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SHORT REPORT

Involving patients as research partners
in research in rheumatology: a literature
review in 2023

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ABSTRACT

Objective The inclusion of patient research partners (PRPs) in research projects is increasingly recognised and recommended in rheumatology. The level of involvement of PRPs in translational research in rheumatology remains unknown, while in randomised clinical trials (RCTs), it has been reported to be 2% in 2020. Therefore, we aimed to assess the involvement of PRPs in recent translational studies and RCTs in rheumatology.

Methods We conducted a scoping literature review of the 80 most recent articles (40 translational studies and 40 RCTs) from four target diseases: rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus and lower extremity osteoarthritis. We selected 20 papers from each disease, published up until 1 March 2023, in rheumatology and general scientific journals. In each paper, the extent of PRP involvement was assessed. Analyses were descriptive.

Results Of 40 translational studies, none reported PRP involvement. Of 40 RCTs, eight studies (20%) reported PRP involvement. These trials were mainly from Europe (75%) and North America (25%). Most of them (75%) were non-industry funded. The type of PRP involvement was reported in six of eight studies: six studies reported PRP participation in the study design or design of the intervention and two of them in the interpretation of the results. All the trials reporting the number of PRPs (75%), involved at least two PRPs.

Conclusion Despite a worldwide movement advocating for increased patient involvement in research, PRPs in translational research and RCTs in rheumatology are significantly under-represented. This limited involvement of PRPs in research highlights a persistent gap between the existing recommendations and actual practice.

INTRODUCTION

It is well established that the active involvement of patients as patient research partners (PRPs) brings valuable knowledge and unique perspectives to medical research. The knowledge, personal experiences and understanding of PRPs of their disease and the care they receive, provide invaluable information that complements and enriches scientific understanding of the diseases. This

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ The active involvement of patients as research partners (PRPs) brings valuable knowledge and unique perspectives to medical research and is recommended by European Alliance of Rheumatology Associations.
- ⇒ However, the implementation of these recommendations in rheumatology research is unknown.

WHAT THIS STUDY ADDS

- ⇒ PRP involvement in randomised trials remains low and is lacking in translational research projects in rheumatology.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Our study identifies areas of rheumatology research (randomised controlled trials and translational research) where the involvement of PRP needs to be improved.
- ⇒ The findings highlight the importance of raising awareness of the benefits of involving PRPs in research and of providing resources and training for researchers and PRPs to facilitate their involvement.

perspective bridges the gap between research and real-life experiences of patients, making research more applicable and effective. Government-supported initiatives, such as the US Patient-Centred Outcomes Research Institute (PCORI) in 2010, have moved patients from research subjects to contributors to the research agenda. Recognising the benefits of PRPs involvement in research, the Food and Drug Administration (FDA) as well as the European Medicine Agency (EMA), have encouraged their involvement in medical research projects.^{1 2}

In rheumatology, the European Alliance of Rheumatology Associations (EULAR) published recommendations in 2011 advocating the inclusion of PRPs in research



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projects at all phases of the project.³ Despite this initiative, it has been reported that PRPs were involved in only 2% of rheumatology randomised clinical trials (RCTs) published between 2016 and 2020.⁴ Whether patient involvement in RCTs has increased since then, remains unknown.

In translational research, it has also been shown that involvement of PRP is beneficial for research, patients and researchers.⁵ A scoping review in 2021 identified 32 studies engaging patients in preclinical laboratory research.⁶ However, most of the studies concerned non-rheumatological disorders. Therefore, the extent of PRPs in translational research in rheumatology remains largely unexplored.

We aimed to assess the involvement of PRP in research in rheumatology by performing a scoping review of recently published RCTs and translational studies.

MATERIALS AND METHODS

We performed a scoping review, which allowed us to obtain an overview of the current state of patient involvement in research in rheumatology.

MEDLINE and EMBASE databases were searched on 1 March 2023 using the following keywords: ‘systemic/epidemiology’ OR ‘systemic/aetiology’ OR ‘systemic/immunology’ OR ‘systemic/metabolism’ OR ‘systemic/pathology’ OR ‘systemic/physiopathology’ (MeSH Terms) (for translational studies) and ‘clinical trial’ (MeSH Terms) (for RCT). The search was performed in four rheumatic diseases (rheumatoid arthritis,

psoriatic arthritis, systemic lupus erythematosus and lower extremity osteoarthritis) using the following keywords ‘arthritis, rheumatoid’ OR ‘lupus erythematosus, systemic’ OR ‘arthritis, psoriatic’ OR ‘osteoarthritis, knee’ OR ‘osteoarthritis, hip’ OR ‘osteoarthritis’.

