

# A classification and treatment protocol for low back disorders: Part 1 – specific manual therapy

Jon Joseph Ford, Sarah Louise Thompson, Andrew John Hahne

Musculoskeletal Research Centre, Faculty of Health Sciences, La Trobe University, Bundoora, Australia

**Background:** It has been widely recommended that clinical trials involving people with low back disorders should identify subgroups and provide specific treatment in order to increase the likelihood of clinically meaningful effects being demonstrated. The Maitland approach to providing manual therapy is an appropriate and widely used clinical method in providing specific treatment. However, few clinical trials have described a detailed clinical protocol that allows replication in clinical and research practice.

**Objectives:** This paper presents a detailed classification and treatment protocol for people with clinical features indicating a likely positive response to specific manual therapy.

**Conclusion:** The presented protocol will be used in the Specific Treatment for Problems of the Spine trials comparing specific physiotherapy to evidence-based advice.

**Keywords:** Back pain, Classification, Clinical reasoning, Manual therapy, Manipulation, Subgroup

## Introduction

Despite some methodological issues, there is general agreement in the literature that low back disorders (LBDs) are a prevalent and costly burden to society and the individual.<sup>1,2</sup> Treatment for LBDs is generally more effective than placebo or no treatment, but the effect sizes are commonly small and few studies have demonstrated superior outcomes favouring one treatment over another.<sup>3,4</sup> A false assumption that sufferers of LBDs are a homogeneous group has been suggested as a reason for these results.<sup>5,6</sup> Heterogeneity can diminish the likelihood of significant treatment effects due to the reduced proportion of a sample for which the treatment is appropriate.<sup>5,6</sup> Researchers have emphasized the importance of identifying homogeneous subgroups in future randomized controlled trials (RCTs)<sup>5,6</sup> and as a consequence, a number of studies have been published describing subgroup based classification systems for LBDs.<sup>6,7</sup>

One approach to developing LBD subgroups and appropriate specific treatment for evaluation in RCTs lies in the refinement of widely used clinical methods. The Maitland approach<sup>8</sup> addresses the complex nature of LBDs through rigorous assessment, generation of preliminary hypotheses regarding the nature of the problem, provision of specific treatment, reassessment of key assessment findings and re-evaluation of hypotheses. Maitland described the manual therapy process inherent in his method as:

*‘... the manipulative physiotherapist, understanding the pathological and biomechanical changes that may be present... (and basing) treatment techniques and subsequent changes to them on analytical assessment of changes in the patient’s symptoms and signs.’<sup>8</sup>*

The Maitland approach has been developed and refined over decades and is one of the most common methods for providing specific physiotherapy treatment to LBDs.<sup>9–12</sup> One of the key, and often unachieved aims of conducting clinical trials is modification of the behaviour of practitioners in clinical practice.<sup>13</sup> Because of the widespread use of the Maitland approach, it is reasonable to assume that the results of a robust RCT on this method would be more likely to impact positively upon practitioners’ clinical behaviour than classification approaches of lesser popularity.

However, conducting an RCT on the effectiveness of specific physiotherapy on subgroups defined by the Maitland approach is not without its challenges. This method, as described in texts<sup>8,14</sup> and taught in undergraduate/postgraduate courses<sup>9</sup> is complex to apply clinically. A ‘pragmatic’ approach<sup>15</sup> to operationally defining manual therapy treatment has been used in some RCTs, where practitioners are permitted to classify and apply treatment within relatively loosely defined boundaries that are considered standard clinical practice. Some of these trials have attempted to improve consistency of treatment provided by only using practitioners with specific post-graduate training.<sup>16,17</sup> However, given the complexity of the Maitland approach,<sup>8</sup> a pragmatic design, irrespective of practitioner qualification, has the potential

Correspondence to: J J Ford, Group Leader, Low Back Research Team, Musculoskeletal Research Centre, Faculty of Health Sciences, La Trobe University, Bundoora, Victoria 3085, Australia. Email: j.ford@latrobe.edu.au

for large and unaccounted variation in treatment provided.<sup>18</sup>

In order to adequately evaluate the Maitland approach in future RCTs, we believe that new classification and specific treatment protocols are required. These clinical protocols should meet important clinical and research requirements including:

- adherence to the key principles outlined in original descriptions of the clinical method;
- being reproducible<sup>19</sup> to allow replication in subsequent trials;
- being generalizable to the broader physiotherapy community maximizing the likely impact on patient outcomes;<sup>19</sup>
- being developed where possible on the best available evidence.<sup>20</sup>

We are unaware of a detailed clinical protocol that refines, operationalizes and standardizes the clinical methods of the Maitland approach in this manner.

