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Preference Trials: An Underexplored Design in Musculoskeletal Research

■ **BACKGROUND:** Incorporating patients' preferences into randomized controlled trials (RCTs) enhances the relevance and applicability of research findings to clinical practice. Person- and patient-centered care are fundamental principles in modern musculoskeletal pain management, requiring consideration of treatment preferences during research endeavors to guide clinical practice.

■ **CLINICAL QUESTION:** How can RCT designs account for patients' preferences in musculoskeletal pain management research, and what are potential benefits of doing so?

■ **KEY RESULTS:** Despite the importance of patient preferences in musculoskeletal pain management, few RCTs adequately integrate these preferences into their designs. This article discusses several methodological strategies for including patient preferences in RCTs. Proposed designs include modifications to conventional trials, comprehensive cohort designs, partially randomized preference designs, and 2-stage randomized preference designs. Each design is assessed for its ability to address real-world clinical questions, with strengths and limitations highlighted.

■ **CLINICAL APPLICATION:** Trialists must carefully consider whether adapting their study design to include patient preferences is necessary for answering their research questions and improving outcomes for patients with musculoskeletal pain.
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■ **KEY WORDS:** *musculoskeletal pain, patient preferences, person-centered care, randomized controlled trial, research design*

Patient preferences are "*statements made by individuals regarding the relative desirability of a range of health experiences, treatment options and health states*."[15] Arguably, patient preferences are the critical bridging element between evidence-based medicine[77] and patient-centered care.[18,78] Aligning with public health strategies, including from the World Health Organization (WHO)[103] and the European Commission,[36] integrating patient preferences into evidence-based medicine represents a changed attitude toward a more holistic and inclusive approach to health care. This approach emphasizes not only the clinical aspects of care but also the personal values, goals, and circumstances of individuals.[92] Also, by recognizing patient preferences as a central component of shared decision-making, health care providers can tailor interventions to be more acceptable and relevant for individuals, thereby improving satisfaction, adherence to treatment plans, and potentially health outcomes.[30,63,102] Although patient perspectives were considered in the initial definition of evidence-based medicine,[77] medical research has traditionally taken a disease-centered approach, often neglecting patient views.[43]

It is widely acknowledged that the effective management of musculoskeletal pain conditions requires patient-centered care and shared decision-making.[5,9,51–53,62,66] Research indicates that patient preferences[9,11,39,67,91] and expectations[10,12,39,67] can affect clinical outcomes and satisfaction, both beneficially and adversely. This also applies to the preferences of health care providers,[11,25] which may or may not align with those of patients.[46] While mechanisms may overlap and vary, the influence of patient preferences on clinical outcomes is likely mediated by expectancy effects and treatment adherence (and thus dosage received). Despite the growing interest in musculoskeletal research[21,90] and steady increase in randomized controlled trials (RCTs) in this field,[64] the assessment of patient preferences and their impact on RCT outcomes remains minimal. Reviewing all areas of medicine of the past 20 years, a recent review retrieved 57 trials and 15 reviews summarizing the evidence for the impact of treatment preferences on intervention processes and outcomes.[83] Only 5 studies (2 reviews and 3 primary studies) specifically targeted musculoskeletal conditions.[83] Arguably, musculoskeletal research in particular would benefit from incorporating patient preferences because there is no definitely superior treatment approach for conditions such as back pain or arthritis.[38,58] Furthermore, the field of musculoskeletal health care encompasses a wide range of approaches, including purely educational interventions, conservative therapies, pharmacological interventions, invasive procedures,

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exercise and lifestyle modifications, and multimodal strategies.[62] Interestingly, the majority of these options necessitate the active involvement of the patient in their therapeutic journey. In instances where there is equipoise between interventions, the provision of an intervention that aligns more closely with the patient's preferences may be advantageous. Nonetheless, while preliminary evidence suggests that patient preferences in musculoskeletal studies may be associated with positive treatment effects,[73] methodological limitations prevent firm conclusions,[34] adding a need to improve the methodological quality and appropriateness of musculoskeletal research designs.[13,32,33,90]

In sum, musculoskeletal research falls short of standards set by international institutions, including the WHO requiring that "*[c]are is coordinated around people's needs, respects their preferences, and allows for people's participation in health affairs.*"[103] To address this, the present commentary aims to show how different research designs can integrate patient preferences in musculoskeletal research, as well as discuss their potential strengths and limitations to guide future research.

