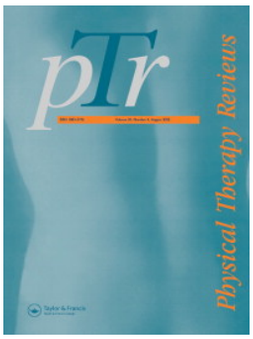

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Use of patient-reported outcome measures in physiotherapy clinical trials in six major physiotherapy journals 2 decades apart (2000–2018): a meta-research design

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Use of patient-reported outcome measures in physiotherapy clinical trials in six major physiotherapy journals 2 decades apart (2000–2018): a meta-research design

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ABSTRACT

Aim: Using patient-reported outcomes in research has been incentivised to encourage patient-centred care and ensure patient views are considered. We compared the use of patient-reported outcome measures (PROMs) in trials published in physiotherapy journals in 2000 and 2018, and evaluated whether the number of PROMs used differed between musculoskeletal, neurological, and cardiopulmonary subdisciplines.

Design: Meta-research.

Methods: Six major physiotherapy journals were searched for trials published in 2000 and 2018. Two independent reviewers extracted data on study characteristics and reporting of PROMs. PROMs were classified according to their outcome domains. Descriptive statistics and inferences were made based on proportions. A 20% difference between 2000 and 2018 was regarded as meaningful.

Results: A total of 140 trials were included, 39 were published in 2000 and 101 in 2018. Eighty-four percent ($n = 118/140$) of trials reported ≥ 1 PROM, while 89% ($n = 125/140$) included ≥ 1 non-PROM. We found no meaningful differences on the average use of PROMs in 2000 and 2018: 74% (29/39) of trials in 2000 versus 88% (89/101) in 2018. PROM use in 2000 and 2018 was 88.5% and 84.4% in musculoskeletal physiotherapy, 57.2% and 86.1% in neurological physiotherapy and 0% and 88% in cardiopulmonary physiotherapy. The most used PROM outcome domains were symptoms and symptom burden (75%) and functional status (65%).

Conclusion: Most trials from the six major physiotherapy journals sampled in 2000 and 2018 used PROMs, with no meaningful differences when comparing years. Fewer publications in 2000 than 2018 may account for the differences seen in neurological and cardiopulmonary physiotherapy.

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Physiotherapy; randomized controlled trials; patient-reported outcomes; patient-reported outcome measures; meta-research

Introduction

Patient-reported outcomes measures (PROMs) are questionnaires that collect health outcomes directly from from patients, including symptoms, health-related quality of life and functional status. There are two categories of PROMs: condition specific and generic, and these are both important for understanding how a condition affects the patient's wellbeing and overall health [1–3].

Measuring patient-reported outcomes is important to assess the effects of treatment and can facilitate personalised care, and is therefore valuable in monitoring symptoms and disability, while capturing the patient's own opinion on the impact of their condition and treatment [4,5]. PROMs can guide the planning and delivery of healthcare interventions by facilitating the inclusion of the patient's views of their own health in the decision-making process [6].

Since 1990, there has been an increased focus on assessing patient-reported outcomes in healthcare settings and clinical research [7,8]. The use of PROMs in clinical and research settings has been

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promoted *via* several initiatives. In 2005, the Consensus-based Standards for the selection of Health Measurement Instruments (COSMIN) initiative was launched [4,5]. This initiative aims to promote and improve the selection of PROMs in research and clinical practice and assess their quality [9]. The COSMIN initiative led to the development of further initiatives to encourage the use of PROMs, including the Initiative on Methods, Measurements and Assessment in Clinical Trials (IMMPACT) [5,9] and the International Consortium for Health Outcomes Measurement (ICHOM) [10]. Through these initiatives, core outcome sets that include PROMs were created and have been recommended for use in clinical trials, such as the Outcome Measures in Rheumatology (OMERACT) [11] and the Core Outcome Measures in Effectiveness Trials (COMET) [12].

