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Treating more than just the back: the role of individualised multidimensional care for chronic low back pain

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UNIVERSITY of LIMERICK
OLLSCOIL LUIMNIGH

**Treating more than just the back:
The role of individualised multidimensional
care for chronic low back pain**

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Supervisors: Dr Kieran O’Sullivan, Dr Norelee
Kennedy and Prof. Peter O’Sullivan

A thesis submitted in fulfilment of the requirements for the degree of
Doctor of Philosophy at the University of Limerick

Submitted to the University of Limerick November 2016

Declaration

My submission as a whole is not substantially the same as any that I have previously made or currently am making, whether in published or unpublished form for a degree, diploma, or similar qualification at any university or similar institution. I am the author of this thesis and the principal author of the studies which form its core.

Signature: _____

Mary O'Keeffe

Abstract

Introduction: Non-specific chronic low back pain (NSCLBP) is a common and costly musculoskeletal disorder, resulting in a significant personal, social and economic burden. NSCLBP is a multidimensional disorder, involving different factors across the biopsychosocial spectrum, whose interaction may vary between individuals. Many conservative interventions are delivered with an emphasis on physical or psychological components or both, and in an individual or group format. It remains unclear what is the most effective content and mode of delivery for NSCLBP interventions. A recent randomised controlled trial (RCT) in Norway suggests that an individualised multidimensional intervention called Cognitive Functional Therapy (CFT) is more effective than most current interventions for NSCLBP. The aims of this doctoral thesis were to systematically review the effectiveness of current conservative interventions for NSCLBP, investigate the factors that may enhance patient-therapist interactions, and compare the effectiveness of CFT with a group delivered multidimensional intervention in people with NSCLBP.

Methods: In the first part of this thesis (Chapter 2-three studies), three systematic reviews were completed. Study I compared the effectiveness of physical, behavioural/psychological and combined interventions in people with non-specific chronic spinal pain (NSCSP). Study II compared the effectiveness of individual and group physiotherapy interventions that incorporated exercise in people with musculoskeletal conditions (MSCs). Study III investigated physiotherapists' and patients' perceptions of factors that influence the patient-therapist interaction in musculoskeletal settings. In the second part (Chapter 3-two studies), a RCT was carried out. Study IV detailed the protocol for the RCT. Study V presented the preliminary data regarding the clinical effectiveness of individualised CFT compared to a multidimensional group exercise and education intervention.

Results: Study I demonstrated no clinically significant differences between physical, behavioural/psychological and combined interventions for reducing pain and disability in NSCSP. All interventions yielded similar small effects on pain and disability. Similarly, Study II demonstrated no clinically significant differences between individual and group physiotherapy interventions that incorporated exercise on pain and disability in MSCs. All interventions yielded similar small effects on pain and disability. Study III demonstrated that physiotherapist communication and interpersonal skills, physiotherapist practical skills, individualised patient-centred care and organisational and environmental factors are perceived to influence the patient-therapist interaction in musculoskeletal settings. Study V demonstrated preliminary results (n=171) that CFT led to superior outcomes for pain and disability compared to a group multidimensional exercise and education intervention at post-intervention, six months and 12 months post-randomisation.

Conclusion: This doctoral thesis demonstrates that most current interventions for NSCLBP have similar small effects on pain and disability. It demonstrates that a mix of interpersonal, clinical and organisational factors are perceived to influence the patient-therapist interaction. This thesis provides preliminary results that CFT has superior outcomes for NSCLBP compared to a multidimensional group intervention. Overall, the findings of this thesis suggest that neither the content nor mode of delivery of most current conservative interventions is critical as effects are generally small. However, the RCT in this thesis, along with the previous RCT using the same approach in Norway, suggests that better outcomes can be yielded by adopting an individualised multidimensional approach to NSCLBP. These promising findings must be interpreted with caution until data collection, including an intention to treat analysis of all randomised participants is completed. Additional analysis of the mediators and moderators of outcome will be analysed to examine the mechanisms of effect. Furthermore, costs and qualitative interviews will also be analysed.

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Dedication

*I would like to dedicate my thesis to my brave Uncle **Connie** who passed away at the young age of 43 last September. Thank you for all your encouragement especially during my earlier years and attending all my sporting events (no matter how small). We really notice your absence since the sunny weather has arrived, as your energy and jokes are no longer here.*

Everybody misses you loads.

Table of Contents

List of Publications	vii
List of Conference Presentations	viii
Prizes and Awards.....	xi
List of Appendices	xii
List of Tables	xiv
List of Figures	xv
CHAPTER 1: Introduction	1
CHAPTER 2: Investigating the most effective content and mode of delivery for non-specific chronic low back pain interventions	23
STUDY I: Comparative effectiveness of conservative interventions for non-specific chronic spinal pain: Physical, behavioural/psychologically informed or combined? A systematic review and meta-analysis.	24
STUDY II: Are group-based and individual physiotherapy exercise programmes equally effective for musculoskeletal conditions? A systematic review and meta-analysis.....	57
CHAPTER 3: An Individualised, Multidimensional intervention for managing non-specific chronic low back pain	124
STUDY IV: Individualised Cognitive Functional Therapy compared with a combined exercise and pain education class for patients with non-specific chronic low back pain: study protocol for a multicentre randomised controlled trial.	125
STUDY V: Individualised cognitive functional therapy compared with a combined exercise and pain education class for patients with non-specific chronic low back pain: Preliminary results of a multicentre randomised controlled trial.	144
CHAPTER 4: Discussion.....	171
Conclusion	195
References.....	196
Appendices.....	254

List of Publications

Primary journal articles used in the main body of this doctoral thesis are as follows;

Chapter 2:

O’Keeffe, M., Purtill, H., Kennedy, N., Conneely, M., Hurley, J., O’Sullivan, P., Dankaerts, W. and O’Sullivan, K. (2016) 'Comparative effectiveness of conservative interventions for non-specific chronic spinal pain: Physical, behavioural/psychologically informed or combined? A systematic review and meta-analysis', *The Journal of Pain*. 17(7), 755-74.

IF: 4.010

O’Keeffe, M., Hayes, A., Purtill, H., McCreesh, K. and O’Sullivan, K. ‘Are group-based and individual physiotherapy exercise programmes equally effective for musculoskeletal conditions? A systematic review and meta-analysis’, *British Journal of Sports Medicine*.