CLINICAL QUESTION

How can RCT designs account for patients' preferences in musculoskeletal pain management research, and what are potential benefits of doing so?

When to Consider Patients' Preferences in Musculoskeletal Research

While it is generally advisable to consider patient preferences in musculoskeletal clinical care, the relevance of incorporating patient preferences in research may vary depending on the specific research question.[50] For instance, mechanistic or efficacy trials that seek to examine treatment effects in a highly controlled environment often deliberately control the influence of patient preferences or expectancies on outcomes. In contrast, research questions about real-world effectiveness may be more inclined to account for patient preferences, particularly in those cases where the available evidence indicates a potential impact of such factors on outcomes, as is the case in musculoskeletal practice and other complex interventions.[100]

Once patient preferences are identified as potentially important in a research question, researchers need to understand the different features of clinical interactions that may drive preferences. In fact, a number of cognitive, emotional, and relational factors (termed "attributes") exert influence on the construction of patient preferences.[31,79] These attributes constitute the specific features or characteristics of the health care intervention or the individual that may influence a patient's decision-making process.[24] Firstly, a number of attributes associated with interventions designed to address musculoskeletal chronic pain conditions have the potential to influence patient preferences.[105] This entails, for example, an evaluation of the impact of the intervention on the patient's daily activities, its effectiveness in reducing the pain, or treatment frequency. Secondly, patient preferences may have to be considered in instances where it is known that distinct subgroups of patients with differing preferences exist. This may be the case, for example, when patients have different socioeconomic backgrounds or distinct symptom profiles.[48,65,79,91] Third, the incorporation of patient preferences in studies is particularly pertinent when the clinical scenario under investigation entails the comparison of intervention options with features that are known to differentially interact with patients' perceptions and beliefs.[8,79,91] This may include the comparison of interventions with varying levels of perceived effectiveness, convenience, safety, or cost.[82] Finally, for musculoskeletal conditions, patients may also have preferences regarding care providers, such as their sex, race, communication and listening skills, confidence, and perceived similarity to themselves.[9] The evidence for various intervention features and patient characteristics/perceptions and their interaction with patient preferences is summarized in the **TABLE**.

Considering the complexity of many musculoskeletal interventions,[29] attempts to elicit patient preferences should extend beyond the simple inquiry of treatment preference (which is often the case[83]) and encompass a broad range of intervention features, including providers, dosage/intensity, treatment components, and modality. Collectively, the evidence suggests that when designing a trial, musculoskeletal trialists should carefully examine the nature and real-world delivery of the interventions being tested regarding the potential impact of patient preferences on study results, and on other aspects such as recruitment, attrition, and adherence. Based on the research question, trial designers can consider several methodological adaptations in study design. As an initial categorization, these designs can be divided into 2 groups: trial designs where patient preferences do not affect the randomization process (**FIGURES 1** and **2**) and those where patient preferences interact with the randomization process (**FIGURES 3** and **4**).

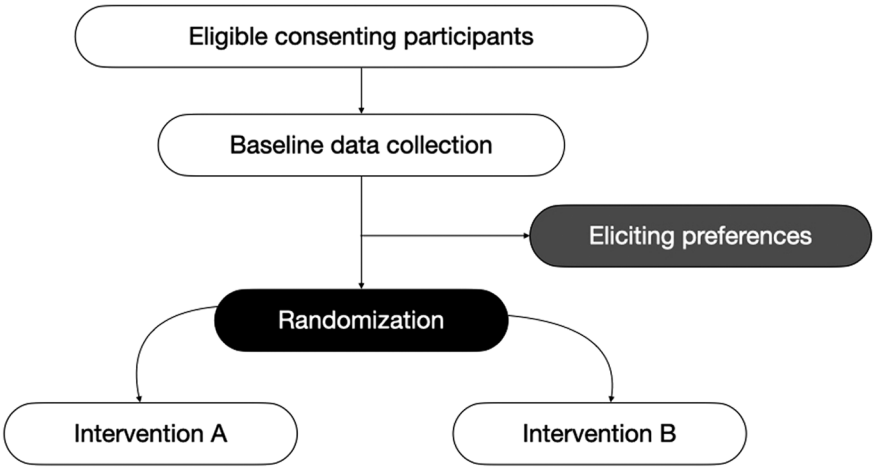
Conventional RCT with the Analytical Consideration of Preference-Related Data

