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Patient and physical therapist perspectives on spinal manipulative therapy for low back pain and associated clinical outcomes: protocol for a prospective, single-arm intervention study

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ABSTRACT

Introduction Spinal manipulative therapy (SMT) is a common manual therapy intervention provided by healthcare providers for patients with low back pain (LBP). Responses to SMT are influenced by interactions between the patient and provider. Contextual factors may be specific to the patient, provider, patient-provider relationship or environment in which treatment is provided, with all capable of influencing clinical outcomes. The overall goal of this study is to gain a deeper understanding of contextual factors associated with manual therapy utilisation, perception and outcomes, from both patient and provider perspectives. A better understanding of modifiable contextual factors will inform future studies testing the impact on how SMT is delivered to patients influences clinical outcomes that could potentially advance the clinical science of manual therapy.

Methods and analysis A prospective, single-arm study design with follow-up measures assessed up to 26 weeks after initiation of physical therapy for LBP will be used to assess relationships between physical therapy clinical outcomes and contextual factors related to the patient (preference, expectation, pain beliefs, pain associated distress and prior manual therapy experiences), the provider (equipoise, expectation, pain beliefs and clinical experience) and the interaction between the two (therapeutic alliance). Multimodal treatment approach of SMT (required during initial three treatment sessions within a 2 week period), exercise and education supported by recent clinical practice guidelines will be encouraged for this study.

Ethics and dissemination Ethics approval for the study was obtained from the University of Florida Institutional Review Board. Informed consent is required for physical therapist and patient participant enrolment in this project. The results of this study will be disseminated at professional scientific conferences and submitted for publication in peer-reviewed journals. Reference or approval number: IRB#: IRB202301700

Trial registration number NCT06590116.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Our prior model describing potential mechanisms of manual therapy-related pain inhibition guided planning of this study.

⇒ Both patient and physical therapist attitudes, beliefs and perspectives will be assessed in this study.

⇒ This study will not randomise patient or physical therapist participants to different groups.

⇒ Spinal manipulative therapy is required for three sessions as part of participation in the study; however, additional interventions and the frequency and duration of treatment are left to the provider's discretion.

INTRODUCTION

Low back pain (LBP) is the leading cause of disability in the USA, ranking first in terms of 'years lived with disability' and fifth in regard to 'disability adjusted life years'.[1 2] In 2016, direct healthcare expenditures for LBP (and neck pain) were estimated at US$134.5 billion, representing the highest healthcare spending in the country.[3] Non-pharmacological interventions are strongly recommended as a first-line treatment approach for people with LBP.[4 5] Manual therapy interventions are a non-pharmacological approach favoured by many people with musculoskeletal pain[6 7] and healthcare providers.[8 9] The importance of patient-centred and individualised care has been emphasised in efforts to optimise the delivery of treatment for people experiencing pain;[10] however, there is a need for better understanding to inform strategies for improving alignment between patients

and healthcare providers during the provision of manual therapy interventions.

Small treatment effect sizes associated with manual therapy interventions can be attributed to variability in individual responses to treatment[11] and the frequent 'one size fits all approach' to treatment decision making.[12] Alternatively, identification of homogeneous subgroups that are based on patient characteristics and clinical findings can provide a more tailored approach to treatment decision making. For example, mechanistic-based approaches require the identification of mechanisms underlying a disorder and establishing the biological effect of treatment.[11 13 14] This approach allows the matching of an intervention of known mechanisms to patients with underlying conditions responsive to these mechanisms.[14 15] Spinal manipulative therapy (SMT) is a common manual therapy intervention provided by many healthcare providers (ie, physical therapists, chiropractors, osteopathic physicians) for patients with LBP. Despite small effect sizes across many clinical trials, SMT is recommended by clinical practice guidelines.[16 17]

Conceptual model

We have developed a model describing likely mediators of manual therapy-related pain inhibition.[18 19] Specific to this study, contextual responses to SMT are influenced by interactions between the provider and patient. Previous observational work identified inconsistent relationships among patient and provider-level factors as predictors of therapeutic alliance (TA) across different musculoskeletal pain cohorts and supports the premise that patient and provider interactions are associated with different contextual factors.[20] Contextual factors may be specific to the patient, the provider, the patient-provider relationship and/or the environment in which treatment is provided, with all capable of influencing patient outcomes.[21–24] Recent systematic review findings indicate that conservative treatment for chronic LBP can be augmented by targeting contextual factors (pain beliefs; symptom expectations; treatment beliefs; TA) and positively impact pain

and function outcomes.[25] Patients and providers believe contextual factors, such as patient-provider interactions, provide beneficial therapeutic effects[26 27]; however, this is a relatively understudied area spanning the spectrum of musculoskeletal pain conditions, including LBP.[28 29] For example, provider skills, patient-centred care and organisational factors may influence patient-provider interactions during musculoskeletal care.[30]

The overall goal with this study is to gain a deeper understanding of contextual factors that are associated with manual therapy utilisation, perception and outcomes, from both patient and provider perspectives. As guided by our modified model,[19] we will consider key contextual factors related to the patient (preference, expectation, pain beliefs, pain-associated distress and prior manual therapy experiences), the provider (equipoise, expectation, pain beliefs and clinical experience), and the interaction between the two (TA).

Successful completion of this study will inform future studies planning to test the impact on how SMT is delivered to patients that could potentially advance manual therapy clinical practice by considering patient and provider level contextual factors for matching patients with providers to maximise outcomes.

METHODS AND ANALYSIS

The study protocol was approved by the University of Florida (UF) Institutional Review Board on 20 February 2024. The study protocol was registered with Clinical-Trials.gov (NCT06590116) on 06 September 2024. Enrolment of physical therapist and patient participants began on 17 December 2024 with completion anticipated for December 2025.

