

# A classification and treatment protocol for low back disorders

## Part 4 — Functional restoration for low back disorders associated with multifactorial persistent pain

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**Background:** It has been recommended that clinical trials on people with low back disorders (LBDs) should have a greater focus on subgroup specific treatment in order to increase the likelihood of clinically meaningful effects being demonstrated. Functional restoration is a treatment approach that has demonstrated some evidence of effectiveness in subacute and chronic LBDs. However, most studies to date have not used a clearly defined and appropriately detailed clinical protocol designed for and applied to a homogenous subgroup.

**Objectives:** This paper presents a detailed classification and treatment protocol for people with a LBD and clinical features indicative of multifactorial persistent pain. The treatment is directed at psychosocial and neurophysiological barriers to recovery.

**Discussion:** The classification and treatment components in the clinical protocol are discussed.

**Conclusion:** The described clinical protocol will be used in the specific treatment of problems of the spine (STOPS) trials comparing specific physiotherapy to evidence-based advice.

**Keywords:** Back pain, Classification, Functional restoration, Exercise, Psychosocial, Cognitive, Behavioural, Subgroup

### Introduction

This is the fourth and final paper in a series describing a clinical protocol for the classification and specific treatment of low back disorders (LBDs). The protocol was developed for the specific treatment of problems of the spine (STOPS) trials.<sup>1</sup> LBDs are a prevalent and costly burden to society and the individual,<sup>2–4</sup> although the precise extent of the problem remains ill defined due to methodological issues.<sup>5</sup> Physiotherapy, as a method of dealing with this problem, has minimal evidence demonstrating clinically meaningful effects.<sup>6–9</sup> Randomized controlled trials (RCTs) evaluating treatment specifically targeting LBD subgroups have the potential of providing stronger evidence for the effectiveness of physiotherapy.<sup>7,10–12</sup>

There are a variety of methods to develop and validate LBD subgroups,<sup>10,13</sup> each having significant limitations.<sup>10,14,15</sup> Parts 1–3 of this series described and provided a justification for our approach to classification based on identifying pathoanatomical subgroups of people with subacute LBDs.<sup>16–18</sup> The

described method involved the refinement of clinical methods in widespread current clinical use within the context of the best available research evidence in a manner consistent with evidence-based principles.<sup>19</sup> In these papers, it was postulated that in the subacute and non-compensable population sampled for the STOPS trials, pathoanatomical barriers to recovery should be the primary target of treatment in most cases. Nevertheless, in planning the STOPS clinical protocol, provision was made for a subgroup where factors other than pathoanatomical were the primary barrier.

The biopsychosocial model of illness<sup>20</sup> was recommended for use with LBDs in a landmark paper by Gordon Waddell.<sup>21</sup> Since that time extensive literature has been published on the predictive value of psychosocial factors<sup>22,23</sup> and the effectiveness of various treatment options directed at the psychosocial component of LBDs.<sup>24–28</sup> Neurophysiological mechanisms have also been identified that inter-relate with psychosocial factors in explaining the non-pathoanatomical component of LBDs.<sup>29–31</sup> On this basis, research investigating the effectiveness of treatment specific to people with LBDs, elevated psychosocial distress and maladaptive neurophysiological

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responses to pain has been recommended.<sup>32,33</sup> We have labelled a subgroup of LBDs with a symptom duration of more than 6 weeks, as well as primarily psychosocial and/or neurophysiological barriers to recovery as multifactorial persistent low back pain (MFP).

The term functional restoration (FR) was first defined by Mayer *et al.* as 'a multimodal pain management program that employs a comprehensive cognitive-behavioural treatment orientation to help patients better cope with, and manage, their pain ... while undergoing the sports medicine physical approach to correct functional deficits.'<sup>34</sup> Despite promising results from earlier studies,<sup>35</sup> there is currently inconsistent evidence supporting the effectiveness of FR programs for subacute and chronic LBDs.<sup>36</sup>

Physiotherapists are suitably qualified to treat subacute and chronic LBDs through FR type programs<sup>32,37</sup> and such an approach may increase patient access and reduce cost compared to multidisciplinary FR.<sup>38</sup> The effect of physiotherapy-based FR on participants selected due to higher levels of psychosocial distress was recently evaluated in a systematic review.<sup>39</sup> Moderate evidence was found of a small effect for physiotherapy FR compared with advice and no effect compared with other interventions including other exercise, other cognitive-behavioural therapy and manual therapy. These conclusions are consistent with other reviews that have included physiotherapy and multidisciplinary FR<sup>36</sup> or have restricted treatment to graded exposure and activity.<sup>26</sup>

Sample heterogeneity<sup>36,39,40</sup> and lack of treatment specificity<sup>39,41</sup> may be responsible for the modest results in trials of FR to date. The purpose of Part 4 in this series of papers was to present a classification and physiotherapy FR treatment protocol for people with MFP. The clinical protocol was developed for use in the STOPS trials which aimed to evaluate the effectiveness of specific physiotherapy treatment in subgroups of people with LBDs.

## Method

The STOPS trials protocol and methodology has been described elsewhere<sup>1</sup> and adheres to accepted guidelines for conducting RCTs.<sup>42–45</sup> Briefly, the key features of the STOPS trials were:

- classification of potential participants into one of five subgroups at baseline assessment (one of the subgroups was MFP);
- consenting participants being randomly allocated to either subgroup 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;
- separate trials being completed for each subgroup including MFP;

- follow-up of participants at 5, 10, 26 weeks and 12 months

## Classification of multifactorial persistent pain in LBDs

For the purposes of the STOPS trials, a hierarchical classification system was developed that firstly identified pathoanatomical causes of low back ± leg pain hypothesized as being more likely to respond to specific treatment.<sup>16–18</sup> It has been claimed that a focus on pathoanatomy-based diagnosis and treatment does not improve treatment effectiveness and may even be counterproductive.<sup>11,46–48</sup> However, a biopsychosocial approach should not exclude pathoanatomical or biomedical methods<sup>32,49–51</sup> which many experts<sup>52–56</sup> and practitioners in the field<sup>57</sup> agree are important to consider in LBD classification and treatment. We believe that within the context of recruiting participants with subacute and non-compensable LBDs, a pathoanatomical approach as the first line of classification is appropriate. For participants who did not have a consistent pathoanatomical pattern, consideration was given to psychosocial risk factors which might place them in the MFP subgroup. The second phase of the STOPS classification system was therefore the identification of participants with MFP who did not have a consistent pathoanatomical clinical pattern, and who also had higher levels of psychosocial risk factors. A schematic representation of the STOPS classification system is presented in Fig. 1.