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O’Keeffe, M., Cullinane, P., Hurley, J., Leahy, I., Bunzli, S., O’Sullivan, P. and O’Sullivan, K. (2015) 'What Influences Patient-Therapist Interactions in Musculoskeletal Physical Therapy? Qualitative Systematic Review and Meta-Synthesis', *Physical Therapy*, 96(5), 609-622. **IF: 2.526**

Chapter 3:

O’Keeffe, M., Purtill, H., Kennedy, N., O’Sullivan, P., Dankaerts, W., Tighe, A., Allworthy, L., Dolan, L., Bargary, N. and O’Sullivan, K. (2015) 'Individualised cognitive functional therapy compared with a combined exercise and pain education class for patients with non-specific chronic low back pain: study protocol for a multicentre randomised controlled trial', *British Medical Journal Open*, 5(6), e007156. **IF: 2.271**

Published studies mostly appear as they do in the relevant journal articles. However, minor changes have been made to some of these studies in the main thesis to ensure consistency across the thesis and to meet the submission requirements of the University of Limerick.

List of Conference Presentations

Invited speaker

Invited speaker on ‘The Multidimensional Nature of Chronic Low Back Pain’. Irish Spine Society Meeting 2016, 4th November, NUI Galway, Ireland.

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Invited speaker on ‘Seated Research for low back pain’. The Back Pain Show 2012, 24th-25th February, London, England.

Oral presentations

O’Keeffe, M., Purtill, H., Kennedy, N., Conneely, M., Hurley, J., O’Sullivan, P., Dankaerts, W. and O’Sullivan, K. (2016) ‘Comparative effectiveness of conservative interventions for non-specific chronic spinal pain: Physical, behavioural/psychologically informed or combined? A systematic review and meta-analysis’. IFOMPT 2016, July 4th-8th, Glasgow, Scotland.

O’Keeffe, M., Purtill, H., Kennedy, N., O’Sullivan, P., Dankaerts, W., Tighe, A., Allworthy, L., Dolan, L., Bargary, N. and O’Sullivan, K. ‘Individualised cognitive functional therapy compared with a combined exercise and pain education class for patients with non-specific chronic low back pain: Preliminary results of a multicentre randomised controlled trial’. IFOMPT 2016, July 4th-8th, Glasgow, Scotland.

O’Keeffe, M., Cullinane, P., Hurley, J., Leahy, I., Bunzli, S., O’Sullivan, P. and O’Sullivan, K. (2015) ‘What Influences Patient-Therapist Interactions in Musculoskeletal Physical Therapy? Qualitative Systematic Review and Meta-Synthesis’. ISCP 2015, November 6th-7th, Dublin, Ireland. **Won Best Oral Presentation.**

O’Keeffe, M., Cullinane, P., Hurley, J., Leahy, I., Bunzli, S., O’Sullivan, P. and O’Sullivan, K. (2015) ‘What Influences Patient-Therapist Interactions in Musculoskeletal Physical Therapy? Qualitative Systematic Review and Meta-Synthesis’. WCPT 2015, 1st-4th May, Singapore.

O’Keeffe, M., Purtill, H., Kennedy, N., O’Sullivan, P., Dankaerts, W., Hurley, J., Conneely, M. and O’Sullivan, K. (2016) ‘Comparative effectiveness of conservative interventions for non-specific chronic spinal pain: Physical, behavioural/psychologically informed or combined? A systematic review and meta-analysis’. WCPT 2015, 1st-4th, Singapore.

O’Keeffe, M., Hayes, A., Purtill, H., McCreesh, K. and O’Sullivan, K. (2016) ‘Are group-based and individual physiotherapy exercise programmes equally effective for musculoskeletal conditions? A systematic review and meta-analysis’. WCPT 2015, 1st-4th May, Singapore.

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O’Keeffe, M., Purtill, H., Kennedy, N., Conneely, M., Hurley, J., O’Sullivan, P., Dankaerts, W. and O’Sullivan, K. (2016) ‘Comparative effectiveness of conservative interventions for non-specific chronic spinal pain: Physical, behavioural/psychologically informed or combined? A systematic review and meta-analysis’. ISCP 2015, November 6th-7th, Dublin, Ireland.

O’Keeffe, M., Hayes, A., Purtill, H., McCreesh, K. and O’Sullivan, K. (2016) ‘Are group-based and individual physiotherapy exercise programmes equally effective for musculoskeletal conditions? A systematic review and meta-analysis’. ISCP 2015, November 6th-7th, Dublin, Ireland.

O’Keeffe, M., Cullinane, P., Hurley, J., Leahy, I., Bunzli, S., O’Sullivan, P. and O’Sullivan, K. (2015) ‘What Influences Patient-Therapist Interactions in Musculoskeletal Physical Therapy? Qualitative Systematic Review and Meta-Synthesis’. ECMT 2015, September 18th-19th, Leuven, Belgium.

O’Keeffe, M., Purtill, H., Kennedy, N., O’Sullivan, P., Dankaerts, W., Hurley, J., Conneely, M. and O’Sullivan, K. (2016) ‘Comparative effectiveness of conservative interventions for non-specific chronic spinal pain: Physical, behavioural/psychologically informed or combined? A systematic review and meta-analysis’. ECMT 2015, September 18th-19th, Leuven, Belgium.

O’Keeffe, M., Hayes, A., Purtill, H., McCreesh, K. and O’Sullivan, K. (2016) ‘Are group-based and individual physiotherapy exercise programmes equally effective for musculoskeletal conditions? A systematic review and meta-analysis’. ECMT 2015, September 18th-19th, Leuven, Belgium.

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Education and Health Sciences Faculty Postgraduate Excellence Award 2016 (Dean's Prize)
at University of Limerick (€500)

Best Oral Research Presentation at Irish Society of Chartered Physiotherapists Conference
2015 (€200)

Chartered Physiotherapists in Musculoskeletal Therapy Research Presentation Award 2015
(€1000)

Chartered Physiotherapists in Occupational Health and Ergonomics Research Award 2012
(€500)

Irish Research Council PhD scholarship (2012-2015) (€72,000)

List of Appendices

1. Doctoral Thesis resources

1a. Cognitive Functional Therapy Clinical Reasoning Framework for targeted management of low back pain

1b. Randomised controlled trial (Study V) patient information leaflets: Sleep, X-rays and MRIs, Mindfulness and Relaxation and Exercise and Physical Activity

1c. Cognitive Functional Therapy in action: A patient case study

2. Public engagement and blogs

2a. Mary O’Keeffe, Dr Kieran O’Sullivan and Dr Derek Griffin. ‘15 things you did not know about back pain’. Published by the Irish Independent newspaper:

<http://www.independent.ie/life/health-wellbeing/15-things-you-didnt-know-about-back-pain-31367264.html>

2b. Mary O’Keeffe and Dr Kieran O’Sullivan. ‘What’s best for chronic spinal back pain? Physical, behavioural/psychologically or combined interventions?’ Body in Mind website.