Study design overview

We will use a prospective, single-arm intervention study design that includes follow-up measures assessed at 2 weeks, 6 weeks, 12 weeks, 18 weeks and 26 weeks after initiation of physical therapy for LBP (figure 1). To the
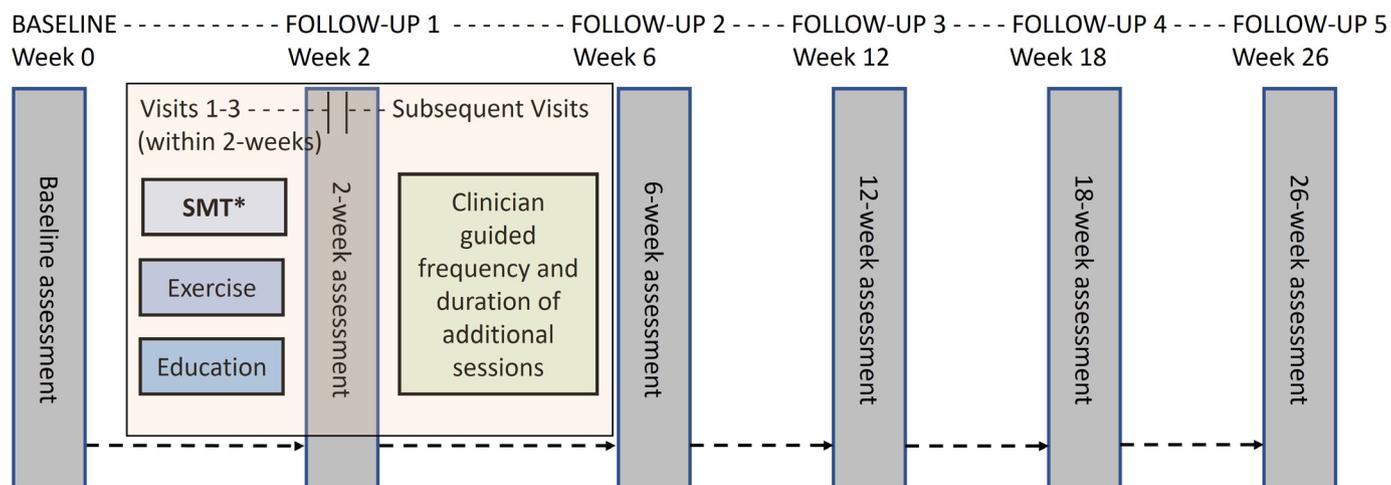
BASELINE - - - - - - - - - - - FOLLOW-UP 1 - - - - - - - - FOLLOW-UP 2 - - - - FOLLOW-UP 3 - - - - FOLLOW-UP 4 - - - - FOLLOW-UP 5
Week 0   Week 2   Week 6   Week 12   Week 18   Week 26

Figure 1 Overview of study design. *The initial three treatment sessions (requiring SMT) will occur within a 2-week period. SMT, spinal manipulative therapy.

best of our knowledge, we are not aware of any longitudinal studies that have investigated the simultaneous relationships of both physical therapist and patient-level contextual factors on clinical outcomes for patients with LBP who have received SMT. Our updated comprehensive model of the mechanisms of manual therapy provides a framework to test several clinically relevant hypotheses specifically surrounding the influence of physical therapist and patient-level factors.

Project aims

Aim 1: identify patient clinical outcome response based on Patient-Reported Outcomes Measurement Information System (PROMIS)-29 score improvement and determine characteristics of providers and patients. To identify positive patient clinical outcome response, we will use the National Institutes of Health (NIH) Task Force on Research Standards for chronic LBP recommended Impact Score that combines results of the pain intensity, physical function and pain interference PROMIS scores (nine items from the PROMIS-29). *We hypothesise patients with positive clinical outcome response (achieving ≥5-point Impact Score improvement) at 12 weeks and 26 weeks and their provider will be associated with similar: (1) high preference for SMT, (2) high expectations for SMT and (3) elevated TA scores.* Sub-Aim: Identify patient clinical outcome response based on Pain Acceptable Symptom State (PASS) to test for convergence across multiple outcome domains.

Aim 2: determine empirically derived clinical outcome trajectory subgroups at 26 weeks based on provider and patient contextual factors. *We hypothesise three empirically derived subgroups that will converge in magnitude and direction in terms of preference, expectations, pain beliefs, experience and TA.*

Settings and participants

Patient participants

Participating physical therapists will recruit patients with LBP, without contraindications to SMT. Patient participants will satisfy all eligibility criteria (box 1). Study flyers will be distributed to outpatient clinics in the Brooks

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<table>
<tr><td>Box 1   Patient eligibility criteria</td></tr>
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1. Pain between the 12th rib and buttocks with or without symptoms into one or both legs, which, in the opinion of the examiner, originate from the lumbar region.
2. Meets NIH Task Force criteria for chronic LBP.[93]
3. Age 18–70 years.
4. No prior surgery to the lumbosacral spine.
5. Not currently pregnant.
6. Not currently receiving SMT or exercise treatment for LBP from a different healthcare provider (e.g., chiropractic, massage therapy).
7. No neurogenic signs indicating radiculopathy.
8. No 'red flags' of a potentially serious condition (eg, cauda equina syndrome, fracture, cancer, infection, etc).

LBP, low back pain; NIH, National Institutes of Health; SMT, spinal manipulative therapy.

Rehabilitation system where participating physical therapists work. Interested participants will contact the research coordinator via email or telephone; potential participants will be provided with the inclusion/exclusion criteria. If potential participants deem themselves eligible, they will be provided with a secure link to complete an electronic informed consent form via REDCap (online supplemental material 1). No data are collected until the participants provide consent. All baseline and follow-up assessments will be self-report and completed electronically by the patient.

Provider participants

We will recruit 10–12 full-time physical therapists to participate in this study (5–6 will be orthopaedic manual physical therapy (OMPT) fellowship trained) that routinely provide care for patients with LBP (ie, at least 3–4 patients over the past month). Potential physical therapist participants made aware of the study through communication with investigators, UF Institutional Review Board (IRB) approved flyers and/or e-mails will contact the research team. Once contact is made, a member of the research team will determine whether the participant meets the criteria for inclusion in the study. Physical therapists meeting the criteria for participation will be scheduled for the formal consent process. At that time, the research coordinator will issue an informed consent document (online supplemental material 2), take the time to explain the study and the purposes of the study and answer any questions that the physical therapist may have. The research coordinator will take the time to make sure the subject clearly understands the procedures and risks associated with this study prior to obtaining informed consent from the physical therapist.

Intervention

With respect to manual therapy intervention, we will encourage a multimodal treatment approach of SMT, exercise and education which is consistent with professional organisation definitions of orthopaedic manual therapy and supported by recent clinical practice guidelines.[16 31 32] For the purpose of this study, we will only require SMT to be provided as an intervention during the initial three treatment sessions. The initial three treatment sessions (requiring SMT) will occur within a 2-week period. Participating providers are free to select between two SMT techniques (figures 2 and 3), both found to be effective for some individuals experiencing LBP.[33 34] All participating physical therapists will undergo a 2-hour training session to familiarise them with the protocol and receive instruction in each of the included SMT techniques. Participating physical therapists are required to demonstrate proficiency in the SMT techniques through a competency assessment including a fidelity checklist. A more pragmatic approach will be followed after the third treatment session, with providers determining the frequency and duration of additional treatment sessions for their individual patients. To control for differences

Figure 2 Supine spinal manipulative therapy technique.

in treatment approaches, participating providers will complete a treatment log following each intervention session specifying the type and dosage of SMT, exercise and education.

Procedures for baseline and follow-up assessments

Assessment data will be collected from physical therapists and patients with Research Electronic Data Capture (REDCap), an NIH-supported, browser-based, software solution that allows for creation of a secure online platform for data capture, management and analysis. At each assessment time point, participants will input data directly into REDCap. If a participant is unable to input data using a computer, paper forms will be available, and data will be uploaded by the research coordinator. Data collection and measures are described in greater detail in table 1.

Demographic and clinical data
Providers

Physical therapists will complete a standard intake form at initial evaluation. Demographic data collected will include age, sex, gender, race and ethnicity. Physical

therapist clinical experience data are described below in the Contextual factor measures section.

Patients

Patient participants will complete a standard intake form at initial evaluation. Demographic data collected will include age, sex, gender, race, ethnicity, household income, education, current employment status and current medical insurance provider. Patient healthcare experience data are described below in the Contextual factor measures section.