For the participant to be classified into the MFP subgroup the following features were necessary:

1. exclusion from all of the following pathoanatomical subgroups: lumbar disc herniation with associated radiculopathy,<sup>18</sup> reducible discogenic pain,<sup>16</sup> non-reducible discogenic pain,<sup>18</sup> and zygapophyseal joint pain;<sup>17</sup>
2. a score of >105/210 on the Örebro Musculoskeletal Pain Screening Questionnaire (OMPSQ).<sup>58</sup> The OMPSQ was given to each participant to complete during the baseline assessment. Questions left blank were replaced with the average score from the answered questions.

The specific detail of the pathoanatomical subgroups has been presented in Parts 1–3 in this series.<sup>16–18</sup> The OMPSQ was developed as a tool to measure risk of poor outcome due to psychosocial factors<sup>58</sup> and is reported to be reliable.<sup>58,59</sup> Systematic reviews have also demonstrated the ability of the OMPSQ to predict outcome for people with subacute LBDs.<sup>60,61</sup> A score >105/210 is indicative of at least moderate risk of poorer outcomes including long-term pain, function, and sick leave<sup>60</sup> and in one specific population identified more than 85% of those with poorer prognosis.<sup>58</sup> A range of sensitivity levels were identified across other populations.<sup>59,61,62</sup> It has been suggested that the OMPSQ is best used in conjunction with other assessment tools to ensure more

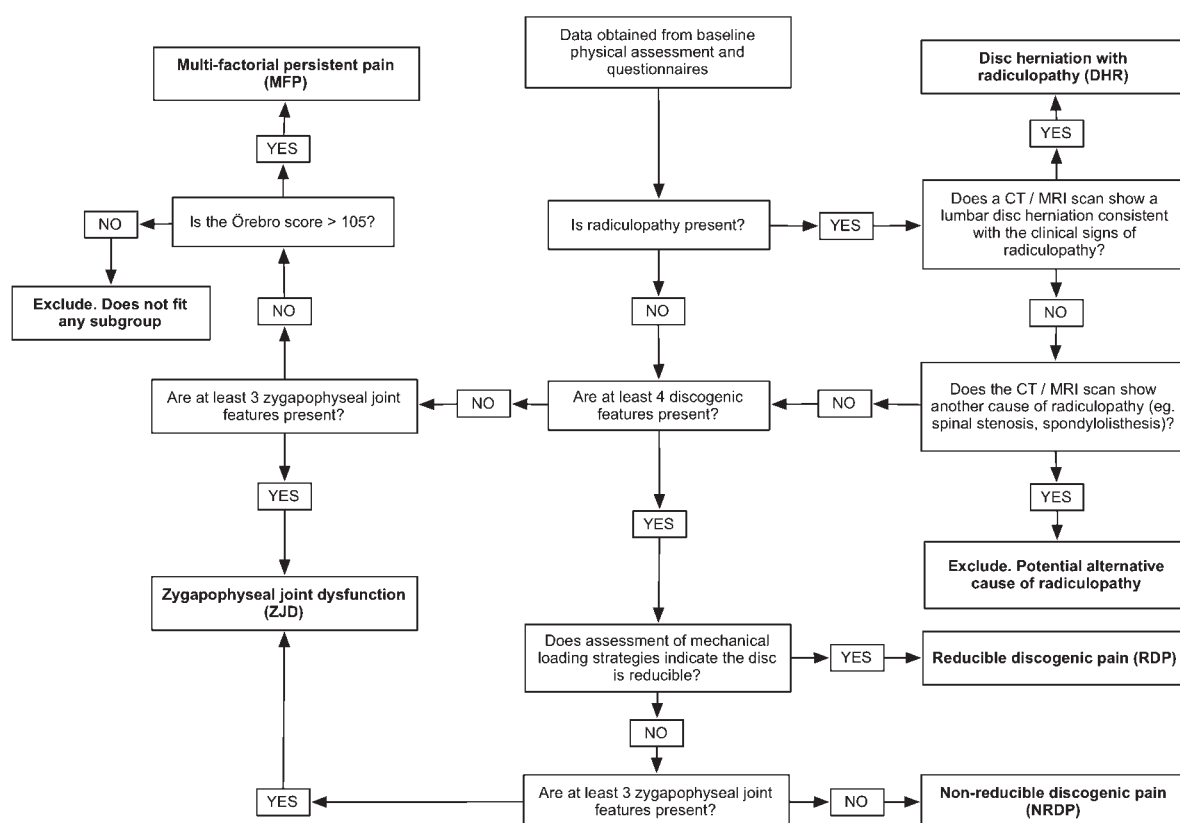


Figure 1 The STOPS classification system.

precise subgrouping<sup>63</sup> and this recommendation is consistent with the methods described above.

### Treatment protocol

The MFP treatment protocol used in the STOPS trials was based on the principles of FR as outlined in original descriptions,<sup>34</sup> recent systematic reviews,<sup>36,64</sup> as well as recommendations, based on the neurophysiology of pain<sup>65</sup> and included:

- an overall aim to restore reasonable capacity for activities of daily living including work;
- education regarding pain neurophysiology;
- negotiation of meaningful activity and exercise based goals at program commencement;
- development of graded exercise and non-exercise based activity schedules;
- the graded exercise program approximating the physical requirements of activity goals and being reviewed in a safe and supervised clinical environment;
- a focus on increasing physical (strength, flexibility, cardiovascular) fitness and psychological tolerance to exercise/activity;
- a cognitive-behavioural approach to address psychosocial barriers to achieving goals;
- promotion of coping and self-management strategies.