<http://www.bodyinmind.org/spinal-back-pain-interventions/#comment-525285>

2c. Mary O’Keeffe and Dr Kieran O’Sullivan. ‘Body-mind interactions in low back pain’. TalkBack Magazine, BackCare: UK’s national back pain charity.

<http://www.backcare.org.uk/wp-content/uploads/2015/04/Body-Mind-Interactions.pdf>

2d. Mary O’Keeffe and Dr Kieran O’Sullivan. ‘I have back pain, what should I do?’

TalkBack Magazine, BackCare: UK’s national back pain charity.

<https://issuu.com/backcare/docs/backcare-talkback-3-2015/16>

2e. Mary O’Keeffe. ‘Physical, psychological or combined interventions: what’s best for treating pain?’ Pain-ed website.

<http://www.pain-ed.com/blog/2016/02/28/physical-psychological-or-combined-interventions-whats-best-for-treating-pain/>

2f. Mary O’Keeffe. ‘Interaction is Intervention, but how do we foster it?’ Pain-ed website. <http://www.pain-ed.com/blog/2016/02/22/interaction-is-intervention-but-how-do-we-foster-it/>

2g. Mary O’Keeffe. ‘Brace yourself’. Body in Mind website. <http://www.bodyinmind.org/evidence-for-bracing-in-lbp/>

3. Co-authored publications

3a. Hurley, J., O’Keeffe, M., Ryan, C., O’Sullivan, P. and O’Sullivan, K. (2016) ‘Effect of education on non-specific neck and low back pain: A meta-analysis of randomized controlled trials: letter to the editor’, *Manual Therapy*, 23, 1-2. **IF: 1.714**

3b. Synnott, A., O’Keeffe, M., Bunzli, S., Dankaerts, W., O’Sullivan, P. and O’Sullivan, K. (2015) ‘Physiotherapists may stigmatise or feel unprepared to treat people with low back pain and psychosocial factors that influence recovery: a systematic review’, *Journal of physiotherapy*, 61(2), 68-76. **IF: 2.255**

4. Letters to the Editor

4a. O’Keeffe, M., O’Sullivan, P. and O’Sullivan, K. (2016) ‘Cell-based Therapies for lumbar discogenic low back pain: A letter to the editor’, *Spine*. Accepted for Publication. **IF: 2.078**

4b. O’Keeffe, M., Dankaerts, W., O’Sullivan, P. and O’Sullivan, K. (2015). ‘Swiss ball enhances lumbar multifidus activity in chronic low back pain: A letter to the editor’, *Physical Therapy in Sport*, 16(2), 202-203. **IF: 1.653**

4c. O’Keeffe, M., Nolan, D., O’Sullivan, P., Dankaerts, W., Fersum, K. and O’Sullivan, K. (2014) ‘Ten-year follow-up of strengthening versus flexibility exercises with or without abdominal bracing in recurrent low back pain: a letter to the editor’, *Spine*, 39(24), 1495–1497. **IF: 2.078**

List of Tables

Table 1. Research questions examined in Chapter 2	23
Table 2. Study I Overview of characteristics of included studies.....	33
Table 3. Study I Quality assessment scores	44
Table 4. Study II Overview of characteristics of included studies	63
Table 5. Study II Quality assessment scores.....	76
Table 6 Study III Overview of characteristics of included studies	95
Table 7. Frequency with which themes and codes were identified across the studies	109
Table 8. Identification of themes from initial coding	110
Table 9. Research question examined in Chapter 3	124
Table 10. Inclusion and exclusion criteria for study participation.....	130
Table 11. Baseline characteristics of study participants	157
Table 12. Baseline, post-intervention, six month and 12 month descriptive statistics for continuous primary and secondary outcome measures.....	158
Table 13. Post-intervention satisfaction.....	159
Table 14. Post-intervention, six month and 12 month data for categorical measures (anxiety, depression and sleep)	160

List of Figures

Figure 1. Triage of CLBP	3
Figure 2. Pain mechanisms in NSCLBP	5
Figure 3. Multiple factors in NSCLBP	6
Figure 4. Study I Literature Search Strategy	29
Figure 5. Study I Flow Diagram	42
Figure 6. Effect of Physical versus Behavioural/Psychologically informed interventions on pain intensity	47
Figure 7. Effect of Physical versus Behavioural/Psychologically informed interventions on disability	48
Figure 8. Effect of Physical versus Combined interventions on pain intensity	49
Figure 9. Effect of Physical versus Combined interventions on disability	51
Figure 10. Study II Literature Search Strategy	60
Figure 11. Study II Flow Diagram	74
Figure 12. Effect of Individual versus Group physiotherapy on pain intensity	79
Figure 13. Effect of Individual versus Group physiotherapy on disability	81
Figure 14. Study III Literature Search Strategy	93
Figure 15. Study III Flow Diagram	106
Figure 16. Systematic Review Themes	108
Figure 17. Study IV Flow Diagram	136
Figure 18. Study V Flow Diagram	155
Figure 19. Effect of sizes of CFT versus current interventions	177

CHAPTER 1: Introduction

The aim of this chapter is to review the scientific literature regarding the prevalence and impact of non-specific chronic low back pain (NSCLBP), the mechanisms which underlie it and the effectiveness of current interventions used to manage it. Finally, it will explain the role of a novel, individualised multidimensional intervention for managing NSCLBP.

The pandemic of low back pain

Low back pain (LBP) is a common and costly musculoskeletal disorder (Deyo *et al.* 2009, Dunn *et al.* 2013, Hoy *et al.* 2014, Ma *et al.* 2014, Maher *et al.* 2016). Studies report that up to 84% of people will report LBP over their lifetime (Walker 2000, Hoy *et al.* 2010). It is responsible for 83 million years lived with disability, making it the leading cause of disability worldwide (Buchbinder *et al.* 2013, Vos *et al.* 2013). It is costly, both at a personal and societal level, resulting in a significant personal, social and economic burden (Dagenais *et al.* 2008, Gore *et al.* 2012, Wynne-Jones *et al.* 2014).