The review was performed by two qualified specialists in rheumatology with experience in translational research and clinical studies (ME and DB). No language restriction was applied. In cases of uncertainty about PRPs’ involvement, the other members of the team were consulted. The 80 most recent articles (40 for translational studies and 40 for RCTs) (20 for each of the target diseases, ie, 10 RCTs and 10 translational studies per disease), published up until 1 March 2023, in rheumatology and general scientific journals with an impact factor >5, were included.

General study features such as study design, disease, geographical location of the study and funding source were collected. The presence and type of PRP involvement were assessed after evaluation of the ‘Methods’, ‘Author affiliations’ and ‘Acknowledgements’ sections. In the case of PRP involvement, we collected data concerning the number and the phase of the study in which PRPs were involved, the way of recruitment and the provided training. Data analysis was descriptive.

RESULTS

A total of 221 studies were initially screened; most of them were excluded due to inappropriate study design or disease focus (flowchart in figure 1A,B). Half of the

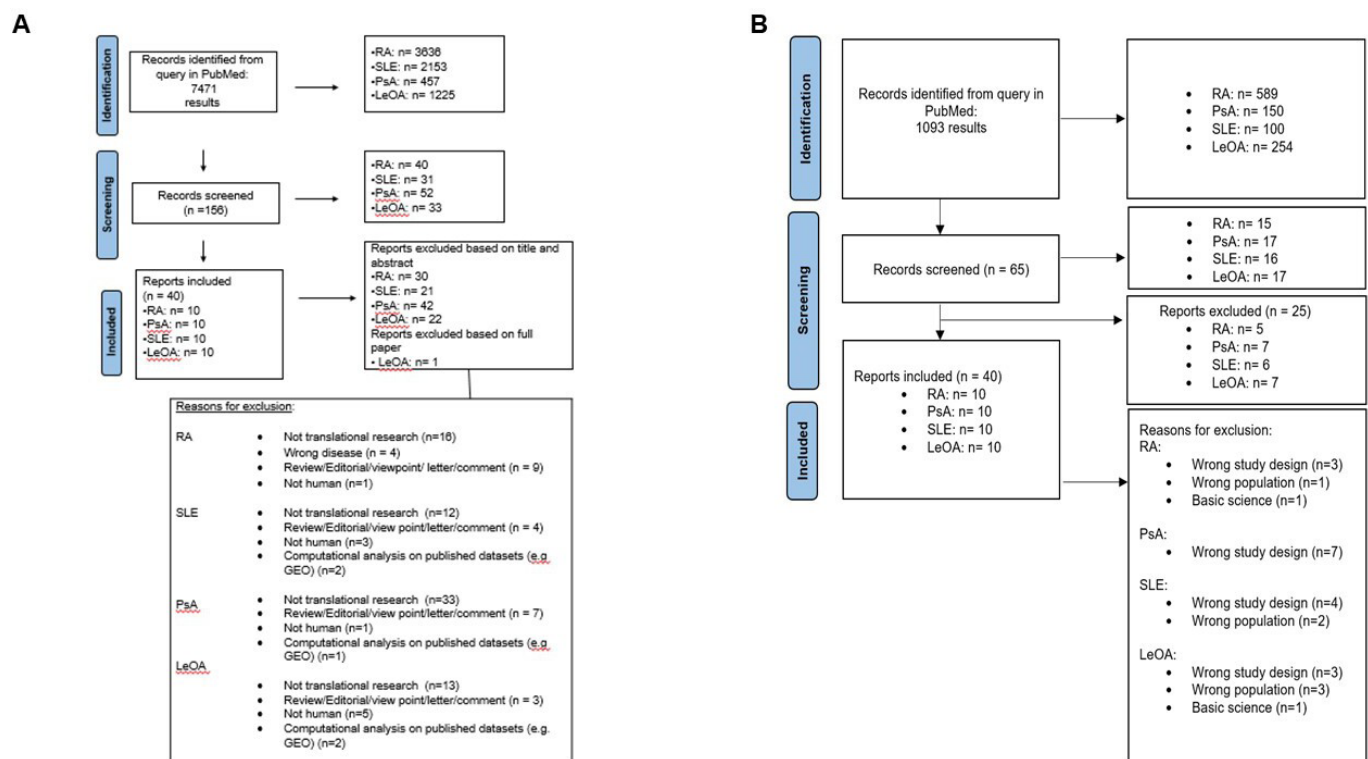


Figure 1 Flowchart of the study. (A) For translational studies and (B) for randomised controlled trials. LeOA, lower extremity osteoarthritis; PsA, psoriatic arthritis; RA, rheumatoid arthritis; SLE, systemic lupus erythematosus