Traditionally in physiotherapy (and healthcare more broadly), the process of problem-solving was based on the biomedical paradigm, where diagnosis and treatment are symptom-focused and highly reliant on the practitioner perceptions, often excluding the patient from the decision-making process [13,14]. The move towards patient-centred care required practitioners to focus on the patient's perspective, hence the growing interest in collecting PROMs [7,15].

In 2014, the Chartered Society of Physiotherapy in the United Kingdom began recommending the incorporation of PROMs as a fundamental aspect of patient-centred care [7]. Emphasizing the significance of PROMs and Patient Experience Measures in contemporary healthcare, the Chartered Society of Physiotherapy guidelines asserted that these measures were pivotal for demonstrating the efficacy of physiotherapy [16]. The Australian Physiotherapy Association took a similar approach in 2013, prompted by the publication of reporting guidelines for PROMs in randomized controlled trials, underscoring the growing recognition of the role of PROMs in enhancing patient-centred practices [17].

Literature on the use of PROMs in physiotherapy practice and research is scarce. A systematic review conducted in 2018 included 38 studies (of all designs) that used one or more PROMs in musculoskeletal physiotherapy alone [10]. The study identified the use of 72 PROMs over a range of outcome domains, with a focus on patient satisfaction, quality of life, functional status, and pain perception. A narrative review evaluated the use of PROMs in physiotherapy trials in 2012 and 2013 and identified that PROMs were mostly used as secondary outcome measures, while a performance-based or clinician-reported outcome tool was used to measure the primary outcome [6]. In addition, there is no data evaluating the uptake of using PROMs in physiotherapy research before and after the establishment of the COSMIN in 2005 and all other initiatives including the publication of the COSMIN reporting guidelines in 2012 [4]. Therefore, our primary aim was to compare the overall use and type of PROMs in randomised clinical trials (RCTs) in the field of physiotherapy in 2000 and 2018 to evaluate the influence of the COSMIN guidelines as a clear focus of the growing interest in and hopefully increasing uptake of patient reported outcomes. Our secondary aim was to evaluate whether the use of PROMs differed across the three main subdisciplines of physiotherapy (Musculoskeletal, Neurological, and Cardiopulmonary).

Methods

Study design

We performed a meta-research study on the use of PROMs in RCTs published in 2000 and 2018. This study is part of a suite of studies that used the same set of RCTs to evaluate different aspects of physiotherapy trials [18,19]. This suite of studies was registered in an internal repository with the University of Technology Sydney, Sydney, Australia (https://doi.org/10.26195/ebqp-8a65).

Search strategy

We searched Embase (Ovid), Medline (Ovid) and PubMed in May 2019 to identify RCTs that evaluated a physiotherapy intervention, published in the year 2000 or 2018 in six high ranked physiotherapy journals, all supporting the CONSORT statement: Archives of Physical Medicine and Rehabilitation (Arch Phys Med Rehab), Clinical Rehabilitation (Clin Rehab), Journal of Orthopedic and Sports Physical Therapy (J Orthop Sports Phys Ther), (Australian) Journal of Physiotherapy (J Physiother), Physical Therapy (Phys Ther), and Spine. The journals were chosen based on their Q1 rating in the SCImago Journal Rank across both years, suggesting that the selected journals have substantial influence within the physiotherapy profession. The search strategy is provided in Supplementary Appendix A. We also hand searched these journals on possibly missing RCTs. Articles were imported into Covidence (https://www.covidence.org/).

Study selection

Two reviewers independently screened for titles and abstracts initially, and then for full text. If required, a third independent reviewer resolved the conflicts at full-text screening. Articles were

included if they were an RCT that used a physiotherapy intervention and were published in the year 2000 or 2018 in the journals of interest. The World Confederation of Physiotherapy Policy statement (https://world.physio/policy/ps-descriptionPT) was used to determine if an intervention was within the international scope of physiotherapy. We excluded conference presentations, published protocols or articles where the intervention was not performed in humans, or when the full text article could not be retrieved.

