Foot and Ankle case studies

Foot and ankle disorders occur in a diverse range of RMDs, and a broad range of interventions exist for these disorders. The OMERACT Foot and Ankle Working Group recognise the potential difficulty in developing a core outcome set that is applicable to all clinical scenarios. As such, three separate PICOCs have been developed in the first instance, focusing on pharmacological, non-pharmacological (conservative) and surgical interventions, with the aim of establishing whether different core outcomes are required according to the type of intervention, or whether a single core outcome set will suffice.

Pharmacological PICOC

Component of PICOC	**Description of the criteria for each component**
Population	Foot and ankle disorders (excluding acute injury), in rheumatic and musculoskeletal diseases (including inflammatory arthritis, osteoarthritis, spondyloarthropathies, connective tissue diseases, crystal and musculoskeletal disorders).
Intervention	Pharmacological interventions.
Control	Other pharmacological, non-pharmacological or surgical interventions, placebo, sham, current care, active monitoring, no treatment.
Outcome	Core Domain Set under development.
Context (Setting)	The Core Domain Set will apply to randomized controlled trials, controlled clinical trials, and longitudinal and cross-sectional observational studies conducted worldwide in the English language. It will be relevant to patients and the public, researchers, clinicians, policymakers, and guideline developers.

Case study

Patient A is participating in a randomized controlled trial of steroid injections for plantar fasciitis in psoriatic arthritis. The trial is investigating cortisone versus placebo injections, under ultrasound guidance. Participants are eligible if they are ≥ 18 years of age, have a confirmed diagnosis of psoriatic arthritis, on stable systemic therapy and pain at one or both plantar fascia entheses (tenderness at medial tubercle of calcaneus upon palpation). All participants will receive conservative treatment (foot orthoses, footwear advice/provision and exercises) and will be randomized to cortisone or placebo injections. Participants are excluded if they have had a previous steroid injection within the last 12 weeks, previous rupture, surgery or trauma to the affected heel, and a diagnosis of diabetes, neurological disease, or any other condition or injury affecting the musculoskeletal systems of the foot. Participants will be followed up at 4, 8 and 12 and 24 weeks.

Non-pharmacological (conservative) PICOC

Component of PICOC	**Description of the criteria for each component**
Population	Foot and ankle disorders (excluding acute injury), in rheumatic and musculoskeletal diseases (including inflammatory arthritis, osteoarthritis, spondyloarthropathies, connective tissue diseases, crystal and musculoskeletal disorders).
Intervention	Non-pharmacological interventions (prevention, treatment).
Control	Other non-pharmacological, pharmacological or surgical interventions, placebo, sham, current care, active monitoring, no treatment.
Outcome	Core Domain Set under development.
Context (Setting)	The Core Domain Set will apply to randomized controlled trials, controlled clinical trials, and longitudinal and cross-sectional observational studies conducted worldwide in the English language. It will be relevant to patients and the public, researchers, clinicians, policymakers, and guideline developers.

Case study 2

Patient B is participating in a randomized controlled trial of foot orthoses for early rheumatoid arthritis. The study is comparing prefabricated versus customized foot orthoses. Participants eligible for inclusion must be ≥ 18 years of age, have been diagnosed with rheumatoid arthritis < 2 years ago (based on the 2010 ACR/EULAR classification criteria), on stable systemic therapy, and have current foot pain. Participants must also be able to walk, and use footwear that can accommodate foot orthoses during weight-bearing activities. Participants are ineligible for this trial if they have a diagnosis of diabetes, neurological disease, or any other condition or injury affecting the musculoskeletal systems of the foot, any fixed bony deformities, or have used any other functional foot orthoses in the previous 6 months. Participants will be followed up at 1, 3, and 6 months.

Surgical PICOC

Component of PICOC	**Description of the criteria for each component**
Population	Foot and ankle disorders (excluding acute injury), in rheumatic and musculoskeletal diseases (including inflammatory arthritis, osteoarthritis, spondyloarthropathies, connective tissue diseases, crystal and musculoskeletal disorders).
Intervention	Surgical interventions.
Control	Other surgical, pharmacological, or non-pharmacological interventions, placebo, sham, current care, active monitoring, no treatment.
Outcome	Core Domain Set under development.
Context (Setting)	The Core Domain Set will apply to randomized controlled trials, controlled clinical trials, and longitudinal and cross-sectional observational studies conducted worldwide in the English language. It will be relevant to patients and the public, researchers, clinicians, policymakers, and guideline developers.

Case study 3

Patient C is participating in a randomized controlled trial of surgical interventions for first metatarsophalangeal (MTP) joint osteoarthritis (OA). The trial is investigating 1st MTP joint cheilectomy versus arthrodesis. Participants are eligible if they have a confirmed diagnosis of first MTP joint OA and in conjunction with their orthopaedic surgeon have made the decision to have surgery. Participants who have undergone previous MTP joint surgery, or who have a diagnosis of diabetes, neurological disease, or any other condition or injury affecting the musculoskeletal systems of the foot are not eligible. Participants will be followed up at 6, 12, and 24 months.