Some of the structure and content of the FR program is identical to the protocol outlined in Part 3 of this series for participants with lumbar intervertebral discogenic pain.<sup>18</sup> However, a key point of difference in the MFP protocol was that no information regarding pain provoking pathology, inflammatory processes, pain contingent pacing, and postural modification

based on biomechanics was provided to the participant. This approach of modifying treatment based on the nature of the participant's barriers to recovery is consistent with the classification approach in the STOPS trials.

A cognitive-behavioural approach was used to address psychosocial factors in the MFP subgroup.<sup>66–68</sup> This incorporated cognitive restructuring which was utilized, whenever a maladaptive thought or belief was verbally expressed by the participant. In this circumstance, the trial physiotherapist educated the participant about the negative impact of that cognition aiming to replace it with more constructive and accurate thoughts.<sup>66–68</sup> Behavioural modification was used mainly in the form of the practitioner positively reinforcing wellness behaviour through verbal praise and where possible not acknowledging or responding to illness behaviours.<sup>69–71</sup> The modification of thoughts and behaviours was also facilitated through strategies such as goal setting, non-pathoanatomical based pacing, learning coping skills, and graded activity.<sup>26,68</sup>

The operational detail in the protocols was derived from clinical training programs developed by the principal author (JF) based on an extensive review of the literature and his 20-year experience as a musculoskeletal physiotherapist providing treatment to patients and clinical mentoring for physiotherapists. In addition, 13 physiotherapists who were working with and had been trained by the principal

author participated in a 1-day forum to refine the MFP clinical methods.

Any physiotherapy treatment should be applied in a personalized manner using clinical reasoning principles; however, such skills are difficult to define and teach, particularly in complex cases.<sup>72,73</sup> Treatment integrity issues have also been identified in clinical trials evaluating the effectiveness of treatment programs aiming to address psychosocial factors.<sup>74</sup> The STOPS treatment protocol therefore had a focus on structured processes to ensure adequate and reproducible clinical decision-making across all physiotherapists and trial participants. The algorithmic nature of the protocol allowed each participant to receive treatment personalized to their individual presentation that stayed within the boundaries of the MFP treatment protocol. Sufficient scope was also provided in the protocol for the physiotherapist to modify the treatment based on their interpretation of the clinical presentation.

### Session 1 treatment

Details regarding the trial physiotherapists, as well as the training and mentoring program, have been described in Part 1 of this series.<sup>17</sup> Physiotherapists participated in a 2-day interactive and problem-solving-based training program. They had a number of resources to assist in provision of the treatment protocol including a 240-page treatment manual, a comprehensive baseline assessment report 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 progress and assisting clinical decision-making in each treatment session. The clinical notes were structured using specific written cues to

ensure all essential components of the treatment protocol were adhered to while allowing the physiotherapist some flexibility to select treatment techniques and rates of progression based on individual participant presentation. A summary of the content of the clinical notes for Session 1 is outlined in Table 1.

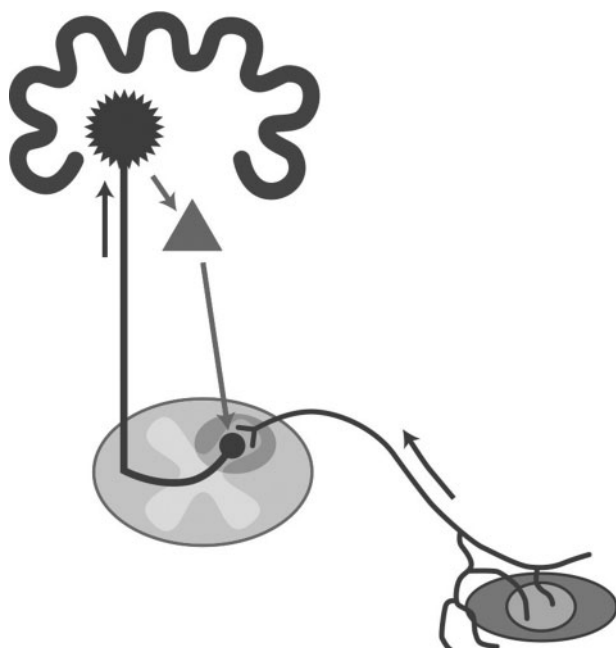
As part of Session 1 the trial physiotherapist was required to review the information retrieved from baseline assessment, complete a body chart/history and gather subjective and physical examination asterisks (measures used for the purpose of reassessing the participant's response to the treatment strategies). This information was required to enable the clinical reasoning methods of the protocol to operate. In the MFP subgroup, this component of Session 1 was particularly important in gaining rapport with the participant, as it allowed an opportunity for less structured two-way communication.

The primary focus of Session 1 was explanation of concepts regarding the neurophysiology of persistent pain and implications for treatment and prognosis.<sup>65</sup> Clinical resources are available for people with persistent pain and their practitioners.<sup>75,76</sup> However, given the limited number of sessions available in the STOPS trials, and based on our own clinical experience where simple explanations were usually most effective, we developed a two page information sheet regarding pain mechanisms. A variety of terms are used to label the central and peripheral maladaptive pain mechanisms that can occur in persistent pain including neurogenic pain,<sup>77</sup> neuropathic pain,<sup>78</sup> maladaptive central processing,<sup>77</sup> and central,<sup>29,30,75</sup> as well as peripheral<sup>75,79</sup> sensitization. For the purposes of a simple participant explanation, we chose to use the term increased neural sensitivity (INS) as a diagnostic label that would be meaningful to the participant. This

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

Treatment protocol component	Rationale
Session 1 assessment Review information from baseline assessment Complete body chart and history Gather asterisks from subjective and physical examination	To gather and interpret information relevant to treatment planning and for reassessment of the participant's response to treatment. To provide an opportunity for the trial physiotherapist to generate rapport with the participant.
Session 1 treatment Explanation and information sheets regarding the neurophysiology of persistent pain, MFP 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	Discussion of appropriate information consistent with a cognitive restructuring approach. <sup>26,68</sup> Engaging the participant with the treatment process is critical to effective specific treatment <sup>72,119</sup>
An emphasis on self-management rather than passive treatment approaches	Self-management is important in conditions with risk of poor outcomes due to psychosocial factors <sup>88-90</sup>
Commencement of specific motor control training	Specific motor control training is an evidence-based active treatment strategy <sup>120</sup> consistent with FR principles that also provides the participant with a plausible explanation for the physical effect of treatment





**Figure 2** Diagrammatic representation of pain pathways from participant information sheet (adapted from [www.ccac.ca](http://www.ccac.ca)).

term also encompasses the broad range of possible maladaptive neurophysiological responses in the MFP subgroup.