The specific treatment of problems of the spine (STOPS) trials are a series of five RCTs investigating the effectiveness of specific physiotherapy compared to evidence-based advice for subgroups of participants with sub-acute LBDs. The aim of this paper, and a series of three papers to follow, is to present four clinical protocols for the STOPS trials based on the Maitland approach,<sup>8</sup> the McKenzie approach,<sup>21</sup> functional restoration for multi-factorial persistent pain<sup>22</sup> and functional restoration for inter-vertebral disc related LBDs.<sup>23</sup> This first paper will present the clinical protocol, including classification and specific treatment protocols, for the manual therapy group (MTG) based on the principles of the Maitland approach.

## Methods

The STOPS trials were designed according to accepted quality guidelines for conducting RCTs.<sup>19,24,25</sup> The key features of the trials were:

- classification of potential participants into one of five subgroups at baseline assessment;
- consenting participants being randomly allocated to either specific physiotherapy (10 sessions over 10 weeks) or evidence-based advice (2 sessions over 10 weeks);
- treatment in both physiotherapy and advice groups being specific to the relevant subgroup;
- follow-up of participant at 5 weeks, 10 weeks, 26 weeks and 12 months.

The MTG treatment used in the STOPS trials was developed from the principles outlined in Geoff Maitland's original text, *Vertebral Manipulation*.<sup>14</sup> The operational detail in the MTG protocol was derived from clinical training programs developed by the principle author (JF) as a musculoskeletal physiotherapist clinically mentoring physiotherapists for the past 15 years. Thirteen physiotherapists who were working with and had been trained by the principle author participated in a one day forum to further refine the MTG clinical methods.

Based on these developmental methods a clinical reasoning process in alignment with the principles of the Maitland approach<sup>8,14</sup> and other clinical decision making models<sup>26</sup> was developed which included:

- completion of an initial subjective examination (history);
- generation of a participant identified problem list;
- formulation of a physical examination strategy based on an initial set of provisional hypotheses regarding the source of symptoms;
- completion of the physical examination, analysis of data, refinement of hypotheses and completion of additional examination procedures as needed to confirm or refute hypotheses;
- consideration of additional hypotheses such as contributing factors as a potential cause of the problem that may not necessarily be the source of symptoms;
- establishment of participant oriented goals and test criteria to evaluate correctness of hypotheses and the treatment strategy (we called these test criteria 'asterisks' and defined them as key measures from the subjective or physical examination that could be used for reassessment of treatment effect);
- pro-active identification and addressing of any anticipated problems that may adversely affect achievement of goals;
- should goals not be achieved, or hypotheses not be confirmed, consideration of whether execution of the treatment, the treatment itself or specific hypotheses need modification.

In a clinical environment, adequate clinical reasoning skills are difficult to define, teach and measure, taking most practitioners many years to develop.<sup>27</sup> As such, the STOPS clinical protocol for the MTG had a particular focus on structured classification and specific treatment processes to ensure adequate and consistent clinical decision making occurred across all trial physiotherapists and participants.

### *Classification of MTG participants*

As part of a reproducible and generalizable clinical protocol, only participants who satisfied a range of subgroup inclusion criteria following baseline assessment were included in the MTG. A specifically designed MICROSOFT EXCEL (2008) spreadsheet was developed to enable reproducible identification of subgroup membership from the baseline data entered. This eliminated the need for sophisticated clinical reasoning and pattern recognition by the trial physiotherapist completing the baseline assessment. To be classified as suitable for the MTG, the participant had to have at least three out of the following four criteria positive:

1. unilateral symptoms:
  - symptoms greater on one side of the spine.
2. a regular compression pattern:<sup>28,29</sup>
  - extension in standing reproducing the participant's clinical pain;
  - ipsilateral lateral flexion or quadrant in standing reproducing the participant's clinical pain;

- contralateral movements showing either greater range of movement or a lesser degree/different type of pain compared to ipsilateral movements.
3. comparable palpatory findings:
    - reproduction of clinical pain on ipsilateral passive postero-anterior accessory movement applied through the transverse process or the zygapophyseal joint at one or two segments;
    - for the clinical pain to be greatest at the palpated segment compared to other segments in the lumbar spine.
  4. a positive response to assessment of the comparable palpatory finding – the ‘mini-treatment’ (discussed in detail in treatment protocol section).

The MTG criteria were selected intending to describe a commonly observed<sup>30</sup> and well defined clinical pattern that responds in a consistent and predictable manner to manual therapy techniques.<sup>8,28,29</sup> However, the criteria are also supported by principles of biological plausibility given there is preliminary evidence that they are indicative of lumbar zygapophyseal joint dysfunction.