In RCTs, random participant allocation aims to mitigate selection bias by restricting the investigators' ability to selectively enroll or allocate patients. Additionally, randomization promotes similarity between treatment groups, ideally balancing patient characteristics[4] and preventing the influence of confounders[7] (including patient preferences). The simplest

TABLE
Intervention Attributes and Patient Characteristics/Perceptions That Influence Patient Preferences

Intervention Attributes	References
Capacity to realize daily life activities	Zhu et al[105]
Risk of adverse events or relapse	Versloot et al[93]
Effectiveness in pain reduction	
Out-of-pocket cost	
Treatment frequency	
Onset of treatment efficacy	
Patient Characteristics	
Gender	Mei et al[65]
Age	Say et al[79]
Socioeconomic status	Morillon et al[68]
Demographic variables	
Educational level	
Health status	Say et al[79]
Experience of illness and medical care	Thomas et al[91]
High symptom severity or dysfunction	Healy et al[48]
	Kløjgaard et al[56]
Patient's Perceptions and Beliefs	
Appropriateness: Whether the intervention is reasonable and matches their lifestyle and circumstances	Sidani[82]
Potential effectiveness: Perceived usefulness of the intervention in addressing the problem	
Safety: Perceived severity of the risks associated with the intervention	
Convenience: Ease of use and adherence to the intervention	

FIGURE 1
Conventional randomized controlled trial (RCT) with preference-related data.



method to account for patient preferences is to request information on preferences prior to randomization (**FIGURE 1**). Subsequently, participants are classified as having received either preference-matched or preference-mismatched treatment, allowing for a post hoc analysis of the impact of preferences on outcomes, attrition, and adherence.[82,87] Asking for patient preferences and treatment expectations before randomization attempts to monitor baseline differences and/or control for covariates in the analyses, which is particularly suitable for pragmatic and open-label trials.[50,73] This option may be good methodological practice and safeguard the external validity of the study without compromising its internal validity. However, limitations include the unclear psychometric properties of the inquiry, challenges of presenting treatment-related information to patients, and the difficulty of capturing the full complexity of patient preferences in a single item or categorical assessment.[34,87] Further, patient preferences may only crystallize with trial progression, for example, after an initial experience with trial providers or the intervention.[79,91] Therefore, validated treatment preference assessment instruments should be used to accurately elicit patient preferences and adequately implement this design option.[83–85] These instruments should take into consideration the attributes that have been previously identified in the literature (see the **TABLE**), in addition to the case-specific preferences that may be applicable. A preliminary study may be necessary to inform the development of these instruments considering the findings of previous research, such as cross-sectional or discrete-choice experiments evaluating patients' preferences in specific conditions. Indeed, a review of musculoskeletal RCTs incorporating preference-related data identified several limitations of this approach,[34] including heterogeneous methods to measure and analyze patient preferences, underpowered studies to assess interactions between preferences and outcomes, and unplanned patient preferences analyses. However, given the review's age, an updated assessment may yield different conclusions. Finally, conventional randomization may be considered unethical if patient preferences are first elicited and then ignored.[60,82,87,96]

FIGURE 2
Comprehensive cohort design.

