The creation and pilot testing of a method to identify strong and instantaneous responders to spinal manipulation therapy

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Declaration

I declare this thesis is my own account of my research and contains as its main content, work which has not been previously submitted for a degree at any tertiary educational institution.

Reece Granger

Date: 17/10/2022

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List of Abbreviations

LBP = Low back pain

HVLA = High velocity low amplitude

NSLBP = Non-specific low back pain

SMT = Spinal manipulative therapy

FABQ = Fear avoidance beliefs questionnaire

TA = Therapeutic alliance

CPRs = Clinical Prediction Rules

AROM = Active range of motion

ROM = Range of motion

Abstract

Introduction: Spinal manipulative therapy (SMT) can provide pain relief for individuals with non-specific low back pain (NSLBP). Clinical prediction rules can be used to identify patients who are likely to respond positively to a particular treatment approach. A list of 18 signs and symptoms across 5 domains have previously been developed by expert manual therapists, and are suggested to be predictors of instantaneous relief in people with NSLBP after SMT. However, these items have yet to be developed into a workable format and tested in a clinical setting.

Objectives: To develop a workable questionnaire and subsequently run a pilot study which tests the feasibility of the study in chiropractic patients with NSLBP, and the preliminary relationships between the 18 signs and symptoms (predictors) and those who have a strong and instantaneous response to SMT.

Methods: Practitioner and patient questionnaires were designed based on the previously identified 18 predictors of instantaneous relief following SMT. Ten chiropractors were recruited and were each asked to recruit 10 NSLBP patients from among their normal patients. Each practitioner and patient answered the questionnaires, and feedback from practitioners was sought on the study and questionnaires. Predictors of immediate improvement after SMT were investigated using linear regression.

Results: Three validated outcome measures were used in designing the questionnaires and a further nine questions were designed to cover gaps in the literature. Of the 10 chiropractors who agreed to participate, two withdrew and two were lost to follow up.

In total there were 63 out of a planned 100 practitioner/patient responses. Three of the five domains had predictors showing statistically significant results for predictive outcomes. These included the patient's prior response to SMT, the patient's expected response, Dr's rating of patient's health status, Dr's rating of how well they felt they understood the patient's goals, and decreased range of motion identified on physical examination.

Conclusion: The design of the questionnaire was based on best available evidence-based literature at the time of development. A fully powered study appears to be feasible; however, suggested changes to the questionnaire and data collection process were made. Pilot testing identified multiple possible predictors for instantaneous relief after SMT in chiropractic patients with NSLBP. These results support the need for a fully powered study to further explore the 18 possible predictors of instantaneous relief after SMT.

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Chapter 1: Introduction

Physiotherapists, osteopaths and chiropractors are among the health professions with a special interest in the diagnosis, management, and prevention of musculoskeletal disorders [1, 2]. Recent research has called for the reduction of low value care as one way of reducing the financial impost of low back pain (LBP) [3, 4]. Patients suffering from musculoskeletal conditions are commonly treated using manual therapy by these practitioners [5], which can include spinal manipulative therapy (SMT) [1]. A recent Delphi study has identified a number of signs and symptoms that manual therapy practitioners believe might enable them to identify patients who have an immediate and strong response to SMT for their LBP [6]. This information might allow manual therapists to reduce the amount of low value care they deliver to patients by targeting those most likely to experience a positive response. What is now required is a way to translate these signs and symptoms developed by Innes et al. [6] into a workable format so that it can be tested in clinical practice.

1.1 Background

The current literature and anecdotal evidence in clinical practice suggests that the aim of SMT is decreasing pain, improving joint ranges of motion, and releasing muscular tension [1, 2] in order to improve joint function and relieve musculoskeletal pain [2, 7]. Some studies suggest that the mechanical force induced by effective application of a high-velocity, low-amplitude force (HVLA) technique to a specific spinal segment can induce immediate pain relief [2, 8, 9], while others disagree [10]. The literature posits a number of theories to explain the outcomes of SMT, including, but not limited to,

neurophysiological and biomechanical effects [11], enhanced facet joint motion, intra-articular or myofascial adhesions, and soft tissue inclusions entrapped between facet joints [9, 10, 12-14].

There has been a call to action by prominent researchers for a change in the way LBP – one of the most commonly encountered musculoskeletal conditions [2] – is managed [3] in an effort to reduce the huge personal and financial impacts [15]. One recommendation is for the reduction of low value care [3]; any intervention should be targeted to those who are likely to gain the most benefit from the treatment implemented [16, 17]. It follows that knowing clinical predictors for improvement would be important when selecting patients for SMT [18]. It is hypothesized and anecdotally reported that there is a subgroup of the population who respond to SMT with instantaneous relief, and that these patients can be identified prior to treatment [8]. The ability to identify a group of people who respond strongly and immediately to SMT could contribute to the reduction of low value care and improve the quality of patient care [8]. Thus, those who do not fit the subgroup could be preferentially offered treatments other than SMT [8]. The characteristics of this subgroup are not well researched [8]; however, a group of Australian researchers have recently conducted an international Delphi study to seek a consensus on what expert manual therapy practitioners who regularly use HVLA SMT for non-specific low back pain (NSLBP) thought were the predictors for patients to respond this way [6]. This process resulted in the identification of 18 items from 5 domains (see Table 1).

Table 1: Predicted signs and symptoms of strong responders identified by SMT experts.

Domain	Item
Patient Factors	A history, including a good response to previous SMT
	Patient has trust and high confidence in the practitioner
	Professional opinion of health status – excellent/very good
	Patient susceptible to placebo effect
	Professional opinion of health status – good
	Patient has a comprehensive understanding of condition
Practitioner factors	Good patient-practitioner relationship
	Practitioner understanding of patient expectations & goals
Signs and symptoms of NSLBP presentation	Duration of symptoms (< 16 days)
	Pain improves with exercise, but not rest
	No symptoms in the lower extremities
	Patient has an acute condition (< 14 days)
	No symptoms of distal to the knee
	Decreased active range of motion
	Decreased passive range of motion
	Symptom reproduction on spinal springing
An instrument of measurement (FABQ)	FABQ work scale score less than 19 out of 42
The presence of a cavitation following SMT	A clicking sound (cavitation) at the moment of thrust

Abbreviations: SMT = spinal manipulative therapy, NSLBP = non-specific low back pain, FABQ = fear avoidance beliefs questionnaire.

1.2 Non-Specific Low Back Pain

Low back pain is one of the most common disabling health conditions worldwide, with reports suggesting over half a billion people have experienced LBP in their lifetime [19-21]. Furthermore, it is one of the leading causes of limitations in daily activities, is responsible for increased absences from work, and is one of the leading causes of years lived with disability [19-21]. LBP is experienced largely by middle-aged to elderly individuals, with children and teens accounting for only a small portion of cases [3, 19-22]. LBP effects not only the economy in high-income countries but also low-to-middle-

income economies worldwide, costing an estimated $88billion in 2013 in the US health care system alone [3, 19-22]. The total cost considers the combined occurrences of decreased work productivity in the form of hours lost, medical expenditure, and other treatment modalities which have been unnecessarily ordered in trying to diagnosis a cause of LBP [3, 19-22].

LBP is defined as localised discomfort and pain occurring between the inferior gluteal folds to the lower parts of the costal margins on either side of the body [4, 21, 22]. This can include referral or radiation patterns down one or both lower extremities [4, 21, 22]. Acute LBP is described as pain which has been present for less than 4–6 weeks with no gap or relief from pain, which may be a first-time occurrence or a new episode after a 10–12-week gap from the original onset [4, 21, 22]. Sub-acute LBP is classified as pain present for between 6–12 weeks with no relief. If pain is persistent for 12 weeks or longer, it is classified as chronic LBP [23, 24]. However, it is important to note that research is challenging the previously held notion that LBP was a self-limiting condition; rather, LBP is now thought of as a persistent condition which can be cyclic, lasting months, if not years [25].

Non-specific low back pain (NSLBP), called mechanical LBP in some instances, is the most common diagnosis under the umbrella term of LBP [23, 24]. This term has evolved in an attempt to deal with the difficulty of diagnosing the tissue-based or pathological causes responsible for many instances of LBP. Some examples of identifiable causes include disc herniation, fracture, tumours, or systemic illness [21, 23, 24]. The term NSLBP is used when there is no underlying pathological cause for a person's pain [26]. This means that NSLBP is rather a symptom and not a specific condition or presenting disease [21, 24]. It is important to note that individuals suffering

from LBP are more likely to have multiple body regions affected by pain as well as other comorbidities compared with those who do not report LBP [24]. This adds to the complexity of treating and managing a person with LBP.

There have been attempts at creating guidelines in recent years to improve the quality of care provided to individuals experiencing both acute and chronic LBP [20]. These guidelines seek to help individuals with LBP select which medical service or healthcare practitioners would be best utilised in order to help manage their condition [20]. Many guidelines for the management of NSLBP include SMT as a treatment option [27]. However, the implementation and adherence to these guidelines has been far from ideal and has further added to the confusion of identifying the most appropriate care whilst also increasing the financial burden of LBP [20]. Though the supporting evidence in the literature is low-to-moderate quality regarding effectiveness, SMT may lead to small and moderate improvements in pain and disability in adults with NSLBP [27, 28]. Despite this, many chiropractors use SMT frequently in a unimodal or multimodal form of care [27, 28].

1.3 Spinal Manipulation

Chiropractors, physiotherapists, osteopaths and other manual therapists undertake specialized training to diagnose, prevent, and manage a range of musculoskeletal disorders [1, 5]. The most common of these conditions are acute and chronic NSLBP, which is commonly treated with the use of SMT [10, 27, 29]. This intervention often results in an audible cracking sound known as cavitation. SMT is delivered with an HVLA force to the targeted area with the aim of decreasing pain, improving joint function

through increasing the range of motion, and aiding the relief of musculoskeletal problems [11, 30]. In addition, there is evidence to suggest that there is an immediate change in experimental pain, such as chemical, electrical, mechanical and thermal stimuli, and that these may correlate with clinical outcomes [31-33]. Some suggest that this may not be exclusive to SMT [31, 34].

Despite the frequent use of SMT by many manual therapists, the evidence for its efficacy is variable, due in part to the complexities of many proposed theories. This in turn hinders its acceptance as a treatment modality by some manual therapist groups and the medical profession [11, 30, 35]. The mechanisms of pain reduction from SMT are thought to be biomechanical and neurophysiological in nature [11, 30, 35]. Some human and animal studies have shown that a force similar to HVLA SMT can have an effect on the proprioceptive input of Golgi tendons neurons [11, 30, 35]. Muscle spindle fibres of the target area are similarly affected and are thought to induce a short-lasting hypoalgesic effect [11, 30, 35-38]. Other neurophysiological explanations are that SMT affects the neurons in the paraspinal muscles, which in turn results in the inhibition of nociception and proprioception due to the effects triggered by the central and peripheral nervous system [11, 30, 35-38]. However, this mechanism is still poorly understood with many explanations focussing on possible biomechanical reasons [11, 30, 35-38]. For example, it has been suggested that SMT may release trapped meniscoids between the zygapophyseal joints, unbuckle buckled segments, or relieve segmental adhesions, and release disc material that might be causing a nociceptive input [11, 38-40]. Other studies have demonstrated a relaxation effect on the muscles surrounding the spine, as shown by electromyographic activity after a HVLA SMT [11, 38-40].

Lastly, all interventions (in this case, SMT) have the ability to induce a placebo effect when delivered as a treatment [41-43]. The placebo effect is generally understood as occurring when a patient's signs and symptoms improve due to non-specific effects of the treatment, particularly expectations [44]. The placebo effect is also linked to the meaning model, where the patient will have a greater positive response to the intervention provided when their illness or condition is treated and explained in a positive way, leading to a more successful outcome [44, 45]. It has been postulated that SMT may improve clinical outcomes partly because it reduces pain via the placebo effect, and this in turn may help change the behaviour patterns of the patient to alter posture and movements [41, 42]. Furthermore, the opposite can occur with the nocebo effect, in which the patient's signs and symptoms worsen after a treatment without scientific explanation [41-43].

It has been hypothesised that the placebo effect can be partially explained by multiple contextual factors, including social, physical and psychological elements that occur when a therapeutic relationship is created between the practitioner providing treatment and the patient [43]. From a clinical perspective, the placebo effect following SMT could play a significant role in instantaneous relief of NSLBP [43, 46]. For a patient, this includes their expectations around the treatment, the atmosphere of the clinical setting, and responses to prior treatment [43]. These factors can also be influenced by the practitioner's behaviour, verbal communications, competency in delivering treatments, and beliefs and expectations, all of which can positively or negatively influence a patient's perception of their pain, creating the opportunity for placebo or nocebo effects to occur [43, 46]. However, due to the incidental nature and complexity of the placebo effect, most clinicians do not intentionally use or are unable to identify it

amongst other therapeutic interventions [43, 46]. The exact mechanism of how SMT inhibits pain is still unknown due to its complexity. However, identifying those who have a strong instantaneous response to SMT may allow us to explore potential measurable factors contributing to clinical responses to SMT.