Contextual factor measures (both providers and patients)
Equipoise and preference

Patient preferences for intervention are an essential component of patient-centred care and the evidence-based practice framework used to guide clinical decisions.[35 36] For example, patient preferences are frequently included in clinical practice guideline development.[37] Participants assigned to their preferred intervention often experience better outcomes than those not receiving their preferred intervention.[38 39] Also, simply providing treatment options and allowing patients to make a choice may result
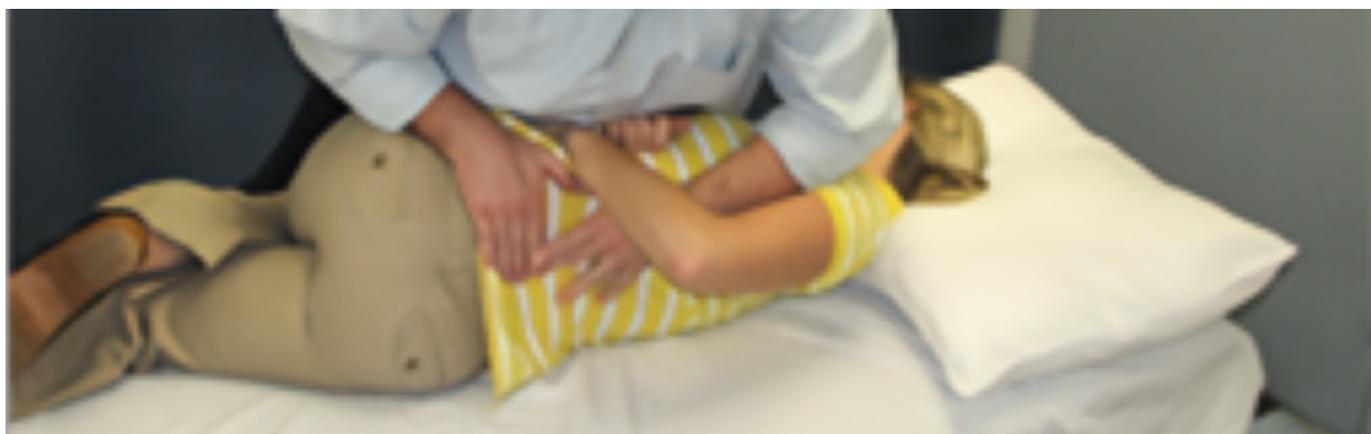

Figure 3 Sidelying spinal manipulative therapy technique.

Table 1 Study variables, measures and data collection assessment points

Contextual factor	Measure	Baseline	2 weeks*	6 weeks*	12 weeks	18 weeks*	26 weeks
Provider level							
Demographics	-	X					
Equipoise	LBP-TBQ	X	X				
Expectation	CEQ	X	X				
Pain beliefs	Back-PAQ	X	X				
Clinical experience	Demographic questionnaire	X					
Therapeutic alliance	WAI-SR-T		X	X			
Patient level							
Demographics	-	X					
Opioid use	Single question	X					
Preference	LBP-TBQ	X	X				
Expectation	CEQ	X	X				
Pain beliefs	Back-PAQ	X	X				
Distress and resilience	OSPRO-YF	X	X	X	X		
Prior healthcare experience	Demographic questionnaire	X					
Therapeutic alliance	WAI-SR		X	X			
Clinical outcomes							
Multiple health domains	PROMIS-29†	X	X	X	X	X	X
Patient satisfaction	PASS	X	X	X	X	X	X

*Data collection at 2 weeks, 6 weeks and 18 weeks, necessary for determining empirically derived SMT outcome trajectory subgroups at 26 weeks based on clinician and patient contextual factors (relevant to specific aim 2).

†To identify positive patient clinical outcome response at 12 weeks and 26 weeks, we will use the NIH Task Force on Research Standards for chronic LBP recommended Impact Score that combines results of the pain intensity, physical function and pain interference PROMIS scores (nine items from the PROMIS-29).

Back-PAQ, Back Pain Attitudes Questionnaire; CEQ, Credibility-Expectancy Questionnaire; LBP-TBQ, Low Back Pain Treatment Beliefs Questionnaire; NIH, National Institutes of Health; OSPRO-YF, Optimal Screening for Prediction of Referral and Outcome Yellow Flag Tool; PASS, Patient Acceptable Symptom State; PROMIS, Patient-Reported Outcomes Measurement Information System; SMT, spinal manipulative therapy; WAI-SR, Working Alliance Inventory – Short Revised (client version); WAI-SR-T, Working Alliance Inventory – Short Revised (therapist version).

in benefits for some patients experiencing pain. This is supported by a systematic review and meta-analysis of the effects of preference in randomised controlled trials[39] as well as the placebo literature.[40 41] Therapeutic preferences or clinical equipoise also influence the treatment choices of providers. For example, manual therapists are more likely to manage patients in ways they believe are effective.[42] Further, secondary analyses of two clinical trials of manual therapy[43 44] showed patient outcomes were more dependent on provider preference for interventions than on the actual interventions provided.

The Low Back Pain Treatment Beliefs Questionnaire (LBP-TBQ) will assess physical therapist equipoise and patient preference for SMT.[45] The LBP-TBQ 4-item version includes one item representing each subscale (perceived credibility, effectiveness, concerns and individual fit) with each item using a 5-point Likert scale (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree). Scores range from (1–5) with higher scores representing positive beliefs about the LBP treatment. The LBP-TBQ is presented with respect

to four treatments (pain medication, exercise, manual therapy and acupuncture) based on UK National Institute for Health and Care Excellence guidelines within the context of UK clinical practice. Authors acknowledge these definitions may need to be modified for different purposes in future research involving other contexts.[45] Therefore, for the purpose of this study conducted in US outpatient physical therapy, treatment options were modified based on updated physical therapy clinical practice guidelines for LBP.[16] Clinicians completed the LBP-TBQ at baseline, on enrolling in the study, in reference to their 'typical patient with LBP'. They then completed additional copies of the LBP-TBQ for each of their patient participants enrolled in the study in reference to that patient specifically. This ensured that therapists' beliefs about SMT were captured with respect to the population, as well as each individual patient specifically.

Expectation
Expectations represent contextual factors with prognostic value for outcomes in individuals with musculoskeletal

pain.[46 47] Specific to this study: (1) expectations are a prognostic factor for individuals receiving manual therapy for musculoskeletal pain complaints[48–50]; (2) expectations specific to manual therapy are modifiable[51–54]; and (3) changes in expectations influence outcomes associated with manual therapy.[51 52 54 55] Provider expectations are associated with outcomes in clinical care.[56 57] Specific to manual therapy, provider outcome expectancies for patients with LBP receiving physical therapy, osteopathy or acupuncture are a significant predictor in improved disability over the course of treatment.[58]

The Credibility-Expectancy Questionnaire (CEQ) will assess physical therapist and patient credibility and expectancy of SMT.[59] The CEQ consists of 6 items with three items related to credibility (how logical therapy offered seems) and three items related to expectancy (expectations for treatment to reduce symptoms). Item response options use a 9-point scale except for two of the expectancy items (11-point percentage scale). Ratings from the 11-point items have previously been transformed to a 9-point scale prior to analysis for obtaining credibility (3 items, possible range: 3–27) and expectancy (3 items, possible range: 3–27) scores.[60 61] Two-factor structure of the CEQ has been supported in previous musculoskeletal pain samples, with CEQ scores predicting several outcome domains.[60] For the purpose of this study, modifications to the CEQ for patients and providers include replacing 'therapy' and 'treatment' with spinal manipulation. Modifications for providers will also include replacing 'you' and 'your' with reference to their specific patient.