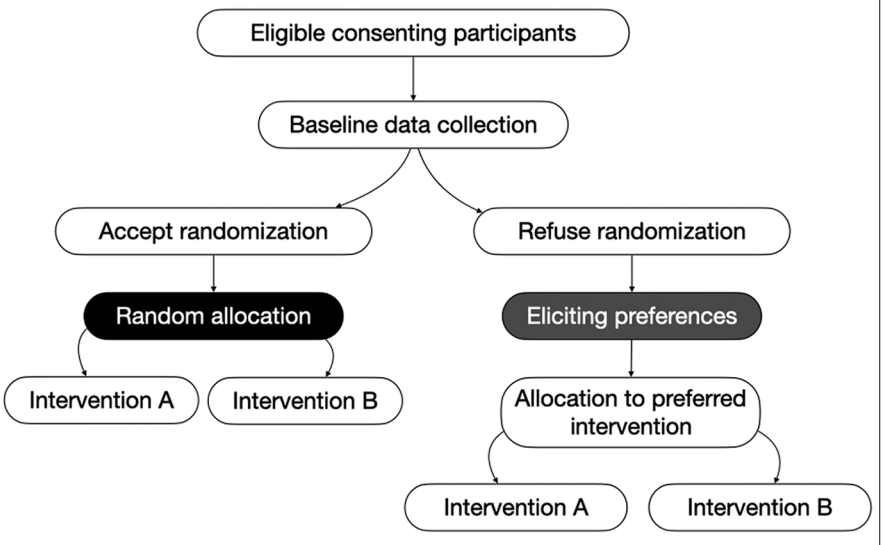
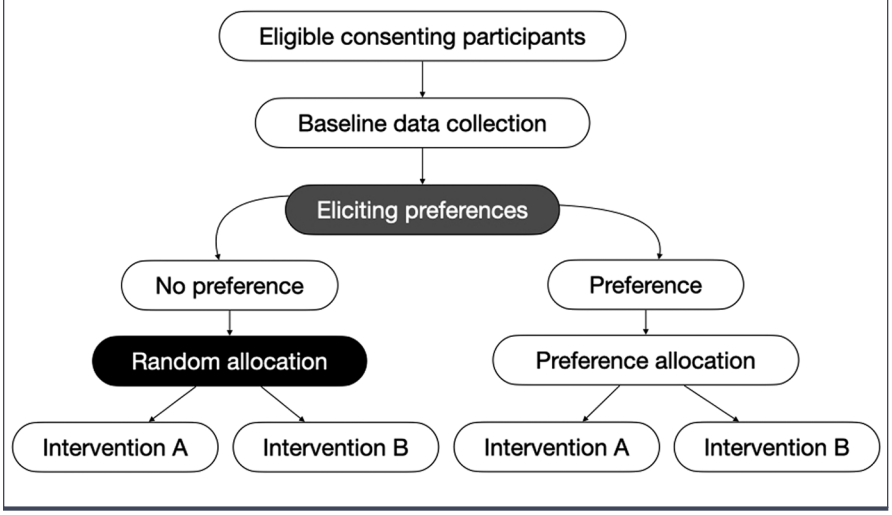


FIGURE 3
Partially randomized preference design.



Examples in Musculoskeletal Research

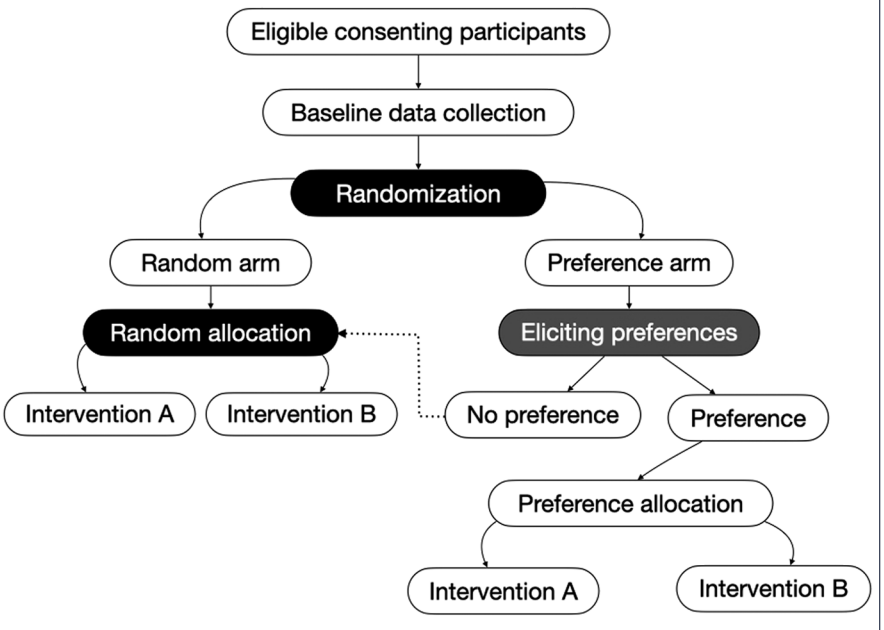
Steven et al conducted a study on behavioral physical therapy interventions for low back pain.[40] Prior to randomization, patient preferences for study arms were recorded to assess their impact in a secondary analysis.[39] Preferences were grouped into matched, unmatched, and no strong preferences. Similarly, an RCT conducted on people with subacromial pain aimed to evaluate the clinical effects and costs of group-based exercise rehabilitation compared with individual exercise and home exercise rehabilitation.[23] A secondary analysis assessed how matching modes of rehabilitation delivery to patient preferences effected overall rehabilitation outcomes.[1] In both studies, the researchers employed no validated treatment preference assessment instrument and preferences were evaluated on a single occasion prior to the commencement of treatment. This methodological shortcoming has the potential to compromise interpretation and introduce bias, as the researchers themselves have acknowledged.[1]