Data extraction

We extracted the following data from each article: year of publication, journal, sub-discipline of physiotherapy, patient population, country of first author, intervention description, the names and numbers of outcome and PROMs used in each article. Data were extracted from each article by two independent assessors with conflicts resolved by a third independent assessor.

Classification of PROMs

The extracted PROMs were classified by two independent assessors according to the domains suggested by Cella et al. [20] and included: *health-related quality of life, functional status, symptoms and symptom burden, health behaviours* and *patient's experience*. We included the use of PROMs to record an adverse event in the classification system. Conflicts were resolved by a third independent assessor.

Analysis

We calculated the frequency of PROMs and non-PROMs (outcome measures that are not patient reported) used within a trial in the years 2000 and 2018, separately per journal. It is worth noting that when RCTs reported multiple subscales of an outcome measure, the outcome measure was counted as one (i.e. if a study reported on all the 8 domains of the Short-form-36 separately, it was counted as one PROM). We *a priori* defined a difference of 20% between 2000 and 2018 as a meaningful difference between years based on previous studies [18,19, 21–23]. PROMs were grouped according to the outcome domain, which were *health-related quality of life, functional status, symptoms and symptom burden, health behaviours* and *patient's experience* [20]. In addition, we evaluated whether the ratio of PROMs vs non-PROMS differed across the three main subdisciplines of physiotherapy (musculoskeletal, cardiopulmonary, and neurological).

Results

Search results

Details of the search results have been published previously [18,19]. In summary, the search resulted in 1211 articles. After duplicate removal, title and abstract screening, and full text screening a total of 140 articles satisfied our eligibility criteria and were included in this review (Figure 1). Of the 140 RCTs, 39 were published in 2000 and 101 in 2018.

Characteristics of included trials

Patient populations

Most RCTs were classified in the musculoskeletal subdiscipline (50.7%) (Table 1). The most common patient populations were people with stroke ($n = 22$), low back pain ($n = 19$), neck pain ($n = 10$) and Parkinson's disease ($n = 7$). Two journals (Spine and J Orthop Sports Phys Ther) published only RCTs on musculoskeletal conditions in both years, while the J Physiother did not publish any RCTs on musculoskeletal conditions in 2018.

Reported outcome measures

Overall, 84% (118/140) of the trials used one or more PROMs and 89% ($n = 125/140$) included at least one non-PROM. In 2000, 74.3% (29/39) of the trials used at least one PROM, while in 2018, 88.1% (89/101) used a PROM. In 2000, 87.2% (34/39) of the trials used at least one non-PROM, while in 2018 the usage increased to 90.1% (91/101) (Table 1).

Two journals (J of Physiother and Spine) had PROMs in all trials published in both years. Two journals (J Orthop Sports Phys Ther and Phys Ther) had an increase from 50% to 100% of their publications using PROMS in 2018 compared to 2000. One journal (Arch Phys Med Rehab) also increased (by 32%) the number of trials using PROMs. Only Clin Rehab slightly reduced the number of trials with PROMs.

Patient-reported outcomes

A range of different PROMs were identified covering six outcome domains (Table 1).

Symptoms and symptom burden

Symptoms such as fatigue and pain intensity were most frequently assessed; in 88/118, (74.6%) trials. The Visual Analog Scale (VAS) was most used to measure symptoms such as pain intensity ($n = 34$). There was a decrease (11%) on the use of PROMs to assess symptoms and symptom burden in 2018.