1.4 Therapeutic Alliance

In recent times there has been a paradigm shift across health care from a disease-centred care approach to a more patient-centred care approach [47]. In order to achieve a patient-centred care approach, it is fundamental to develop an effective therapeutic alliance (TA) between practitioner and patient. The concept of TA is based on Bordin's three elements of a working alliance [48]: an agreement on goals; tasks and treatment strategies; and the building of a relationship between patient and practitioner [48]. The final element, building a relationship, involves developing mutual acceptance and trust between practitioner and patient [48].

More recent research has identified four core components which impact the TA, namely empathy, trust, collaboration, and agreement on treatment strategies/goals [47]. Empathy has been shown to be the most crucial and valuable factor in building TA between practitioner and patient as it has shown to lower patients' anxiety, apprehensiveness, and distress, whilst improving patient satisfaction and adherence to treatment plans [47, 49]. The construct of trust may overlap with empathy and builds over time with positive interactions from clinicians who listen and show genuine sensitivity toward the patient [50]. Even though little research has been conducted on collaboration, positive patient outcomes are highly unlikely if there is no collaboration

between practitioner and patient, as this forms the fundamental basis for agreement on rehabilitation and treatment strategies/goals [47, 49, 51]. Agreement must also be sought to enhance the likelihood that a patient will adhere to a treatment plan. This becomes even more important for conditions which require ongoing self-management [47, 52]. Communication is also considered to be a core component of TA as it mediates and solidifies all four elements described above [50]. The implementation of all four elements together helps engage and facilitate patient participation whilst building a working relationship between practitioner and patient [50].

It has been shown that when a practitioner and patient have a strong TA, the psychosocial aspects of the treatment are equally as meaningful as the main manual therapy modality in decreasing pain and providing clinical benefits [53]. The interpersonal skills of the practitioner play a supportive role for the patient relationship and may provide critical components of the placebo effect during treatment, providing further relief from discomfort [53]. It is important to understand the core elements when building a TA with a patient in clinical practice. This rapport not only improves the working relationship but is essential in helping an individual reach their short- and long-term goals via the use of appropriate interventions, self-management, and the placebo effect [47, 53].

1.5 Predicting Clinical Outcomes

The best way forward in identifying people with NSLBP who are likely to experience instantaneous relief after SMT is to create a reliable and valid tool for practitioners to predict this outcome [54]. One way to do this is through a clinical prediction rule (CPR) [55]. CPRs are a collection of mathematical data which are employed as a tool to guide clinicians in their decision-making processes [56]. The main aim of CPRs is to help guide clinicians in choosing the most appropriate care or most likely diagnosis. In clinical practice, CPRs require the clinician to understand the main aim, development processes, validity and applicability in order to use it effectively and achieve the best clinical outcomes [55, 56]. This can then potentially identify patients who respond best to particular treatments with the intention to optimize the implementation of effective management in clinical practice [57].

To understand CPRs generally, we must understand how to predict a clinical outcome, the strengths and weaknesses of CPRs, their validity and reliability, how they are formulated, and the existing research on CPRs regarding LBP and rapid responders to SMT. There is an extensive body of literature exploring the ability of researchers to predict clinical outcomes [6, 18, 58-63], often with the intention of reducing the financial cost and ultimately lead to improved patient safety and quality of care [64]. Such predictions generally involve multiple factors which can include features of the condition, reliable outcome measures, practitioners' clinical knowledge, and clinical assessments that identify functional limitations [64]. The clinical assessment must be well-defined, succinct and display properties that reliably predict treatment outcomes [64].

There are four broad types of outcomes that can be included in CPRs:

1- Patient-reported outcome: Here the rater is the patient and provides responses based on questions delivered by either a computer, paper questionnaire forms, or interviews. This allows a mechanism to record observations of pain, activities of daily living/functions and distress [64].
2- Clinician-reported outcomes: This is when the condition of the patient is observed, evaluated and reported by a trained practitioner. Among others, this can be achieved by numerical pain scale questionnaires and clinical test results [64].
3- Observer-reported outcomes: This is when someone other than the patient or practitioner observes and reports on the patient's daily life practices. This is usually performed by non-clinical care providers [64].
4- Performance outcome: This is where the rater takes a specific and objective measure of a performance outcome, meaning they have no influence or impact on what is being measured. The task is quantified and usually compared to what the patient's score was when previously tested [64].

It has been suggested that, through these four different predictive outcomes, we can assess the reliability and validity of a CPR in predicting possible outcomes [63-65]. If this is possible, it could in turn provide a useful tool when implemented on LBP to determine those patients who are most likely to respond positively to SMT. The current research suggests that a mix of patient, practitioner, observer and performance outcomes is the best way to measure patient responses after an intervention [64].

Manual therapists are commonly sought-after primary care providers; therefore, it is imperative that an appropriate diagnosis and plan of management is reached based on a clinical assessment to aid in improving patient outcomes [55, 56]. This is where a CPR identifying positive responders to manual therapy may benefit clinical practice [55, 56]. All clinical assessments start with a history, intended to gain as much information as possible for making a diagnosis [55, 56]. This is followed by a physical examination and, possibly, special tests such as diagnostic imaging [55, 56]. It is after the physical examination where successful implementation of a CPR may help guide treatment decisions or necessary special tests [55, 56]. The hope is that this process will provide the practitioner with relevant information to make the most accurate diagnosis, and in turn enable the practitioner to select the most appropriate management plan for the patient [55, 56].

Two of the most successful CPRs that have been widely implemented into clinical practice are the Ottawa Knee and Ankle rules, used for deciding when it is appropriate to take radiographic imaging after knee or ankle injuries [61, 66-68].The Ottawa CPRs are easy to use and implement with patients, each asking a series of five questions as a screening tool to assess if diagnostic imaging is required. The Ottawa Ankle rule CPR has 100% sensitivity for detecting fractures; however, with high sensitivity there is a loss of specificity, resulting in some negative imaging [61, 66-68]. The Ottawa Ankle rules have been shown to reduce unnecessary ankle imaging in emergency departments by 28–30% [61, 66-68]. The CPRs have saved valuable time, resources and cost whilst improving patient quality of care regarding knee and ankle injuries [61, 66-68].

Some researchers have raised concerns about the limitations of CPRs [60]. Currently, CPRs are still seen as being in a developmental stage and the substantiating evidence for CPRs ranges from weak to strong [29, 55, 56, 61]. Nonetheless, they can still provide a useful tool to manual therapists when seeking guidance on predicting patient outcomes by reducing uncertainty and employing the best available evidence [56]. This supports the overarching goal of evidence-based practice of incorporating sound clinical expertise, the best available evidence (which includes, but not limited to, CPRs), and patient preferences [29, 55, 56, 61].

Validity and Applicability

There is considerable debate in the current literature as to the clinical application of CPRs for NSLBP and SMT, which is partly due to the lack of evidence on the validity of available CPRs [60, 69, 70]. The current evidence has not successfully differentiated between general outcomes and outcomes found in response to more specific interventions for LBP [60, 69, 70]. Perhaps this is because many CPRs regarding LBP are still being developed and only a select few have been validated with randomised control trial designs when testing the quality of their predictive ability [60, 69, 70]. When used for making treatment decisions, CPRs only have the ability to classify patients into a solitary intervention group [18, 29]. Recent research suggests that one intervention is unlikely to yield a positive patient outcome for musculoskeletal conditions [60]. This is because musculoskeletal pain is a multifaceted condition that can be influenced by a wide range of patient factors [71]. A manual therapist's treatment perspective should include biopsychosocial factors and an interdisciplinary approach to pain management with other health services [71].

From a treatment perspective, the best practice for high patient satisfaction levels are management plans that incorporate a combination of different treatment modalities. This can include SMT, soft tissue massage, and rehabilitation exercises, among others [60, 71-74]. There are many examples where a multimodal approach has been shown to be more effective for common musculoskeletal conditions of the spine or other joints (such as shoulder, hips, knees and ankles) compared to a unimodal approach [72-74]. Until more high-quality research supports the validity of CPRs, manual therapists should continue to use sound, evidence-based practices in conjunction with existing CPRs for best practice.

Finally, CPRs may be either prescriptive or interventional in nature, the latter being a classification system which leads to a diagnosis. This normally includes a patient history, physical examination and cluster of specific signs and symptoms. This information helps to place patients with similar profiles into smaller subgroups where a specific treatment modality produces a more favourable outcome than if they were left in a larger group [72-74]. Some think of this in terms of the larger heterogeneous group being burdened by non-responders that weigh down the group with their poor outcomes. The identification of smaller homogenised groups is most likely to improve patient outcomes. Examples of this are the test clusters identified by Laslett et al. and Van Der Wurff et al. for sacroiliac joint pain [75, 76].

Formulation of a Clinical Prediction Rule

In order to improve decision making with the help of CPRs, a three-step process was developed which can be used for wider implementation of CPRs in clinical practice [77-79]. This process was developed to help clinicians across multiple disciplines reach appropriate decisions regarding patient care [78].

Step one involves creating the CPR. Practitioners and/or researchers list a set of possible predictive factors that they feel may identify the given outcome. These are commonly based on previous research, clinical experiences, and factors already shown to have potential for prognostic and diagnostic accuracy [29, 61, 77-79]. During this step, researchers should take into consideration the many predictor variables as well as the prevalence of the outcome tested [61]. Sample size decisions must consider the risks and benefits of the CPR's outcome, particularly if needing to reduce the risk of the CPR failing to identify a serious outcome [61]. Relatively rare or severe injuries must enlist larger numbers of participants to achieve narrower confidence intervals [61]. This helps guide practitioners' judgment and instils confidence that the CPR's application will not lead to an error in the decision-making process [61].

Step two involves validating the CPR. Validation typically involves testing, then re-testing in varying populations and settings before widespread use can be recommended [29, 61, 77-79]. This test-retesting of the predictor variables ensures reliability, and that measurements and calculations have not occurred by chance [61]. A CPR's validity means it is generalizable to broader populations. Lastly, validation studies set a standard for how practitioners are expected to use the CPR appropriately [61].

Step three seeks to conduct an Impact Analysis. Once the CPR is established as reliable and valid, it can then be investigated for its ability to guide practitioners in

improving patient outcomes, overall satisfaction, and to explore cost savings associated with the use of the CPR [29, 61, 77-79]. There are three different approaches to investigating the successful implementation of a CPR, with each being dependent on feasibility [61]. The first and preferred method is randomly assigning patients to care based on either the CPR or the practitioner's usual approach [61]. This may not be feasible due to clinics having high volumes of patients with many practitioners, which creates difficulties as the patient may fluctuate between their usual care and that dictated by the CPR [61]. The second approach is to randomly assign clinical practices to implement the CPR for all patients. The third is a non-randomized approach which can be undertaken utilizing a 'before and after' design. Here the patient outcomes are assessed before and after the CPR was implemented. While this is still a successful approach, it is not as robust as randomised approaches [61].

Clinical Prediction Rules for Low Back Pain

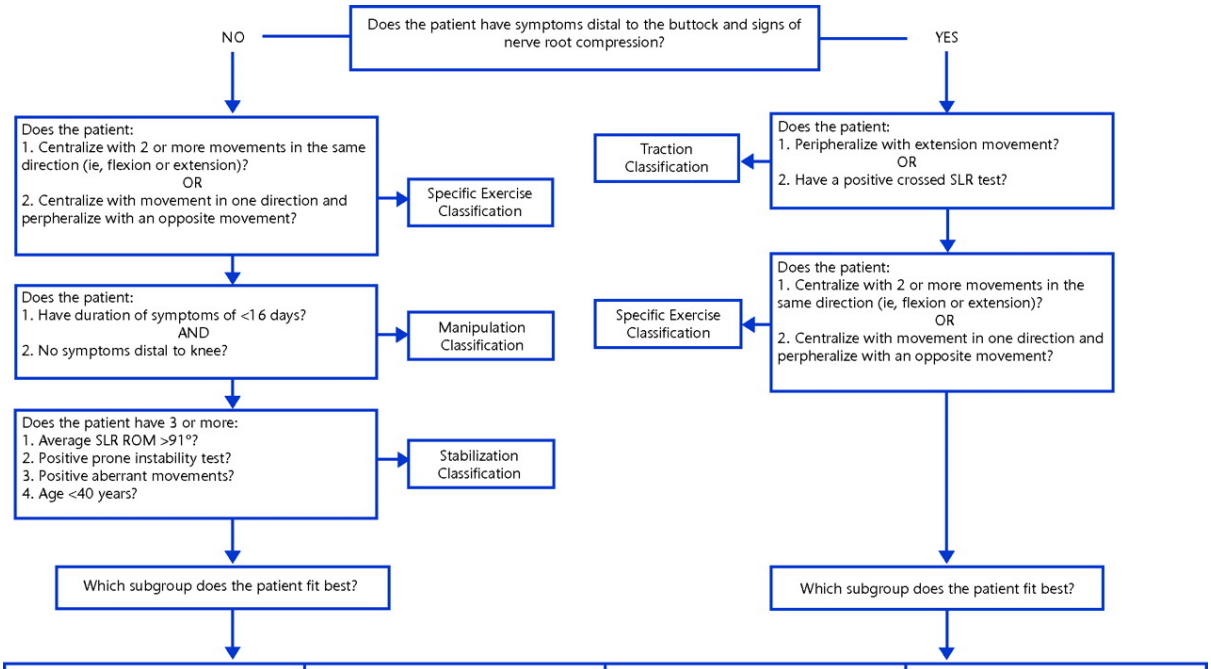
The high prevalence of LBP has contributed to many high-quality clinical trials and systematic reviews being conducted over many years [29, 69, 80-83]. LBP is very complex: there are many hypothesised causes and diverse symptoms, with a multitude of treatment options and, perhaps unsurprisingly, the benefits of these interventions have been described as modest at best [80, 84]. This has driven researchers to look closely for the presence of subgroups with classifications based on symptomatology, diagnosis, prognosis and response rates to various treatments [80].