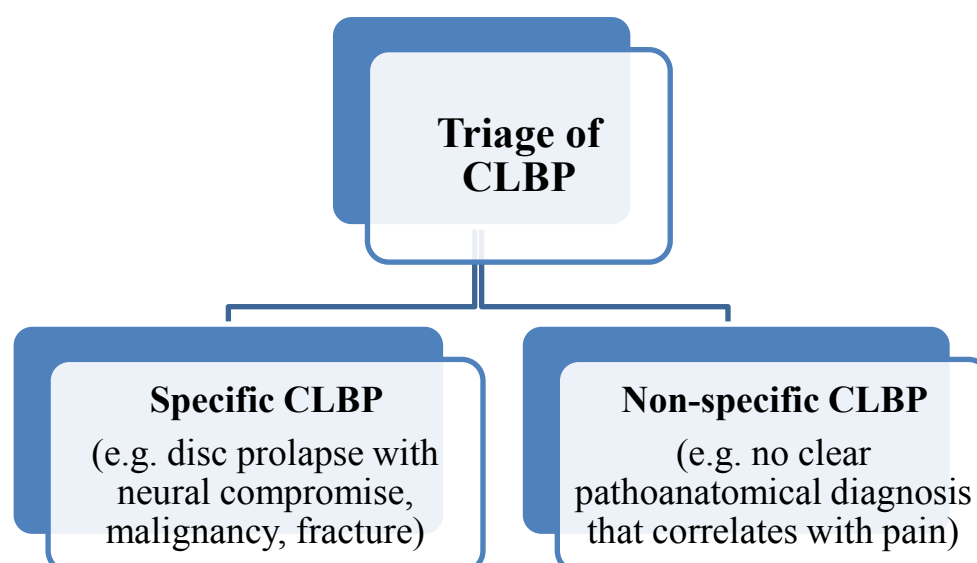
While it is widely believed that most episodes of LBP are short-lived, and improve rapidly within four to six weeks (Croft *et al.* 1998, Pengel *et al.* 2003), chronic low back pain (CLBP) is common, with studies reporting that 42% to 75% of people do not recover from an episode within a year (Henschke *et al.* 2008, Itz *et al.* 2013, Scheele *et al.* 2013). In fact, the costs of CLBP presentations in particular, are greater than that of cancer and diabetes combined (Hoy *et al.* 2014). In addition, disability secondary to CLBP is on the increase (Deyo *et al.* 2009, Freburger *et al.* 2009), with current interventions failing to make any substantial changes in pain and disability levels (Keller *et al.* 2007, Artus *et al.* 2010, O'Sullivan 2012). This highlights the need for a change in the management of CLBP (O'Sullivan 2012, Mafi *et al.* 2013).

Diagnosis

Current clinical guidelines recommend the use of a triage system to aid the diagnosis of CLBP (Airaksinen *et al.* 2006, Koes *et al.* 2010). This involves a case history and physical examination to exclude serious causes of CLBP or nerve root pathology. These are classified as “specific” causes of CLBP and warrant onward referral and investigation (Koes *et al.* 2001). However, while CLBP has traditionally been attributed to specific structural abnormalities (i.e. patho-anatomical findings) (Albert *et al.* 2011, Hancock *et al.* 2011), only an estimated 1% to 2% of people presenting with CLBP will have a serious or systemic disorder, such as systemic inflammatory disorders, infections, spinal malignancy or a spinal fracture (Henschke *et al.* 2009). Furthermore, approximately only 5% to 10% of people have LBP associated with nerve root features with or without neurological deficit such as cauda equina syndrome, sciatica secondary to disc prolapse, canal stenosis or spondylolisthesis (Deyo *et al.* 1992).

For the remainder (85%-90%) of people with CLBP, there is a weak correlation between patho-anatomical findings and the development of CLBP (Borenstein *et al.* 2001, Karppinen *et al.* 2001, Carragee *et al.* 2005, Kanayama *et al.* 2009, Kalichman *et al.* 2010). While some cross-sectional research shows that specific imaging findings like endplate (Modic) changes and severe disc degeneration are associated with CLBP (Jensen *et al.* 2008, Cheung *et al.* 2009, Takatalo *et al.* 2011, Mok *et al.* 2016), they are poor predictors of future CLBP (Jarvik *et al.* 2005, Deyo 2013). A recent systematic review and meta-analysis (Brinjikji *et al.* 2015a) found that specific imaging findings (e.g. disc degeneration, disc bulges, Modic changes) are more prevalent in people with LBP than asymptomatic individuals. This suggests that specific imaging findings may play a role in the pain experience. However, patho-anatomical findings on spinal imaging are very common across people with CLBP and asymptomatic individuals (Ranson *et al.* 2005, Alyas *et al.* 2007, Maurer *et al.* 2011, Brinjikji *et al.* 2015b). For instance, approximately 52% of individuals without CLBP have disc bulges and up to 90% have signs of disc degeneration which are age-dependent (Jarvik *et al.* 2005). In addition, there is a lack of specific clinical tests to accurately identify a structure (e.g. disc, facet joint) as the source of a person's CLBP (Hancock *et al.* 2007). Therefore, if there is a patho-anatomical contributor to a person's pain, current tests are unable to confidently identify it, and given the high prevalence of patho-anatomical findings in the pain-free population, it is difficult to decipher what is clinically relevant to outcome. This has resulted in most CLBP being referred to as "non-specific" CLBP (NSCLBP).

Figure 1. Triage of CLBP



Despite this, management of NSCLBP has relied increasingly on guideline discordant care, with over-imaging for NSCLBP endemic across the world (Jarvik *et al.* 2005). Furthermore, patients prefer to get imaging for their NSCLBP (Jenkins *et al.* 2016). However, strong evidence shows that imaging findings at baseline are not predictive of pain and disability (Steffens *et al.* 2014, de Schepper *et al.* 2016), and that early imaging is more often linked to poorer outcomes in people with NSCLBP, such as work absenteeism, surgery and increased medication prescription (Chou *et al.* 2009, Sloan and Walsh 2010, Webster and Cifuentes 2010, McCullough *et al.* 2012). This approach has reinforced negative beliefs about the spine, and has resulted in an exponential increase in healthcare costs, with a concurrent increase in disability and chronicity (Deyo *et al.* 2009, Mafi *et al.* 2013). While there is a potential role for patho-anatomy as a contributing factor to CLBP (Hancock *et al.* 2011), it is unlikely to represent the primary driver of pain related distress and disability in the majority of people.