Given the unilateral nature of the lumbar zygapophyseal joint it is self-evident that the presence of unilateral symptoms and reproduction of typical symptoms on palpation should assist in classification. The regular compression pattern observed during active lumbar extension and lateral flexion was described by Brian Edwards based on a hypothesis of intra-articular compression of the lumbar facets reproducing the patient’s typical symptoms.<sup>28</sup> This hypothesis is supported by the anatomical literature.<sup>31,32</sup> The existence of a plausible mechanism for the MTG subgroup criteria provides preliminary support of validity. Research surveying practitioners and clinical experts also supports the described MTG criteria as being indicative of lumbar zygapophyseal joint dysfunction and pain.<sup>30,33</sup>

Based on preliminary evidence of subgroup validity, and expert clinical observations that have stood the test of time over the past 25 years, the MTG criteria were deemed appropriate for defining a subgroup for the STOPS trials suitable for treatment by specific manual therapy.

### *Treatment protocol*

The only requirement for trial physiotherapists was registration with the Physiotherapy Board of Australia. Trial physiotherapists from the Spinal Management Clinics group in Australia provided the treatment according to the treatment protocol. As part of initial training and ongoing monitoring of treatment quality, trial physiotherapists were required to read a 240 page treatment manual, attend a two day training program, participate in monthly clinical mentoring sessions, and submit the clinical notes of each participant for feedback at the four and seven week point of the 10 week MTG treatment program. The monthly clinical mentoring was conducted with all trial physiotherapists and STOPS researchers. The sessions

were teleconferences where participant case studies and examples from the submitted clinical notes were discussed with reference to the treatment protocol.

The trial physiotherapist had a number of resources to assist in provision of the treatment protocol including the treatment manual, a comprehensive baseline assessment completed when determining eligibility for the trial, a series of professionally produced participant information sheets and a blank copy of the clinical notes specifically designed for recording the progress of the MTG sessions. The clinical notes were structured in a manner to ensure all essential components of the treatment protocol were adhered to whilst allowing the practitioner some flexibility to develop and test hypotheses regarding relevant structures and treatment techniques of potential benefit to individual participants. A summary of the content of the clinical notes for Session 1 is outlined in Table 1.

Our concept of the ‘mini-treatment’, used in Session 1 assessment, is based on a number of principles fundamental to the Maitland approach. There is a balance between identifying a manual therapy technique that will result in a positive treatment effect in Session 1 and performing an excessive number of techniques that may result in negative between-session effects. For example, the trial physiotherapist could hypothetically trial a treatment of central L4 posterior–anterior mobilization followed by ipsilateral L4 posterior–anterior mobilization before identifying a technique, such as L4/5 ipsilateral rotation, that has a positive effect on the identified asterisks. In this example, if the physiotherapist has underestimated the ease with which the participant’s condition can be exacerbated, it is possible that combinations of the three treatment techniques used will have a negative effect on pain and/or function between sessions. At Session 2 the participant could therefore present as exacerbated by the interaction of the three Session 1 techniques, despite the fact that L4/5 rotation may have been helpful if done in isolation. In this hypothetical sequence of events, the practitioner may discard L4/5 rotation as a treatment under the erroneous reasoning that it had a negative effect. This potential for between session exacerbation and flawed clinical reasoning is heightened in complex participants and with less experienced manual therapists.

The mini-treatment is a method of minimizing the risk of masking the effects of positive Session 1 treatment techniques and consists of:

- a quick check of passive accessory movements of the lumbar spine to identify areas of stiffness and/or pain;
- re-identification of comparable palpatory findings. As part of the MTG inclusion criteria, all participants will have focal reproduction of their typical pain unilaterally during lumbar palpation of passive accessory movements;
- determining the predominant limiting factor to accessory movement (pain or stiffness);

**Table 1 Clinical notes content for Session 1**

Treatment protocol component	Rationale
Session 1 assessment	
Review information from baseline assessment	To gather and interpret information relevant to treatment planning and for reassessment of the participant's response to treatment
Complete body chart and history	
Gather asterisks from subjective and physical examination	
Determine whether clinical evidence exists of inflammation (At least 2 of: constant symptoms, getting out of bed at night due to the pain, morning symptoms >60 minutes)	Manual therapy is predominantly for mechanical problems and inflammation if present requires specific management <sup>9</sup>
Perform mini-treatment (if no inflammation) and reassess	A mini-treatment is a primary method of confirming/refuting provisional hypotheses
Session 1 treatment	
Explanation of information sheets regarding zygapophyseal joint pain, treatment options, treatment timeframes and recovery expectations. Open questions to the participant regarding understanding the explanation and level of engagement with the proposed treatment plan	Engaging the participant with the treatment process is critical to effective specific treatment <sup>27,35</sup>
Management of inflammation if applicable (provision of information sheet, lumbar taping, recommend pharmacy consultation regarding non-prescription NSAIDs*, walking program within pain free duration)	Relative rest from aggravating postures/activities, NSAIDs* and sub-clinical activity in neutral spine position may assist in reducing an excessive and counter-productive inflammatory response
In the absence of inflammation provide a single manual therapy technique, reassess asterisks, provide warning regarding potential post-treatment soreness, provide homework based on information sheets	Additional hypothesis testing and re-engagement of the participant with the treatment plan

Note: \*NSAIDs, non-steroidal anti-inflammatory drugs.