The most common approach to subgrouping LBP patients used among manual therapists was devised by Delitto et al. in 1995, and subsequently revised by Fritz et al. [62, 63]. This classification system utilized a network of subgroups aimed at directing

manual therapists' care in NSLBP patients [62, 63]. The four classifications were based on the supposed best type of intervention, namely traction, specific directional exercises, stabilization exercises, or SMT. Using this CPR, each patient is matched with a specific treatment once they have undergone a tailored examination to identify which subgroup they belong to [62, 63].

The original classification system was designed for acute pain patients presenting with symptoms of LBP that affected activities of daily living [62, 63]. The classification criteria were developed on best available evidence at the time of development, clinical experience and expertise [62, 63]. A cross-sectional study was later conducted by Tasha et al. (2011) revisiting the reliability and translation of the developed algorithm with the subgroup classification criteria. This led to a more comprehensive algorithm being developed based on the original work by Delitto et al. [63] and Fritz et al. [62]. Figure 1, below, shows the final algorithm based on the CPRs of the three previous studies [62, 63, 85].

Figure 1: *Evaluation of a Treatment-Based Classification Algorithm for Low Back Pain*



MANIPULATON		STABILIZATION		SPECIFIC EXERCISE		TRACTION	
Factors favoring	Factors against	Factors favoring	Factors against	Factors favoring	Factors against	Factors favoring	Factors against
▪Hypomobility with spring testing ▪Low FABQ scores (FABQ-W <19) ▪Hip medial (internal) rotation ROM >35°	▪Symptoms below the knee ▪Increasing episode frequency ▪Peripheralization with motion testing ▪No pain with spring testing	▪Hypermobility with spring testing ▪Increasing episode frequency ▪3 or more prior episodes	▪Discrepancy in SLR ROM (>10°) ▪Low FABQ scores (FABQ-PA <9)	▪Directional preference for extension or flexion ▪Centralization with motion testing ▪Peripheralization in direction opposite to centralization	▪Low back pain only (no distal symptoms) ▪Status quo with all movements	▪Peripheralization of symptoms, with no ability to centralize with movement	▪Low back pain only (no distal symptoms) ▪No sign of nerve root compression

Abbreviations: SLR = straight leg raise, ROM = range of motion, FABQ-W = Fear-Avoidance Beliefs Questionnaire work subscale, FABQ-PA = Fear-Avoidance Beliefs Questionnaire physical activity subscale.

Figure reproduced from Stanton et al. [85].

In a recent Delphi study by Innes et al. [6] a group of manual therapists identified five domains and a total of 18 predictive factors which could potentially identify patients who gain instantaneous relief following SMT [6]. The five domains consist of patient factors, practitioner factors, signs and symptoms of NSLBP presentation,

workplace fear-avoidance beliefs, and the presence of cavitation following SMT [6]. However, the predictive value of the 18 items have not yet been tested.

The factor that was most highly rated by practitioners to have the strongest predictive value for instantaneous relief after SMT was a “good response to previous SMT” [6]. This was followed by “a trusting and confident therapeutic relationship” , “signs and symptoms of NSLBP presentation”, and “instrument of measurement” in the form of the fear avoidance beliefs questionnaire (FABQ) [6]. The FABQ has been shown to have predictive capabilities when assessing disability levels from persistent LBP [6, 18, 61, 86-88]. Other factors associated with poor outcomes that are strongly related to the FABQ are psychological health, physical limitations, cognitive distress, depression and anxiety [18, 61, 86-88]. Past research has shown that unhelpful fear-avoidance belief patterns can be reduced by pain reduction that in turn decreases the severity of these disabilities [6, 18, 61, 86-88].

While some of the LBP diagnostic CPRs have undergone validation studies, none have been subject to impact analysis testing [80]. Impact analysis investigates the implementation of the CPR into clinical practice setting with the aim of improving patient care [54]. This is best achieved through a randomised controlled trial [54]. The main limitation confronting diagnostic CPRs and LBP is the lack of a standardized and validated tool appraising the accuracy throughout the stages of development [80]. Without impact analyses, an overarching concluding statement about CPRs cannot be made [80]. Future research is still required to validate a standardized tool which can clinically appraise each stage of CPR testing. This will help increase the reliability and validity of the CPR’s subgrouping process [80]. Once concluded, manual therapists will

have a widely accepted, gold standard CRP tool that can be used systematically in practice [80, 82].

Some have suggested that CPRs provide a valuable resource when integrated with the best evidence-based practice and clinical experience of manual therapists [80]. This combination is thought to add valuable additional information and avoid relying only on CPRs for clinical decisions [61, 62, 80]. Thus, the making of clinical decisions, whilst considering the variables of CPRs, assists with diagnosis and appropriate management planning as a personalised and tailored approach to treatment, is shown to yield maximum benefit for the patient [62, 63, 80]

1.6 Rapid Responders

The literature hypothesises that patients who gain instantaneous or rapid pain relief following SMT can be identified [9, 29, 89]. These identified traits to date are based on the demographic and physical characteristics of the patients [9, 29, 89]. Multiple, larger-scale attempts have tried to replicate these studies of identifying people who gain rapid pain relief following SMT; however, they have been unsuccessful [58, 90]. A possible correlation was found between patients who had favourable responses to SMT, and patients who experience rapid pain relief post treatment [58, 90]. Natural history, where a patient can experience pain relief and recovery without treatment, was also noted as a possible factor [58]. However, there was limited evidence linking rapid pain relief to demographic or physical characteristics of the patient [58, 89, 90].

Treatment guidelines suggest that improvements in LBP after treatment can be expected to occur over a two- to four-week period or six to twelve sessions for pain

relief [89, 91]. Individual response rates may be faster or slower than these guidelines, as recovery can be influenced by a variety of factors, including treatment approach or biopsychosocial factors at play within individual patients [58, 89, 91]. Predicting pain relief response rates of patients appears to be complex due to the multiple influences effecting treatment outcomes. Therefore, clinicians should be mindful of factors that may act as barriers to recovery and thereby influence patient outcomes [58, 89, 91].

1.7 Rationale and Objectives

Some international guidelines recommend SMT as form of treatment for NSLBP [92]; however, SMT can have a variable effect on reducing pain and increasing function [93, 94]. It can be difficult to identify which individuals will respond positively to SMT, which may be reflected in the generally small effect sizes seen in clinical trials [95]. If we are able to predict which LBP patients are likely to respond positively to SMT, practitioners will not only be able to provide pain relief for patients, but potentially decrease the financial burden LBP places on the healthcare system [19, 93, 94]. A Delphi Study was conducted in which manual therapists identified items they believed where predictors of NSLBP patients who are likely to experience instantaneous pain relief following SMT [6]. These items, however, are yet to be tested.

Therefore, our study aimed to develop and pilot test questionnaires assessing those factors to predict patients with NSLBP who are likely to have a strong and instantaneous response to SMT, based on the items identified by Innes et al. [6]. This was achieved by:

1. Designing questionnaires for use in clinical practice to assess the 18 items identified by Innes et al. [6].
2. Investigating the feasibility of recruitment and the procedure for testing the 18 items as predictors of instantaneous responders to SMT.
3. Investigating potential changes in the 5 domains hypothesized as measures of those people with NSLBP who would experience an instant and strong response to SMT.

We hypothesized that the recruitment would be achieved in the expected time frame and that each of the 18 identified items from the 5 domains would be significant predictors of those who experienced an instant and strong response to SMT for NSLBP.

Chapter 2: Methods

This pilot study was approved by the Murdoch University Human Research Ethics Committee (Project No. 2020/152).

2.1 Designing the Questionnaires

Two questionnaires were designed: one for practitioner-related questions; and one for the patient-related questions. The practitioner questionnaire covered six items, and the remainder were covered by the patient questionnaire. Between both questionnaires, all 18 items across the 5 domains where assessed.

The first step consisted of a literature review to identify if any valid and reliable questionnaires existed which could assess any of the 18 items of interest. Outcome measures were made for items which remained without a valid outcome measure using the most up-to-date literature available [96].

The second step required consolidating the multiple sets of outcome measures into a patient and practitioner questionnaire, which were then put forth to a focus group to assess content validity, usability, and interpretability along with clinical and biological plausibility [97]. The focus group comprised of six expert manual therapists with a minimum of 10 years clinical experience who reviewed the questionnaires and provided feedback, which is consistent with recommendations for content validity panels [97, 98]. A Content Validity Index (CVI) was used to assess content validity of the newly developed questions. For this, focus group members were asked to assess the items created by the authors using four categories: not relevant; needs major revision; needs

minor revision; and very relevant. Consistent with guideline recommendations, a value of '*one*' was awarded to either the "needs minor revision" or "very relevant" categories, and '*zero'* was awarded to either the "not relevant" or "needs major revision" categories [97, 98]. Focus groups members were not asked to assess the previously validated questionnaires that were included (ARM-5, PDRQ-9, and FABQ). An Item-Content Validity Index (I-CVI) was calculated for each item by summing the values for each rater and then dividing by the number of raters. Changes to the questionnaires were subsequently implemented based on feedback and the I-CVI value of each question. Based on previous research, an item would be retained if its I-CVI was greater than 0.79 [97, 98] and removed or substantially reworked if the I-CVI was lower.

The third step required taking the questionnaires and giving them to four selected practicing manual therapists with a minimum of five years clinical and practical experience. The four manual therapists reviewed the practitioner and patient questionnaires for interpretability, simplicity to read, and usability in a clinical setting. Advice and recommendations for possible changes for better understanding and to streamline outcome measures where provided [99]. Questionnaires where revised again and changes made based on manual therapists' input and in accordance with the available evidence in the literature.

The fourth step involved the focus group re-assessing the questionnaires for further changes and to ensure all 18 items across the 5 domains were covered whilst further testing interpretability. A general consensus amongst the expert manual therapists was reached, providing the final questionnaires for the practitioners and patients. See Table 2 for a summary of the items.

Table 2: Details of Questionnaire Items Used in Analyses

Domain	Item #	Item	Outcome measure name	Measurement
Patient Factors	1	Patient's prior immediate response to SMT	Patient's prior response to SMT	0-10 NRS
	2	Patient's expected immediate response to SMT today	Patient's expected response to SMT	0-10 NRS
	3	Patient's rating of the therapeutic alliance, patient ARM-5	Patient's rating of therapeutic alliance (ARM-5)	5-35
	4	Patient's understanding of their LBP condition	Patient's understanding of their condition	0-10 NRS
	5	Patient's rating of how well they think the chiropractor understands their goals and expectations	Patient's rating of Dr's understanding of goals	0-10 NRS
Practitioner Factors	6	Chiropractor's rating of the therapeutic alliance, Dr ARM-5	Dr's rating of therapeutic alliance (ARM-5)	5-35
	7	Chiropractor's rating of patient's health status	Dr's rating of patient's health status	6-point Likert scale
	8	Chiropractor's rating of their understanding of the patient's goals and expectations	Dr's rating of understanding of goals	0-10 NRS
Signs and Symptoms of NSLBP Presentation	9	Whether this episode has lasted less than 16 days	Symptoms <16 days	Yes/No
	12	Whether pain has been severe for less than 14 days this episode	Severe pain <14 days	Yes/No
	10	Whether pain improves with exercise, but not with rest	Pain improves with exercise	Yes/No
	11	Whether the patient has symptoms in their lower extremities	Symptoms in lower extremities	Yes/No
	13	Whether the patient has symptoms distal to the knee	Symptoms distal to knee	Yes/No
	14	Whether the patient has decreased lumbosacral active range of motion	Decreased AROM	None/Mild/Moderate/ Severe
	15	Whether the patient has decreased lumbosacral passive range of motion	Decreased PROM	None/Mild/Moderate/ Severe
	16	Whether spinal joint springing or end-range of motion elicited patient's symptoms	Spinal springing/end-ROM recreating pain	Unsure/Yes/No
FABQ-W	17	Fear Avoidance Beliefs Questionnaire - Work subscale (FABQ-W)	FABQ-W	0-42
Cavitation	18	Whether the patient heard a cavitation during spinal manipulation	Presence of cavitation	Yes, easily heard / Yes, just heard / No / Unsure

Abbreviations: SMT = spinal manipulative therapy, FABQ-W = Fear Avoidance Beliefs – Work Questionnaire – Work subscale, NRS = Numerical rating scale, NSLBP = non-specific low back pain.