The multidimensional nature of NSCLBP

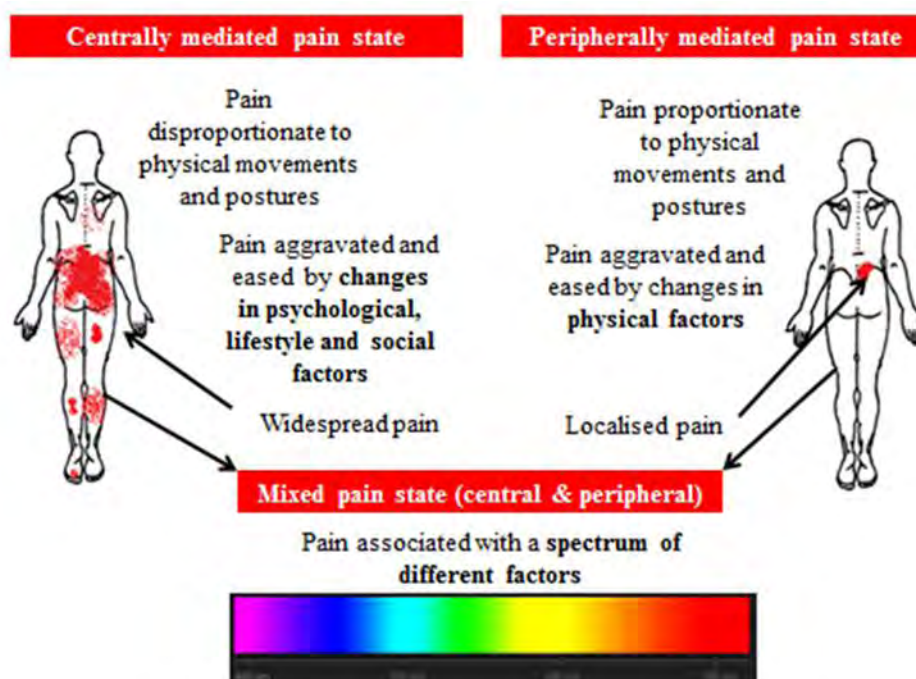
There is strong research that NSCLBP is a multidimensional experience mediated by changes in the structure and function of many different systems, including the nervous (Moseley 2003), immune (Watkins and Maier 2005), endocrine (Vachon-Preseu *et al.* 2013) and motor (Hodges and Tucker 2011) systems. Changes may include a loss of grey matter in the brain and spinal cord (Smallwood *et al.* 2013), reduced immune function (Marchand *et al.* 2005), dysregulation of the hypothalamo-pituitary-adrenal axis that alters the stress response (Generaal *et al.* 2015), neurochemical changes and alterations in brain activity (Sharma *et al.* 2012), loss of endogenous pain inhibition (Wand *et al.* 2011) and reduced pain thresholds (Imamura *et al.* 2013, Rabey *et al.* 2015a, Rabey *et al.* 2015b).

These systems interact with each other, and their structures and functions are influenced by multiple factors across the biopsychosocial spectrum (Gatchel *et al.* 2007). These include physical, psychological, lifestyle, social and additional non-modifiable factors (e.g. genetics) (Dunn *et al.* 2013), which may be unique for each individual with NSCLBP (O'Sullivan 2005). Interestingly, the emerging evidence reveals that many of these factors are inter-related, rather than being mutually exclusive (Geisser *et al.* 2004, Elfving *et al.* 2007, Thomas *et al.* 2008, Hulst *et al.* 2010, Costa *et al.* 2011, Scholich *et al.* 2012, Plaas *et al.* 2014, Massé-Alarie *et al.* 2016). These interacting factors influence tissue sensitivity through inflammatory processes, altered body perception and proprioception (Bray and Moseley

2011, O'Sullivan *et al.* 2013c), heightened distress, and maladaptive responses to pain in terms of posture, movement and activity (Hodges and Tucker 2011, DeVon *et al.* 2014). Therefore, CLBP is complex with changes in many different systems.

The dominance and unique interactions of certain factors will affect the overall nature of a person's NSCLBP. NSCLBP can range from low to high levels of complexity, and people can possess different pain characteristics (Figure 2).

Figure 2. Pain mechanisms in NSCLBP



For example, many people with NSCLBP present with pain that is localised to the lower back, that is intermittent in nature and is proportionately provoked and relieved by different spinal postures, movements and activities (Rabey *et al.* 2015a, Rabey *et al.* 2015b). This clinical profile may reflect a peripherally-mediated pain state (Smart *et al.* 2012b, Rabey *et al.* 2015b), secondary to unhelpful movement and postures, causing abnormal tissue loading and sensitivity (O'Sullivan 2005). For other people with NSCLBP, pain is more widespread, constant in nature and is disproportionately provoked by innocuous changes in physical loading, linked to amplification of nociceptive inputs related to high levels of psycho-social distress and negative lifestyle factors. This clinical profile is likely to reflect a centrally mediated pain state (central sensitisation) (Woolf 2011, Smart *et al.* 2012a, Rabey *et al.* 2015a). This type of pain is thought to be more complex and is associated with higher

levels of pain and disability and poorer outcome (Sterling *et al.* 2003a, Smart *et al.* 2012a). People who present with these more widespread pain features often present with co-morbid health complaints, such as fatigue, migraines and irritable bowel syndrome (Hestbaek *et al.* 2004, Hagen *et al.* 2006, Dunn *et al.* 2011, Tschudi-Madsen *et al.* 2011). Similar to pain, these health complaints are thought to be mediated by multiple central factors such as psychological and lifestyle factors. Screening people with NSCLBP for these subjective health complaints may therefore be useful in determining a person's underlying pain mechanism and guide management. However, boxing people into 'central' or 'peripheral' pain mechanisms could be reductionist and not reflect the individual and complex nature of NSCLBP. While pain characteristics may appear 'defined' in some people with NSCLBP, NSCLBP can present as a mixed pain state, with a spectrum of different contributing factors, reflecting a combination of both peripheral and central pain mechanisms. In summary, it is proposed that both modifiable and non-modifiable factors need to be assessed in order to determine which factors influence a person's NSCLBP and associated disability levels, and so provide targets for interventions. The various factors (Figure 3) and their roles will now be discussed.