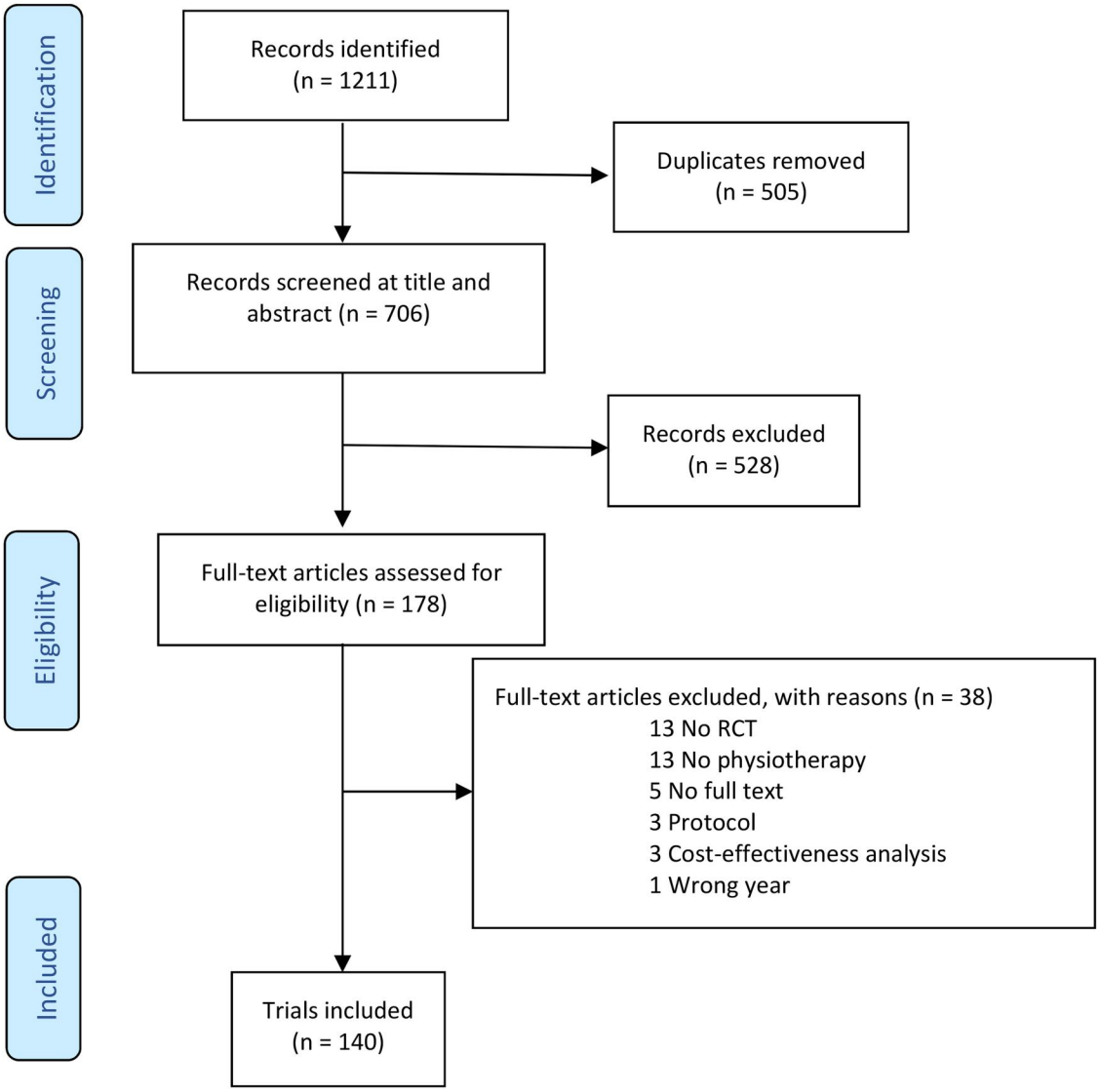

Figure 1. Flow chart of study selection.

Functional status

Most trials (77/118 (65.2%)) evaluated the effectiveness of their respective treatments using PROMs that assessed functional status, which could include physical function, cognitive function, and sexual function. The Roland-Morris Disability Questionnaire ($n = 7$) was most used to assess functional status, followed by the Barthel index ($n = 5$). The use of functional status PROMs remained similar in 2000 (65.5%) and 2018 (65.1%).