In contrast, Lanier et al compared motor skill training in functional activities to strength and flexibility exercises for improving function in people with chronic low back pain (CLBP).[61] At baseline and 12 months after treatment, patient preferences were assessed using a validated instrument based in a cross-sectional study previously conducted in patients with CLBP.[35] In a notable finding, participants' overall preference ratings of the 2 exercise-based treatments shifted following exposure to the respective treatments, demonstrating that preferences are not static.[61] Of particular interest was the observation that improvements in preference ratings among the initially less preferred group were attributable to factors other than improvements in outcomes. The authors concluded that intervention-related education is of particular importance when participants are faced with an unfamiliar intervention, to increase the perceived acceptability and suitability of the treatment.[61] Additional examples of musculoskeletal RCTs incorporating preference-related data can be found in a review by Franco et al.[34]

Comprehensive Cohort Design

The comprehensive cohort design offers all eligible patients who decline to be randomized the opportunity to choose their preferred treatment.[80,82] The randomized patients and the nonrandomized patients are treated and followed according to the same protocol (**FIGURE 2**). This design results in an extended prospective cohort, which includes a classical RCT as a subcohort.[80] In musculoskeletal

FIGURE 4
Two-stage randomized preference design.



and rehabilitation medicine, patient samples in RCTs often represent only a small proportion of those who meet the inclusion criteria, including willingness to be randomized. Among other reasons, this sampling can be due to strong patient preferences for 1 therapy over another,[26,42,70] leading to recruitment difficulties[55,99] and differences in outcomes between participants and nonparticipants of RCTs. While previous systematic reviews assessing these differences concluded that the outcomes of participating and nonparticipating patients in RCT were similar,[94] a recent prospective cohort study showed that among rheumatology and musculoskeletal patients, research participants reported more positive illness perceptions and better health-related quality of life than nonparticipants.[42] To avoid this potential bias and to account for patient preferences, the comprehensive cohort design recruits all patients regardless of their consent to randomization, allowing for the inclusion of more patients[70,80] while partly preserving the benefits of randomization. This design is relatively straightforward to implement and might thus be considered where limited statistical expertise and trial management capacities are available.

Examples in Musculoskeletal Research

Patients with musculoskeletal conditions commonly face the choice between conservative treatment and surgery. Available RCTs provide low-certainty evidence, lacking support of surgery over nonsurgical alternatives for most musculoskeletal conditions.[88] However, RCTs comparing surgical and nonsurgical interventions have recruitment difficulties, often relating to patient preferences.[28,81] In this scenario, the comprehensive cohort design can improve recruitment and retention rates while accounting for patient preferences. A good example is the study by Weinstein et al, comparing surgical and nonsurgical interventions for lumbar spinal stenosis.[101] In this trial, participants who refused randomization were enrolled in a prospective cohort where patients were assigned to their preferred arm. Similarly, Kim et al conducted a comprehensive cohort study to assess outcomes of nonsurgical management among patients who were recommended surgery for lumbar disc herniation but sought a second opinion.[54] In this type of study, crossover between arms is usually allowed and specific statistical analysis should be performed to preserve statistical power and to better infer causality.[27]

Partially Randomized Preference Design

This design is like the comprehensive cohort design, except that all participants are asked before randomization if they have a preference. If they do not (undecided), these participants are randomized. The other participants will be allocated to their preferred arm, resulting in 4 groups following the same intervention protocols.[16,82,83,95] (**FIGURE 3**). Compared to a fully randomized design, the partially randomized preference design is more attractive from an ethical point of view because the randomization process is aligned with patient choice.[95] Wasman et al conducted a systematic review assessing the influence patient preferences in trials by analyzing partially randomized preference trials, RCTs, and comprehensive cohort designs combined.[99] The conclusions from this study are supported by an earlier review:[55] First, patients' preferences adversely affect their trial participation, as demonstrated by the low participation rate in the randomized cohort of partially randomized preference design (with refusal rates of more than 50% in 26 of 44 RCTs). For this reason, some preference studies consider implementing a stopping rule in the preference arm to power the primary analysis and balance the groups throughout recruitment.[45,104] Once a predetermined number of participants have entered the preference arm, the