Pain beliefs

Recent systematic review findings indicate conservative treatment for chronic LBP can be augmented by targeting contextual factors, including patient pain and treatment beliefs to positively impact pain and function outcomes.[25] Systematic review findings provide evidence that healthcare provider beliefs about back pain are associated with the beliefs of their patients. There is moderate evidence that providers with a biomedical treatment orientation are more likely to advise patients to limit work and physical activities and less likely to adhere to treatment guidelines.[62 63] Cross-sectional findings indicate provider attitudes and beliefs about LBP influence clinical decisions and advice.[64] Specifically, optimistic beliefs were more frequent among physical therapists with fewer years of clinical experience, while pessimistic beliefs were associated with treatment and advice involving back protection, avoidance of movement and passive treatment strategies.[64] In previous work, predominant biomedical to biopsychosocial shifts were observed in physical therapist attitudes and beliefs that were associated with greater improvement in patient clinical outcomes at 4 weeks, compared with patients receiving care from physical therapists where attitudes and beliefs were stable.[65]

The Back Pain Attitudes Questionnaire (Back-PAQ) (10-item version) will assess physical therapist and patient beliefs about back pain.[66 67] The Back-PAQ contains five two-item components: vulnerability of the back (items 1 and 2); relationship between back pain and injury (items 3 and 4); activity participation during back pain (items 5 and 6); psychological influences on back pain (items 7 and 8); prognosis of back pain (items 9 and 10). Responses are scored on a 5-point Likert scale from −2 ('true') to +2 ('false') with total score ranges from −20 to +20 (items 6, 7 and 8 are reversed for calculation). More negative scores indicate beliefs that are unhelpful to recovery. The Back-PAQ has been recommended for people with back pain and healthcare professionals for direct comparison of beliefs between groups.[66]

Distress and resilience (only patients)

Psychological factors, including pain-associated distress, can influence LBP, disability and response to treatment through different mechanisms.[68] For example, recent systematic review and meta-analysis findings indicate that pain-related fear, pain catastrophising and anticipated pain are consistently and negatively associated with maximal physical performance in people with chronic LBP; however, pain self-efficacy demonstrated a positive relationship.[69] There is a research gap with respect to the influence pain-associated distress has on SMT outcomes. Therefore, it is not surprising that an increased understanding of the complex role of psychological factors, related to both evaluation and treatment effect, has been recently recommended as high priority to facilitate the needed paradigm shift in orthopaedic manual therapy education.[70]

The Optimal Screening for Prediction of Referral and Outcome Yellow Flag Tool (OSPRO-YF) is a multidimensional screening tool used for assessment of pain-related psychological characteristics for individuals with musculoskeletal pain conditions.[71] The OSPRO-YF evaluates discrete pain-related psychological characteristics across three constructs: (1) negative mood (anxiety, depression and anger); (2) fear-avoidance (pain catastrophising, fear avoidance (work and physical activity), pain anxiety and kinesiophobia); and (3) positive affect/coping (pain self-efficacy, self-efficacy for rehabilitation and pain acceptance). The yellow flag count method will be used to score the OSPRO-YF Tool for pragmatic purposes, as previous results found no scoring method (simple summary score or yellow flag count) effect on predictive accuracy.[72] Higher OSPRO-YF yellow flag counts indicate higher psychological distress as evidenced by higher pain vulnerability and lower pain resilience. For this study, we will use the 10-item version of the OSPRO-YF Tool, which was found to be 81% accurate at predicting full-length psychological questionnaire scores.[71] Previous studies found that repeated assessment of the OSPRO-YF Tool beyond baseline assessment alone improved prediction accuracy for pain and disability outcomes.[72 73]

Experience

Placebo analgesia is dependent on learning.[74–78] Specifically, placebo analgesia is achieved through verbal

instruction, observation and conditioning.[74 78] For example, a study conditioned healthy participants to either a positive pain-relieving response using a placebo patch (surreptitiously lowered the painful stimulus) or a negative pain-relieving response (maintaining the intensity of the stimulus).[79] Following 2 days of conditioning trials, the participants were brought back on a third day and received a placebo cream (different intervention). Participants conditioned to the positive experience with the placebo patch experienced greater relief to the placebo cream than those experiencing a negative experience to the placebo patch.[79] Therapist experience may influence outcomes as well. For example, fellowship-trained physical therapists achieved better outcomes in their patients with musculoskeletal pain than those without fellowship training.[80] Further, physical therapists who were certified as orthopaedic specialists achieved similar outcomes in fewer visits and at a lower cost than therapists without specialty certification.[81]

Provider and patient experience will be assessed separately as described below. The provider demographics questionnaire will include items to assess physical therapist clinical experience (years of clinical experience, post-professional training, including residency and fellowship status and SMT utilisation for patients with chronic LBP). Provider experience is not an inclusion or exclusion criterion as it will be assessed as a contextual factor. The patient demographics questionnaire will include items to assess patient healthcare experience (prior experiences and healthcare utilisation for LBP, including SMT).

Therapeutic alliance

TA is a contextual factor described as the working rapport or positive social connection between patient and provider.[82 83] Originally described by Bordin,[84] TA is established through multiple components including patient-provider: (1) agreement on treatment goals, (2) agreement on tasks required to accomplish goals and (3) personal bonding based on positive reciprocal feelings. TA has been extensively studied in psychotherapy settings[85 86]; however, not thoroughly investigated during routine clinical practice in outpatient physical therapy. Systematic review results provide support for TA as an important contributor to musculoskeletal pain-related clinical outcomes in physical therapy settings.[29 87] Additional support for the impact of TA in physical therapy practice is provided by TA as a predictor of functional outcomes and a consistent relationship among patient and physical therapist factors with TA specifically observed in a cohort of individuals with LBP.[20 88] The impact of TA may be particularly relevant for patients with LBP in physical therapy settings because of the extended interactions between physical therapists and patients over an episode of care. Additionally, communication is imperative in the context of a condition usually lacking specific pathological aetiology and requiring frequent use of touch during both assessments and manual therapy interventions.[23 89]

The Working Alliance Inventory – Short Revised (WAI-SR) (therapist version) will assess TA from the physical therapist perspective.[90] The WAI-SR (client version) will assess TA from the patient perspective.[91] Both 12-item versions of the WAI-SR provide subscale scores for Goal, Task and Bond dimensions of TA. Each item is scored from 1 ('never') to 5 ('always') resulting in subscale scores ranging from 4 to 20, with higher scores indicating greater TA. Subscale scores are summed to provide a total score (range: 12–60).