Participant education in Session 1 was considered a component of cognitive restructuring and commenced with an explanation of the multifactorial nature of pain in people with INS. The neurophysiology of acute pain was firstly explained using a macroscopic picture of the lumbar spine, spinal cord, and brain. Pain was described as originating from a lumbar generated nociceptive ‘pain signal’ that was transmitted up the spinal cord and to the brain where it was perceived as ‘pain’. The concept of INS in persistent pain was then described where the sensitized spinal cord ‘amplifies’ the pain signal resulting in higher perceived level of pain. These concepts were then reiterated to the participant within the context of Fig. 2. Once normal and sensitized processing of nociceptive signals was understood by the participant, the trial physiotherapist then explained descending influences on nociception. The triangle shown in Fig. 2 was described as the participant’s ‘emotional centre’ in the brain and the neuromodulatory effects of positive and negative emotions and thoughts were explained. Although not comprehensively reflecting central and peripheral sensitization processes, the education provided simple and plausible mechanisms to assist the participants’ understanding of the neurophysiology of pain. Importantly these mechanisms included physical (nociceptive), neurophysiological, and psychosocial factors all potentially influencing perceived pain. This information was then used to assist in challenging and altering unhelpful

thoughts as part of further cognitive restructuring later in the treatment protocol.

In the second part of Session 1, a description of the different treatment options for people with INS was provided. It was explained that standard treatment modalities, such as surgery, manual therapy, and injections, were often ineffective in INS due to the focus on the injured lumbar structure while not addressing the sensitized nervous system or psychosocial factors. Functional restoration was then introduced as a treatment that would ‘strengthen the back and help support the injury’ but also over time desensitize the nervous system or ‘turn the amplifier down’. Positive emotions associated with more effectively learning to manage the pain were also related to descending neural pathways that would result in inhibition of dorsal horn nociception and a resultant lessening of perceived pain.

The final explanation for Session 1 was around expected timeframes for improvement. Three phases of the MFP treatment program were described commencing with neurophysiological education, self-management of symptoms and basic motor control training. The second phase was explained as a functional motor control program performed under physiotherapy supervision and also regularly at home. The final phase of moving to self-management with discharge from the treatment program and ongoing exercise at home for 3–6 months was then described. These phases were pictorially represented and it was emphasized that capacity for engaging in activities was usually the first improvement noted followed by a slow reduction in perceived pain as the ‘sensitized nerves normalized’. Maximum potential recovery was suggested as occurring at 6 months post commencement of treatment.

Part 3 of this series described in detail a specific motor control training program focusing on transversus abdominis, lumbar multifidus, the pelvic floor muscles, and subsequently the global muscles of the lumbar spine.<sup>18</sup> The MFP treatment specifically avoided detailed education regarding pathoanatomical mechanisms for the participant’s pain in an attempt to reduce a somatic/cure-based focus.<sup>65</sup> However, a limited specific motor control program was provided on the basis of:

- minimal risk of creating treatment dependency or adversely affecting participant self-efficacy (as motor control training is an active rather than passive treatment strategy);<sup>80</sup>
- potential to improve pain and activity capabilities based on specific muscle impairments relevant to recovery<sup>81</sup> independent of psychosocial and neurophysiological factors;
- enabling plausible participant education regarding a treatment component that addressed the physical component of the LBD consistent with a complete biopsychosocial explanation.<sup>50</sup>

## Session 2 treatment

Much of the operational detail regarding Sessions 2–10 has been described and justified in Part 3 of this series of papers.<sup>18</sup> Briefly, the timing of Sessions 2–10 was determined by the trial physiotherapist; however, a general recommendation was made for treatment to be more frequent, approaching twice weekly, in the early stages of the program. A summary of the content of the clinical notes for Session 2 is outlined in Table 2.

When reviewing response to Session 1 treatment at the beginning of Session 2 the primary focus was not on symptomatic improvement, as rapid between session changes were not consistent with MFP.<sup>75</sup> Rather, the trial physiotherapist was predominantly concerned with any increase in symptoms and associated causal factors such as social/recreational activity and/or psychosocial factors influencing the participant's perception of response to treatment. This evaluation if required, was conducted based on information gained from detailed subjective and physical examination including reassessment of key asterisks.

For Session 2 treatment, key explanations/information sheets from Session 1 were reinforced. The trial physiotherapist also enquired regarding the impact of the LBD on work participation. Any work issues identified were discussed using a problem solving approach as part of the treatment program.

A goal setting information sheet was also discussed with the participant. Collaborative identification of activity and exercise-based goals was seen as an important part of the treatment protocol to maximize participant motivation and engagement with the treatment process, particularly in relation to exercise compliance. An explanation was given to the participant regarding how achieving the exercise goals would increase the likelihood of achieving activity goals. From Session 2 onwards, exercise and activity goals were reviewed with the participant every fortnight and positive reinforcement of progress provided as well as further explanation if required.