- if pain predominantly limits the movement, providing a 'neuromodulatory' mini-treatment consisting of large amplitude mobilizations short of initial pain;<sup>34</sup>
- if stiffness predominantly limits the movement, providing a mobilizing mini-treatment moving past initial pain and into resistance;
- the mini-treatment should be sufficient to create a within- but not between-session change. In this way treatment techniques can be trialled in Session 1 with minimal risk of positive effects of a technique being masked. Typically the mini-treatment is of 10–20 seconds duration depending on severity and irritability (potential for the participant's condition to be exacerbated);
- reassessment of resting pain (if applicable) and examination asterisks and hypotheses modified or confirmed accordingly;
- a positive response is defined as a significant reduction in resting pain (at least 1 point on a numerical rating scale) or a significant improvement in asterisk range or quality of movement (e.g. segmental motion). The definition of clinical significance is defined by the physiotherapist.

Experienced manual therapists, particularly those working with patients where pattern recognition is the predominant method of clinical reasoning, may not require the structured approach of the mini-treatment. However, given the wide range of experience in the STOPS trial physiotherapists a conservative approach was taken to minimize the risk of unnecessary and counterproductive exacerbation resulting from MTG treatment. The clinical reasoning principles upon which the mini-treatment were based are consistent with the Maitland approach<sup>8</sup> and clinical reasoning

theory.<sup>26</sup> To further minimize risk to the participant, only a single mini-treatment was provided as opposed to Maitland's recommendation of up to four in a single consultation.<sup>8</sup> Mini-treatments were completed in every MTG treatment session when the practitioner wished to explore the potential value of additional manual therapy techniques.

Other key components of the Session 1 protocol (see Table 1) included detailed education as well as procedures to engage and actively encourage participant feedback. These methods are consistent with recommendations from the research and clinical reasoning literature.<sup>27,35</sup>

As the symptoms were unilateral and presumed to be arising from the lumbar zygapophyseal joint, techniques with a unilateral bias were recommended in the treatment manual. These techniques comprised rotation, ipsilateral posterior–anterior mobilization or transverse mobilization towards the side of pain. High velocity thrust in a rotation direction was also recommended. The grade (intensity) and duration of the technique were determined according to whether pain or resistance was the primary problem at the comparable palpatory finding. The rationale for this determination was documented by the trial physiotherapist in the clinical notes according to standard protocols.<sup>8,34</sup> The timing of Session 2–10 was determined by the trial physiotherapist but a general recommendation was made for treatment to be more frequent, approaching twice weekly in the early stages to enable emerging hypotheses to be

confirmed. A summary of the content of the clinical notes for Session 2 is outlined in Table 2.

The Session 2 mini-treatment allowed for further testing of competing hypotheses. This information added to that gained from Session 1 and the response to the Session 1 treatment to allow an ongoing refinement of hypotheses regarding the source of symptoms, contributing factors and anticipated problems. New areas for potential assessment in the Session 2 mini-treatment included but were not limited to:

- passive physiological intervertebral movements of the lumbar spine;
- structures not related to the lumbar spine which may be contributing to a somatic referred pain scenario such as the hip (physiological or accessory movements);
- potential contributing factors, such as upper lumbar stiffness for a lower lumbar dysfunction;
- secondary symptom generators, such as compensatory muscle spasm in piriformis, erector spinae, quadratus lumborum or iliopsoas;
- peripheral neural structures such as the sciatic or femoral nerve.