Patient primary clinical outcome measures

The primary outcome for this study will be both the PROMIS-29 V.2.1 and the NIH Task Force on Research Standards for chronic LBP recommended Impact Score. The rationale for including both as primary outcomes is that PROMIS-29 V.2.1 scores are used to calculate the NIH Task Force on Research Standards for chronic LBP recommended Impact Score as described below.

PROMIS-29

The PROMIS-29 V.2.1 profile will assess pain intensity using a single item and seven health domains (physical function, fatigue, pain interference, depressive symptoms, anxiety, ability to participate in social roles and activities and sleep disturbance) using four items per domain.[92] The single item assessing pain intensity is measured using a 0 to 10 numerical rating scale with 0 = 'No pain' and 10 = 'Worst pain imaginable.' The remaining 28 items ask respondents to rate the symptom or item using 1–5 Likert scales.

NIH chronic LBP Impact Score

To identify positive patient clinical outcome response at 12 weeks and 26 weeks, we will use the NIH Task Force on Research Standards for chronic LBP recommended Impact Score that combines results of the pain intensity, physical function and pain interference PROMIS scores (nine items from the PROMIS-29).[93] Impact Score calculation requires reversing the usual scoring scale of physical function items so that (1) represents (least severe) and (5) represents (most severe). Impact Scores are then calculated as *(reversed raw physical function score + raw pain interference score + pain intensity score)* with a potential score range from 8 (least impact) to 50 (greatest impact). For this study, positive patient clinical outcome response will be operationally defined as participants achieving ≥5-point improvement on the NIH Task Force on Research Standards for chronic LBP recommended Impact Score. Our rationale for this approach is twofold: (1) ≥3-point improvement in NIH Impact Score[94] and (2) ≥5-point improvement in each respective PROMIS-29 subscale[95] have both been suggested to be clinically important.

Patient secondary clinical outcome measure

The secondary outcome for this study will be the PASS as described below.

Patient Acceptable Symptom State

The PASS is a self-report, single item question asking: *'Taking into account the many ways your pain affects your daily life, if you were to remain for the next few months as you are now, would you consider your current state to be satisfactory?'* with response options being 'Yes' or 'No'.[96–98] PASS is perhaps more aligned with recovery as it reflects the highest level of symptom beyond which a patient considers their condition to be satisfactory. Despite binary response options, PASS is a relevant patient perceived metric for clinical outcome, as it reflects the patient's perception of achieving well-being (*feeling good*) instead of achieving a benchmark for clinical improvement (*feeling better*).[96]

Data collection methods

All study-related data will be collected through REDCap. The option of completing hard copy questionnaires will also be provided to patients who do not have access to the internet or prefer alternative data collection methods. Patients will be provided with a single prorated gift card after a 6-month follow-up (ie, patients completing assessments at all time points will receive US$50.00) for time completing questionnaires and as an unconditional incentive.

Data security

The UF has a secure, Health Insurance Portability and Accountability Act (HIPAA) and IRB compliant customised REDCap data capture and storage platform adapted for clinical and research use at UF and external enrolment locations at Brooks Rehabilitation. Clinician and patient-reported data is entered by participants at home or on-site via a secure web-based portal outside of clinic visits. Patient level data may also be captured in clinic by tablet computers provided by the study clinicians; however, clinicians will not have access to patient-level data. All electronic data collected for research purposes will be stored in UF's secure REDCap system. If hard copy questionnaire data are captured as per patient preference, hard copies will be stored in secured and locked file cabinets located at clinic sites until retired by the study team.

Statistical analysis plan

Prior to analysing research hypotheses, descriptive statistics will be provided for all baseline demographic and contextual factor measures across the overall sample and for providers and patients specifically. Continuous variables will be reported using mean and SD estimates, while categorical variables will be reported using frequency counts and percentages.

For specific aim 1, to identify positive patient clinical outcome response at 12 weeks and 26 weeks, we will use the NIH Task Force on Research Standards for chronic LBP recommended Impact Score that combines results of the pain intensity, physical function and pain interference PROMIS scores (nine items from the PROMIS-29). Those with positive patient clinical outcome response will be operationally defined as participants achieving ≥5-point improvement on the NIH Task Force on Research Standards for chronic LBP recommended Impact Score.[94 95] We will use a hierarchical logistic regression model to compare those with positive and negative clinical outcome response with regards to patient and provider contextual factors: preference, expectation, pain beliefs, distress and resilience, experience and TA scores. In this statistical model, the responder status is considered as the outcome and patients will be nested (or clustered) within provider. Clinical level measures including demographic data will be included in the logistic regression model as covariates. In our study design, our team will take all appropriate measures to reduce missing data. In the case with missing data, we will use multiple imputation methods to address the presence of missing data.

For specific aim 2, we will use the longitudinal cluster analysis method based on the shapes of each trajectory of the longitudinal clinical outcome measures (PROMIS-29 and NIH Impact Score). This model will be fitted by R software packages, such as kmlShape.[99] We expect the subgroups from the longitudinal clustering model to be able to predict patient clinical outcome response.

Sample size justification

For this proposed single-arm treatment study and based on our pilot data, to detect the correlation between pain score change and expectation change of 0.35, we need 72 patients. A total of 90 patients are needed to account for a 20% drop-out. The change was calculated as the difference of the score at week 4 from baseline. Our pilot data show the correlation could be as high as 0.5, but that value may not be stable as the sample size was small. No formal sample size justification was conducted for providers.

DISCUSSION

Findings from this study have the potential to inform clinical decision making that supports a personalised approach to providing manual therapy interventions based on contextual factors associated with physical therapists and patients. To advance this line of research, there is a need for improved understanding about contextual factors that are associated with manual therapy utilisation, perception and outcomes, from both provider and patient perspectives. Results from this study will distinguish between modifiable and non-modifiable contextual factors that are associated with clinical outcomes for patients who have received SMT that can inform which contextual factors might require special emphasis as part of OMPT fellowship training. Collectively, the influence of the healthcare provider administering the intervention is not typically considered in rehabilitation literature and in clinical practice. The likelihood of successful outcomes in response to interaction with an individual provider (regardless of intervention) compared with a more beneficial intervention response when administered by one provider compared with another represents a real and

current gap in clinical practice. Results from this study would provide opportunities for future studies to investigate the feasibility and effectiveness of matching patients with providers that share similar attributes versus typical scheduling assignment. Alternatively, results from this study can be used for future studies that investigate the targeting of modifiable provider and patient-level contextual factors to optimise SMT outcomes.

There are several strengths to this study. Our prior model describing mechanisms of manual therapy-related pain inhibition guided planning of this study.[18 19] Further, the study is designed to empirically test our model. Both patient and physical therapist attitudes, beliefs and perspectives will be assessed in this study using previously validated measures. Physical therapist data will be collected on two levels: (1) based on their general perspectives and (2) based on their specific perspectives related to an individual patient. We will include an equal distribution of physical therapists who have and do not have advanced training in manual therapy to account for any potential bias towards SMT.