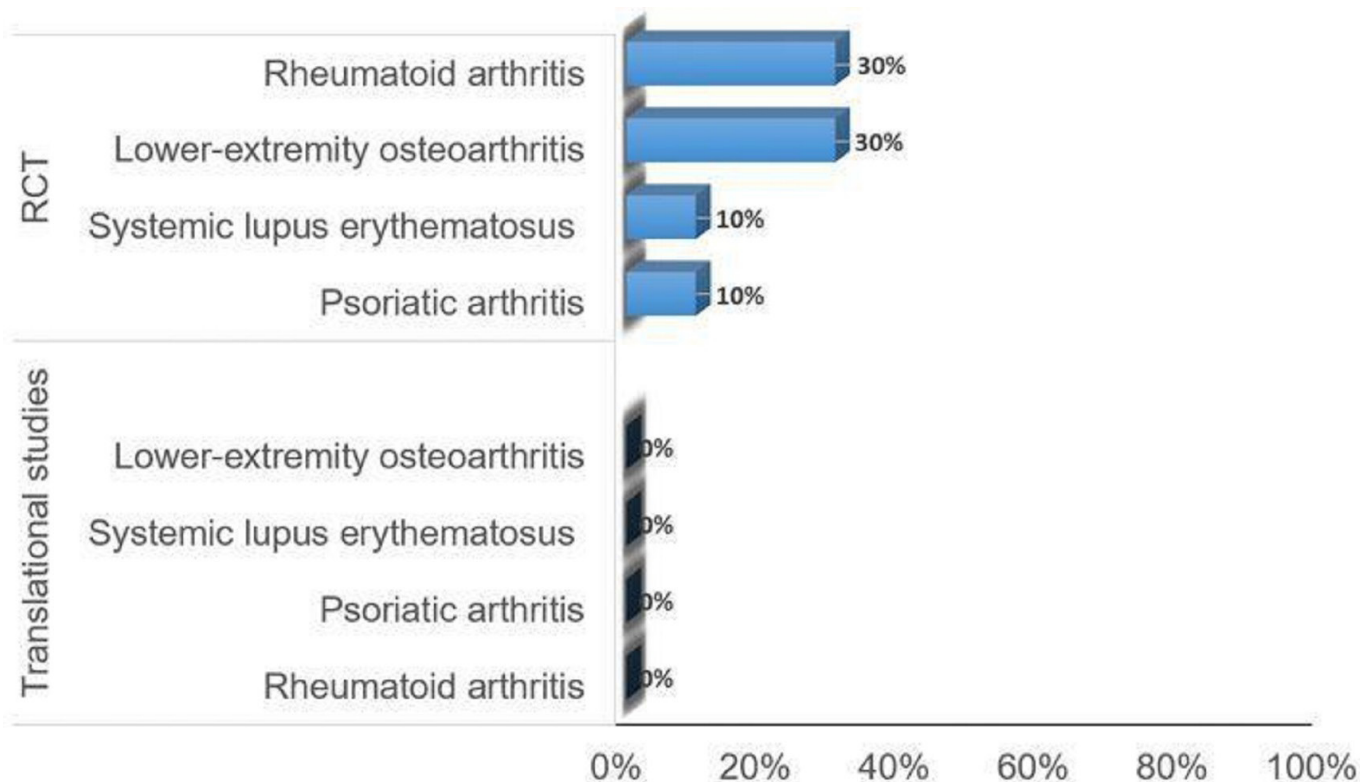


Figure 2 Percentage of studies involving patient research partners in recent translational studies and randomised controlled trials (RCTs) in rheumatology.

translational studies were published in rheumatology journals. Geographically, 50% of the studies were conducted in Asia, 30% in Europe, and 20% in North America. Most of the studies (77%) had a local setting and 75% were non-industry funded. None of the translational studies involved PRPs (figure 2). However, one study mentioned patient engagement for the dissemination of results to patients and the general public, which is not usually considered a research partnership.