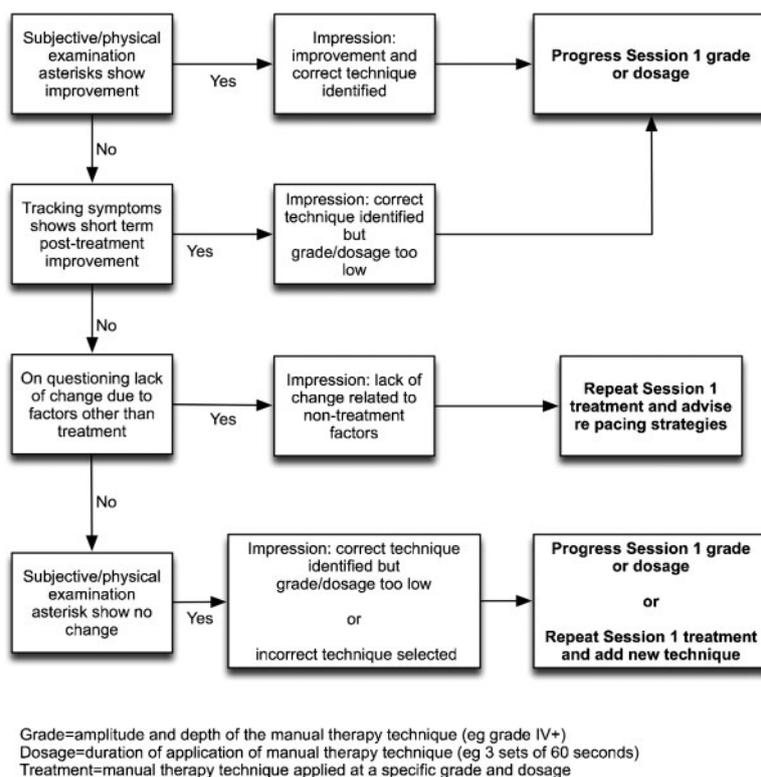
A specific decision making algorithm based on the Maitland approach was used in determining Session 2 treatment selection. If on questioning and examination in Session 2, there was clear evidence of between session and treatment related improvement the following contingencies applied:

- if on reassessment of asterisks, stiffness and pain was the predominant problem, the grade of the Session 1 treatment technique was progressed (eg from a grade IV to a IV+);
- if on reassessment of asterisks, pain was the predominant problem the duration of the Session 1 technique was increased in Session 2 while maintaining the grade (e.g. from 3 lots of 30 seconds to 3 lots of 60 seconds).

If the participant reported no change between sessions, the trial physiotherapist checked that the Session 2 subjective and physical examination asterisks were also unchanged. Specific questioning tracking symptom pattern was also conducted to ensure there was no short term post treatment improvement, and that non-treatment related factors, such as excessive social or recreational activity, had not

**Table 2 Clinical notes content for Session 2**

Treatment protocol component	Rationale
Session 2 assessment	
Participant report on progress following Session 1 Detailed questioning regarding possible causes of change in symptoms following Session 1	To assist in determination of between session treatment effect. Differentiation of treatment effect from other factors (e.g. social/recreational activity)
Follow-up on presence of inflammation and compliance with homework	Review of inflammatory status and the need for ongoing treatment. Check homework to continue the process of encouraging and evaluating participant engagement
Questioning regarding any work issues as a result of the low back disorder	The STOPS trials excluded participants with a compensation claim but managing work incapacity remained important in non-compensable participants
Check Session 1 asterisks from subjective and physical examination	To confirm whether the participant is better, same or worse compared with Session 1
Perform mini-treatment on a new area (if inflammation not significant) and reassess	To further test competing hypotheses regarding the source of symptoms, contributing factors and secondary symptom generators
Session 2 treatment	
Consider hypotheses based on physiotherapist judgement of the participant being better, same or worse and the response to the mini-treatment	Information from between session change and response to Session 2 mini-treatment leads to Session 2 treatment selection
Briefly review explanations and information sheets regarding zygapophyseal joint pain, treatment options, treatment timeframes and recovery expectations	Repeat explanation ensures engagement of the participant with the treatment program and enables further practitioner feedback/questions to be asked
Consider provision of additional information sheets as required on pacing, posture, relaxation, sleep management and pain management strategies	Self-management strategies and specific advice are an important component of any treatment regime including manual therapy
Ongoing management of inflammation if applicable	As per Session 1 rationale
In the absence of inflammation decide on either progressing the grade or duration of the Session 1 technique or keeping the Session 1 technique the same and adding a new technique.	As per Session 1 careful application of assessment and treatment assists in determining cause and effect relationships
Reassess asterisks, provide warning regarding potential post-treatment soreness, provide homework based on information sheets	As per Session 1 rationale



**Figure 1** Decision making when participant reported no change at the beginning of Session 2.

masked Session 1 treatment effect. Improvement as measured by Session 2 asterisks or on a short term duration of Session 1 treatment effect was interpreted in the same manner as clear evidence of improvement described above. If, however, Session 1 treatment effect had been 'undone' by non-treatment related factors, the Session 1 technique was repeated with advice given regarding pacing strategies.