There are several limitations in the design of this study that need to be acknowledged. Physical therapists are the only healthcare providers that will be enrolled in this study; therefore, results may not be generalisable to other healthcare disciplines that commonly provide SMT for patients with LBP (eg, chiropractors or osteopathic physicians). This study will not randomise patient or physical therapist participants to different treatment groups. There is potential that patients may not complete the consent process and intake assessment prior to the initial physical therapy treatment session; therefore, the initial three treatment sessions (requiring SMT) will occur within a 2-week period, and we will monitor for any deviations. We acknowledge that SMT is not the only intervention being provided to patient participants, which may influence clinical outcomes. Therefore, our methods include a minimum number of initial treatment sessions (n=3) that require SMT to be provided, while also allowing physical therapists to provide treatment based on clinical expertise and judgement. We believe this approach and recommendations for subsequent treatment sessions are consistent with recent clinical practice guidelines for LBP and broad definition of orthopaedic manual therapy.[16 32] We also acknowledge that this study will not be sufficiently powered to test for statistical interactions between physical therapist and patient contextual factors which may impact how results are interpreted. Therefore, we plan to conduct future exploratory analyses at the completion of the study that may be used to inform future study planning.

ETHICS AND DISSEMINATION

Ethics approval for the study was obtained from the UF Institutional Review Board. Informed consent is required for physical therapist and patient participant enrolment in this project. The results of this study will be disseminated at professional scientific conferences and submitted for publication in peer-reviewed journals.

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REFERENCES
1 Mokdad AH, Ballestros K, Echko M, *et al*. The State of US Health, 1990-2016: Burden of Diseases, Injuries, and Risk Factors Among US States. *JAMA* 2018;319:1444–72.
2 Wu A, March L, Zheng X, *et al*. Global low back pain prevalence and years lived with disability from 1990 to 2017: estimates from the Global Burden of Disease Study 2017. *Ann Transl Med* 2020;8:299.
3 Dieleman JL, Cao J, Chapin A, *et al*. US Health Care Spending by Payer and Health Condition, 1996-2016. *JAMA* 2020;323:863–84.
4 Qaseem A, Wilt TJ, McLean RM, *et al*. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med* 2017;166:514–30.
5 *WHO guideline for non-surgical management of chronic primary low back pain in adults in primary and community care settings*. Geneva: World Health Organization, 2023.
6 Hurwitz EL. Epidemiology: Spinal manipulation utilization. *J Electromyogr Kinesiol* 2012;22:648–54.

7 Aickin M, McCaffery A, Pugh G, *et al*. Description of a clinical stream of back-pain patients based on electronic medical records. *Complement Ther Clin Pract* 2013;19:158–76.

8 Carlesso LC, MacDermid JC, Gross AR, *et al*. Treatment preferences amongst physical therapists and chiropractors for the management of neck pain: results of an international survey. *Chiropr Man Therap* 2014;22:11.

9 Sherman KJ, Cherkin DC, Deyo RA, *et al*. The diagnosis and treatment of chronic back pain by acupuncturists, chiropractors, and massage therapists. *Clin J Pain* 2006;22:227–34.

10 Human Services. Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations, 2019. Available: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html

11 Edwards RR, Dworkin RH, Turk DC, *et al*. Patient phenotyping in clinical trials of chronic pain treatments: IMMPACT recommendations. *Pain* 2016;157:1851–71.

12 Hancock MJ, Hill JC. Are Small Effects for Back Pain Interventions Really Surprising? *J Orthop Sports Phys Ther* 2016;46:317–9.

13 Cruz-Almeida Y, Fillingim RB. Can Quantitative Sensory Testing Move Us Closer to Mechanism-Based Pain Management? *Pain Med* 2014;15:61–72.

14 Granovsky Y, Yarnitsky D. Personalized pain medicine: the clinical value of psychophysical assessment of pain modulation profile. *Rambam Maimonides Med J* 2013;4:e0024.

15 Clauw DJ. Diagnosing and treating chronic musculoskeletal pain based on the underlying mechanism(s). *Best Pract Res Clin Rheumatol* 2015;29:6–19.

16 George SZ, Fritz JM, Silfies SP, *et al*. Interventions for the Management of Acute and Chronic Low Back Pain: Revision 2021. Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability and Health From the Academy of Orthopaedic Physical Therapy of the American Physical Therapy Association. *J Orthop Sports Phys Ther* 2021;51.

17 Oliveira CB, Maher CG, Pinto RZ, *et al*. Clinical practice guidelines for the management of non-specific low back pain in primary care: an updated overview. *Eur Spine J* 2018;27:2791–803.

18 Bialosky JE, Bishop MD, Price DD, *et al*. The mechanisms of manual therapy in the treatment of musculoskeletal pain: a comprehensive model. *Man Ther* 2009;14:531–8.

19 Bialosky JE, Beneciuk JM, Bishop MD, *et al*. Unraveling the Mechanisms of Manual Therapy: Modeling an Approach. *J Orthop Sports Phys Ther* 2018;48:8–18.

20 Beneciuk JM, Brown-Taylor L, Alodaibi F, *et al*. Patient- and Physical Therapist-Level Predictors of Patient-Reported Therapeutic Alliance: An Observational, Exploratory Study of Cohorts With Knee and Low Back Pain. *Arch Phys Med Rehabil* 2021;102:2335–42.

21 Rossettini G, Camerone EM, Carlino E, *et al*. Context matters: the psychoneurobiological determinants of placebo, nocebo and context-related effects in physiotherapy. *Arch Physiother* 2020;10:11.

22 Rossettini G, Carlino E, Testa M. Clinical relevance of contextual factors as triggers of placebo and nocebo effects in musculoskeletal pain. *BMC Musculoskelet Disord* 2018;19:27.

23 Testa M, Rossettini G. Enhance placebo, avoid nocebo: How contextual factors affect physiotherapy outcomes. *Man Ther* 2016;24:65–74.

24 Cook CE, Bailliard A, Bent JA, *et al*. An international consensus definition for contextual factors: findings from a nominal group technique. *Front Psychol* 2023;14:1178560.

25 Sherriff B, Clark C, Killingback C, *et al*. Impact of contextual factors on patient outcomes following conservative low back pain treatment: systematic review. *Chiropr Man Therap* 2022;30:20.

26 Rossettini G, Palese A, Geri T, *et al*. Physical therapists' perspectives on using contextual factors in clinical practice: Findings from an Italian national survey. *PLoS One* 2018;13:e0208159.

27 Rossettini G, Palese A, Geri T, *et al*. The Knowledge of Contextual Factors as Triggers of Placebo and Nocebo Effects in Patients With Musculoskeletal Pain: Findings From a National Survey. *Front Psychiatry* 2019;10:478.

28 Babatunde F, MacDermid J, MacIntyre N. Characteristics of therapeutic alliance in musculoskeletal physiotherapy and occupational therapy practice: a scoping review of the literature. *BMC Health Serv Res* 2017;17:375.

29 Taccolini Manzoni AC, Bastos de Oliveira NT, Nunes Cabral CM, *et al*. The role of the therapeutic alliance on pain relief in musculoskeletal rehabilitation: A systematic review. *Physiother Theory Pract* 2018;34:901–15.

30 O'Keeffe M, Cullinane P, Hurley J, *et al*. What Influences Patient-Therapist Interactions in Musculoskeletal Physical Therapy? Qualitative Systematic Review and Meta-Synthesis. *Phys Ther* 2016;96:609–22.