preference option is no longer available to subsequent patients. Since this may potentially impact adherence to treatment and result in a higher attrition rate going forward, this strategy constitutes a design limitation and a potential source of bias that should be recognized and addressed in the data analysis. However, it may represent a reasonable compromise in small trials that aim to consider patient preferences without compromising trial feasibility, statistical power, and comparability. The second conclusion of Wasman et al is that the primary outcomes in the randomized and preference cohorts were similar, suggesting that internal validity was preserved while enhancing external validity.[99]

Examples in Musculoskeletal Research

There are few partially randomized preference design in the musculoskeletal literature. Most studies labeled as such are comprehensive cohort designs studies. However, there is the important difference between these designs regarding whether patient preferences were elicited before or after randomization. A partially randomized preference design example is the study by Cao et al, assessing the effect of acupuncture and cupping therapy on patients with fibromyalgia.[20] The study protocol[19] clearly states that patient preferences were obtained as the initial step, followed by allocation to randomized and nonrandomized groups accordingly. Kurz et al used a similar design to evaluate the effects of postoperative rehabilitation timing as well as the type of surgical intervention in patients with lumbar spinal stenosis.[59] However, the study committee only "self-monitored" patient preferences and allocation ratios. It is unclear why no formal stopping rules were implemented to prevent overrecruitment into the preference arm.[59]

Two-Stage Randomized Preference Design

First proposed by Rücker in 1989[75] and known as "double randomized preference trial," "2-stage trial design," or "2-stage partially randomized preference/clinical trial," this design is considered the most robust and appropriate design to account for patient preferences while protecting internal validity. As the name suggests, a double randomization occurs in this design. Participants are first assigned randomly to either a random or a preference arm. In the random arm, participants are randomly assigned to the interventions. In the preference arm, participants are allocated to their preferred treatment.[82,83,86] Furthermore, if patients assigned to the preference arm are undecided, they can be randomized to the study groups to strengthen the randomized arm (**FIGURE 4**).[97] Among all preference designs, only the 2-stage randomized preference design provides unbiased estimates of all treatment, selection, and preference effects.[95,97] Compared to other preference designs, the 2-stage randomized preference design has the key strength that patient preferences does not influence the first randomization, reducing potential bias that may arise from treatment and outcome measures being disclosed to patients at baseline. It is at this first stage that randomization ensures comparability.[86] After the second randomization, the resulting subgroups can be analyzed by attrition rate, intervention adherence, and outcomes across treatment arms. The impact of patient preferences is determined by comparing patients who received the same treatment but were allocated either randomly or according to preference.[86] Despite its strengths, conducting a 2-stage randomized preference design is challenging due to its complexity.[86] Additional guidance, including possible problems and solutions, can be found elsewhere.[86,87,95,97]

Examples in Musculoskeletal Research

There are no 2-stage randomized preference trials in the musculoskeletal field. Neither the most recent general reviews on preference designs[82,83] nor the specific review on preference studies in the musculoskeletal field[34] identified a study that follows a 2-stage randomized preference design. Although not yet widespread in other disciplines, 1 field in which these designs are present is mental health.[22] A substantial piece of research in this domain is the study by Brenes et al, which appraised the efficacy of cognitive-behavioral therapy and yoga in the management of worry in anxious older adults, while also investigating the impact of patient preference on outcomes, attrition, and adherence.[14]

The absence of such trials in the musculoskeletal field may be due to a lack of awareness, methodological challenges, and limited attention to the impact of patient preferences. Nevertheless, because it may mitigate confounding factors more than other designs,[95] we propose that musculoskeletal trialists should consider the potential and pragmatic features of 2-stage randomized preference designs.