If after specific questioning and Session 2 assessment of asterisks the participant was judged by the trial physiotherapist to be clearly unchanged the following interpretations and decision making rules were applied:

- the correct technique may have been selected at Session 1 but the dosage was too low. In this scenario, Session 1 treatment was repeated with the grade usually progressed or dosage increased, or
- the incorrect technique may have been selected at Session 1 and a new technique was therefore provided in addition to the Session 1 treatment.

Given the clear clinical criteria necessary for inclusion in the MTG trial, and the suitability of the Session 1 technique options for such a clinical pattern, physiotherapists were encouraged to opt for the progressing the Session 1 technique option as a preference to adopting a new technique. A schematic representation of the decision making when the participant reported no change at Session 2 is presented in Fig. 1.

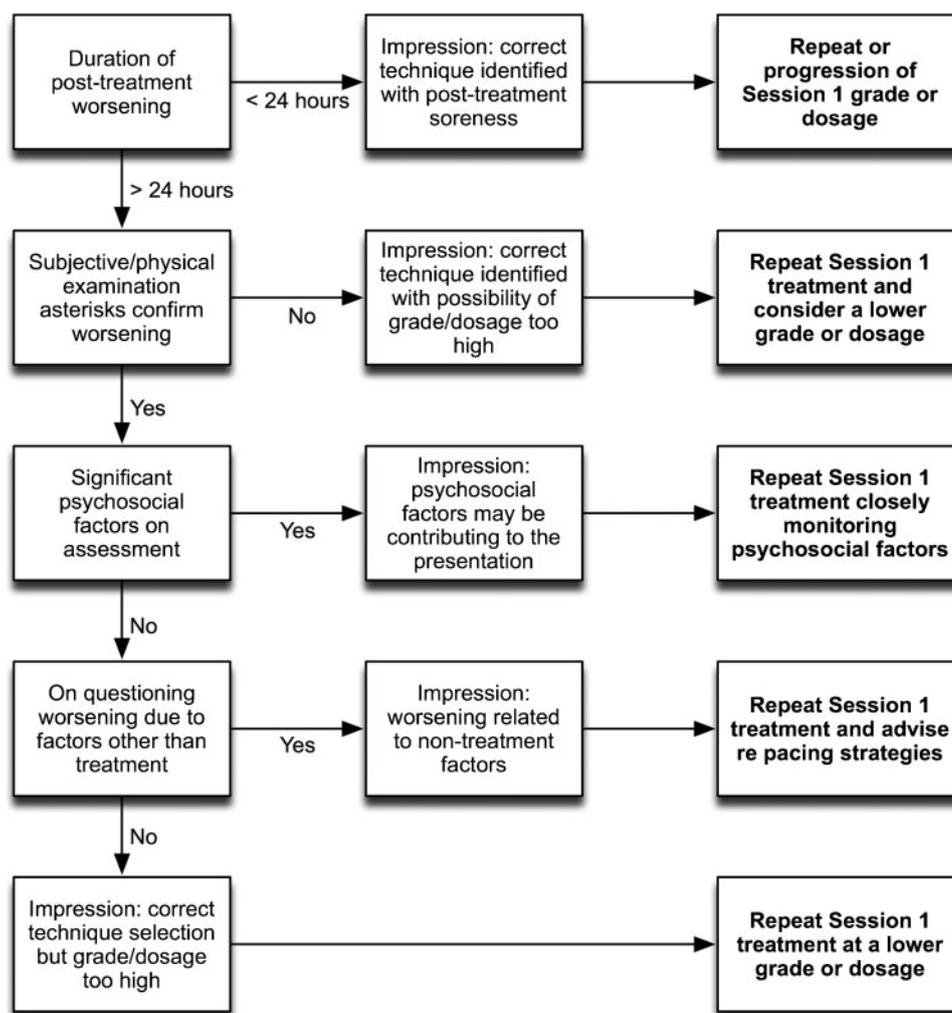
If the participant reported being worse, the trial physiotherapist clarified through specific questioning whether the worsening was immediately following treatment and had since eased. Short term post treatment soreness of up to 24 hours duration was

interpreted as the correct structure/technique having been selected at Session 1, signified by the participant's typical pain being exacerbated. Such post treatment soreness is common after an initial session of manual therapy when the correct technique has been identified, and the Session 1 technique was therefore repeated, usually at the same grade and duration. If this soreness lasted for longer than 24 hours and was not due to any other factors, the Session 1 treatment was also repeated with a preference for a lower grade or dosage given the more significant degree of post treatment soreness.

In participants where non-treatment related factors had resulted in worsening, Session 1 treatment was repeated with advice given regarding pacing strategies. Finally for participants with clear between session worsening, the physiotherapist checked that psychosocial factors such as symptom amplification were not contributing to the participant's report. In this scenario, Session 1 treatment was repeated and psychosocial factors were closely monitored.