31 Orthopaedic Manual Physical Therapy (OMPT) Definition. IFOMPT: OMPT Definition, Available: https://www.ifompt.org/About+IFOMPT/OMPT+Definition.html

32 Silvernail JL, Deyle GD, Jensen GM, *et al*. Orthopaedic Manual Physical Therapy: A Modern Definition and Description. *Phys Ther* 2024;104:pzae036.

33 Childs JD, Fritz JM, Flynn TW, *et al*. A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: a validation study. *Ann Intern Med* 2004;141:920–8.

34 Cleland JA, Fritz JM, Kulig K, *et al*. Comparison of the Effectiveness of Three Manual Physical Therapy Techniques in a Subgroup of Patients With Low Back Pain Who Satisfy a Clinical Prediction Rule. *Spine (Phila Pa 1986)* 2009;34:2720–9.

35 Sackett DL, Rosenberg WM, Gray JA, *et al*. Evidence based medicine: what it is and what it isn't. *BMJ* 1996;312:71–2.

36 Haynes B. *Evidence-based medicine: how to practice and teach it*. London: Churchill Livingston, 2010.

37 Boivin A, Green J, van der Meulen J, *et al*. Why consider patients' preferences? A discourse analysis of clinical practice guideline developers. *Med Care* 2009;47:908–15.

38 Preference Collaborative Review Group. Patients' preferences within randomised trials: systematic review and patient level meta-analysis. *BMJ* 2008;337:a1864.

39 Delevry D, Le QA. Effect of Treatment Preference in Randomized Controlled Trials: Systematic Review of the Literature and Meta-Analysis. *Patient* 2019;12:593–609.

40 Geers AL, Rose JP, Fowler SL, *et al*. Why does choice enhance treatment effectiveness? Using placebo treatments to demonstrate the role of personal control. *J Pers Soc Psychol* 2013;105:549–66.

41 Rokke PD, al Absi M, Lall R, *et al*. When does a choice of coping strategies help? The interaction of choice and locus of control. *J Behav Med* 1991;14:491–504.

42 Boulanger K, Campo S. Are personal characteristics of massage therapists associated with their clinical, educational, and interpersonal behaviors? *Int J Ther Massage Bodywork* 2013;6:25–34.

43 Bishop MD, Bialosky JE, Penza CW, *et al*. The influence of clinical equipoise and patient preferences on outcomes of conservative manual interventions for spinal pain: an experimental study. *J Pain Res* 2017;10:965–72.

44 Cook C, Learman K, Showalter C, *et al*. Early use of thrust manipulation versus non-thrust manipulation: A randomized clinical trial. *Man Ther* 2013;18:191–8.

45 Dima A, Lewith GT, Little P, *et al*. Patients' treatment beliefs in low back pain: development and validation of a questionnaire in primary care. *Pain* 2015;156:1489–500.

46 Hayden JA, Wilson MN, Riley RD, *et al*. Individual recovery expectations and prognosis of outcomes in non-specific low back pain: prognostic factor review. *Cochrane Database Syst Rev* 2019;2019:CD011284.

47 Wassinger CA, Edwards DC, Bourassa M, *et al*. The Role of Patient Recovery Expectations in the Outcomes of Physical Therapist Intervention: A Systematic Review. *Phys Ther* 2022;102:pzac008.

48 Bishop MD, Bialosky JE, Cleland JA. Patient expectations of benefit from common interventions for low back pain and effects on outcome: secondary analysis of a clinical trial of manual therapy interventions. *J Man Manip Ther* 2011;19:20–5.

49 Bishop MD, Mintken PE, Bialosky JE, *et al*. Patient expectations of benefit from interventions for neck pain and resulting influence on outcomes. *J Orthop Sports Phys Ther* 2013;43:457–65.

50 Palmlöf L, Holm LW, Alfredsson L, *et al*. Expectations of recovery: A prognostic factor in patients with neck pain undergoing manual therapy treatment. *Eur J Pain* 2016;20:1384–91.

51 Bialosky JE, Bishop MD, Robinson ME, *et al*. The influence of expectation on spinal manipulation induced hypoalgesia: an experimental study in normal subjects. *BMC Musculoskelet Disord* 2008;9:19.

52 Bialosky JE, George SZ, Horn ME, *et al*. Spinal manipulative therapy-specific changes in pain sensitivity in individuals with low back pain (NCT01168999). *J Pain* 2014;15:136–48.

53 Riley SP, Bialosky J, Cote MP, *et al*. Thoracic spinal manipulation for musculoskeletal shoulder pain: Can an instructional set change patient expectation and outcome? *Man Ther* 2015;20:469–74.

54 Wilson AT, Bishop MD, Beneciuk JM, *et al*. Expectations affect pain sensitivity changes during massage. *J Man Manip Ther* 2023;31:84–92.

55 Malfliet A, Lluch Girbés E, Pecos-Martín D, *et al*. The Influence of Treatment Expectations on Clinical Outcomes and Cortisol Levels in Patients With Chronic Neck Pain: An Experimental Study. *Pain Pract* 2019;19:370–81.

56 Kapoor S, Shaw WS, Pransky G, *et al*. Initial Patient and Clinician Expectations of Return to Work After Acute Onset of Work-Related Low Back Pain. *J Occup Environ Med* 2006;48:1173–80.

57 Witt CM, Martins F, Willich SN, *et al*. Can I help you? Physicians' expectations as predictor for treatment outcome. *Europ J Pain (London)* 2012;16:1455–66.

58 Bishop F, Al-Abbadey M, Roberts L, *et al*. Direct and mediated effects of treatment context on low back pain outcome: a prospective cohort study. *BMJ Open* 2021;11:e044831.

59 Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry* 2000;31:73–86.

60 Smeets RJEM, Beelen S, Goossens MEJB, *et al*. Treatment expectancy and credibility are associated with the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. *Clin J Pain* 2008;24:305–15.

61 Salsich GB, Yemm B, Steger-May K, *et al*. A feasibility study of a novel, task-specific movement training intervention for women with patellofemoral pain. *Clin Rehabil* 2018;32:179–90.

62 Darlow B, Fullen BM, Dean S, *et al*. The association between health care professional attitudes and beliefs and the attitudes and beliefs, clinical management, and outcomes of patients with low back pain: a systematic review. *Eur J Pain* 2012;16:3–17.

63 Gardner T, Refshauge K, Smith L, *et al*. Physiotherapists' beliefs and attitudes influence clinical practice in chronic low back pain: a systematic review of quantitative and qualitative studies. *J Physiother* 2017;63:132–43.

64 Christe G, Nzamba J, Desarzens L, *et al*. Physiotherapists' attitudes and beliefs about low back pain influence their clinical decisions and advice. *Musculoskelet Sci Pract* 2021;53:S2468-7812(21)00066-7.

65 Beneciuk JM, George SZ. Pragmatic Implementation of a Stratified Primary Care Model for Low Back Pain Management in Outpatient Physical Therapy Settings: Two-Phase, Sequential Preliminary Study. *Phys Ther* 2015;95:1120–34.