Additional Innovative Options: Preference-Informed Complementary and Platform Trials

The innovative preference-informed complementary trial design has been proposed by Ali et al.[3] In this design, 2 complementary trials are implemented within a single study, allowing patients to select between trials at study entry. The 2 complementary trials differ in the number of interventions included. One trial includes all possible interventions, while the other excludes the intervention subject to strong negative preferences. This approach permits patients to partake in research while avoiding a specific treatment option. In the work of Ali et al, the design permitted caregivers of pediatric patients with musculoskeletal injuries to be included despite a reluctancy to receive opioids.[3] According to the authors, the preference-informed complementary trial design enhances both internal and

external validity compared to traditional RCTs and existing preference-informed trial designs.[3]

Furthermore, patient preferences may be considered during a platform trial, which is a randomized, adaptive trial that assesses multiple interventions against the same control condition. These trials are comparatively more efficient[72] and may lack a predefined end date. Platform trials may evolve over time through the addition or discontinuation of treatment arms according to pre-established rules.[74] Platform trials are arguably more patient-centered and more aligned with clinical care compared to other designs because they directly compare multiple treatment regimens, rather than focusing on a single intervention.[17,57] Consideration of patient preferences may be feasible in platform trials, adding to their efficiency and addressing clinically relevant questions. However, such trials require integrated international research efforts and substantial funding to conduct.[57]

Potential Limitations and Needs for Further Methodological Work

Beyond the challenges discussed above, a limitation affecting all preference designs are suboptimal methodologies employed to accurately elicit patient preferences, coupled with minimal information reported on the procedure used if patient preferences are assessed. As consistently demonstrated in reviews,[55,69,83] most trials use a single (nonstandardized) item to assess patient preferences, wherein participants merely indicate their preferred treatment, with no consideration of other important attributes like appropriateness, effectiveness, risk, suitability, or intervention delivery features such as specific clinicians and delivery mode. To ensure reliable assessment of preferences, validated instruments should be developed and consistently employed.[85] In addition to the potential inaccuracy of the expressed preference, the lack of prior treatment experience may lead to withdrawal, dissatisfaction, or low adherence.[83] Similarly, patients frequently possess limited knowledge regarding the available interventions, leading to uninformed preferences. While the provision of education is a fundamental aspect of shared decision-making in clinical practice, participant information in the context of a preference trial should enable a fully informed choice and reduce uncertainty.[34,61,87] Nevertheless, preliminary data on preferred intervention features for patients can be explored through alternative means before attempting to conduct a preference trial, such as stakeholder involvement, qualitative methods, pilot testing, and discrete-choice experiments. Originally developed in behavioral economics and market research, discrete-choice experiments have been used in health care research to elicit preferences,[68] but how they can inform RCT design may require further investigation. Creating situations in which individuals must select from competing options, discrete-choice experiments enable the assessment of attributes that influence choices.[2,76] We argue that this information and other pilot work could enable researchers to select study interventions more effectively and to better plan the patient preference assessment. Examples of discrete-choice experiments in musculoskeletal research can be found for chronic pain,[105] CLBP,[44,68] low back pain,[56] osteoarthritis,[47,49] shoulder arthroplasty,[71] shoulder pain,[93] or Achilles tendon pain.[89]

Beyond the methodological shortcomings identified, preference trials must be reported carefully for adequate understanding. This can be ensured by detailed compliance with relevant items of Consolidated Standards of Reporting Trials (CONSORT) checklists (notably the "Description of trial design (such as parallel, factorial) including allocation ratio" [item 3a], eligibility criteria [item 4a], and details on randomization, allocation, and implementation of randomization [items 8-11]). Given the comprehensive coverage provided by existing CONSORT statements and the substantial effort required to comply with multiple CONSORT checklists, we do not see the need for a new extension specifically for preference designs.[41]

Finally, the sample size and statistical analysis of preference trials must be carefully planned to ensure that selection and preference effects are controlled for, as well as treatment effects accurately identified, and potential attrition bias is considered.[95,96] The increased complexity of patient preferences trial designs requires substantial statistical support, which may limit their feasibility. Furthermore, it is necessary to consider the potential impact of participants in the preferred (unblinded) arm when blinding can be maintained in the random arm.[37,95] Extensive guidance on statistics in different preference designs can be found elsewhere.[27,37,95–98]

CONCLUSION

Person- and patient-centered care is important in the contemporary care for people with musculoskeletal conditions.[52] To effectively implement patient-centered care in practice, research findings should incorporate patient perspectives.[6,78] Among other elements, patient preferences for specific interventions can affect outcomes, as well as attrition rates and treatment adherence.[82,83] While the conventional RCT is the gold standard for testing interventions, these trials usually fail to capture the impact of patient preferences.[60] Therefore, methodological and pragmatic adaptations must be considered to account for patient preferences. Four potential trial designs have been presented (**FIGURE 5**). Our search indicates that, despite their potential value, these designs are underutilized in musculoskeletal research. Given the pivotal role of patient preferences in the musculoskeletal

FIGURE 5
Infographic summary of the clinical commentary (Alvarez et al. 2025).