2.2 Pilot Testing the Questionnaires

Using the developed questionnaires, we then carried out a pilot study in the form of a cross-sectional study to collect data on the feasibility of recruitment and the study procedure, as well as identify potential relationships between each of the 5 domains and patients' immediate responses to SMT. This data could subsequently be used to inform a fully powered trial. See Appendices A through E for the ethical approval letter, as well as information letters and consent forms for practitioners and patients.

Participants

We recruited practitioners who met the following inclusion criterion:

- Manual therapists who routinely used HVLA SMT in clinical practice.

Patients selected by the practitioner had to meet the following inclusion criteria:

- Patient to be diagnosed with NSLBP with no etiological or underlying cause responsible for patient's back pain.
- HVLA SMT of the lumbar spine was to be used as part of the treatment modality.
- Minimum age of 18 years old.
- No underlying condition responsible for low back pain.

Sample Size

Previous studies have suggested the recommended sample sizes for pilot studies [100]. A common rule of linear regression is there should be at least a 10:1 ratio for subjects to predictors [100, 101]. Current research suggests a sample size of 100 is necessary for when five predictor variables are correlated with one another [100, 101]. We sought to achieve a sample size of 100 participants who voluntarily agreed to be in the study.

This was done by recruiting 10 chiropractors who subsequently distributed the questionnaire to 10 consecutive eligible participants.

Survey Implementation and Recruitment

The 10 practitioners were recruited via snowball sampling, direct contact, and advertisements on the Western Australian Chiropractic Facebook Page. Practitioners were informed they were free to withdraw consent at any time without consequence, and likewise for the patient. Furthermore, practitioners where informed of inclusion/exclusion criteria, and in addition where to perform spinal manipulation therapy for the back condition they were treating.

Expression of interest emails were sent to known chiropractors with an information letter outlining all the details of the study and what it entails. When an expression of interest was confirmed, signed consent was obtained from the participating practitioners. Set up then included 10 practitioner and patient survey questionnaires and further information letters which were to be left with reception staff at the front desk.

If a patient agreed to participate in the study, they were asked to complete a survey after their consultation, which was then put in a sealed envelope and placed in an enclosed sealed box at reception for patient confidentiality; practitioners also followed the same procedure. All questionnaires where pre-marked with corresponding numbers so each survey could be compared for analysis. Finally, feedback from the chiropractors was sought on their experience of using the inventory. This feedback was reviewed for changes which could be made accordingly to improve its usability.

Data Analysis

Data was scanned for incomplete data, then analysed in SPSS v.28 (IBM Corp, Armonk NY, USA). The presence of floor and ceiling effects were assessed and considered to be present if at least 15% of responses for continuous variables achieved the highest or lowest score, in sample sizes of more than 50 people [102].

All questionnaire items had descriptive statistics generated with frequencies or mean and standard deviations. Three variables underwent some modification prior to analysis. The results of the FABQ-W were dichotomised as Low (score <19) and High (score ≥19) in keeping with the item as described by Innes et al. (2020), but raw descriptive data is also reported. For the variable Spinal springing/end-ROM recreating pain, only the *Yes* or *No* responses were analysed and the *Unsure* responses were treated as missing data. The variable for Presence of cavitation was dichotomised with *Yes, easily heard* (n=35) and *Yes, just heard* (n=18) responses being grouped as *Yes*, and *No* (n=5) and *Unsure* (n=1) forming the *No* group.

For objective 3, independent t-tests and linear regression were performed to explore relationships between the patient's immediate responses to spinal manipulation and variables hypothesised as potential predictors by Innes et al. (2020). Dummy variables were created where necessary for regression analyses. All analyses used the dependent variable Actual change after SMT (0-10 NRS). Linear regression or multiple linear regression was used to assess whether the independent variables (items) predicted the patient's actual change after SMT. As a pilot investigation, we chose to perform separate regressions for the variables within each domain. The analyses performed are outlined in Table 3.

Table 3: Details of statistical analyses performed.

Domain	Analysis	Outcome measures	Dependent variable used in analysis
Patient factors	1. Multiple linear regression	Patient's prior response to SMT Patient's expected response to SMT Patient's rating of therapeutic alliance (ARM-5) Patient's understanding of their condition Patient's rating of Dr's understanding of goals	Actual change after SMT (0-10 NRS)
Practitioner factors	2. Multiple linear regression	Dr's rating of therapeutic alliance (ARM-5) Dr's rating of patient's health status Dr's rating of understanding of goals	Actual change after SMT (0-10 NRS)
Signs and symptoms of NSLBP presentation	3. Multiple linear regression	Symptoms <16 days Severe pain <14 days Pain improves with exercise Symptoms in lower extremities Symptoms distal to knee Spinal springing/end-ROM recreates pain Decreased AROM Decreased PROM *(removed from final model)*	Actual change after SMT (0-10 NRS)
FABQ-W	4. Simple linear regression	FABQ-W	Actual change after SMT (0-10 NRS)
Presence of Cavitation	5. Simple linear regression	Presence of cavitation	Actual change after SMT (0-10 NRS)

Abbreviations: SMT = Spinal manipulation therapy, AROM = Active range of motion, PROM = Passive range of motion, ROM = Range of motion, FABQ-W = Fear Avoidance Beliefs-Work, NRS = Numerical rating scale.

Chapter 3: Results

Objective 1: Designing the Questionnaires

Across the 18 items and five domains, three validated outcome measures existed in the literature which where applicable to two items. These included the Modified Patient-Dr Relationship Questionnaire (PDRQ-9 scale), Agnew Relationship Measure (ARM-5), and Fear-Avoidance Beliefs Questionnaire work section (FABQ-Work). Multiple questions were designed to cover the gaps in the literature.

We designed the following questions for the patient questionnaire:

- Patient's previous response to SMT ("How did you respond to previous manipulation for back pain?" on 0-10 NRS)
- Expected change after SMT ("Expected change immediately after the treatment" on 0-10 NRS)
- Actual change after SMT ("Actual change immediately after the treatment" on 0-10 NRS)
- Patient's understanding of their condition ("How well do you understand your back pain condition?" on a 0-10 NRS)
- Whether the patient heard a cavitation occur ("Presence of cavitation" with Yes, easily heard, Yes, just heard, None, or Unsure responses)
- Patient's belief about how well the practitioner understood their expectations and goals ("To what degree do you think your chiropractor understood your expectations and goals today?" on a 0-10 NRS).
- Five Yes or No symptom-based questions relating to the individuals' condition

- "On this occasion has your pain been severe for less than 14 days?"
- "On this occasion have you had symptoms for less than 16 days?"
- "Does your pain improve with exercise, but not rest?"
- "Do you have symptoms below the knee?"
- "Do you have any symptoms in the legs?"

We also designed the following questions for the practitioner questionnaire:

- Chiropractor's opinion of the patient's health status ("I rate the patients' health status as:" using a Likert scale with options from Very poor to Excellent and Unsure)
- Chiropractor's opinion of their understanding of the patient's goals and expectations ("To what degree do you think you understand this patient's expectation and goals?" with a 0-10 NRS)
- Active lumbosacral range of motion ("Was there a decreased active range of motion?" with No, Mild, Moderate, and Severe options)
- Passive lumbosacral range of motion ("Was there a decreased passive range of motion?" with No, Mild, Moderate, and Severe options)
- Whether spinal joint springing or end-range of motion elicited patient's symptoms ("Did spinal springing and/or end range loading closely reproduce the patient's symptoms?" with No, Yes, and Unsure options)

Draft copies of the questionnaires were created by the researchers based on the literature review and the newly-designed outcomes. The questionnaires were then reviewed by a focus group consisting of six experts. Of the items created specifically for this questionnaire, three recorded an I-CVI of 0.83 and the remainder rated 1.0.

Subsequently all items were retained with no or minor revisions. Suggestions from the focus group resulted in the implementation of relatively minor changes. This involved changes from a numerical scale to a Likert scale for some questions, language changes to create more succinct questions, revision of the practitioner questionnaire to make it shorter, along with grammar and formatting changes for clarity.

When reviewed by four manual therapists for additional feedback, further grammar and formatting changes where implemented. However, a suggestion of shortening the practitioner questionnaire further was not feasible. No other changes where suggested when revised again by one participating focus group member. This resulted in the final questionnaires for the commencement of the pilot study. See Appendix A for the finalised questionnaires that were used in the pilot study.

See Appendices F and G for copies of the final questionnaires.

Objective 2: Investigating the feasibility of recruitment and the procedure

Data Collection and Recruitment

COVID-19 impacted data collection due to the restrictions imposed in Western Australia. This resulted in the closure of the chiropractic practices involved in the study on multiple occasions. A total of 10 registered chiropractors were recruited for the study, who in turn were asked to recruit 10 patients who met the eligibility criteria from their private practice.

Chiropractors were recruited through a Facebook advertisement on the Western Australian Chiropractic and Student Facebook group (one participant), snowballing (one participant), and via email contact of known associates (eight participants).

A Facebook post was seen by approximately 250 people with only one comment indicating a willingness to participate. A total of 36 emails were sent to various chiropractic clinics across the Perth region using Google search, of which only three clinics replied. However, they were unable to participate. A further 15 recruitment emails were sent to chiropractors known to the researcher through the Murdoch University chiropractic program, of which eight replied confirming participation. One of these participants also recruited their work colleague. The participants were selected on a first to reply basis.

Out of the ten recruited chiropractic practitioners, six completed the study by recruiting ten patients each, two withdrew from the study (but completed one and two patient recruitment forms respectively), two were lost to follow up and only three feedback sheets were completed. Four of the practitioners who participated contacted the researcher to collect the questionnaires when they completed recruiting patients,

while two had to be emailed and followed up on twice to collect their questionnaires. Two participants who withdrew from the study received three reminder emails and a phone call; however, they replied two months after the last email informing their wish to withdraw from the study. Two participants who were lost to follow up did not respond to two emails and one phone call each. In total, across the ten practitioners recruited there were 63 practitioner and patient responses. Data was collected over a ten-month period due to various COVID-19 lockdowns affecting the manual therapist availabilities and recruitment processes.

Practitioner Feedback on Questionnaire Functionality

Only three of the six clinicians who completed the study provided feedback, as below:

1. “Don’t have the consent form on the same page back to back with the survey. I had questions from participants about confidentiality”.
2. “Need differentiating between sciatica + knee pain in question about pain below hip/leg pain”.
3. For practitioners: “How long have they seen this patient for? / The number of appointments they had with the patient at the time of survey”.

No written feedback was given by the two practitioners who withdrew from the study; however, one practitioner verbally expressed the boxes consumed too much office space in an already condensed environment. The two lost to follow up and two who withdrew were sent an email asking for feedback; however, they did not reply.

Objective 3. Investigating changes in the 5 domains

Descriptive Data

See Table 4 for descriptive data of the continuous variables, Table 5 for dichotomous variables, and Table 6 for ordinal variables. See Figure 2 for frequency histograms of the continuous variables.

The raw FABQ-W scores had a mean of 12.13 (SD 7.77), and the distribution can be seen in Figure 2. For the variable Spinal springing/end-ROM recreating pain, there were n=4 *Unsure* responses but only the *Yes* or *No* responses were analysed.

The variable for Presence of cavitation was also dichotomised with *Yes, easily heard* (n=35) and *Yes, just heard* (n=18) responses being grouped as *Yes*; *No* (n=5) and *Unsure* (n=1) formed the *No* group. The PDRQ-9 results are not reported due to an error in the Likert scale in the questionnaire, rendering the scores invalid. Substantial ceiling effects were observed for most continuous variables (see Table 4). No floor effects were observed.