66 Darlow B, Perry M, Mathieson F, *et al*. The development and exploratory analysis of the Back Pain Attitudes Questionnaire (Back-PAQ). *BMJ Open* 2014;4:e005251.

67 Moran RW, Rushworth WM, Mason J. Investigation of four self-report instruments (FABT, TSK-HC, Back-PAQ, HC-PAIRS) to measure healthcare practitioners' attitudes and beliefs toward low back pain: Reliability, convergent validity and survey of New Zealand osteopaths and manipulative physiotherapists. *Musculoskelet Sci Pract* 2017;32:44–50.

68 Hill JC, Fritz JM. Psychosocial influences on low back pain, disability, and response to treatment. *Phys Ther* 2011;91:712–21.

69 Matheve T, Janssens L, Goossens N, *et al*. The Relationship Between Pain-Related Psychological Factors and Maximal Physical Performance in Low Back Pain: A Systematic Review and Meta-Analysis. *J Pain* 2022;23:2036–51.

70 Keter D, Griswold D, Learman K, *et al*. Priorities in updating training paradigms in orthopedic manual therapy: an international Delphi study. *J Educ Eval Health Prof* 2023;20:4.

71 Lentz TA, Beneciuk JM, Bialosky JE, *et al*. Development of a Yellow Flag Assessment Tool for Orthopaedic Physical Therapists: Results From the Optimal Screening for Prediction of Referral and Outcome (OSPRO) Cohort. *J Orthop Sports Phys Ther* 2016;46:327–43.

72 George SZ, Li C, Luo S, *et al*. Longitudinal Monitoring of Pain Associated Distress With the Optimal Screening for Prediction of Referral and Outcome Yellow Flag Tool: Predicting Reduction in Pain Intensity and Disability. *Arch Phys Med Rehabil* 2020;101:1763–70.

73 George SZ, Beneciuk JM, Lentz TA, *et al*. Optimal Screening for Prediction of Referral and Outcome (OSPRO) for Musculoskeletal Pain Conditions: Results From the Validation Cohort. *J Orthop Sports Phys Ther* 2018;48:460–75.

74 Bajcar EA, Bąbel P. How Does Observational Learning Produce Placebo Effects? A Model Integrating Research Findings. *Front Psychol* 2018;9:2041.

75 Colloca L. Placebo, nocebo, and learning mechanisms. *Handb Exp Pharmacol* 2014;225:17–35.

76 Colloca L, Miller FG. How placebo responses are formed: a learning perspective. *Philos Trans R Soc Lond B Biol Sci* 2011;366:1859–69.

77 Colloca L, Sigaudo M, Benedetti F. The role of learning in nocebo and placebo effects. *Pain* 2008;136:211–8.

78 Peerdeman KJ, van Laarhoven AIM, Peters ML, *et al*. An Integrative Review of the Influence of Expectancies on Pain. *Front Psychol* 2016;7:1270.

79 Kessner S, Forkmann K, Ritter C, *et al*. The effect of treatment history on therapeutic outcome: psychological and neurobiological underpinnings. *PLoS One* 2014;9:e109014.

80 Rodeghero J, Wang Y-C, Flynn T, *et al*. The impact of physical therapy residency or fellowship education on clinical outcomes for patients with musculoskeletal conditions. *J Orthop Sports Phys Ther* 2015;45:86–96.

81 Hart DL, Dobrzykowski EA. Influence of orthopaedic clinical specialist certification on clinical outcomes. *J Orthop Sports Phys Ther* 2000;30:183–93.

82 Joyce AS, Ogrodniczuk JS, Piper WE, *et al*. The alliance as mediator of expectancy effects in short-term individual therapy. *J Consult Clin Psychol* 2003;71:672–9.

83 Fuentes J, Armijo-Olivo S, Funabashi M, *et al*. Enhanced therapeutic alliance modulates pain intensity and muscle pain sensitivity in patients with chronic low back pain: an experimental controlled study. *Phys Ther* 2014;94:477–89.

84 Bordin ES. The generalizability of the psychoanalytic concept of the working alliance. *Psych: Theory, Res Pract* 1979;16:252–60.

85 Allen ML, Cook BL, Carson N, *et al*. Patient-Provider Therapeutic Alliance Contributes to Patient Activation in Community Mental Health Clinics. *Adm Policy Ment Health* 2017;44:431–40.

86 Corso KA, Bryan CJ, Corso ML, *et al*. Therapeutic alliance and treatment outcome in the primary care behavioral health model. *Fam Syst Health* 2012;30:87–100.

87 Kinney M, Seider J, Beaty AF, *et al*. The impact of therapeutic alliance in physical therapy for chronic musculoskeletal pain: A systematic review of the literature. *Physiother Theory Pract* 2020;36:886–98.

88 Alodaibi F, Beneciuk J, Holmes R, *et al*. The Relationship of the Therapeutic Alliance to Patient Characteristics and Functional Outcome During an Episode of Physical Therapy Care for Patients With Low Back Pain: An Observational Study. *Phys Ther* 2021;101:pzab026.

89 Bishop MD, Torres-Cueco R, Gay CW, *et al*. What effect can manual therapy have on a patient's pain experience? *Pain Manag* 2015;5:455–64.

90 Hatcher RL, Lindqvist K, Falkenström F. Psychometric evaluation of the Working Alliance Inventory-Therapist version: Current and new short forms. *Psychother Res* 2020;30:706–17.

91 Hatcher RL, Gillaspy JA. Development and validation of a revised short version of the working alliance inventory. *Psychother Res* 2006;16:12–25.

92 PROMIS-29 Profile v2.1, Available: https://www.healthmeasures.net/index.php?option=com_instruments&view=measure&id=849&Itemid=992

93 Deyo RA, Dworkin SF, Amtmann D, *et al*. Report of the NIH Task Force on research standards for chronic low back pain. *J Pain* 2014;15:569–85.

94 Deyo RARamseyKBuckley DI, *et al*. Performance of a Patient Reported Outcomes Measurement Information System (PROMIS) Short Form in Older Adults with Chronic Musculoskeletal Pain. *Pain Med* 2016;17:314–24.

95 Khutok K, Janwantanakul P, Jensen MP, *et al*. Responsiveness of the PROMIS-29 Scales in Individuals With Chronic Low Back Pain. *Spine (Phila Pa 1976)* 2021;46:107–13.

96 Tubach F, Dougados M, Falissard B, *et al*. Feeling good rather than feeling better matters more to patients. *Arthritis Rheum* 2006;55:526–30.

97 Tubach F, Wells GA, Ravaud P, *et al*. Minimal clinically important difference, low disease activity state, and patient acceptable symptom state: methodological issues. *J Rheumatol* 2005;32:2025–9.

98 Tubach F, Ravaud P, Beaton D, *et al*. Minimal clinically important improvement and patient acceptable symptom state for subjective outcome measures in rheumatic disorders. *J Rheumatol* 2007;34:1188–93.

99 Genolini C, Ecochard R, Benghezal M, *et al*. kmlShape: An Efficient Method to Cluster Longitudinal Data (Time-Series) According to Their Shapes. *PLoS One* 2016;11:e0150738.