Figure 3. Multiple factors in NSCLBP



Physical Factors

Physical factors refer to a person's movement, posture, muscular strength and patterns of spinal loading. While some cohort studies have displayed weak to moderate relationships between exposure to repeated bending, lifting and twisting activities and NSCLBP in some populations (Hoogendoorn *et al.* 2000a, Bakker *et al.* 2009, Coenen *et al.* 2013), their presence does not establish cause and effect. For instance, the majority of systematic reviews on physical factors have reported a lack of evidence to support any clear relationships between different spinal curvatures (Christensen and Hartvigsen 2008), spinal muscle morphology and timing at baseline (Wong *et al.* 2013), awkward work postures (Roffey *et al.* 2010c), sitting duration (Hartvigsen *et al.* 2000, Lis *et al.* 2007, Roffey *et al.* 2010b), standing duration (Roffey *et al.* 2010a), bending and twisting (Wai *et al.* 2010a), lifting (Wai *et al.* 2010b), manual handling (Roffey *et al.* 2010b), trunk flexion (Ribeiro *et al.* 2012), work-related pushing and pulling (Roffey *et al.* 2010c) and the development of future NSCLBP.

While there is a lack of strong evidence to demonstrate a causal relationship between these physical factors and the development of NSCLBP, emerging evidence is showing the importance of physical behaviours in response to pain (Hodges and Tucker 2011, Laird *et al.* 2014). These are changes in the way an individual usually postures or moves his/her body/back during activities associated with pain or the threat of pain (e.g. sitting, bending, and lifting). These alterations in postures and movements are usually adaptive and protective in the presence of an acute tissue injury. However, when they persist beyond the time lines for natural healing, they usually aggravate NSCLBP and are maladaptive (O'Sullivan 2005).

The nature of the maladaptive movements and postures are highly variable across individuals, with different activities and directions of movements (e.g. bending forward, bending backward, moving to the side, rotating, sitting, lifting, standing, walking) being provocative for different people (O'Sullivan 2005, Dankaerts *et al.* 2006). For example, pain aggravated by sitting, bending or lifting may be linked with sensitivity to lumbar flexion (too little flexion or excessive flexion). In contrast, pain for other individuals may be linked with the same activity where the person is sensitised to extension loading and where the person actively holds their lower back in lordosis during daily tasks. For some people, these physical behaviours are often associated with deconditioning (O'Sullivan 2005, Dankaerts *et al.* 2009), slower and reduced movements (e.g. not able to bend forward) (Laird *et al.* 2014), increased co-contraction, stiffness and hyperactivity of spinal and abdominal muscles and difficulty reducing the activation of these muscles (Geisser *et al.* 2004, Dankaerts *et al.* 2009,

Gubler *et al.* 2010, Moreside *et al.* 2014). Emerging evidence shows that these behaviours are exacerbated by other protective responses like propping with hands, breath-holding, avoidance of particular movements or activities (O'Sullivan 2005).

Despite the variation in postures and movements that can be provocative for individuals with NSCLBP, the majority of health care professionals (HCPs) and members of the general public still contend that upright, straight back postures and movements are advantageous for the prevention and treatment of NSCLBP (O'Sullivan *et al.* 2013a, O'Sullivan *et al.* 2013b). Furthermore, interventions often do not seem to explicitly assess for, or address maladaptive physical behaviours that an individual can present with (e.g. propping, breath-holding, avoiding flexion). This may partly explain the frequent provision and limited effectiveness of generic, “one-size fits all” postural or exercise interventions for NSCLBP (Van Middelkoop *et al.* 2011).

Of vital importance is the now emerging evidence that maladaptive postural and movement behaviours are influenced by psychological factors (e.g. catastrophizing and fear associated with pain amplification, muscle guarding, reduced movement and altered body perception) (Sullivan *et al.* 2001, Geisser *et al.* 2004, Sheeran *et al.* 2012, Karayannis *et al.* 2013). The role of psychological factors will be discussed later. Maladaptive physical responses to pain, where present, can act to maintain NSCLBP, through abnormal tissue loading and avoidance. They are modifiable, and so provide opportunity for targeted management (Van Hoof *et al.* 2011, Sheeran *et al.* 2012, Cañeiro *et al.* 2013, Kent *et al.* 2015).

Psychological Factors

Psychological refers to cognitive (thoughts) and emotional (feelings) factors that a person may have in relation to their pain or otherwise. Cognitive factors include a person's beliefs, catastrophic thoughts and self-efficacy. Negative patient beliefs about the cause, prognosis and management of NSCLBP in particular, have been consistently shown to predict future pain and disability (Chou and Shekelle 2010, Main *et al.* 2010). Decades of social conditioning has given society and HCPs the false belief that NSCLBP is caused by structural damage (e.g. disc out of place) and/or poor postural and movement behaviours (Zusman 1999, Ramond *et al.* 2011, Zusman 2013). Many people with NSCLBP subsequently report that the spine is a vulnerable structure, and that physical activities and movement of the spine are detrimental to the condition (Darlow *et al.* 2015, Darlow *et al.* 2016). These beliefs can

contribute to patients' catastrophizing their NSCLBP experience, where the perceived threat and consequences of the pain experience are magnified (Sullivan *et al.* 2001, Picavet *et al.* 2002, Wertli *et al.* 2014a). It is commonly characterised by hypervigilance (attention to pain) (Van Damme *et al.* 2013). These thoughts and beliefs have guided the provision and/or expectation of passive interventions for NSCLBP, contributing to poor recovery expectations, all of which are more related to poor outcome (Iles *et al.* 2009). Negative beliefs can have many origins, including social conditioning, parental responses to pain and the advice of HCPs (Daykin and Richardson 2004, Palermo *et al.* 2014). HCPs in particular, play a crucial role in the transfer of these beliefs to patients (Darlow *et al.* 2012, Lin *et al.* 2013). This has prompted some researchers to consider certain NSCLBP presentations as iatrogenic disorders (Lin *et al.* 2013). Despite some successful attempts to positively influence back pain beliefs (Buchbinder *et al.* 2001, O'Sullivan *et al.* 2012), many HCPs still maintain negative beliefs and attitudes about NSCLBP, which directly affects the beliefs of people with NSCLBP (Daykin and Richardson 2004, Coudeyre *et al.* 2006). These same beliefs guide many of the current interventions for NSCLBP, which aim to protect and strengthen the spine, and have limited effectiveness (Smith *et al.* 2014).