A schematic representation of the decision making when the participant reported being worse is presented in Fig. 2.

In Sessions 3–10 the trial physiotherapist continued the above described process of assessment, provision of a mini-treatment with new techniques, hypothesis modification, treatment provision and reassessment. In order to carefully and systematically test hypotheses within and particularly between sessions, only one change in treatment technique, dosage or duration occurred until the participant's progress was



Grade=amplitude and depth of the manual therapy technique (eg grade IV+)  
 Dosage=duration of application of manual therapy technique (eg 3 sets of 60 seconds)  
 Treatment=manual therapy technique applied at a specific grade and dosage

Figure 2 Decision making when participant reported worse at the beginning of Session 2.

consistently positive and hypotheses were confirmed. Once this stage was reached the trial physiotherapist was able to change treatment techniques more freely.

The trial physiotherapist modified or progressed asterisks as the values measured at Session 1 normalized. Progression of asterisks ensured all relevant stiffness or pain associated with that asterisk had been identified and addressed through treatment. This concept is particularly important in participants with high level functional requirements such as athletes or people with manual handling type work. Methods of progressing asterisks included:

- overpressure applied to active movements;
- combining movements such as extension/lateral flexion shown in Fig. 3;
- repeated and/or rapid and/or resisted variations to active movements;
- replication of functional movements.

If treatment effect plateaued but asterisks remained, the trial physiotherapist progressed the treatment technique



Figure 3 Extension/lateral flexion overpressure as an example of progressing the extension asterisk.

into combined movement positions that replicated significant asterisks.<sup>28</sup> The treatment technique was then performed in the combined movement position (e.g. unilateral posterior–anterior mobilization in extension and ipsilateral lateral flexion). An important component of the Maitland approach is to adequately treat comparable stiffness by using techniques at end of available range of physiological and accessory motion.<sup>8</sup>

All participants in the MTG commenced functional lumbar specific motor control training once consistent improvement in asterisks was noted. This was usually between weeks three and six of the 10 week treatment program. The training followed a standard protocol (to be published in Part 3 of this series) and occurred in parallel with the provision of manual therapy.

If the participant reported a lack of progress five weeks into the treatment program and their Orebro Musculoskeletal Pain Questionnaire score was over 105/210,<sup>36</sup> the treatment focus shifted away from a pathoanatomical emphasis. Instead the participant received education regarding increased neural sensitivity, pacing strategies and graded activity. The trial physiotherapists provided this education using basic cognitive-behavioural principles following a standard protocol (to be published in Part 4 of this series). There is moderate evidence supporting this approach in sub-acute LBDs with suspected psychosocial factors.<sup>22</sup>

## Discussion

A detailed clinical protocol has been presented for a subgroup of participants in the STOPS trials likely to respond to specific manual therapy. The protocol is reproducible, generalizable and developed on the best available evidence in combination with the principles of the Maitland approach. Some may criticize the ‘non-empirical’ judgemental processes needed in preparing such a protocol. However, the use of patient oriented clinical judgement combined with the latest research literature is consistent with an evidence-based approach.<sup>20</sup>

The treatment protocol was designed to be specific for the MTG group participants. The criteria for inclusion in the MTG were developed from the writings of clinical experts,<sup>14,28</sup> principles of biological plausibility<sup>31,32</sup> and surveys of practitioners in the field as well as clinical experts.<sup>30,33</sup> Whilst not a comprehensively validated subgroup of LBDs we believe there is sufficient clinical and research evidence to support an RCT of specific manual therapy targeting a sample of participants who fulfil the MTG criteria. In justifying our approach to classification, it is important to explore other current methods of developing subgroups of LBDs.

Clinical prediction rules are combinations of variables that predict the outcome of specific treatment

types and have been used as a means of identifying homogenous subgroups of LBDs.<sup>37</sup> For a clinical prediction rule to be of widespread clinical value it must be rigorously developed over the three phases of derivation, validation and evaluation of impact on clinical practice.<sup>38,39</sup> In the derivation phase the strongest predictor variables are identified for the outcome of interest. These variables, as part of a clinical prediction rule, are then tested for internal and external validity within different settings and populations. Finally, the clinical prediction rule should be shown to change clinical behaviour and improve patient outcomes, thereby demonstrating significant impact and clinical utility.<sup>38</sup> A recent interpretation of these principles has recommended that all developmental phases from derivation through to analysis of impact should involve controlled and ideally randomized controlled trials.<sup>40</sup>

