC	How should we conduct our patient focus groups?	• Should we aim to include participants where we don't have much information from the existing qualitative literature, or organise them based on the types of treatments that participants have received? • We are currently planning focus groups in the UK, Australia and the USA or Canada – should we reach out further, whilst still needing to remain English-speaking? • How should we phrase our questions for the focus groups?
3	OMERACT Executive: BS Content expert: HJS Rapporteur: TOS	Who should we involve in our Delphi consensus study, and what are the best methods to engage?	• Who should we approach? e.g., patients, health professionals, researchers, industry representatives, policymakers, commissioners? • How should we engage with each stakeholder group? • What are the best methods for Delphi retention?

structure.

Breakout Group 1: 'Can we have a single core outcome set for foot and ankle disorders across multiple RMDs?'

There were no objections to including both foot and ankle disorders in the scope of the core domain set, but delegates encouraged the discussion of foot versus ankle problems in future qualitative work to determine whether patients consider these problems to be the same.

Delegates discussed how patients with certain RMDs have flare states and steady states, and suggested that change over time should be accounted for within a core domain set for foot and ankle disorders. Delegates also identified systemic and local manifestations, which should be captured in domains.

Delegates also suggested that some outcome domains would undoubtedly be common across multiple RMDs, while acknowledging that there needs to be some recognition of differences (e.g., 'bolt-on' outcome domains). The possibility of a core domain set for foot and ankle disorders 'bolted-on' to existing OMERACT core sets for specific conditions, e.g., RA and gout, was discussed.

Breakout Group 2: 'How should we conduct our patient focus groups?'

Delegates identified the need to focus on foot and ankle disorders in conditions where there is little or no information from the existing qualitative literature, particularly systemic sclerosis, lupus, spondyloarthropathies, and other foot problems in the absence of systemic disease. The importance of capturing breadth in the first instance, and filling gaps in the literature, was discussed.

Delegates highlighted how patients from outside of the UK, Europe and North America are under-represented and should be targeted for the focus groups, and that this could be achieved by reaching out to the wider OMERACT Foot and Ankle Working Group. Involvement of patients from the UK, Europe and North America whose first language is not English was considered equally as important.

Delegates suggested identifying what patients have and have not been asked about previously, and tailoring focus group questions around any information missing from the current literature. It was highlighted that questions could be classified according to domains, or differences between domains. In relation to the wording of questions, delegates discussed the importance of not phrasing questions as domains (e.g., 'function' is unlikely to be a term that patients would recognise). Delegates discussed the need to reconcile broader questions, which could potentially dilute experience, and more specific questions, which could be difficult to relate to.

Breakout group 3: 'Who should we involve in our Delphi consensus study, and what are the best methods to engage?'

Delegates considered how the core domain set would ultimately be used (e.g., in both clinical practice and research studies) and agreed that stakeholders to invite to participate in the Delphi should include: people with foot and ankle problems (and patient organisations to offer greater representation); health professionals who see these people (e.g., orthopaedics, rheumatologists, podiatrists, physical therapists, nurses); researchers; policy makers (e.g., senators, politicians); industry representatives such as footwear and medical device manufacturers, and health insurers. Delegates expressed the need to support patients to contribute, and to handle patient responses separately so as not to lose the patient voice.

Delegates recognised the importance of increasing Delphi participants' understanding of the value of voting, and of promoting both diversity of groups and geographical spread, including lower income countries. Delegates also identified the role of social and traditional media e.g., sharing templates with organisations to aid Tweets, Instagram posts and TikTok media for wider promotion, but recognised that some patients may not have technology to allow their voice to be heard.

To retain Delphi participants, delegates recommended increased personalisation, e.g., updating respondents on their response with follow-up reminders and changes to the template reminder email to increase interest. Delphi design (e.g., not too lengthy, able to complete in more than one sitting, and visually appealing) to reduce respondent-burden and improve engagement was deemed important.

SIG poll

Following feedback from the breakout groups, 29 out of the remaining 42 delegates (69%) voted 'yes' to developing a single core domain set for foot and ankle disorders in multiple RMDs.

Discussion

The OMERACT Foot and Ankle Working Group have demonstrated progress towards developing a core domain set for foot and ankle disorders in RMDs, and were encouraged by the feedback obtained during the virtual Special Interest Group held in October 2022.

The scoping review indicated considerable heterogeneity in the outcome domains reported in clinical trials and observational studies of interventions for foot and ankle disorders in RMDs. Foot/ankle pain was the outcome domain most commonly specified by researchers, in 78% of all studies, and was the most frequently specified outcome domain across all RMDs. Foot/ankle function/disability was also frequently specified. Few studies measured outcomes mapping to societal/resource use, and only one study measured death.

