National Rheumatoid Arthritis Society

Resource

SOCRATES study

Patient Reported Measurement and Monitoring of Rheumatoid Arthritis Disease Activity

Print

Patient-reported Outcome measures for Rheumatoid Arthritis Symptom Severity: development of a computer adaptive test and item bank using Rasch model methodology

Background

Disease activity (DA) monitoring is a standard of care in Rheumatoid Arthritis (RA). The current DA assessments require laboratory tests and/or health care professional (HCP) input. Patient Reported Outcome Measures (PROMs), which are tools completed by patients to ascertain perceptions of their health, may therefore be preferable. However, there is no consensus on how to measure RA DA using a PROM.

The current standard of care in RA is “Treat-to-Target”, in which regular assessment of RA DA is an integral part. Few HCPs have the capacity to assess patients as frequently as stipulated by guidelines and thus treatment is not adjusted sufficiently. The COVID-19 pandemic has made the problem more conspicuous with remote rather than face-to-face consultations. Previous research has suggested that PROMs are the most informative way to assess RA DA, and that they allow for a more efficient use of NHS resource.

There is a pressing clinical need to improve close monitoring of symptom severity and adjust treatment accordingly. It would be preferable for people living with RA to self-monitor at home, akin to patients with diabetes monitoring blood sugar or patients with hypertension measuring blood pressure. This would reflect a more person-centred approach to treatment. This monitoring could be achieved using PROMs. People living with RA locally and nationally express a desire to have a simple PROM for monitoring their own disease at home. If devised well, with data flowing from people living with RA to clinical teams to make the necessary assessments, people living with RA with stable disease would not need to attend routine outpatient clinic appointments; whilst for people living with RA whose disease is gradually worsening, their clinical team could schedule an immediate consultation before a major flare. With the advent of electronic health in the NHS a PROM of this nature has the potential to transform clinical care in the future.

What was the SOCRATES study?

The SOCRATES study was funded from October 2019 until July 2023. Multiple methods were used, which included:

1. a review of the literature following up-to-date international guidelines;
2. analyses of data collected through questionnaires sent to people living with RA across four South Wales University Health Boards (UHBs). Questionnaires were sent out to people living with RA in September 2020, plus June, October and November 2021;
3. analyses of discussions held with people living with RA. Discussions with people living with RA took place between November 2022 and February 2023. And;
4. the development of an online tool that decides on question order.

The PhD thesis was submitted in January 2024.

Outcome

The objective of finding a PROM for DA monitoring to facilitate delivering standard of care showed that none of the legacy PROM can be used. It was found that no existing RA DA PROMs can be recommended for future use and that no existing RA DA PROMs, or other relevant PROMs, are fully valid, which means there is no evidence that they measure RA DA correctly. However, within these PROMs, there are questions that, when combined, can assess RA DA. It was shown that the Patient global domain is two distinct domains of Disease activity and General health. 12 questions from the domains of Pain, Disease activity, Tenderness and swelling, Physical functioning and Stiffness can be used to measure RA DA.

Through discussions with people living with RA, it was established there were no questions, or concepts, missing that should be covered. Lastly, it was discovered that an online tool that decides on question order does not provide a major advantage for the purpose of asking the 12 questions. Therefore, RA DA can be measured with just five questions, with one from each of the Pain, Disease activity, Tenderness and swelling, Physical functioning and Stiffness domains. The next steps are to discover how best to design these five questions and to test their ability to measure RA DA, before using them as part of a weekly DA monitoring tool.

Contributions

The SOCRATES study was conducted by Tim Pickles through a Health and Care Research Wales NIHR Doctoral Fellowship and as a PhD student at Cardiff University. Tim was supervised by Professor Ernest Choy (primary supervisor of this fellowship and PhD, Cardiff University), Doctor Mike Horton (University of Leeds), Professor Karl Bang Christensen (University of Copenhagen), Doctor Rhiannon Phillips (Cardiff Metropolitan University) and Doctor David Gillespie (Cardiff University).

Acknowledgements

The SOCRATES study was sponsored by Cardiff University. Four South Wales UHBs acted as patient identification centres to send out questionnaires: Cardiff and Vale UHB, Swansea Bay UHB, Cwm Taf Morgannwg UHB and Aneurin Bevan UHB. Discussions with people living with RA took place with a representative sample of 20 from those who returned questionnaires and were identified by Cardiff and Vale UHB.

Patient and Public Involvement (PPI) is vital to research, though research into RA PROMs has been surprisingly lacking in this area. It would not have been possible to do this research with PPI input so it was wonderful that Jan Davies and Sue Campbell came forward following an advert through the Health and Care Research Wales Involving People Network.

Jan and Sue have been a constant throughout the NIHR Doctoral Fellowship application process, and the fellowship and PhD. Together, their involvement included co-writing plain English summaries, co-developing study materials, such as participant information sheets, consent forms, questionnaires and topic guides, piloting cognitive interviews and dissemination. Their input around the cognitive interviews was particularly crucial. Jan kindly let me do a pilot cognitive interview with her, allowing me to better formulate and streamline the prompts and questioning. This was very useful for a very inexperienced interviewer like myself, and meant that the interviews all generally went smoothly. Discussions following the cognitive interviews also helped understand the themes that were collated and also what modifications would and would not be useful.

What’s to come? PLAN-HERACLES

Study title: Plan for Determining the Psychometric Properties of, and the Feasibility of Implementing, an Electronic Patient Reported Outcome Measure Tool to Monitor Rheumatoid Arthritis Disease Activity

A Next Steps Award from Health and Care Research Wales, which started in February 2024. Through this there will be three surveys and analyse the data collected.

The first and second surveys will be about the use of the future data collection and presentation of the weekly DA monitoring tool for people living with RA and HCPs involved in the care of people living with RA. The survey for people living with RA will be sent out through NRAS and will ask questions on how useful a weekly DA monitoring tool would be to them, how likely they would be to use the tool, how often they would want to enter data into the tool (currently hypothesised to be weekly), how many items they would want to complete and how effective the tool would have to be to make the repeated collection of data worth it.

The survey for health care professionals will be sent out through the British Society of Rheumatology (BSR) to ask questions about how they would envisage using the tool, how useful the tool would be to them, how likely they would be to use it and how easy they think it would be to implement.

The third survey will be sent out via social media and adverts in relevant clinics to current users of the My Clinical Outcomes (MCO) system in Cardiff and Vale University Health Board (C&VUHB) to ask them about their interactions with the system, what they like and what they think could be improved. The reasoning behind asking about the MCO system is because MCO have a contract with C&VUHB for the collection of electronic PROMs. Therefore, any notions of improvements we can make in this system will improve it for people living with RA ahead of them using it and will lead to improvements in the MCO system for all users.

The purpose of the Next Steps Award is also to apply for a postdoctoral fellowship and will be applied by the end of 2024.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

SOCRATES

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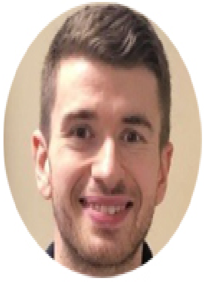

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Publication
https://rmdopen.bmj.com/content/8/1/e002093

Blogs
https://blogs.cardiff.ac.uk/centre-for-trials-research/nihr-doctoral-fellowship-interview-with-tim-pickles/
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Websites for SOCRATES
https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/socrates
https://healthandcareresearchwales.org/researchers/our-funded-projects/patient-reported-outcome-measures-rheumatoid-arthritis-symptom