Such negative thoughts and belief systems can affect a person's pain self-efficacy, which reflects the level of confidence a person has in their ability to control pain and/or achieve a desired outcome in the presence of pain (Jackson *et al.* 2014). Low levels of pain self-efficacy have been shown to be among the most important mediators of the relationship between pain and disability in NSCLBP (Woby *et al.* 2007b, Thompson *et al.* 2010, Costa *et al.* 2011, de Moraes Vieira *et al.* 2014). Furthermore, changes in self-efficacy have been shown to be crucial to improvements in disability (Costa *et al.* 2011).

Emotional factors reflect a person's feelings, which may be indicative of pain-related distress, linked to social factors (e.g. family, work) or an underlying mental health issue. These can include fear, depression, anxiety, stress, anger and perceived injustice. High levels of fear are prognostic of increased disability levels and poorer outcomes in NSCLBP (Zale *et al.* 2013, Wertli *et al.* 2014c). Reasons for fear seem highly variable across individuals, and seem to stem from beliefs about one's spine being a vulnerable structure (e.g. disc damage, unstable spine) and/or fear of the consequences of pain itself (Vlaeyen and Linton 2000, Pincus *et al.* 2006a, Leeuw *et al.* 2007, Vlaeyen and Linton 2012, Wertli *et al.* 2014b, Bunzli *et al.* 2015a, Bunzli *et al.* 2015b). Fear may be task-specific (e.g. fear of lifting versus fear of running), depending on the patient (Vlaeyen and Linton 2012, Meulders and Vlaeyen 2013, Linton and Fruzzetti 2014).

Depression has a bidirectional relationship with NSCLBP. Research displays that low mood/depression is a strong risk factor for the development or maintenance of pain (Pineiro *et al.* 2016), and other research reporting its development in response to pain (Fishbain *et al.* 1997, Bunzli *et al.* 2013b). Similar bidirectional relationships have been found for anxiety and stress (Bener *et al.* 2013, Hannibal and Bishop 2014, Generaal *et al.* 2015, Østerås *et al.* 2015). Anger and perceived injustice are also common in NSCLBP patients, and are related to poorer prognosis (Scott *et al.* 2013, Sullivan *et al.* 2014).

The presence of cognitive and emotional factors can lead to the adoption of unhelpful coping strategies in response to pain (Hasenbring and Verbunt 2010). The stressor (e.g. pain, bending, lifting), as well as the individual's appraisal of it and ability to handle it, varies depending on environmental conditions, personal factors, time frame and earlier experiences or a combination of all these factors (Lazarus and Folkman 1984, Folkman 2013). As a consequence, identification and assessment of the stressor may be both necessary to understand the process. How an individual judges the meaning and significance of a stressful event could influence the coping process (Lazarus and Folkman 1984). Some people with NSCLBP display avoidance behaviours, which may manifest as work absenteeism, and the avoidance of specific postures (e.g. slouching), movements and activities (e.g. bending) (Vlaeyen and Linton 2000). Other people with NSCLBP can persist with activities in spite of high levels of pain (Andrews *et al.* 2012). This endurance coping strategy may be a distraction from pain/distress or represent a fear of a loss of sense of self (Hasenbring *et al.* 2012, Kohl *et al.* 2013). While such a pattern is less passive, it has been associated with a boom-bust pattern of pain and eventual disability (Hasenbring and Verbunt 2010, Andrews *et al.* 2012).

Changes in psychological factors (e.g. fear, catastrophizing, and self-efficacy) mediate changes in pain and disability after treatment in people with NSCLBP (Spinhoven *et al.* 2004, Smeets *et al.* 2006, Wertli *et al.* 2014b, O'Sullivan *et al.* 2015). However, it must be acknowledged that while many psychological factors have been shown to be modifiable (e.g. self-efficacy, negative beliefs), some factors may be more difficult to modify depending on the patient's life story (e.g. high levels of depression, anxiety disorders, stress linked to social factors (e.g. traumatic life events, family life)). While these factors may be difficult to modify, they are likely to be at least as modifiable as physical factors (e.g. posture, muscle thickness), which are often the main targets for treatment, but often do not change as pain and disability improve (Wong *et al.* 2014, O'Sullivan *et al.* 2015, Halliday *et al.* 2016).

Lifestyle Factors

Lifestyle factors refer to sleep problems, physical activity levels, sedentary behaviours, diet and smoking. Emerging evidence is demonstrating the role of lifestyle factors in musculoskeletal conditions, including NSCLBP (Briggs *et al.* 2011, Dean and Söderlund 2015). While all these are theoretically modifiable, certain factors may be difficult to change.

Sleep problems and NSCLBP are highly comorbid. Strong research displays a bidirectional relationship between them, with poor sleep being identified as a predictor for the development of NSCLBP (Auvinen *et al.* 2010, Pinheiro *et al.* 2016), and NSCLBP associated with the development of sleep problems (Kundermann *et al.* 2004, Kelly *et al.* 2011, Mäntyselkä 2012, Finan *et al.* 2013, Lusa *et al.* 2015, Paanalahti *et al.* 2015).

Physical activity and exercise levels are increasingly being researched in NSCLBP (Bjorck-van Dijken *et al.* 2008). A recent systematic review and meta-analysis (Steffens *et al.* 2016) displayed that exercise alone or in combination with education is effective for preventing primary and secondary LBP. The type of exercise (e.g. general exercise or motor control) seems less important (Ferreira *et al.* 2007, Hoffmann *et al.* 2016) than the quality of implementation (e.g. supervision, inclusion of a home program and duration of the program) (Hayden *et al.* 2005). There is an inverse relationship between physical activity and NSCLBP (Bjorck-van Dijken *et al.* 2008), with both low levels of physical activity/sedentary behaviours and high levels of physical activity having a relationship with NSCLBP. Other research however demonstrates no strong links between physical activity levels and NSCLBP and that physical activity levels have no link with NSCLBP (Hendrick *et al.* 2011). Furthermore, while some studies show that patients with high levels of pain and disability due to NSCLBP are less likely to be engaged in physical activity than healthy individuals (Lin *et al.* 2011), other research display that activity patterns may not differ between individuals with and without NSCLBP (Verbunt *et al.* 2003, Griffin *et al.* 2012). This may indicate that physical activity levels may be a contributing factor for certain people with NSCLBP, but not for others.