Table 4: Descriptive data for continuous variables

Variable	Scale	Responses, N (missing)	Mean (SD)	Range (actual)	% responses at ceiling
Patient's actual change after SMT	0-10	60 (3)	9.51 (1.24)	5-11	26.7%
Patient's prior response to SMT	0-10	50 (13)	9.42 (1.14)	7-11	22.0%
Patient's expected response to SMT	0-10	60 (3)	9.22 (1.39)	7-11	18.3%
Patient's rating of therapeutic alliance (ARM-5)	0-35	59 (4)	33.31 (2.28)	28-35	54.2%
Patient's understanding of their condition	0-10	60 (3)	9.43 (1.18)	5-11	18.3%
Patient's rating of Dr's understanding of goals	0-10	59 (4)	10.19 (1.06)	7-11	50.8%
Dr's rating of therapeutic alliance (ARM-5)	0-35	60 (3)	31.72 (3.27)	20-35	38.3%
Dr's rating of patient's health status	0-6	61 (2)	4.56 (1.10)	4-6	21.3%
Dr's rating of understanding of goals	0-10	58 (5)	9.64 (1.04)	8-11	27.6%
FABQ-W (raw)	0-42	46 (17)	12.13 (7.77)	0-28	0.0%

Abbreviations: SMT = Spinal manipulation therapy, ARM-5 = Agnew Relationship Measure-5, FABQ-W = Fear Avoidance Beliefs-Work.

Table 5: Descriptive data for categorical variables.

Variable	Total responses, N (missing)	Responses, n (%)
Symptoms <16 days	59 (4)	Yes: 41 (65.1), No: 18 (28.6)
Severe pain <14 days	60 (3)	Yes: 42 (66.7), No: 18 (28.6)
Pain improves with exercise	60 (3)	Yes: 34 (54.0), No: 26 (41.3)
Symptoms in lower extremities	60 (3)	Yes: 16 (25.4), No: 44 (69.8)
Symptoms distal to knee	60 (3)	Yes: 5 (7.9), No: 55 (87.3)
Spinal springing/end-ROM recreates pain	58 (5)	Yes: 40 (63.5), No: 14 (22.2), Unsure: 4 (6.3)
FABQ-W (dichotomised)	46 (17)	Low: 37 (58.7), High: 9 (14.3)
Presence of cavitation	59 (4)	Yes: 53 (84.1), No: 6 (9.5)

Abbreviation: ROM = Range of motions, FABQ-W = Fear Avoidance Beliefs-Work

Table 6: Descriptive data for ordinal variables.

Variable	Total responses, N (missing)	Mild, n (%)	Moderate, n (%)	Severe, n (%)
Decreased AROM	59 (4)	37 (58.7)	14 (22.2)	4 (6.3)
Decreased PROM	57 (6)	35 (55.6)	12 (19)	5 (7.9)

Abbreviation: AROM = Active range of motion, PROM = Passive range of motion

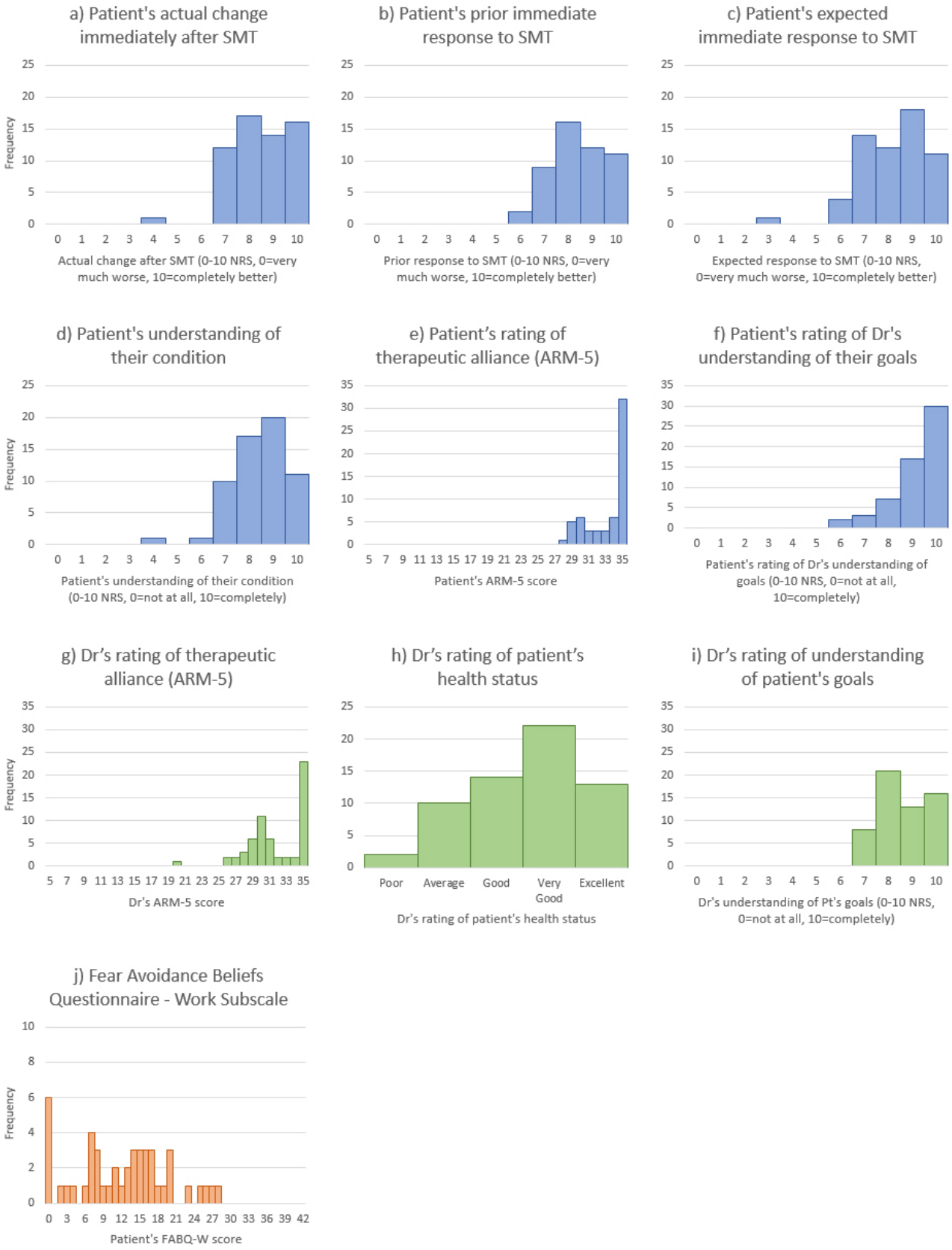


Figure 2: Frequency histograms for continuous variables.

Statistical Analyses

Patient Factors

The multiple linear regression equation showed independence of residuals (Durbin-Watson statistic = 2.070), and no multicollinearity (all independent variable correlations were less than 0.7 and Tolerance was above 0.1 for all).

The multiple regression equation was statistically significant ($F(5,42) = 21.092$, $p < .001$) with an adjusted $R^2 = 0.681$ ($R^2 = 0.715$) (see Table 7 for details of the coefficients). The items Patient's prior immediate response to SMT, and Patient's expected immediate response to SMT were statistically significant predictors of the Actual response to SMT.

Table 7: Multiple Linear Regression Coefficients of Patient Factors Predicting Actual response to SMT.

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	-2.577	1.683	-	-1.531	.133	-5.975	.820
Patient's prior response to SMT	.446	.126	.394	3.543	<.001*	.192	.700
Patient's expected response to SMT	.305	.105	.334	2.894	.006*	.092	.518
Patient's rating of therapeutic alliance (ARM-5)	.080	.056	.144	1.424	.162	-.034	.194
Patient's understanding of their condition	.166	.117	.157	1.414	.165	-.071	.403
Patient's rating of Dr's understanding of goals	.076	.170	.063	.446	.658	-.268	.420

Abbreviations: SMT = spinal manipulative therapy.
** p < .05*

Practitioner Factors

The multiple linear regression equation showed independence of residuals (Durbin-Watson statistic = 2.643), and no multicollinearity (all independent variable correlations were less than 0.7 and Tolerance was above 0.1 for all).

The multiple regression equation was statistically significant ($F(3,52) = 10.793$, $p < .001$) with an adjusted $R^2 = 0.348$ ($R^2 = 0.348$). See Table 8 for details of the coefficients. The items Dr's rating of patient's health status, and Dr's rating of understanding of goals/expectations were statistically significant predictors of the Actual response to SMT.

Table 8: Multiple Linear Regression Coefficients of Practitioner Factors for Predicting Actual response to SMT.

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	2.640	1.545	-	1.709	.093	-.460	5.739
Dr's rating of therapeutic alliance (ARM-5)	.058	.050	.151	1.157	.253	-.043	.159
Dr's rating of patient's health status	.410	.146	.355	2.798	.007*	.116	.704
Dr's rating of understanding of goals	.325	.155	.266	2.097	.041*	.014	.635

Abbreviations: SMT = spinal manipulative therapy.
** p < .05*

Signs and Symptoms of NSLBP Presentation

In the initial multiple linear regression equation, multicollinearity was observed. The variables Decreased AROM, and Decreased PROM were highly correlated with r = 0.876, although Tolerance was above 0.1 for all. Therefore, we chose to refine the model by removing Decreased PROM as a variable.

The final multiple regression equation showed independence of residuals (Durbin-Watson statistic = 1.851) and no multicollinearity (all independent variable correlations were less than 0.7 and Tolerance was above 0.1 for all).

The model was statistically significant ($F(7,44) = 4.058$, $p = .002$) with an adjusted $R^2 = 0.269$ ($R^2 = 0.392$) (see Table 9 for details of the coefficients). The items Severe pain <14 days, Symptoms distal to knee, and Decreased AROM were statistically-significant predictors of the Actual response to SMT.

Table 9: Multiple Linear Regression Coefficients of Signs and Symptoms Factors for Predicting Actual response to SMT.

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	10.988	.600	-	18.304	<.001	9.778	12.198
Severe pain <14 days	-.797	.358	-.289	-2.229	.031*	-1.518	-.076
Symptoms <16 days	.708	.371	.246	1.907	.063	-.040	1.457
Pain improves with exercise	.491	.314	.189	1.563	.125	-.142	1.124
Symptoms distal to knee	-1.258	.558	-.291	-2.254	.029*	-2.382	-.133
Symptoms in lower extremities	.096	.382	.034	.252	.802	-.674	.866
Spinal springing/end-ROM recreates pain	.005	.358	.002	.015	.988	-.717	.727
Decreased AROM	-.681	.226	-.383	-3.010	.004*	-1.137	-.225

Abbreviations: SMT = spinal manipulative therapy, ROM = Range of motion, AROM = Active range of motion.
** p < .05*

FABQ-W

The simple linear regression equation was not statistically significant ($F(1,44) = 3.442$, $p = .070$) with an adjusted $R^2 = 0.051$ ($R^2 = 0.073$) (see Table 10 for details of the coefficients).

Table 10: Analysis 4 - Simple Linear Regression Coefficient of FABQ-W for Predicting Actual response to SMT.

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	9.757	.207	-	47.154	<.001	9.340	10.174
FABQ-W	-.868	.468	-.269	-1.855	.070	-1.811	.075

Abbreviations: SMT = spinal manipulative therapy, FABQ-W = Fear Avoidance Beliefs-Work.

Presence of Cavitation

The simple linear regression equation was not statistically significant ($F(1,57) = 1.032$, $p = .314$) with an adjusted $R^2 = 0.001$ ($R^2 = 0.018$) (see Table 11 for details of the coefficients).

Table 11: Analysis 5 - Simple Linear Regression Coefficient of Presence of Cavitation for Predicting Actual response to SMT.

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	9.000	.511	-	17.629	<.001	7.978	10.022
Presence of cavitation	.547	.539	.133	1.016	.314	-.531	1.626

Abbreviations: SMT = spinal manipulative therapy.

Results Summary

Three validated outcome measures were found in the literature when designing the questionnaires. These were Modified Patient-Dr Relationship Questionnaire (PDRQ-9 scale), Agnew Relationship Measure, and Fear-Avoidance Beliefs Questionnaire work section. Nine questions were designed to cover gaps in the literature. Feedback was sought from a focus group and manual therapist experts to refine the questionnaires.

Ten registered chiropractors were recruited, with each asked to recruit 10 patients who met the eligibility criteria. Two practitioners withdrew from the study and two were lost to follow up. A total of 63 patients were subsequently recruited out of a target of 100.

The multiple regression analyses investigating Patient factors, Practitioner factors, and Signs and Symptoms factors were all statistically significant, accounting for 68.1%, 34.8%, and 26.9% of the variance in patients' immediate responses to SMT, respectively. Individually significant variables were Patient's prior response to SMT and Patient's expected response to SMT in the Patient factors analysis, Dr's rating of patient's health status and Dr's rating of understanding of goals in the Practitioner factors analysis, and Severe pain <14 days, Symptoms distal to knee, and Decreased AROM in the Signs and Symptoms factors analysis. The linear regression analyses investigating the effects of FABQ-W and the presence of a cavitation on the patients' immediate responses to SMT were both non-significant.