RCTs were predominantly published in rheumatology journals (78%) and were conducted in North America (52%), Europe (25%) and Asia (23%). Among the 40 RCTs, eight (20%) reported PRP involvement (three on rheumatoid arthritis, three on lower extremity osteoarthritis, one on systemic lupus erythematosus and one on psoriatic arthritis) (figure 2).^{7–14} The trials reporting PRP involvement were mainly from Europe (6/8, 75%) and North America (2/8, 25%) with the majority of them non-industry funded (6/8, 75%).

The phase of the study in which PRPs were involved was specified in six of the RCTs, with all reporting PRP participation in the study design or design of the intervention and two of them also reporting involvement in the interpretation of the results.^{8–12 14} Specifically, in two of the studies, PRPs were involved in the process of designing the intervention (a website for patient education in both cases).^{10 11} All the trials reporting the number of PRPs (6/8, 75%) involved at least two PRPs (four RCTs involved two PRPs, one involved four PRPs and one involved five PRPs).^{8–10 12–14} Only one study reported gender of

the involved PRPs ('1 female and 1 male').¹³ No other information on PRP diversity was reported. Two studies mentioned that PRPs were recruited through patient organisations. One study reported training for PRPs for the study. Further information is reported in table 1.

DISCUSSION

In this scoping review of recent published studies in rheumatology research, PRPs were involved in 20% of the RCTs and in none of the translational studies. These findings underline a significant gap between recommendations and actual practice.^{13 15}

This is the first study assessing involvement of PRPs in translational studies and we showed that not a single study reported PRP involvement. This is a significant concern, as translational research is an important step in bringing laboratory findings to clinical practice. Involvement of PRPs at this stage can ensure that the research is grounded in patient experiences and needs, thereby improving its applicability and potential impact on patient care.⁶ The reasons behind this lack of involvement need to be explored, and strategies need to be developed to promote PRP inclusion in translational research.

There has been a modest improvement in PRP involvement in RCTs, rising from 2% in trials published 2016–2020⁴ to 20% in the present review. This finding may suggest that there is a growing recognition of the value of PRP contributions in clinical trials. However, there is still considerable room for improvement. Given that

Table 1 Patient engagement characteristics of included studies (n=8)

| First author, year | Country | Disease | Main objective | # of PRPs | Funding | PRP recruitment | PRP type of involvement | Training |
|--------------------------------|----------------|---------|---|-----------|---------------|-----------------------|---|---------------------------|
| Michielsens, 2022 ⁷ | Netherlands | PsA | T2T strategy with tapering non-inferiority investigation | NR | Public | NR | NR | NR |
| Pouls, 2022 ⁸ | Netherlands | RA | Impact of game intervention on DMARD adherence | 4 | Pharma | NR | Study design and discussion of the results | NR |
| Latocha, 2023 ⁹ | Denmark | RA | Comparison of cognitive behavioural therapy for insomnia to usual care for sleep efficiency | 2 | Public | NR | Study design (manual for intervention) | NR |
| LopezOlivo, 2022 ¹⁰ | US&Canada | R A | Effects of Facebook online peer group | 2 | Private | NR | Study design (creation of website) | NR |
| Fortin, 2023 ¹¹ | USA and Canada | SLE | Evaluation of web-based programme for self-management | NR | NR | NR | Study design (creation of website) | NR |
| Blom, 2022 ¹² | UK | LeOA | Outcomes of single stage vs two-stage revision surgery for joint infection | 5 | Public | University of Bristol | Study design Dissemination strategy | Yes, led by a coordinator |
| Henriksen, 2023 ¹³ | Denmark | LeOA | Identification of contextual factors that modify treatment effect | 2 | Public | NR | NR (Designing of the parent RCT, but not in the current secondary analysis) | NR |
| Paskins, 2022 ¹⁴ | UK | LeOA | Effectiveness of ultrasound-guided injection | 2 | Public (NIHR) | NR | Study design study set-up, recruitment and interpretation | NR |

DMARD, Disease-modifying antirheumatic drugs; LeOA, lower extremity osteoarthritis; NR, not reported; PRP, patient research partners; PsA, psoriasis arthritis; RA, rheumatoid arthritis; SLE, systemic lupus erythematosus; T2T, Treat-to-target.



RCTs form the backbone of evidence-based medicine, it is crucial that PRPs are adequately consulted to ensure that research outcomes are relevant and meaningful to patients.¹⁶ In addition, whether this increase in PRP involvement in RCTs reflects a form of tokenism or corresponds to genuine participation has not been investigated and should be further studied.