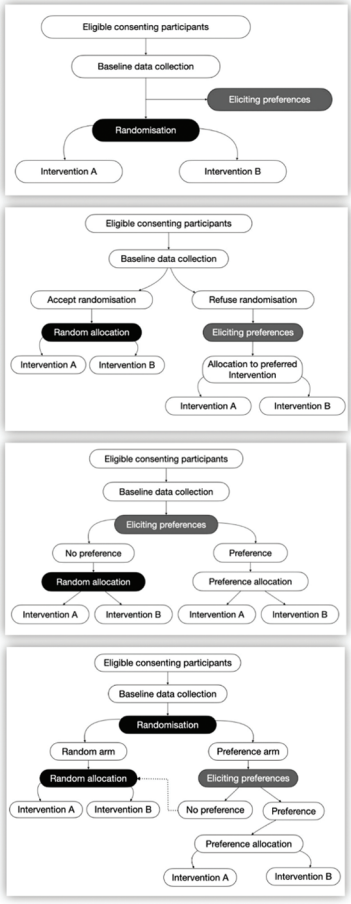
Preference trials: An underexplored design in musculoskeletal research

Gerard Alvarez, PhD*, Matthew J Bair, MD, David Hohenschurz-Schmidt, PhD

Findings:
Integrating patient preferences into musculoskeletal pain trials can improve treatment outcomes. Musculoskeletal pain trials often overlook preferences, potentially leading to incomplete or less relevant results.

Implications:
Incorporating preference-based designs into musculoskeletal research promotes a more patient-centered approach, potentially enhancing clinical outcomes and satisfaction with care.

Caution:
Conducting high-quality preference trials in musculoskeletal research requires careful planning and robust methodological and statistical support. These added requirements may limit their broader use.



1 Conventional RCT with the analytical consideration of preference-related data

- Assessing patient preferences before allocation helps analyze their impact on adherence and outcomes.
- Using validated instruments ensures accurate preference assessment.

2 Comprehensive cohort design

- Allows patients who decline randomization to choose their treatment while following the same study protocol.
- Reduce bias, increases patient inclusion, and maintains some benefits of randomization.

3 Partially randomized preference design

- Allows undecided patients to be randomized while those with a preference choose their treatment.
- Outcomes remain comparable between randomized and preference groups, preserving internal validity while enhancing external validity.

4 Two-stage randomized preference design

- Ensures a robust method to account for patient preferences while maintaining internal validity.
- Minimizes bias by preventing patient preferences from influencing initial randomization, allowing for unbiased estimates of treatment, selection, and preference effects.

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field, we propose that future musculoskeletal research should consider the integration of patient preferences to develop effective care strategies,[6,53,66] optimize patient-centered care, and produce patient-oriented research.[78]

KEY POINTS

FINDINGS: Integrating patient preferences into musculoskeletal pain treatment trials can improve treatment outcomes. However, musculoskeletal pain trials frequently overlook patient preferences, which may lead to incomplete or less relevant results.

IMPLICATIONS: Incorporating preference-based designs into musculoskeletal research promotes a more patient-centered approach, potentially enhancing clinical outcomes and satisfaction with care.

CAUTION: Conducting high-quality preference trials in musculoskeletal research requires careful planning and robust methodological and statistical support. These added requirements may limit their broader use.

STUDY DETAILS

AUTHOR CONTRIBUTIONS: G.A. conceptualized the study, developed the research framework, and drafted the initial manuscript. M.J.B. and D.H. provided significant contributions through critical revisions, enhancing the quality and depth of the content. All authors have read and approved the final manuscript, affirming their contributions and agreement with the content

DATA SHARING: There are no data in this manuscript.

PATIENT AND PUBLIC INVOLVEMENT: Study participants were not involved in the design, conduct, interpretation, or translation of the current research. ■

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