Chapter 4: Discussion

A study was conducted to explore the possible use of 18 suggested predictors of instantaneous relief after spinal manipulation for NSLBP which was identified by Innes et al. [6]. It identified several potential issues with recruitment of practitioners and patients that would impact on a fully powered study. Also, it suggests that the instruments used are sensitive to the domains under investigation.

Objective 1: Designing of Questionnaire

The main purpose of the questionnaires was to collect data from the respondents to answer the research questions in the most efficient and convenient way possible over the allocated time period. The questionnaire was to be reliable, valid, and succinct to ensure that accurate data was collected from all participants [103]. This would in turn allow for a fully powered study where outcomes could be tested with a larger group of participants. The framework for the questionnaires was established based firstly on a literature review for previously validated questionnaires that would assess our suggested predictors. Three appropriate questionnaires were identified in the literature, which were the Agnew Relationship Measure-5 (ARM-5), Fear-Avoidance Beliefs Questionnaire (FABQ-Work), and Patient-doctor relationship questionnaire (PDRQ-9 scale).

The ARM-5 is a concise version of the ARM-12, which is itself derived from the ARM-28. The ARM-5 consists of 5 questions assessing therapeutic alliance between practitioner and patient in the form off their bond, partnership, and confidence in

therapy provided [104]. The ARM-5's validity and reliability were tested by against the original ARM-28 [104]. The ARM-5 suffers from ceiling effects due to patients rating the practitioner very highly; however, it was shown to have high levels of predictive value and acceptable levels of internal consistency. The ARM-5 was included in both the patient and practitioner questionnaires to assess the patient's trust and confidence in the practitioner, and the practitioner's opinion of the patient-practitioner relationship.

We used FABQ-W section from the FABQ questionnaire to assess for fear avoidance beliefs in relation to an individual and their work for item 17 [105]. The FABQ has been subject to many prospective studies supporting its subscales score's validity, whilst also being widely recognised and used in clinical practice [106, 107].

The PDRQ-9 is also used to assess and look at the patient-doctor relationship [108]. Porcerelli et al. [109] assessed levels of validity and reliability of the PDRQ-9 in a primary care setting by assessing the convergent validity against the Difficult Doctor Patient Relationship Questionnaire-10. The internal consistency was 0.96, providing support for the use of the PDRQ-9 in assessing patient-doctor relationships [109]. In this study we used the PRDQ-9 to assess the patient-practitioner relationship.

To develop questions for the remaining suggested predictive items we had to take into consideration the dependent and independent variables along with the style of question being asked in the form of open-ended or close-ended questions [103]. Due to time constraints on participants and for the interpretation of the data, closed-ended questions were chosen which were then put forth to a focus group.

We encountered some practical issues with the focus group. Organising a focus group meeting itself was difficult and extended the process by four to five weeks.

Changes that were suggested by the focus group, and subsequently implemented, included the use of Likert scales for some questions, the option to skip the FABQ-W questionnaire if an individual is retired or currently unemployed, and a number of grammar and formatting corrections. The questionnaire was then given to four manual therapists in order to receive feedback regarding the questionnaire's readability and usability if being implemented in a clinical setting. Grammar and formatting issues where corrected where possible to increase usability; however, feedback relating to time constraints on the practitioner were unable to be addressed due to the nature of the questions and the information we required. No patient concerns were raised and all practitioners relayed that patients could easily fill in the questionnaire in the waiting room after their treatment. Unfortunately, the final questionnaire could not go back to the full focus group for further examination due to the complexities of re-organising a mutual meeting time to fit around focus group members' prior commitments. However, the questionnaires were re-examined by one member with no additional changes suggested. After this, the questionnaires were finalised and ready to be implemented and distributed to ten manual therapists for the commencement of the pilot study.

If we were to perform a similar study, we would consider some changes to ensure more successful implementation of questionnaire development. Consideration could be given to moving the focus group questionnaires online in the initial design phase [110]. This could involve an email link or QR Code to a survey platform such as Survey Monkey or a purpose-built site to complete outcome measures and provide feedback [111]. This would allow for all focus group members to access and complete the original questionnaires in a timely and convenient manner removing the logistics of needing all members present in the same space.

Objective 2: Investigating the feasibility of recruitment and the procedure

Recruitment

The study had a small sample size due to the nature of it being a pilot study to test feasibility for larger scale implementation. The initial recruitment period for practitioners took longer than expected, with recruitment commencing in September 2020 and finishing in March 2021. A range of restrictions due to the COVID-19 pandemic, from the university, and state and federal governments, delayed the start of this study. Further government-imposed lockdowns interrupted the collection of data after it commenced. These factors likely disrupted businesses and created apprehension in both practitioners and patients resulting in fewer people seeking manual therapy treatment, thus fewer people meeting the inclusion criteria. While no feedback was provided by any of the participating practitioners on difficulties with recruitment of their patients, it is likely that COVID-19 impacted practitioners' willingness to participate.

Social media was an unsuccessful method for recruiting practitioners. The most successful method was by personal contact with practitioners known to the project supervisors. If a larger scale study was to be conducted, incentives for practitioner participation are recommended to aid recruitment. Expanding the participant recruitment pool to other states of Australia and to other countries could also be considered. This would improve the generalisability of the data.

Questionnaire Confidentiality

To our knowledge, the sealed envelopes and boxes provided security for patients and practitioners which was, anecdotally, well received. The only feedback related to this was that the boxes for the sealed envelopes took up already limited space in the practice reception space. However, this feedback was verbal when collecting the data and was not written or expressed on the feedback form by the participating practitioners. Other methods of collecting the data were considered; however, they were too costly and would be more suited to larger scale studies. This includes using iPads so that the questionnaires could be completed online, taking up less room and being more environmentally friendly. However, the cost of purchasing iPads and the potential for damaged property are a barrier to this option.

Practitioner Feedback

It is common practice for many surveys or questionnaires to include a feedback section as it acts as a guide in helping researchers identify possible issues that have occurred throughout the questionnaires [112, 113]. Only three of the ten practitioners provided open-ended feedback in the sections provided. Two of the three feedback sheets where related to the formatting of the questionnaires, suggested greater clarification on confidentiality from a patient's point of view, and a clearer definition of sciatic related pain versus hip and leg pain. Given the limited and brief feedback provided by participants, it cannot be concluded as to whether the feedback was given with constructive intention or if it was used as a platform for participants to express negative feelings they may have about the study or the questions asked [112, 113].

The last practitioner highlighted an aspect which could affect the TA between practitioner and patient along with a suggestion on how to address this. They suggested asking how long the patient has been seeing the practitioner before the study. Even though this is a valuable suggestion and would be simple to include, it would change the context by looking at the development of the strength and bond between practitioner and patient over time. The purpose of the item is to look at the current relationship between practitioner and patient, which is likely adequately assessed via the ARM-5 or PDRQ-9.

Lastly, it is problematic that seven of the ten practitioners did not provide any feedback. We can only hypothesize why no feedback was given. This could have been due to COVID-19 disruptions, time constraints of the practitioner, possible fatigue after completing a lengthy questionnaire, or lack of motivation to do so. A possible solution is to provide an incentive to the practitioner which might decrease the numbers of non-respondents [113]. However it is important to note that by providing an incentive we may be creating a bias or false feedback as individuals could be possibly seeking the reward [113].

Overall Procedure

Overall, the pilot study was disjointed due to the multiple disruptions related to COVID-19. This delayed the start of the project and ethics approval, and hindered data collection. Furthermore, some practitioners took longer than anticipated to complete the questionnaires with no specific reason or explanation provided. Data collection itself ran smoothly with no problems reported, and, anecdotally, most practitioners conveyed

that the questionnaires had no impact on their time with patients, schedule or their daily routines. This could possibly be due to the short nature of the practitioner questionnaire with only four outcome measures. Practitioners stated that all patients that participated where happy to fill in the questionnaire, which was completed in the waiting room after their appointments.

Study Feasibility

If the current study design was run as a full-powered study, it could only be implemented in the local regions where the researchers are based. This is due to the limitations of the paper-based design set up and the logistics of organising a mutual time where the researcher and practitioner were both available for explanation of how the study worked, implementation of the data collection boxes in clinics, and signing of the consent forms. To overcome this limitation, it is recommended that the study move to an online format for data collection as it would allow for greater participant reach and the removal of the complexity in the initial set up. This could be done on devices such as a tablet provided by the researchers, or using a link or QR code and having practitioners and patients complete the questionnaires on their own devices. Furthermore, an online method would provide many advantages which include, but are not limited to: data being easier to analyse and standardize; data collection being more convenient; larger numbers of participants with greater reach; less expensive; enhanced anonymity; only one person is required for administrative purposes related to collection; and faster to carry out [110, 111].

However, some of the disadvantages of an online study include possible economical barriers stemming from the need for a digital platform device in the form of a computer, tablet or phone with internet connection. Other possible disadvantages to online questionnaires include lack of motivation or willingness to login to fill out a questionnaire [110].

A fully powered paper-based or online study would have to take into consideration the possibility of a high drop-out rate when considering further research and would be a vital aspect of recruitment and planning. A high drop-out or loss to follow up rate has the ability to create bias in the result and threatens the internal validity of the study [114, 115]. In this study, it is important to note the drop-out and loss to follow up rate is from the practitioners themselves and not the subsequently recruited patients. However, it is inevitable that most studies will have some form of participant withdrawal, with current research stating that <5% loss to follow is expected and causes little bias in the result [115]. Practitioner drop-out and non-response can possibly be solved by providing incentives for practitioners, as mentioned above.

Objective 3: Investigating changes in the 5 domains hypothesized as measures of those people with NSLBP who would experience an instant and strong response to SMT

Patient Factors

The patient factors of *Previous positive response to SMT* and *Expected response to SMT* were associated with immediate improvement in NSLBP after SMT. While the analysis is preliminary, our results agree with prior literature which has found that a patient's short-term response to SMT is a strong predictor of their longer-term response to SMT [116]. *A patient's previous response to a treatment and their expected response to future treatments* are likely closely related concepts, since expectations about the future are in part based on information from prior experiences.

The positive or negative effects one expects to experience after treatment are likely closely linked to placebo and nocebo effects [117]. Prior research comparing the hypoalgesic effect of SMT have shown that an individual's expectations influence pain sensitivity outcomes [13, 117]. People who are in pain or discomfort will likely have a greater desire for an SMT intervention to alleviate their pain, subsequently leading to greater expectations of the treatment [118].

However, the Patient Factors linear regression accounted for a high percentage of variance (68.1%) in the outcome. This is likely due to the underpowered nature of this pilot study and not a true reflection of the relative contribution of patient factors to the outcome of rapid improvement after SMT.

Practitioner Factors

The predictor *Practitioner's rating of patient's health status* was associated with instantaneous responses post SMT. A possible explanation for this finding is that the patients who the practitioner rated as having better health status are likely to have fewer co-morbidities such as cardiovascular disease, diabetes, respiratory or mental illness [119, 120], and more likely to engage in regular physical activity. Patients with fewer co-morbidities and engaging in more physical activity may tend to have fewer complex contributors to NSLBP, and therefore may be more likely to respond positively to SMT. However, it is important to note that a practitioner's views of a patient's health status may be different to how a patient views their own health status [119, 120].

A practitioner tends to rate health status through a biomedical model, assessing if a disease is causing body structures to function outside of what is considered normal. If this is not occurring, then the rating in most cases will be good to excellent [119]. However, a patient assigns value to their health not only based on function but also social impacts and symptoms they are experiencing [119]. So, while our results were statistically significant, it is important to note these limitations with a practitioner's rating of a patient's health status.

The predictor of *Practitioner's understanding of goals/expectations* may reflect, in part, the therapeutic alliance and the process of setting mutual goals between the manual therapist and patient [121-123]. Our study found that, with higher ratings of this factor, patients were more likely to respond positively to SMT. This supports previous research that the main expectation for both practitioner and patient is to diagnose and provide appropriate treatment for the condition which is the cause of the patient's

complaint, whilst also informing the individual of a prognosis and treatment plan [121]. By both the practitioner and patient sharing the same goals and explaining the expectations of the treatment, greater understanding is built by the practitioner, possibly contributing to positive responses after SMT. Both chiropractors and patients often expect that patients feel symptomatic relief after treatment sessions [121, 123].