This persistent gap in the implementation of the 2011 recommendations on the involvement of PRP in research³ needs to be set against the now-demonstrated benefits of involving PRPs in research and clinical trials. First, patient's involvement has been shown to improve the quality and relevance of research, as well as the implementation and dissemination of study results.^{17,18} In addition, the participation of PRPs improves the recruitment of participants in clinical trials¹⁷⁻¹⁹ especially if it includes people with lived experience of the health condition under study.¹⁹ Furthermore, a PRP intervention specifically targeting retention (ie, the use of lay community health advisers to support participants) was significantly associated with a lower drop-out rate.¹⁹ These observations underline the central role of patient participation and reaffirm that it is not merely a ceremonial inclusion, but an essential element that amplifies the power and relevance of research.

Interestingly, most of the trials involving PRPs were conducted in Europe and North America versus none in Asia. This raises questions about potential regional differences in the recognition and implementation of PRP involvement in rheumatology research.

Similarly, in another study, articles from the UK were 10 times more likely to include PRPs than those from China.²⁰ This geographical trend may be influenced by the changing research landscape in these regions, where patient involvement is increasingly recognised as an essential component of holistic research in Europa. European institutions and initiatives, for example, have actively encouraged public and patient participation in healthcare research, which may explain the greater representation of PRP involvement in studies in this region.³ Similarly, there appears to be a convergence in the way PRPs are conceptualised in Europe, with similar attitudes and approaches in different European countries.²⁰ In addition, public funding can encourage the inclusion of PRPs: for example, the UK NIHR has for several years included in its application process a section in which applicants can either apply for funding to include PRPs, or justify why they are not doing so. In Asia, it has been shown that patient involvement and participation in Chinese hospitals is influenced by factors such as the level of involvement of civil society, the move towards commercialisation and the cultural resources of individuals. Furthermore, in terms of political context, China lacks political support for involving patients in healthcare.²⁰

Thus, efforts to enhance PRP involvement should consider the local cultural context and work with local

patient advocacy groups to foster a culture that supports patient engagement in research.

In addition, it should be noted that the majority of studies reporting PRP involvement were not funded by industry. One possible explanation could be the intrinsic nature of grants and public funding, for example, the UK NIHR, which often prioritise or even mandate patient and public involvement, ensuring that researchers incorporate PRP views from the proposal stage. Conversely, industry-funded studies may face a different set of challenges, such as legal restrictions, proprietary concerns or time constraints that could discourage PRP involvement. It would be essential for future research to delve deeper into these nuances to understand the dynamics between funding sources and PRP involvement.

Although our study sought to provide an overview of the involvement of PRP in rheumatology research, our approach may have inherent limitations. First, it is possible that important studies have been missed due to the use of a scoping review. However, our aim was not to analyse the most important articles in the field, but rather the most recent ones, in order to provide an overview of the current state of PRP involvement in rheumatology research and to identify any gaps. Furthermore, our review focuses on four prespecified rheumatic diseases and does not explore the involvement of PRP in all rheumatological disorders. However, to provide a comprehensive overview, we have decided to focus on four frequent rheumatic diseases, of varied aetiology and dynamic in terms of research. Further specific studies will be needed to confirm our findings in other specific rheumatic diseases. In addition, the methods used to determine the involvement of PRPs were based on the data reported in the articles; it is possible that some studies included an involvement of PRPs that was not explicitly mentioned. However, EULAR recommends acknowledgement of PRP in published studies,³ and the lack of mention of PRP in the study may indicate a form of tokenism rather than genuine involvement.

Despite greater patient involvement in rheumatology research, particularly in the development of guidelines and in international research networks,³ the involvement of PRPs is not similar in all areas of rheumatology research. Our study highlights persistent gaps in RCTs and translational research, where PRP involvement remains low.² To address these disparities, concerted efforts are needed from all stakeholders, including researchers, funding bodies and patient advocacy groups. There is a need to raise awareness about the benefits of PRP involvement, provide resources and training to facilitate their engagement.

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Contributors ME and DB performed the literature review. ME, DB, KA, PS, JP, MdW and LG designed and analysed the study. ME, DB, KA, PS, HB, JP, CZ, MdW and LG interpreted the results. ME, DB, MdW and LG wrote the first draft of the manuscript. All authors critically reviewed the manuscript.

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