Whilst this approach to developing a subgroup based classification system has undoubted methodological rigour, there are significant practical concerns for researchers working with the LBD population. The complexity of LBDs, particularly when longer than six weeks in duration, is undisputed. From a pathoanatomical,<sup>41</sup> psychosocial<sup>42</sup> and neurophysiological<sup>43,44</sup> perspective there are a large number of variables that have the potential to modify the effect of treatment. In such complex domains it may not be feasible or even appropriate to develop a clinical prediction rule using the derivation, validation and impact evaluation phases.<sup>39</sup> In addition, there is a series of necessary methodological requirements for developing clinical prediction rules that may not be achievable in LBD populations. These include all important predictors being included in the derivation process, an adequate sample size being achieved, and the prediction rule making clinical sense.<sup>39</sup> No doubt there will be substantial future research into clinical prediction rules as a means of identifying homogenous subgroups in the LBD population. However, there are significant issues with this methodology for LBDs and alternative approaches are also worthy of consideration.<sup>6</sup>

The clinical prediction rule approach to classification contrasts with our methods of developing the criteria for the MTG group, as well as other LBD subgroups (to be presented in subsequent papers in this series). The STOPS trials have been designed to recruit participants with sub-acute, non-compensable LBDs with clinical features indicative of pathoanatomical injuries to the lumbar spine. For those with significant psychosocial/neurophysiological issues in a clear absence of a pathoanatomical clinical pattern, a specific functional restoration treatment protocol is applied. It is our view that developing a classification system of such complexity would not be feasible using

a rigorously applied clinical prediction rule approach. Importantly our classification subgroups and treatment methods are commonly used by physiotherapists<sup>9–12,30</sup> and are therefore more likely to result in change in practitioner behaviour than a clinical prediction rule that has the potential for limited clinical meaning.

An alternative approach to clinical prediction rules for developing classification subgroups for LBDs is pathoanatomical diagnosis based on specific diagnostic tests.<sup>6</sup> Substantial research has been published on the diagnosis of LBDs using clinical, radiological, and invasive tests.<sup>6</sup> In these studies the accepted methodology, best described as diagnostic accuracy or concurrent validity,<sup>45</sup> has involved evaluating the ability of a proposed diagnostic test to predict the result of a criterion or diagnostic ‘gold’ standard.<sup>6</sup> Moderate evidence has been published supporting the concurrent validity of a number of clinical tests for sacro-iliac joint and discogenic pain.<sup>46</sup> However, a major limitation in this methodology for LBDs is the absence of suitable gold standards.<sup>6,47</sup> Numerous studies have shown high false positive results for gold standards used in concurrent validity studies on LBDs including radiological imaging, diagnostic blocks and even surgical exploration.<sup>47</sup> Some authors have suggested that inadequate gold standards, sometimes referred to as ‘reference’ standards, are the best option available for validation of tests of potential utility for the diagnosis and classification of LBDs.<sup>48</sup> However, as with the clinical prediction rule approach, there are inherent limitations in the exclusive use of concurrent validity as a method of developing and validating homogenous subgroups in the LBD population.<sup>6</sup>

Our approach to developing the MTG criteria shares a common pathoanatomical nomenclature with the concurrent validity literature. However, because of the limitations of a concurrent validity approach to LBD classification, conclusive validation of pathoanatomically based classification criteria is not possible. We believe our method is justified by the convergence of a range of clinical and research evidence, and is an appropriate approach to classification in the complex domain of LBDs. The concept of convergence of evidence in the classification of LBD will be more comprehensively discussed in Part 2 of this series.

A final comment is necessary on the potential for the described clinical protocol to be overly prescriptive. Our aim was to develop a structure for clinical decision making based on the principles of the Maitland approach. Our experience to date in both clinical and research settings is that practitioners of all levels of competency value this structure as a reference point from which individualized patient treatment can be provided. On close examination of the protocol it is clear that the trial physiotherapist

has many options to exercise clinical decision making in areas including (but not limited to):

- selection of manual therapy technique in Session 1;
- progression of manual therapy techniques in Sessions 2–10;
- assessment of new areas and provision of relevant manual therapy techniques in Sessions 2–10;
- timing, content and progression of a specific motor control program.

By providing a clear and reproducible clinical protocol for physiotherapists in the STOPS trials we believe readers of the study will be well placed to modify their clinical practice, based on the trial results, in the way that best suits their patient population.

## Summary

A clinical protocol for the classification and specific treatment of an LBD subgroup with criteria indicating a likely positive response to specific manual therapy has been presented. This protocol was used in the STOPS trials evaluating the effectiveness of specific physiotherapy on the MTG. Should the trials demonstrate significant effects, the protocol will be useful for practitioners and researchers wanting to replicate the protocol in clinical and RCT settings.

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