A pacing and graded activity information sheet was then discussed with the participant in Session 2. This firstly explained the importance of finding a

**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 worsening symptoms following Session 1 (if applicable)	To assist in determination of between session treatment effect. Detailed questioning conducted to differentiate treatment effect from other factors (e.g. social/recreational activity)
If the participant reported a perceived increase in pain, reassessment of Session 1 asterisks from the subjective and physical examination	To confirm whether the participant was significantly exacerbated compared with Session 1
Follow up on compliance with between session exercise	To continue the process of encouraging and evaluating participant engagement with the treatment program
Questioning regarding any work issues as a result of the LBD	The STOPS trials excluded participants with a compensation claim but managing related work incapacity (if relevant) remained an important focus
Session 2 treatment Briefly review explanations and information sheets regarding INS, treatment options, treatment timeframes and recovery expectations	Repeat explanation ensured engagement of the participant with the treatment program and enabled further questions to be asked
Collaborative setting of participant goals	To align the FR program content with goals that were meaningful for the participant, thereby increasing treatment effectiveness and participant motivation <sup>121</sup>
Discussion of pacing and graded activity	Understanding of pacing (with regards to all activity) and graded activity (particularly regarding exercise and specified goals) with reference to the neurophysiology of pain was essential information for people with MFP
Manage participant's perceived increase in pain, if appropriate	Specific management of perceived increases in pain was an important process for settling exacerbations and improving self-management skills <sup>85</sup>
A general emphasis on self-management rather than passive treatment approaches	Self-management is important in conditions with risk of poor outcomes due to psychosocial factors <sup>88–90</sup>
Weaning from passive treatment such as manual therapy (if applicable)	There is minimal evidence to support passive treatment in LBD with associated psychosocial factors, and there is also a risk of treatment dependency <sup>88–90</sup>
Progression of specific motor control training usually in non-weight bearing positions	Progression of specific motor control training provides a plausible participant explanation for the physical effect of FR treatment <sup>81</sup>

stable baseline level of activity that did not involve over or under activity. The concept of graded activity was then introduced with incremental and time contingent activity increases in quota not likely to result in significant exacerbations.<sup>26</sup> The concept of graded activity was related to the activity and exercise goals. Graded activity was explained as a principle method of reversing 'increased neural sensitivity'. Finally as part of the pacing and graded activity information sheet, the principle of 'hurt versus harm' was described where minor variations in symptoms in response to graded activity was explained as unlikely to represent 'harm' or significant tissue damage.

In the event of the participant reporting a perceived increase in pain a specific protocol was followed. Managing a participant's perceived increase in pain within an FR program for MFP can be a challenging clinical reasoning exercise. In Part 3 of this series on FR for discogenic problems, a detailed tracking of symptoms to identify genuine pathoanatomical exacerbations in symptoms was completed. While this same assessment process was followed in the MFP subgroup to ensure no significant exacerbation had occurred, the management of the perceived increase in pain was based predominantly on cognitive-behavioural rather than pathoanatomical principles. In most cases, brief reassurance was provided and the perceived pain response interpreted within the context of INS. If the increase was due to poor pacing techniques, then the information from the pacing and graded activity information sheet was emphasized. Consistent with a graded activity approach, planned progression in the exercise program was encouraged on a time contingent rather than pain contingent basis.<sup>82</sup> If participant reluctance to progress the exercise program persisted despite the above education, the dosage was maintained at the previous session's levels. These explanations were in alignment with current evidence-based advice aiming to minimize development of fear avoidance beliefs<sup>83-85</sup> and were predicated on the assessment that despite the participant's perception, no significant physical exacerbation had in fact occurred.

It is common for people with LBD to have fluctuating symptom levels particularly when recovery is slow.<sup>86</sup> Adequate self-management strategies were seen as critical in the MFP treatment, particularly as a means of managing a perceived increase in pain, and to enable the participant to reduce any counterproductive focus on the need for passive treatment methods.

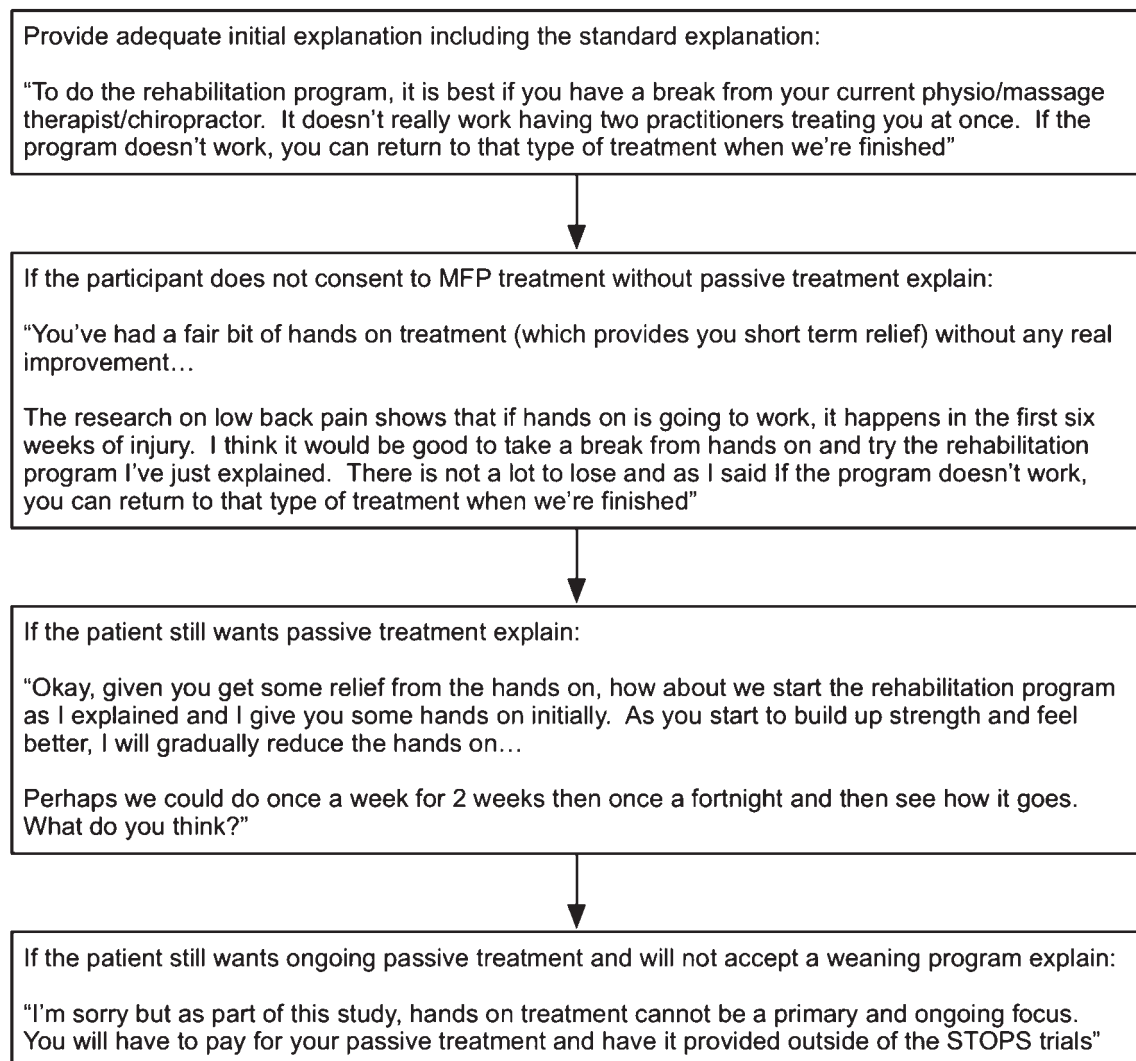
A key principle of the MFP treatment protocol was the exclusion of any 'passive' treatment; that is, modalities or manual therapy delivered by the physiotherapist to alleviate pain.<sup>87</sup> There is moderate evidence demonstrating poorer prognosis in people with MFP.<sup>22</sup> In these cases, passive treatment strategies have been hypothesized as falsely reinforcing