Signs and Symptoms

A *decrease in AROM* prior to SMT was found to be negatively related to relief following SMT: as AROM became more restricted, patients were less likely to report improvement following SMT. There does not appear to be any prior research investigating decreased spinal AROM as a predictor of improvement after SMT. Changes in ROM after SMT have been investigated in numerous studies; however, the research is conflicting. Some literature provides supporting evidence for improvements in ROM after SMT [124-126]. A systematic review on the effects of SMT on range of motion found inconsistency in the research, and concluded that SMT may sometimes have a small effect on ROM, especially in the cervical spine [127]. However, it is important to consider that AROM in our study was assessed subjectively, rather than objectively, through a visual estimation method based on perception and interpretation of the practitioner. Overall, it appears that the relationships between ROM and SMT are unclear.

Our results also found that people who answered yes to the predictors 'Severe pain <14 days' or 'Pain below the knee' were less likely to report a strong and instantaneous response to SMT. This finding for the 'Pain below the knee' predictor parallels the classification system of Fritz et al. [62] and later revised by Stanton et al.

[85], which also includes pain below the knee as a factor which counts against the manipulation classification. These findings are also supported by previous research which tested the CPRs for reliability and validity, demonstrating patients who had pain for >14 days or below the knee, responded less favorably to manipulation [18, 61, 85].

FABQ-W

Whilst only being a pilot study inherently limits the strength of our findings, we found no strong relationship between the FABQ-W and instantaneous response after SMT. However, there was a trend toward participants with a low FABQ-W being more likely to have a positive response to SMT. A low FABQ-W is reported as a factor favouring SMT in the Fritz et al. manipulation classification [62]. This factor was likely included because the practitioners in the original Delphi study were familiar with the Fritz classification system and may apply it in clinical practice [6].

Cavitation

We found no relationship between the presence of an audible cavitation and instantaneous response to SMT, which aligns with prior research [128, 129]. Clinically, many people consider a cavitation to be a positive indicator of a successful SMT [130]. However, research has found that the hypoalgesic effect or decrease in subjective pain occurs independently of cavitation [129, 130]. Therefore, our preliminary results agree with prior literature.

Therapeutic Alliance Outcome Measures

The PDRQ-9 was not used in the statistical analyses (despite data being collected), due to human error on the researchers' behalf when designing the questionnaire for implementation. The PDRQ-9 is a shorter version of the PDRQ-15 which was developed in 2004 and based on the Dutch 11-item Helping Alliance Questionnaire [108, 131]. The questions included in the pilot study questionnaires were the full PDRQ-15 and not the PDRQ-9. Furthermore, the response scale was incorrect.

The correct response scale should have been a Likert scale with 1-5 (not at all appropriate to totally appropriate). Our questionnaires had a Likert scale of 1-4 (never to always). Therefore, all the PDRQ data collected was inappropriate and effectively amounted to using an untested and unvalidated outcome measure. Fortunately, an additional mistake was made in designing the questionnaires. We also included the ARM-5, which is an additional measure of TA. Therefore, we made the decision not to use the PDRQ data in the results, but we were able to use the ARM-5 as our measure of TA. If this pilot study is to be replicated in a fully powered trial, the questionnaires should be modified to remove the PDRQ.

We discovered we had very high ratings of TA when analysing the ARM-5 and this could be due to multiple reasons. First, when Cahil et al. [104] assessed the ARM-5 against the ARM-12 for validity and reliability, they found most clients rated their therapist very highly. Therefore, the ARM-5 suffers from ceiling effects and our results were no different. There are numerous consequences of ceiling effects. In our study, the ceiling effect likely means that we would be unable to differentiate between good and poor responders to SMT based on the ARM-5 scores [132]. Consequently, we could not

see an effect of the independent variable (predictor) on the dependant variable (actual response to SMT) as almost all independent variable values clustered towards the maximum score, thus effecting the internal validity [132]. It is possible that the PDRQ may not suffer from the same ceiling effects and may have been a better measure of therapeutic alliance in this study; unfortunately, however, we were unable to use the PDRQ, as explained above.

Secondly, we did not assess the duration for which the patient had been in the care of the treating practitioner. Some of the practitioners and patients who participated in the study had likely formed a TA over multiple visits, which likely skews the results. If a poor TA was formed between practitioner and patient, this would likely result in a patient seeking care elsewhere, hence why patients who seek ongoing care with a particular practitioner will be those who feel they have a higher TA with them.

Limitations

The design process of the questionnaire was limited by the possibility of selection bias. When the questionnaires were reassessed by the focus group, only one member was available to do so. Furthermore, the four manual therapists who reviewed the questionnaires prior to the focus group reassessment were selected from Murdoch University Chiropractic Clinic staff and were known to the researcher.

The study was also limited in terms of sample size due to the nature of being a pilot study. In addition, we did not reach the planned sample size of 100 participants. For these reasons, no firm conclusion can be drawn about the relationships between predictive variables and instantaneous response after SMT, and our results should act as a guide for future research only.

Furthermore, our population were all patients visiting a chiropractor and suffering from NSLBP. We did not collect data on the patients' age, gender, or other demographic information. This means our findings may not be applicable to other populations outside of those who have not been diagnosed with NSLBP.

The COVID-19 pandemic created multiple disruptions and setbacks to data collection. This in turn delayed the practitioner's recruitment of their own 10 patients for the study. There is also the potential for external psychological factors related to COVID-19 (such as fear avoidance and anxiety) which could bias some of the outcome measures as it has been demonstrated that psychological factors can influence pain [133-135]. However, it was deemed low risk; therefore, we continued exploring the feasibility of the pilot testing and ran the project knowing the potential for impacts from COVID-19.

Feedback on how the questionnaires worked was limited by the fact that feedback was purely at the discretion of the practitioner. If the practitioner decided to fill out the feedback form or note their experience, it provided invaluable input and data. However, the researchers had little control over this, limiting the possibility for improvement for further studies.

Further Research

We can conclude that a fully powered study is feasible; however, there are challenges to consider and aspects that could be improved for simplicity and for overall success, as mentioned above. Further research is needed with recruitment of a larger number of participants before a conclusion can be reached on the predictive value of the 18 items across the 5 domains for identifying strong and instantaneous responders to SMT. Our preliminary data suggests there may be relevant predictors of instantaneous relief after SMT in adults with NSLBP from among the 18 items examined in our pilot study. Therefore, a fully powered and robust study would be valuable to explore these predictors further.

For a fully powered study, we make the following comments and recommendations:

- Changes in the questionnaire
    - Either remove the PDRQ-9 from the questionnaires, or correct PDRQ-9 and remove the ARM-5 to measure TA.
- Recruitment process
    - Possibly use incentives for participating practitioners.

    - Recruit from practices in multiple state, and potentially multiple countries.

- Demographic information
    - Consider collecting demographic data such as age, gender, country and living location.
- Study design
    - Move to an electronic format for data collection allowing for instant data collection and simplifying the data collection process.
- Anticipate delays in data collection and potentially high rates of practitioner non-response and withdrawal.

Chapter 5: Conclusion

As has been demonstrated, the creation and pilot testing of questionnaires to identify strong and instantaneous responders to spinal manipulation therapy yielded positive results, indicating the need for a fully powered study. Though this was a pilot study and clinical significance cannot be concluded, some predictors of immediate response to spinal manipulation were statistically significant. This highlights the need for further high-quality research to build upon our findings to see if the 18 predictive items can be used to develop a clinical prediction rule to identify those who suffer from non-specific low back pain who are likely to respond with instantaneous relief after spinal manipulation.

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Appendices

Appendix A – Ethics Approval

Research and Innovation
Research Ethics and Integrity

Chancellery Building, Room 1.006
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Wednesday, 09 September 2020

Dr Stanley Innes
SHEE - Psychology, Counselling, Exercise Science and Chiropractic
Murdoch University

Dear Stanley,

Project No.	2020/152
Project Title	Creating a measure for identifying strong and instantaneous responders to spinal manipulation therapy

Thank you for addressing the conditions placed on the above application to the Murdoch University Human Research Ethics Committee. On behalf of the Committee, I am pleased to advise the application now has:

OUTRIGHT APPROVAL

Approval is granted on the understanding that research will be conducted according the standards of the ***National Statement on Ethical Conduct in Human Research 2007*** **(Updated 2018), the *Australian Code for the Responsible Conduct of Research*** **(2007)** and **Murdoch University policies** at all times. You must also abide by the **Human Research Ethics Committee's standard conditions of approval (see attached).** All reporting forms are available on the Research Ethics and Integrity web-site.

I wish you every success for your research.

Please quote your ethics project number in all correspondence.

Kind Regards,

Dr. Yvonne Haigh
Chair
HREC Committee

Dr. Erich von Dietze
Manager
Research Ethics and Integrity

cc: Dr Sasha Aspinall, Mr Reece Granger

CRICOS Provider Code: 00125J
ABN 61 616 369 313

Human Research Ethics Committee: Standard Conditions of Approval

a) The project must be conducted in accordance with the approved application, including any approved conditions and amendments, and any subsequent conditions that the HREC may require.
b) Anything which might affect the ethical acceptance of your project must be reported promptly, including:
   - *Adverse effects on participants*
   - *Significant unforeseen events*
   - *Other matters that may impact the ethical acceptability of the project.*
c) Proposed changes or amendments to the research must be applied for, using an Amendment Application form, and approved by the HREC before these may be implemented.
d) An Annual Report must be provided by the due date specified each year (usually the anniversary of approval).
e) A Closure Report must be provided at the conclusion of the project (once all contact with participants has been completed).
f) If, for any reason, the project does not proceed or is discontinued, you must advise the committee in writing, using a Closure Report form.
g) If an extension is required beyond the end date of the approved project, an Extension Application should be made allowing sufficient time for its consideration by the committee. Extensions of approval cannot be granted retrospectively.
h) The HREC must be advised promptly, in writing, if any complaint is made about the conduct of the project.
i) Other Murdoch approvals (e.g. fieldwork approval) or approval from other institutions may also be necessary before the research can commence.
j) Any equipment used must meet current safety standards. Purpose-built or modified equipment must be tested and certified by independent experts for compliance with safety standards.
k) Research Ethics & Integrity must be notified of any changes to contact details including address, phone number and email.
l) Graduate research degree candidates should also have Program of Study approval prior to commencing the research. Exceptions must be approved by the HREC.
m) The HREC may conduct random audits and / or require additional reports concerning a research project.
n) Any external hard drives (such as thumb drives or flash drives) storing research data must be password protected

Failure to comply with the *National Statement on Ethical Conduct in Human Research* (2007) (updated 2018) and with the conditions of approval may result in the suspension or withdrawal of approval for the project.

The HREC seeks to support researchers in achieving strong results and positive outcomes.

The HREC promotes a research culture in which ethics is considered and discussed at all stages of the research.

If you have any issues you wish to raise, please contact the Research Ethics & Integrity in the first instance.

Appendix B – Practitioner Information Letter

Practitioner Information Letter

Dear Participant

We invite you to participate in a research study looking at "Identifying strong and instantaneous responders to spinal manipulation therapy". This study is part of my Honours Degree in chiropractic science, supervised by Dr Stanley Innes at Murdoch University

Nature and Purpose of the Study
It is common that many people will experience discomfort from non-specific lower back pain in their life. Some researchers have tried to identify those who gain strong instantaneous relief from non-specific lower back pain by spinal manipulation therapy, however the evidence has been inconclusive.

Therefore, the aim of this study is to investigate if 18 identifiable items can predict a subgroup of people who will gain instantaneous pain relief from non-specific lower back pain following spinal manipulation therapy.

If you consent to take part in this research study, it is important that you understand the purpose of the study and the tasks you will be asked to complete. Please make sure that you ask any questions you may have, and that all your questions have been answered to your satisfaction before you agree to participate.

What the Study will Involve
To participate in this study, you must be over 18 years of age, practice manual therapist techniques and complete the derived questionnaires with 10 consecutive non-specific lower back pain patients. It is estimated that the questionnaire will take approximately 5-10 minutes to complete.

Voluntary Participation and Withdrawal from the Study
Your participation in this study is entirely voluntary. You may withdraw at any time without discrimination or prejudice. All information is treated as confidential and no names or other details that might identify you will be used in any publication arising from the research. If you withdraw, all information you have provided will be destroyed. Sometimes data cannot be withdrawn or destroyed after a certain point. If your data has already been de-identified or published, it may not be possible to destroy data that you provided in the earlier stages of the research. In this instance, all your information will be attributed anonymously.

Privacy
Your privacy is very important to us. Your participation in this study and any information will be treated in a confidential manner. Your name and identifying details will not be used in any publication arising out of the research. Following the study, the data will be kept in a de-identified format, in a locked cabinet in the office of the Chief Investigator.

CRICOS Provider Code: 00125J
ABN 61 616 369 313

Benefits of the Study

While there is no guarantee that you will personally benefit, the knowledge gained from your participation may help others in the future by improvement in the quality and effectiveness of care in lower back pain.

