



## Introduction

- Rheumatoid Arthritis (RA) is a chronic, disabling, autoimmune disease that can attack the entire body.
- No cure is available, so disease modification and symptom management are key for people living with RA (plwRA).
- Monitoring guidelines for RA suggest a frequency far greater than currently seen in UK hospitals.
- Standard measurement instruments for RA disease activity (DA) are DAS28, SDAI and CDAI, which require a laboratory test or a healthcare professional assessment to complete the calculation.
- PlwRA want a DA patient reported outcome measure (PROM) for monitoring their disease. This has the potential to transform clinical care in the future.

## Aims

Over the course of the SOCRATES and PLAN-HERACLES studies, there were five aims:

1. determine whether legacy PROMs can be recommended for use;
2. determine which items can be used to measure RA DA;
3. determine the comprehensibility, comprehensiveness and relevance of these items;
4. determine how these items would function in a computer adaptive test (CAT) algorithm;
5. explore plwRA opinions regarding a DA monitoring tool.

## Methodology

The five aims aligned with five differing methodologies:

1. A systematic review of legacy RA DA PROMs following COSMIN guidelines;
2. Multiple psychometric analyses, including those based on Rasch measurement theory (RMT), of legacy RA DA PROM (plus a further RA DA PROM, a foot-specific RA DA PROM, two RA Flare PROMs, plus a non-measurement group of items, further pain area-specific items and items relating to discomfort when walking, standing and exercising, plus fear of falling when walking) data collected from plwRA across four health boards in South Wales;
3. Cognitive interviews with plwRA;
4. CAT simulations based on parameters set by RMT analyses;
5. Descriptive analyses of a UK-wide survey disseminated by the National Rheumatoid arthritis Society (NRAS).

## Results

### From the systematic review<sup>1</sup>:

- None of the legacy RA DA PROMs could be recommended for use;
- There was insufficient evidence to place any of the legacy RA DA PROMs into recommendation for use category A, which was driven by a lack of evidence for content validity;
- Care should be taken when making use, or interpreting the results, of any of these legacy RA DA PROMs;

### From the psychometric analyses of the questionnaire<sup>2</sup>:

- The total sample size was 691, with n = 398 in the development dataset and n = 293 in the validation dataset.
- 145 Items were grouped by OMERACT domains and entered into a principal components analysis. 30 items from the *Tenderness and swelling*, *Patient global*, *Pain*, *Fatigue*, *Physical functioning* and *Stiffness* domains were taken forward to RMT analyses;
- RMT analyses indicated that the *Patient global* domain was in fact two distinct domains of *General health* and *Disease activity*;

- Further RMT analyses confirm that *General health* and *Fatigue* domain items measure a quality-of-life construct separate to the construct of RA DA;
- A set of 12 *Pain*, *Disease activity*, *Tenderness and swelling*, *Physical functioning* and *Stiffness* domain items can be used to measure the construct of RA DA;
- These results were confirmed in confirmatory factor analysis bi-factor models;
- All legacy RA DA PROMs were analysed under RMT, and none were shown to fully fit the Rasch measurement model;
- Using the combined dataset, anchored item threshold locations have been calculated to form an item bank.

### From the cognitive interviews with plwRA<sup>3</sup>:

- Twenty participants completed one-to-one cognitive interviews;
- No participants raised concerns relating to comprehensiveness, comprehensibility or relevance aspects of items;
- There was a lack of consensus on the ease of distinguishing RA symptoms from other conditions, or whether tenderness and swelling should be asked about in a single item or as separate symptoms;
- The majority view was that fatigue and general health were not specific to RA DA;
- The 12 items adequately capture relevant concepts of RA DA, with no additional items required, and this provides content validity evidence.

### From the CAT simulations:

- Initial simulations using common stopping rules were satisfied after the administration of five items, but these did not cover all five domains;
- Two sets of five items (one item per domain) were generated, with summary measures equivalent to the initial simulations;
- A CAT does not provide any major advantage, so administering one item from each of the five domains is therefore sufficient.

### From the UK-wide survey:

- The sample size was 1298;
- The DA monitoring tool was deemed useful, acceptable, likely to be used and weekly scheduling would be feasible.

## Conclusions

The next steps will be to:

- develop and validate a new RA DA PROM through a psychometric study involving qualitative and quantitative components;
- Determine facilitators and barriers for healthcare professionals and plwRA around adoption of a DA monitoring tool;
- develop a DA monitoring tool and implementation materials for and with healthcare professionals and plwRA, also involving NRAS and tool developer COHESION Medical Ltd;
- a feasibility randomised controlled trial of the DA monitoring tool as a complex intervention.

## References

1. Pickles T, Macefield R, Aiyegbusi OL, et al. Patient Reported Outcome Measures for Rheumatoid Arthritis Disease Activity: a systematic review following COSMIN guidelines. *RMD Open*. 2022;8:e002093. doi: 10.1136/rmdopen-2021-002093
2. Pickles T, Horton M, Christensen KB, et al. Patient Reported Outcome Measures for Rheumatoid Arthritis Disease Activity: Rasch measurement theory to identify items and domains. *Rheumatology*. 2025;64(9):4902–4912. doi: 10.1093/rheumatology/keaf189
3. Pickles T, Phillips R, Horton M, et al. Assessing the content validity of a Patient Reported Outcome Measure item pool for Rheumatoid Arthritis Disease Activity using cognitive interviews. *Rheumatology*. 2025;keaf421. doi: 10.1093/rheumatology/keaf421

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