patient expectations of rapid recovery, where in fact a longer period of self-managed rehabilitation is required.<sup>88-90</sup> In addition, passive treatment in a condition with a slower recovery time in combination with psychosocial distress has the potential risk of participants developing a treatment dependence for short term symptomatic relief.<sup>91</sup> Such a dependency was not desirable within the context of a 10-week physiotherapy program as part of the STOPS trials. In participants where a strong dependency on passive treatment was observed early in the treatment program, a short period of weaning from such treatment was negotiated. This negotiation process is described in Fig. 3.

The final and mandatory component of Session 2 treatment was a progression of the specific motor control training exercise provided in Session 1. In Part 3 of this series, a precise and specific training protocol for the core muscles was described for intervertebral disc-related LBDs.<sup>18</sup> Given the emphasis within the MFP treatment on neurophysiological and psychosocial mechanisms, trial physiotherapists were instructed to be less particular on the requirement for precise activation of the core muscles before progressing onto more functional exercise. This approach was taken to minimize the risk of the participant spending the majority of the treatment program focusing on a pathoanatomy-based treatment (specific motor control training) when subsequent treatment methods such as graded activity would be more likely to have an effect.<sup>92</sup> Progression of non-weight bearing specific motor control training in the early stages of the MFP treatment was in most cases from side lying to standing and then to walking.<sup>18</sup>

Procedures from Session 2 continued for the remainder of the trial including: participant report on progress following the previous sessions, detailed questioning with or without reassessment of asterisks, follow-up on exercise compliance, follow-up of work issues, brief review of content of relevant information sheets, management of participant perceived increases in pain, self-management strategy education and weaning from passive treatment if required. Additional content for Sessions 3-10 is outlined in Table 3.

Additional participant information sheets were provided and explained as required including relaxation, sleep management, and pain management strategies.<sup>18</sup> Non-weight bearing motor control training was progressed into functional positions<sup>81,93</sup> that related to the participant's activity goals as described in detail in Part 3 of this series.<sup>18</sup> Functional exercises commonly included walking, step-ups, dumbbell exercises (bicep curls, forward raises, side raises), lunges, squats, and lifting. Integration of the global muscles into the motor control training program was done through the functional exercises, but also specific strength exercises including half sit-ups (abdominals) and trunk raises over