Possible Risks

There are no specific risks anticipated with participation in this study. However, if you find that you are becoming distressed or anxious you will be advised to receive support from the health care provider. Alternatively, we will arrange for you to see a counselor at no expense to you.

If you have any questions about this project please feel free to contact either myself reece.granger.murdoch.uni@gmail.com or my supervisor Dr Stanley Innes, at S.Innes@murdoch.edu.au
My supervisor and I are happy to discuss with you any concerns you may have about this study.

Once we have analysed the information from this study, results will be shared on PESCC web page and with 10 practitioners who will place information where patients may view the summary of our findings. You can expect to receive this feedback in approximately 6 months' time.

If you are willing to consent to participation in this study, please read the Consent Form at the top of the survey questions.

Thank you for your assistance with this research project.

Sincerely

Reece Granger

This study has been approved by the Murdoch University Human Research Ethics Committee (Approval 2020/152). If you have any reservation or complaint about the ethical conduct of this research, and wish to talk with an independent person, you may contact Murdoch University's Research Ethics Office (Tel. (+61 8) 9360 6677) or e-mail ethics@murdoch.edu.au). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

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ABN 61 616 369 313

Appendix C – Patient Information Letter

Murdoch UNIVERSITY

www.murdoch.edu.au

We need your help

We invite you to participate in a research study looking at "Identifying strong and instantaneous responders to spinal manipulation therapy". This study is part of my Honours Degree in chiropractic science, supervised by Dr Stanley Innes at Murdoch University

Nature and Purpose of the Study
It is common that many people will experience discomfort from non-specific lower back pain in their life. Some researchers have tried to identify those who gain strong instantaneous relief from non-specific lower back pain by spinal manipulation therapy, however the evidence has been inconclusive.

Therefore, the aim of this study is to investigate if 18 identifiable items can predict a subgroup of people who will gain instantaneous pain relief from non-specific lower back pain following spinal manipulation therapy.

If you consent to take part in this research study, it is important that you understand the purpose of the study and the tasks you will be asked to complete. Please make sure that you ask any questions you may have, and that all your questions have been answered to your satisfaction before you agree to participate.

What the Study will Involve
To participate in this study, you must be over 18 years of age and have non-specific lower back pain.

If you decide to participate in this study, you will be asked to complete the following:

- 8 small questionnaire's that ask about your experiences regarding manual therapy
- It is estimated that the questionnaire will take approximately 5-10 minutes to complete.

Voluntary Participation and Withdrawal from the Study
Your participation in this study is entirely voluntary. You may withdraw at any time without discrimination or prejudice. All information is treated as confidential and no names or other details that might identify you will be used in any publication arising from the research. If you withdraw, all information you have provided will be destroyed. Sometimes data cannot be withdrawn or destroyed after a certain point. If your data has already been de-identified or published, it may not be possible to destroy data that you provided in the earlier stages of the research. In this instance, all your information will be attributed anonymously.

Privacy
Your privacy is very important to us. Your participation in this study and any information will be treated in a confidential manner. Your name and identifying details will not be used in any publication arising out of the research. Following the study, the data will be kept in a de-identified format, in a locked cabinet in the office of the Chief Investigator.

CRICOS Provider Code: 00125J
ABN 61 616 369 313

Benefits of the Study

While there is no guarantee that you will personally benefit, the knowledge gained from your participation may help others in the future by improvement in the quality and effectiveness of care in lower back pain.

Possible Risks

There are no specific risks anticipated with participation in this study. However, if you find that you are becoming distressed or anxious you will be advised to receive support from the health care provider. Alternatively, we will arrange for you to see a counselor at no expense to you.

If you have any questions about this project please feel free to contact either myself 32644867@student.murdoch.edu.au or my supervisor Dr Stanley Innes, at S.Innes@murdoch.edu.au
My supervisor and I are happy to discuss with you any concerns you may have about this study.

Once we have analysed the information from this study, results will be shared on PESCC web page and with 10 practitioners who will place information where patients may view the summary of our findings. You can expect to receive this feedback in approximately 6 months' time.

If you are willing to consent to participation in this study, please read the Consent Form at the top of the survey questions.

Thank you for your assistance with this research project.

Sincerely

Reece Granger

This study has been approved by the Murdoch University Human Research Ethics Committee (Approval 2020/152). If you have any reservation or complaint about the ethical conduct of this research, and wish to talk with an independent person, you may contact Murdoch University's Research Ethics Office (Tel. (+61 8) 9360 6677) or e-mail ethics@murdoch.edu.au). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

CRICOS Provider Code: 00125J
ABN 61 616 369 313

Appendix D – Practitioner Consent Form

Practitioner Consent Form

Identifying strong and instantaneous responders to spinal manipulation therapy

1. I agree voluntarily to take part in this study.
2. I have read the Information Sheet provided and been given a full explanation of the purpose of this study, the procedures involved and of what is expected of me.
3. I understand that I will be asked to answer a survey questionnaire which will take approximately 5-10 minutes.
4. The researcher has answered all my questions and has explained possible problems that may arise as a result of my participation in this study.
5. I understand I am free to withdraw from the study at any time without needing to give any reason.
6. I understand I will not be identified in any publication arising out of this study.
7. I understand that my name and identity will be stored separately from the data, and these are accessible only to the investigators. All data provided by me will be analysed anonymously using code numbers.
8. I understand that all information provided by me is treated as confidential and will not be released by the researcher to a third party unless required to do so by law.

Name of participant: _____

Signature of Participant: _____ Date: …../…../…….

I confirm that I have provided the Information Letter concerning this study to the above participant; I have explained the study and have answered all questions asked of me.

Signature of researcher: _____ Date: …../…../…….

Appendix E – Patient Consent From

Murdoch UNIVERSITY

www.murdoch.edu.au

Patient Predictive Factors Questionnaire

Patient Consent Form

Identifying strong and instantaneous responders to spinal manipulation therapy

1. I agree voluntarily to take part in this study.
2. I have read the Information Sheet provided and been given a full explanation of the purpose of this study, the procedures involved and of what is expected of me.
3. I understand that I will be asked to answer a survey questionnaire which will take approximately 5-10 minutes.
4. The researcher has answered all my questions and has explained possible problems that may arise as a result of my participation in this study.
5. I understand I am free to withdraw from the study at any time without needing to give any reason.
6. I understand I will not be identified in any publication arising out of this study.
7. I understand that my name and identity will be stored separately from the data, and these are accessible only to the investigators. All data provided by me will be analysed anonymously using code numbers.
8. I understand that all information provided by me is treated as confidential and will not be released by the researcher to a third party unless required to do so by law.

Name of participant: _____

Signature of Participant: _____ Date: ...../...../.....

I confirm that I have provided the Information Letter concerning this study to the above participant; I have explained the study and have answered all questions asked of me.

Signature of researcher: _____ Date: ...../...../.....

CRICOS Provider Code: 00125J
ABN 61 616 369 313

Appendix F – Practitioner Questionnaire

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Practitioner ID# _____ **Patient ID# _____**

Survey Questions

Thank you for being part of this study that is looking to see which factors determine how well your patients low back symptoms are likely to respond to HVLA SMT.

Please complete the following questionnaire which measures the strength of the relationship between the client and chiropractor.

Agnew Relationship Measure (ARM-5)							
	Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
I feel supportive	1	2	3	4	5	6	7
My client and I agree about how to work together	1	2	3	4	5	6	7
My client and I have difficulty working jointly as a partnership	1	2	3	4	5	6	7
My client has confidence in my techniques	1	2	3	4	5	6	7
I feel confident in my techniques	1	2	3	4	5	6	7

Patient Predictor Factors

In your opinion please rate the patient's health status on the following scale

Professional opinion of health status						
I rate the patients' health status as:						
Very Poor	Poor	Average	Good	Very good	Excellent	Unsure

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Please rate your understanding of the patient's expectations and goals.

To what degree do you think you understand this patients' expectations and goals										
Do not understand at all				Not sure					Completely understand	
0	1	2	3	4	5	6	7	8	9	10

Please respond to the following statements regarding your patient's LBP signs and symptoms at today's visit.

Signs and Symptoms of LBP Presentation				
Was there a decreased active range of motion?	No	Mild	Moderate	Severe
Was there a decreased passive range of motion?	No	Mild	Moderate	Severe
Did spinal springing and/or end range loading closely reproduce the patient's symptoms.	No	Yes	Unsure	

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Appendix G – Patient Questionnaire

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Practitioner ID# _____ **Patient ID# _____**

Survey Questions

Thank you for being part of this study that is looking to see which factors determine how well people with low back symptoms respond to spinal manipulation (or adjustments).

Once you have completed the questions, please put your response into the provided envelope, seal the envelope, and return it to your practitioner. Your responses will remain confidential and only be known to the researchers.

Patient Previous Response to Manipulation for Back Pain

Have you had manipulation for low back pain in the past? Circle: YES NO.
If no skip the next question.

How did you respond previous manipulation for back pain										
Very much worse				No change					Completely better	
0	1	2	3	4	5	6	7	8	9	10

Please complete the following questions that describe your relationship with the chiropractor.

Modified Patient Dr Relationship Questionnaire (PDRQ-9 Scale)				
	Never	Rarely	Sometimes	Always
My chiropractor understands me.				
I trust my chiropractor.				
My chiropractor is dedicated to help me.				
I can talk to my chiropractor.				
I feel content with my chiropractor's treatment.				
I think my chiropractor finds me hard to deal with.				
My chiropractor helps me.				
My chiropractor has enough time for me.				
I benefit from the treatment of my chiropractor.				
My chiropractor and I agree on the nature of my medical symptoms.				
I find my chiropractor easily accessible.				
Thanks to my chiropractor I feel better.				
Thanks to my chiropractor I gained new insight.				
I can handle my symptoms now (even if my chiropractor and I have no further meetings).				
My symptoms will disappear.				

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Patient Predictor Factors

Before your treatment today, please rate what you expected to happen to your low back symptoms immediately after the low back manipulation.

Expected change immediately after the treatment										
A very great deal worse				No change					A very great deal better	
0	1	2	3	4	5	6	7	8	9	10

On the following scale, rate how your low back symptoms actually changed immediately after the low back manipulation you received today.

Actual change immediately after the treatment										
Very much worse				No change					Completely better	
0	1	2	3	4	5	6	7	8	9	10

On the following scale, rate how well you understand your low back pain condition.

How well do you understand your back pain condition?										
I do not understand my low back condition at all				No change					I completely understand my low back condition	
0	1	2	3	4	5	6	7	8	9	10

CRICOS Provider Code: 00125J
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Please complete the following questions on your views about your chiropractor.

Agnew Relationship Measure (ARM-5)							
	Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
My chiropractor is supportive	1	2	3	4	5	6	7
My chiropractor and I agree about how to work together	1	2	3	4	5	6	7
My chiropractor and I have difficulty working jointly as a partnership	1	2	3	4	5	6	7
I have confidence in my chiropractor and his/her techniques	1	2	3	4	5	6	7
My chiropractor is confident in him/herself and his/her techniques	1	2	3	4	5	6	7

Please rate the degree of "cracking" or "popping" noises you heard during the low back manipulations you received today?

Presence of cavitation			
Yes, easily heard	Yes, just heard	None	Unsure

Patient Predictor Factors

Please rate to what degree you think the chiropractor understood your expectations and goals today.

To what degree do you think you the chiropractor understood your expectations and goals today										
Did not understand at all				Not sure					Completely understood	
0	1	2	3	4	5	6	7	8	9	10

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Are you employed in a workplace? Circle **YES** **NO** If no skip the next question.

Please complete the following questionnaire which measures how you feel about your low back symptoms and work.

FABQ (Work Only) Skip if you are NOT employed							
The following statements are about how your normal work affects or would affect your back pain.	Completely Disagree			Unsure			Completely Agree
My pain was caused by my work or by an accident at work.	0	1	2	3	4	5	6
My work aggravated my pain.	0	1	2	3	4	5	6
I have a claim for compensation for my work.	0	1	2	3	4	5	6
My work is too heavy for me.	0	1	2	3	4	5	6
My work makes or would make my pain worse.	0	1	2	3	4	5	6
My work might harm my back.	0	1	2	3	4	5	6
I should not do my regular work with my present pain.	0	1	2	3	4	5	6
I cannot do my normal work until with my present pain.	0	1	2	3	4	5	6
I cannot do my normal work until my pain is treated.	0	1	2	3	4	5	6
I do not think that I will be back to my normal work within 3 months.	0	1	2	3	4	5	6
I do not think that I will ever be able to go back to work.	0	1	2	3	4	5	6

Circle the appropriate answer:

On this occasion has your pain been severe for **less** than 14 days?	YES	NO
On this occasion have you had symptoms for **less** than 16 days?	YES	NO
Does your pain improve with exercise, but not rest?	YES	NO
Do you have symptoms below the knee?	YES	NO
Do you have any symptoms in the legs?	YES	NO

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