Despite the established prevalence of foot and ankle involvement in spondyloarthropathies, gout, systemic sclerosis and lupus, the majority of studies identified in the scoping review involved participants with OA or RA, reflecting how foot and ankle disorders in other RMDs have been historically understudied. Findings from this review will inform the development of a COS for use in future studies as research interest in foot and ankle disorders in rheumatology continues to increase. The presupposition is that core outcomes will be measured and reported, as a minimum, in all future relevant studies, facilitating meta-analyses. Whilst OMERACT COSs for specific RMDs such as RA [22] and ankylosing spondylitis [23] have already been established, they do not consider foot and ankle disorders, which frequently persist regardless of overall disease activity [24]. A COS for foot and ankle disorders will 'bolt-on' to existing core sets in studies including patients with RMDs where foot and ankle interventions are the focus [25].

SIG discussions suggested that a core domain set incorporating both foot and ankle disorders is feasible. However, the result of the poll indicates that it will be important to maximise the acceptability of a single core domain set for foot and ankle disorders across multiple RMDs to a wide range of stakeholders. Limitations in both the wording and timing of the poll are acknowledged. Firstly, the poll question referred to a core outcome set (this, by definition, includes outcome measurement instruments), rather than a core domain set. Whilst the scoping review involved the extraction of outcome measurement instruments, this was primarily to enhance understanding of the domains that were measured; instrument heterogeneity will be addressed later in the OMERACT process of COS development [15]. No evidence relating to instruments was presented in the SIG, thus some participants may have voted 'no' due to uncertainty. Secondly, the SIG overran, and ten participants had left the meeting prior to the poll, therefore the result may not accurately represent the opinions those who did not vote. However, the poll was not intended to be a formal OMERACT voting mechanism; the aim was to obtain feedback rather than consensus.

The SIG exercise was effective in directing a future research plan and next steps. Feedback from SIG delegates will be incorporated into the design of qualitative focus groups and Delphi, with an aim to target patient participants with under-represented conditions and to involve under-represented countries in future work. This will further strengthen the evidence for the scope of the proposed COS. Notably, the proposed core domain set will allow findings from foot and ankle studies to be compared and combined without limiting the measurement of additional outcome domains that may be of interest to researchers. Following established OMERACT methodology [15], it would also be possible to specify that a core domain is mandatory for certain trials only [26].

Strengths of the scoping review include independent screening and extraction of data by two reviewers, broad inclusion criteria for rheumatic conditions, study types and date range, and an extensive search of databases and trial registries. Categorisation of some studies according to the broad outcome domains measured by an outcome measurement instrument, in the absence of any specified outcome domains, could also be considered a limitation. The aim of the scoping review was to ascertain outcome domains of importance to researchers, and assumptions were made when this information was unavailable; however, foot and ankle outcome measurement instruments typically measure multiple outcome domains and categorisation of these differ depending on the instrument and the interpretation of the researcher, particularly with regards to the measurement of function. The OMERACT initiative is currently undertaking work to achieve consensus on a common definition of function, which will inform the development of this COS (OMERACT Common Domains Definitions Project - personal communication, 23 January 2023).

A further limitation of the scoping review was that only papers published in English were included, which potentially omitted identification of additional outcome domains that are potentially important to researchers from low- and middle-income countries and other under-represented groups. This is a frequent limitation in literature reviews for COS development where representation is incredibly valuable. Notwithstanding, the review included studies from 26 countries, and future qualitative and consensus work will focus on increased representation of broader perspectives globally. The diversity in outcome domains identified in this scoping review emphasises the need for an internationally agreed COS for foot and ankle disorders in RMDs. Further work could then be undertaken to understand whether the core set would be applicable to additional populations not within the current scope, for example, studies involving children and young adults with foot and ankle disorders in RMDs.

A limitation of the virtual SIG was that there was no systematic recruitment and therefore the group lacked representation from certain relevant healthcare professions (e.g., nursing and orthotics). All relevant stakeholders will be targeted therefore during the Delphi study, utilising the suggested methods of recruitment and retention. Findings from the planned qualitative research and Delphi consensus study may lead to further refinement of the scope of the proposed core domain set; this will be followed by an OMERACT consensus meeting aiming to achieve core domain set endorsement.

Conclusion

Foot and ankle disorders are common and debilitating in RMDs. Our scoping review of existing clinical trials and observational studies highlighted heterogeneity in the outcome domains measured by clinicians and researchers. The OMERACT Foot and Ankle Working Group aims to develop a COS that addresses the current lack of outcome standardisation that contributes to limited high-quality evidence for foot and ankle treatments. A virtual, international OMERACT Foot and Ankle SIG brought together patients, clinicians, and researchers to discuss and agree on the scope of this COS and the methods to be employed.

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Declaration of Competing Interest

None.

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Supplementary materials

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