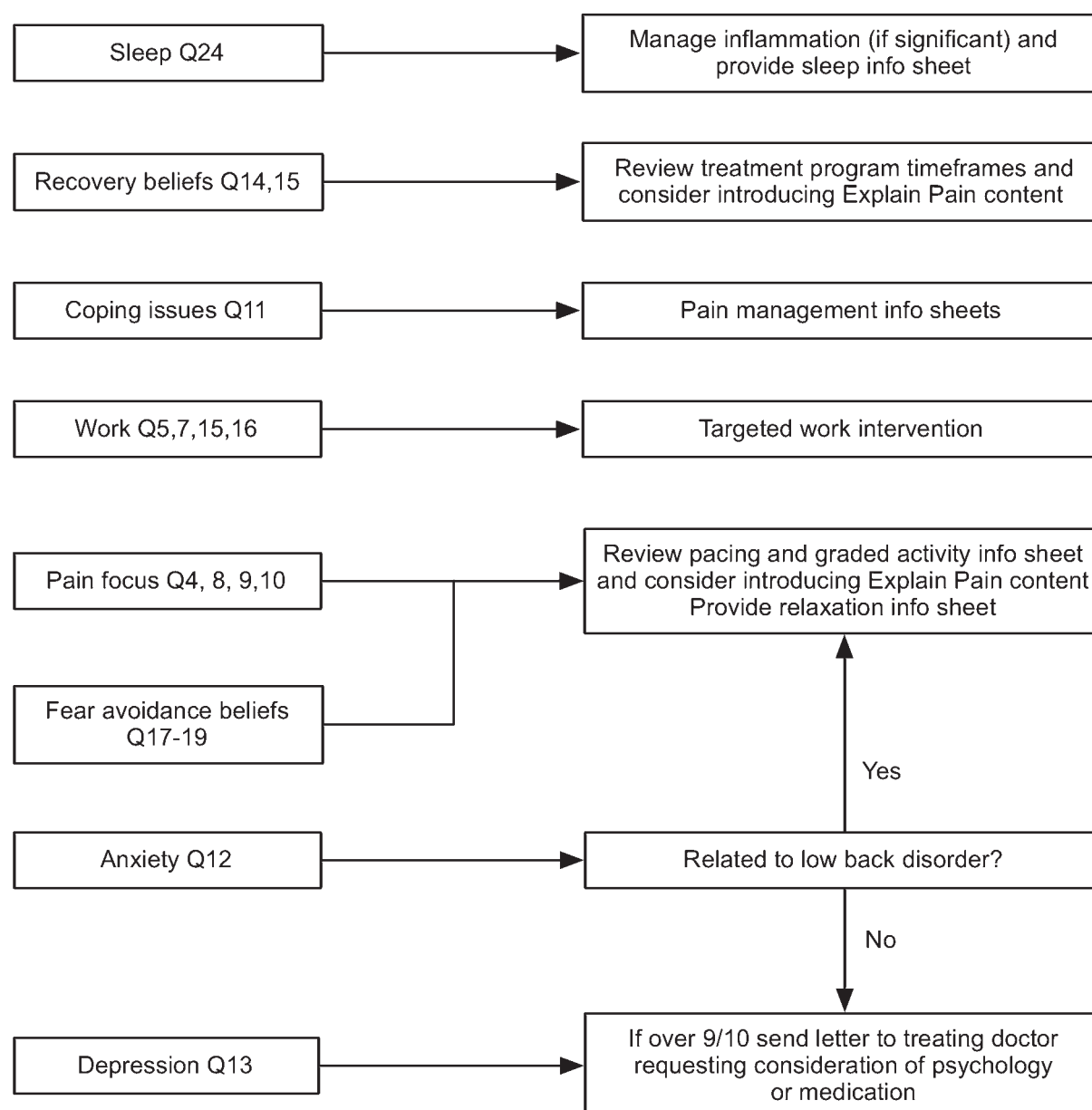


**Figure 3** Process of negotiating a wean from passive treatment.

**Table 3** Clinical notes content for Sessions 3–10

Treatment protocol component	Rationale
Session 3–10 additional treatment strategies	
Review of participant goals	To maintain participant focus on goals and the associated importance of the FR program content, thereby increasing treatment effectiveness and participant motivation <sup>121</sup>
Provision of additional information sheets as required on relaxation, sleep management and pain management strategies, as required	Self-management strategies and specific advice are an important component of any treatment regime <sup>85</sup>
Progression of specific motor control training from non-weight bearing to functional positions related to participant goals	Progression of specific motor control training provides a plausible physical explanation for the effect of treatment and attainment of goals <sup>81</sup>
Management of specific psychosocial factors based on individual and composite items from the OMPSQ	Functional restoration should be administered in a manner specific to the individual's psychosocial barrier to recovery <sup>64</sup>





**Figure 4** Decision-making algorithm related to OMPSQ score.

a fitball (erector spinae). In the event of participants not being able to adequately gain control of the core muscles, specific motor control training was ceased in Session 7.

In Session 3, the trial physiotherapist reviewed the individual item scores on the OMPSQ for the purposes of guiding intervention specific to relevant psychosocial factors. The decision-making algorithm based on the OMPSQ scores is presented in Fig. 4.

The OMPSQ was developed to assess psychosocial risk factors of a poor outcome and has demonstrated validity.<sup>60</sup> We grouped questions from the OMPSQ that related to a specific construct. These groupings were identified based on previous research<sup>58,62,63,94</sup> and clinical judgement. For example, questions 14 and 15 relate to recovery beliefs, a construct that has been shown to be predictive of outcome.<sup>95</sup> The validity of individual questions in the OMPSQ has not yet been demonstrated although the constructs the questions measure have significant evidence supportive of

predictive ability.<sup>22</sup> The average score for each grouping of questions and a table ranking each grouping was created. Specific treatment was prioritized to groupings of OMPSQ questions that had the highest ranking based on average question score.

The interventions specific for each of the OMPSQ grouped items was based on the clinical judgement of the researchers and the available evidence. People with LBD commonly have associated poor sleep habits,<sup>96,97</sup> and in MFP sleep has complex interactions with mood and maladaptive pain mechanisms.<sup>97</sup> In relevant participants, an information sheet was provided with an explanation on practical strategies to improve sleep including sleep routines and body positioning. In the event of clear clinical features of inflammation being present this was managed according the protocols presented in Part 3 of this series.<sup>18</sup> Negative recovery expectations have been shown in a recent systematic review to predict poor

outcomes<sup>95</sup> and are a counterproductive belief that has the potential to respond to appropriate education.<sup>98</sup> In such participants, the program timeframes information sheet was reiterated, and in difficult cases sections from the text *Explain Pain*<sup>75</sup> were used to provide a more detailed explanation. Poor coping skills are a common problem with persistent LBDs and predict poor outcome.<sup>98,99</sup> In such cases, information sheets on strategies for self-management of pain were provided outlining the use of medications for pain management, as well as other strategies including ice, heat, exercise, and relaxation.<sup>85,100</sup> Issues around work and work beliefs may influence an individual's LBD prognosis and these were addressed by return to work planning and communication with key stakeholders.<sup>36,101</sup> Cognitive processes can neuromodulate pain signals<sup>102</sup> and misunderstandings regarding the effect, nature, and course of pain should be challenged through cognitive restructuring.<sup>98</sup> This process was facilitated using sections of the text *Explain Pain*<sup>75</sup> and promotion of recommended goal-directed activity<sup>102</sup> via pacing and graded activity information. Augmenting cognitive restructuring in cases with a heightened pain focus was an information sheet and specific instruction on relaxed breathing and progressive muscle relaxation techniques.<sup>76</sup>

The fear and anxiety response comprises psychophysiological, cognitive, and behavioural elements.<sup>103</sup> Fear avoidance behaviour involves a cycle of disability, disuse, and depression<sup>104</sup> requiring promotion of physical and social activation though graded activity.<sup>98</sup> If significant levels of fear or anxiety were deemed by the practitioner to be unrelated to the LBD or if a threshold score for depression was reached then a referral for medical practitioner review was made.