Health-related Quality of life (HRQoL)

Of the 118 trials using PROMs, 44 (37.3%), assessed HRQoL, including physical, social, and emotional health and well-being. Health-related Quality of Life Short form (SF-36) was the most common PROM for measuring HRQoL ($n = 16$). There was an increase (17.4%) on the use of PROMs to assess HRQoL between 2000 and 2018.

Health behaviour

Thirty-four trials (28.8%) used PROMs to assess health behaviour. The International Physical Activity Questionnaire (IPAQ) was the most reported PROM ($n = 9$). The usage of health behaviour PROMs decreased (3%) in 2018 compared to 2000.

Patient experience

A total of 37/118 (31.4%) trials assessed patient experience that included patient satisfaction, patient motivation and activation, and patient reports of their actual experiences. Global rating/perception of change scale was the most common PROM for measuring Patient experience ($n = 6$). A decrease (8.7%) in the use of patient experience PROMs was observed in 2018 compared to 2000.

Adverse events

Ten (8.5%) trials reported on self-reported adverse events or number of patient complaints related to adverse events. There was an increase (6.7%) in

Table 1. Patient-reported outcome measures per journal.

Journals	Arch phys med rehab		J physiother		Clin rehabil		J orthop sports phys ther		Phys ther		Spine	
Year	2000	2018	2000	2018	2000	2018	2000	2018	2000	2018	2000	2018
N of RCTs	11	30	2	7	5	45	4	6	6	6	11	7
Usage of patient-reported outcome measures												
Total PROMs	32		9		42		8		9		18	
PROMs/Journal year	6	26	2	7	5	37	2	6	3	6	11	7
Classification of patient-reported outcome measures												
Symptoms and symptom burden	4/6 (66.7%)	19/26 (73.1%)	2/2 (100%)	6/7 (85.7%)	3/5 (60%)	26/37 (70.3%)	2/2 (100%)	6/6 (100%)	2/3 (66.7%)	3/6 (50%)	10/11 (91%)	6/7 (85.7%)
Functional status	3/6 (50%)	16/26 (61.5%)	1/2 (50%)	3/7 (42.9%)	4/5 (80%)	27/37 (73%)	1/2 (50%)	4/6 (66.7%)	1/3 (33.3%)	4/6 (66.7%)	9/11 (81.8%)	4/7 (57.1%)
Health related Quality of life	1/6 (16.7%)	15/26 (55.7%)	0/2 (0)	4/7 (57.1%)	2/5 (40%)	13/37 (35.1%)	0/2 (0)	2/6 (33.3%)	2/3 (66.7%)	1/6 (16.7%)	2/11 (18.2%)	2/7 (28.6%)
Health behaviour	1/6 (16.7%)	9/26 (34.6%)	0/2 (0)	2/7 (28.6%)	1/5 (20%)	9/37 (24.3%)	0/2 (0)	1/6 (16.7%)	0/3 (0)	3/6 (50%)	7/11 (63.6%)	1/7 (14.3%)
Patient experience	3/6 (50%)	6/26 (23.1%)	0/2 (0)	1/7 (14.3%)	0/5 (0)	12/37 (32.4%)	0/2 (0)	2/6 (33.3%)	1/3 (33.3%)	3/6 (50%)	7/11 (63.6%)	2/7 (28.6%)
Adverse events	1/6 (16.7%)	3/26 (11.5%)	0/2 (0)	0/7 (0)	0/5 (0)	4/37 (10.8%)	0/2 (0)	0/6 (0)	0/3 (0)	1/6 (16.7%)	0/11 (0)	1/7 (14.3%)

J Physiother: (Australian) Journal of Physiotherapy; Arch Phys Med Rehab: Archives of Physical Medicine and Rehabilitation; Clin Rehabil: Clinical rehabilitation; J Orthop Sports Phys Ther: Journal of Orthopaedic and Sports Physical Therapy; Phys Ther: Physical Therapy; PROMS: Patient-reported Outcome measures; OMs: Outcome Measures.

PROMs used to report adverse events in 2018 compared to 2000.

