

**Letter:** The GRAPPA-OMERACT Core Outcome Measures for Psoriatic Arthritis Clinical Trials (COMPACT) study- an approach to standardise outcomes in Psoriatic Arthritis trials

**Reply to:** How are enthesitis, dactylitis and nail involvement measured and reported in recent clinical trials of psoriatic arthritis? A systematic literature review

Dear Sir,

We read with interest the recent letter by Ramiro *et al* reporting data from a systematic literature review on the measurement of enthesitis, dactylitis and nail disease in Psoriatic Arthritis (PsA) clinical trials. The authors highlight the great variety in the outcome measures chosen, cut points and the statistical analysis performed (percentage change, proportion resolved). We are pleased the authors have highlighted this problem and agree with their viewpoints on the clear lack of standardisation of domains and instruments in clinical trials evidenced by the data. Indeed this inconsistency of data reporting has led to significant heterogeneity in both physician assessed and patient reported outcomes particularly in the field of PsA. It is the domains of enthesitis, dactylitis, nail disease as well as skin and axial disease, and the unique impact they subsequently have on physical function and quality of life for patients with PsA, that differentiate psoriatic arthritis from other types of inflammatory arthritis like rheumatoid arthritis (RA). Therefore the accurate assessments of these disease manifestations are of vital importance in drug effectiveness trials.

In an effort to standardise outcome assessment in PsA a core set of domains to be measured was developed in 2006 by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) Outcome Measures in Rheumatology (OMERACT) working group.<sup>1</sup> This PsA core domain set represented the minimum set of outcomes to be measured randomized controlled trials (RCTs) and longitudinal observational studies and a systematic review demonstrated the subsequent change in PsA Core Domain Set assessed; rising to 59% of RCTs in 2010–2015 compared to 23.5% RCTs in 2006–2010.<sup>2</sup> An updated PsA core domain set, with enhanced patient representation, was endorsed by OMERACT in 2016 following an extensive program of work.<sup>3</sup> As Ramiro *et al* state the next step is to generate instruments and cut offs for the measurement of these domains; a Core Outcome Measurement Set.

Several international work streams within the Core Outcome Measures for Psoriatic Arthritis Clinical Trials (COMPACT) study have been underway since 2016 to address specifically this problem. The GRAPPA-OMERACT PsA Core Set working group is leading this work. This

program of work includes multiple systematic reviews, incorporating data up to 2017, in order to synthesise the existing evidence on PsA instrument properties (across RCT and LOS data sources as the authors suggest), a Delphi process with stakeholders (including patients, clinicians, trialists, methodologists and payers), consensus meetings and a final discussion and voting at OMERACT 2018 and beyond?. The resulting Core Outcome Measurement Set will synthesise the evidence and provide guidance for the use of PsA outcome instruments, including not only enthesitis, dactylitis and nail involvement, as discussed by Ramiro *et al*, but all pathophysiological manifestations, life impact and resource use defined in the PsA core domain set.

The OMERACT and Core Outcomes Measurement for Effectiveness Trials (COMET) methodology<sup>4</sup> we are following in the COMPACT study will provide evidence based guidance with international consensus on the best instruments to measure the domains of psoriatic disease and, equally importantly identify current gaps and a research agenda to generate the evidence. In the near future, this should allow standardisation of outcomes chosen in clinical trials whilst ensuring that key domains important to both physicians and patients are assessed.

The report by Ramiro *et al* highlights the importance of developing a framework of domains and valid instruments for the consistent assessment of Psoriatic Arthritis in RCT's and observational studies and we suggest herein a robust framework, underway, to achieve this standardisation.

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## References

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2. Kalyoncu U, Ogdie A, Campbell W, Bingham CO, 3rd, de Wit M, Gladman DD, et al. Systematic literature review of domains assessed in psoriatic arthritis to inform the update of the psoriatic arthritis core domain set. *RMD open* 2016;2:e000217.
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4. Prinsen CA, Vohra S, Rose MR, King-Jones S, Ishaque S, Bhaloo Z, et al. Core Outcome Measures in Effectiveness Trials (COMET) initiative: protocol for an international Delphi study to achieve consensus on how to select outcome measurement instruments for outcomes included in a 'core outcome set'. *Trials* 2014;15:247.