As part of the STOPS trials, a goal was for the participant to become independent and able to self-manage by the completion of 10 sessions. To achieve this, the trial physiotherapist reduced treatment frequency and encouraged the participant in problem-solving and goal-oriented progression in exercises particularly after Session 8. As described in Part 3 of this series, the trial physiotherapist provided a discharge information sheet outlining expectations of further progression towards goals and improvement in pain and activity over the ensuing 6 months.<sup>18</sup>

## Discussion

A detailed clinical protocol has been presented for people with subacute, non-compensable LBDs classified into the subgroup of MFP who participated in the STOPS trials. We believe the protocol is reproducible, generalizable, and developed on the best available evidence in combination with the clinical principles of FR. As the final paper in this series, it is appropriate to overview the complete STOPS classification system.

Classification of LBDs is a complex exercise<sup>10</sup> and there is a lack of consensus on the most appropriate methodological model for developing and validating classification systems.<sup>10,105</sup> This conundrum is made more difficult by the absence of adequate gold/reference standards for the diagnosis of LBDs.<sup>10,51,106</sup>

The classification of MFP described in this clinical protocol was predicated on the exclusion of membership to a series of pathoanatomical subgroups described and justified in Parts 1–3 of this series.<sup>16–18</sup> In this sense, the classification system was hierarchical<sup>107</sup> prioritizing pathoanatomical factors over psychosocial and neurophysiological factors in determining subgroup membership and specific treatment.

A pathoanatomical approach to classification and treatment decision-making has been widely criticized<sup>47,108–111</sup> and guidelines only recommend such methods in the identification of red flags.<sup>112</sup> However, the biopsychosocial model of classifying LBDs, which is now widely accepted, was developed with reference to psychosocial, neurophysiological, and biomedical dimensions.<sup>50,51</sup> In the population sampled for the STOPS trials (non-compensable and subacute), it is reasonable to prioritize pathoanatomical factors in the process of classification on the basis of:

- the lower likelihood of non-pathoanatomical factors being relevant;
- the greater relevance of pathoanatomical factors in classification and treatment provision in people not yet in the chronic phase of injury;<sup>113</sup>
- pathoanatomical factors being the primary mechanism behind the specific treatment components being investigated;<sup>16–18</sup>
- the fact that people with relevant psychosocial and/or neurophysiological factors usually have significant inconsistency on clinical assessment<sup>114</sup> which typically obscures pathoanatomical clinical presentations. These participants would therefore not have met the pathoanatomical subgroup inclusion criteria and would have been classified into MFP.

Incorporating pathoanatomical mechanisms in a classification approach does not diminish the importance of psychosocial or neurophysiological factors as potential barriers to recovery requiring specific treatment. Indeed, the STOPS trials clinical protocols considered the relative importance of all potential factors in a sophisticated and algorithmic approach to classification and specific treatment.

Treatment with inadequate consideration of pathoanatomical mechanisms has a risk of being ineffective or harmful<sup>10,115,116</sup> particularly with FR where progressive loading of the lumbar spine is being encouraged by the practitioner. For example in Part 3 of this series, it was argued that providing time contingent graded activity to so-called 'non-specific LBP' had potential to aggravate genuine pathology.<sup>18</sup> A recent systematic review showed around 30% of participants failed to complete graded activity

treatments in RCTs<sup>26</sup> and insufficient consideration of pathoanatomical mechanisms may have been a factor in this high dropout rate. The STOPS hierarchical classification systems minimizes this risk in the MFP subgroup, because relevant pathoanatomical causes of LBD are excluded.

Upon exclusion of significant pathology, the second subgroup criterion for MFP was an OMPSQ score of at least 105/210. This threshold has been shown to identify cases with moderate risk of poor outcomes including long-term pain, function, and sick leave.<sup>60</sup> More sophisticated tests are available for measuring specific aspects of psychosocial status;<sup>117,118</sup> however, the OMPSQ measures a broad range of psychosocial risk factors in a simple questionnaire suitable for use by physiotherapists in the represented population.<sup>61</sup>

The STOPS classification system was based on tests with established reliability and validity.<sup>1</sup> Determination of subgroup membership was completed using a specifically developed EXCEL spreadsheet to eliminate the possibility of practitioner error in the classification process. The classification system could therefore be considered to have acceptable reliability. The case supporting the validity of the STOPS subgroups has been discussed in Parts 1–3 of this series.

As described in Part 1 of this series, in order to adequately evaluate the efficacy of specific physiotherapy in future RCTs, we believe that new classification and specific treatment protocols are required. These clinical protocols should adhere to the key principles outlined in original descriptions of the clinical method, be reproducible<sup>44</sup> to allow replication in subsequent trials, be generalizable to the broader physiotherapy community,<sup>44</sup> and be developed where possible on the best available evidence.<sup>19</sup> The treatment of subacute and chronic pain is complex to administer and in the context of an RCT treatment integrity is important.<sup>32</sup> Physiotherapists are in general not provided with specific clinical protocols for the management of people with MFP using FR. Texts, written for the pain sufferer, as well as practitioners,<sup>75,76</sup> do not provide sufficient specific decision-making information required to attain adequate treatment integrity in clinical trials and potentially in clinical practice. As part of planning for the STOPS trials, we believed that a refined clinical protocol targeting MFP that could be easily repeated in future clinical trials, as well as in the field by physiotherapists worldwide, was required. We are unaware of a detailed clinical protocol that refines, operationalizes and standardizes the clinical methods of the FR approach for MFP in this manner.

## Summary

A clinical protocol for the classification and specific treatment of a LBD subgroup with MFP has been presented. This protocol is currently being used in the

STOPS trials evaluating the effectiveness of specific physiotherapy. 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.

## Acknowledgements

The following physiotherapists participated in a 1-day forum to further develop the clinical protocol: Jon Ford, Andrew Hahne, Luke Surkitt, Alex Chan, Matthew Richards, Ross Lenssen, Justin Moar, Joel Laing, Aidan Rich, Meghan Dean, Adam Walters, Ben Sheat, and Daniel Di Mauro.

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