PROMs per subdiscipline

Overall, the percentage of trials that used PROMs in 2000 ranged from 0 in the cardiopulmonary subdiscipline to 88.5% in the musculoskeletal subdiscipline. There was a decrease (4%) in the use of PROMs in musculoskeletal RCTs between the 2 years, while neurological and cardiopulmonary RCTs had an increase in the use of PROMs of 29% and 88%, respectively (Table 1).

Discussion

This study identified the number of PROMs used in physiotherapy RCTs published in the years 2000 and 2018 in six physiotherapy journals; however, no meaningful differences were found between years. Most trials (74.3%) published in 2000 and in 2018 (88.1%) used at least one PROM to measure their outcomes. The total number of trials that used non-PROMs was 89.2% and similar between years (87.2% in 2000 and 90.1% in 2018). Musculoskeletal physiotherapy was the subdiscipline with the highest overall use of PROMs (86%). However, there was an increase in the use of PROMs in the cardiorespiratory subdiscipline from 0 to 88% and of 28.9% in the neurological subdiscipline in 2018 compared to 2000. Overall, PROMs were mostly used to measure symptoms and symptom burden (74.6%) and functional status (65.2%) and were only used to assess adverse events in 8.5% of the total trials included. There were no significant changes between the years in the domains of PROM usage, except for a slight increase (7%) in the use of PROMs to measure adverse events in 2018. Over the past decade, the integration of PROMs into physiotherapy has gained momentum globally, as an overall increasing trend has been observed, indicating a growing recognition of the value of PROMs in enhancing patient-centered care and informing clinical decisions [1,24].

The overall high use of PROMs in physiotherapy RCTs reflects the importance of including the patient, and their perceptions, in the process of clinical research [14,25]. PROMs can empower patients, allowing them to provide input to the physiotherapy care process [25–28]. By incorporating PROMs into practice, physiotherapists can better understand and address patient values and expectations in their care, potentially leading to more successful treatments [29]. In the subdiscipline of musculoskeletal physiotherapy, the high usage of PROMs might be influenced by research initiatives that developed core outcome sets to standardise assessment procedures

across clinical trials that include PROMs [9,30]. Core outcome sets are important to standardise measurements so that studies measure similar outcomes, allowing comparisons and facilitating outcomes to be pooled in meta-syntheses [12]. Even though core outcome sets have been suggested in neurological [31] and cardiopulmonary [32] physiotherapy, these are not as largely used as in the musculoskeletal and rheumatology physiotherapy trials [10,11].

The non-use of PROMs in the two cardiopulmonary RCTs in the year 2000 might be explained by the specific clinical aspects when determining the outcomes of interest in the different subdisciplines of physiotherapy. For patients with musculoskeletal and neurological conditions, the goals of physiotherapy are to reduce symptom burden and improve functionality and participation [10,33]. On the other hand, cardiopulmonary physiotherapists, especially those working in hospital settings might focus on reducing hospital length of stay, removal of secretions, early decannulation, and improving ventilation [34]. For critically ill patients that require mechanical ventilation or present with altered levels of consciousness, these outcomes cannot be measured using PROMs [35].

We found that PROMs were largely used to measure symptoms and symptom burden and functional status in the included trials. Moreover, the usage of PROMs to measure HRQoL, patient experience and health behavior was lower, showing that researchers seem to prioritise patient-reported measurements of impairments and activity limitations over participation-type measures. Even though the attention has shifted towards participation outcomes clinically and in medical research in recent years [36,37], we found no meaningful changes between the use of PROMs to measure participation outcomes in the years analysed. Assessing patient experience and quality of life is crucial for patient-centred care, including the shared decision-making among clinicians, patient, and families [37,38]. PROMs have been recognised as a valuable tool in healthcare by facilitating better decision-making and enabling comparisons of providers' performances to stimulate improvements in services [38,39]. The use of impairment and activity limitation measures, while important, fail to fully capture patients' perspectives and priorities. Given this, we encourage authors to incorporate more participation-type measures when performing clinical trials.

We found very low usage of PROMs to assess adverse events (8.5%), despite the availability of questionnaires to assess them [40,41]. This suggests that in this sample of high-quality physiotherapy journals, adverse events are either recorded by the researchers (i.e. not patient-reported) or are not reported at all. Relying on researchers as the only source for reporting adverse events, may neglect patients' experiences and perspectives around these events. Using PROMs could help identify adverse events that may be underreported or overlooked by researchers, leading to more complete reporting of adverse events in clinical trials [42]. Although PROMs can provide a more complete overview of patient adverse events, patients may experience nocebo effects, i.e. they experience adverse effects solely because they expect those effects to occur, thus potentially over inflating adverse event reporting. PROMs often require patients to actively participate and complete questionnaires, which may be burdensome for some patients, leading to incomplete or missing data [43]. We believe that when reporting adverse events, both PROMs and clinician-reported measures should be used. The lack of PROMs used to measure adverse events suggest that in physiotherapy trials the patient perspective on adverse events is not sufficiently considered.

Limitations

A limitation of this study was that we restricted our search strategy to six journals and two years, with a significant proportion of articles included on musculoskeletal physiotherapy, potentially not representative of all physiotherapy journals or physiotherapy areas. The predominance of RCTs in the musculoskeletal domain may reflect the focus of half of the included journals, such as Journal of Orthopaedic and Sports Physical Therapy and Spine, which primarily publish research in this area. The six journals were chosen as they publish high-quality trials, follow CONSORT recommendations and advocate for practice guidelines and therefore, the high use of PROMs in both years, may differ in other physiotherapy journals. Furthermore, these journals only publish in English, and as a result we did not include trials published in other languages. Hence, the data presented may not be an accurate representation of all physiotherapy RCTs. Lastly, we only compared the use of PROMs in two years, it would also be beneficial to investigate the evolution of PROMs over a longer period to clarify how the scope of the use of PROMs as outcome measures in research has changed over time.

Recommendations

Since 2018, the integration of PROMs into physiotherapy practice and research has seen a notable increase, driven by the growing emphasis on patient-centered care and the need to evaluate

treatment effectiveness from the patient's perspective. PROMs are now routinely employed in clinical settings to monitor patient progress, inform clinical decision-making, and enhance the quality of care [44]. Their usage spans various domains, including musculoskeletal disorders, chronic pain management, and rehabilitation programs [44,45]. The adoption of digital health technologies has further facilitated the collection and analysis of PROMs, enabling more efficient and accurate assessments [46]. Despite these advancements, challenges such as ensuring the validity and reliability of PROMs across diverse patient populations and integrating them seamlessly into clinical workflows remain areas for ongoing development [45]. Overall, the past seven years have marked significant progress in the utilization of PROMs within physiotherapy, underscoring their value in enhancing patient outcomes and advancing evidence-based practice.

However, further research on the use of PROMs in physiotherapy is needed to increase the understanding of how and why PROMs are being used. For example, it was unclear why there was low usage of PROMs that measured adverse events, when compared to other outcomes. There remains a need to develop a minimum set of PROMs to be used in physiotherapy clinical practice. The use of PROMS in physiotherapy RCTs could be further incentivised in neurological and cardiopulmonary subdisciplines by initiatives to implement specific core outcomes set for those subdisciplines.

Conclusion

The majority of RCTs in six major physiotherapy journals published in 2000 and 2018 used PROMs, with no meaningful differences between years. The musculoskeletal practice area used more PROMs than neurology and cardiopulmonary in 2000, although PROM use in all practice areas was high in 2018. However, the use of PROMs to monitor adverse events was low. The widespread use of PROMs in physiotherapy research reflects the focus on a patient-centred approach in physiotherapy clinical practice.

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Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors used SciteAI in order to compile references to support statements in the discussion section. After using this tool/service, the author(s) reviewed and edited the content as needed and take full responsibility for the content of the publication.

Disclosure statement

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