There is some evidence showing a modest association between smoking and NSCLBP (Shiri *et al.* 2010b). Furthermore, a poor diet (Western lifestyle practices) has been hypothesised to contribute to chronic pain disorders such as NSCLBP, based on evidence displaying obesity as a risk factor for the development of NSCLBP (Shiri *et al.* 2010a, Dean and Söderlund 2015). Factors such as high cholesterol and diabetes have been shown to have a potential role in tendon pain (Ranger *et al.* 2015, Tilley *et al.* 2015), though have not been

specifically examined in NSCLBP. Smoking and diet are deemed to contribute to musculoskeletal pain conditions, like NSCLBP through increasing systemic inflammation (Dean and Söderlund 2015). However, the overall body of evidence for smoking and diet as causative risk factors in NSCLBP is low in comparison to other factors.

Social Factors

Social factors refer to a plethora of family, work and personal life issues, culture and socio-economic status, each of which have shown associations with NSCLBP (Hoogendoorn *et al.* 2000b). The factors can be contextual, and can be in the past or present. Depending on the individual's life story and circumstances, it must be acknowledged that many social factors may not be modifiable (e.g. socio-economic status, culture or a very stressful family life).

Adverse life events (e.g. childhood abuse (physical or sexual), death of a loved one) have been linked to an increased risk of development of NSCLBP and/or chronic widespread pain (Linton 1997, Goldberg *et al.* 1999, Davis *et al.* 2005, Kopec and Sayre 2005, Generaal *et al.* 2015). Work factors such as physical exposures (e.g. twisting, lifting), low job satisfaction, night shift work, perceived lack of support from colleagues or superiors, perceived lack of a pleasant and supporting environment have been shown to increase a person's risk of NSCLBP (Hoogendoorn *et al.* 2000b, Elfering *et al.* 2002, Eriksen *et al.* 2004).

Family factors such as financial difficulties, interpersonal conflict and a parental history of NSCLBP increases the risk of NSCLBP in some groups, and are associated with certain pain beliefs and poorer psychological status (Hoogendoorn *et al.* 2000b, Saunders *et al.* 2007, Hoftun *et al.* 2013). Private life factors such as perceived loneliness and perceived lack of social support have been linked to an increased risk of NSCLBP (Hoogendoorn *et al.* 2000b, Jacobs *et al.* 2006). Cultural factors have an influence on beliefs, coping strategies and treatment preferences and linked with pain presentations (Honeyman and Jacobs 1996, Lin *et al.* 2013, Nortjé and Albertyn 2015). Furthermore, socioeconomic factors, including educational attainment, familial educational background and health literacy are predictors of increased risk of NSCLBP and disability (Dionne *et al.* 2001, Mustard *et al.* 2005, Hestbaek *et al.* 2008, Briggs *et al.* 2010, Lallukka *et al.* 2014).

Genetics and other non-modifiable factors

Emerging research is increasingly recognising the role of genetics in some people with NSCLBP. While genetics may not be relevant to every individual with NSCLBP, strong research displays that disc degeneration (Battié *et al.* 2004, Battié *et al.* 2007, Näkki *et al.* 2014), levels of pain sensitivity (Diatchenko *et al.* 2005, Nielsen *et al.* 2008) and psychological factors such as some catastrophizing (Fillingim 2015, Trost *et al.* 2015) and certain cases of depression (Burton *et al.* 2015) have strong genetic underpinnings. While genetic factors, for the most part, are not modifiable, assessing for their role in NSCLBP is important, with some research showing that their role may be more significant in people with severe levels of NSCLBP (Ferreira *et al.* 2013a).

Other non-modifiable factors include sex and transitioning through various life stages (e.g. adolescence, pregnancy, older persons). Being female is associated with higher pain sensitivity and an increased risk of chronic pain (Bartley and Fillingim 2013). There are physiological changes associated with certain life stages that are linked to the onset or exacerbation of NSCLBP. For example, NSCLBP generally starts in adolescence (Dunn *et al.* 2011), and localised NSCLBP often transforms into more chronic widespread pain among menopausal women (Dugan *et al.* 2006).

Interplay between factors

The various factors involved in NSCLBP have been discussed above, and it is now worth considering how they interact or dominate in NSCLBP patient presentations. This is very important, with emerging evidence demonstrating that the above factors co-exist, with intricate moderating and mediating relationships between them. There is mounting evidence showing that psychological factors (e.g. fear, depression) can affect pain processing, partly through physical responses to pain in terms of spinal movement patterns and levels of muscle tension (Linton 2000, Pincus *et al.* 2002, Geisser *et al.* 2004, Ramond *et al.* 2011, Karayannis *et al.* 2013) and changes in lifestyle (e.g. sleep problems, reduced physical activity) (Riemann *et al.* 2001, Elfving *et al.* 2007, Gupta *et al.* 2009). There is also emerging evidence that self-efficacy mediates the effect of emotional factors (e.g. depression) on pain intensity and can moderate lifestyle behaviours (e.g. exercise participation) in many conditions, including NSCLBP (Arnstein *et al.* 1999, McAuley and Blissmer 2000, Muris 2002, Sawatzky *et al.* 2012, Skidmore *et al.* 2015).

A poor lifestyle (e.g. sleep problems, low physical activity levels) can influence inflammatory processes, psychological wellbeing, and patterns of spinal loading (Chiu *et al.* 2005, O'Sullivan *et al.* 2006, Nimmo *et al.* 2013, Schuh-Hofer *et al.* 2013). In contrast, engaging in physical activity can reduce depression, stress and anxiety (Rosenbaum *et al.* 2015). Social factors (e.g. culture, socio-economic status, low social support/loneliness) can impact health and pain beliefs, emotional status and lifestyle choices and so increase pain susceptibility and risk of chronicity (Beenackers *et al.* 2012, Bernstein and Claypool 2012, Eisenberger 2012, Konttinen *et al.* 2013, Lin *et al.* 2013). In contrast, other social factors like high levels of perceived social support can reduce pain sensitivity and improve coping with psychological distress (Grav *et al.* 2012, Roberts *et al.* 2015). In terms of sex, males have been shown to engage in more behavioural distraction and problem-focused tactics to manage pain, whereas females tend to catastrophize more, and use a range of coping techniques including social support, positive self-statements, emotion-focused techniques, cognitive reinterpretation, and attentional focus (Unruh *et al.* 1999, Keogh and Eccleston 2006, Fillingim *et al.* 2009, Forsythe *et al.* 2011, Racine *et al.* 2012). Therefore, it seems that while certain factors can be present, the presence of other factors can either buffer or intensify their impact. Consequently, given the interactions and inter-relationships between different factors (e.g. psychological factors affecting physical factors, lifestyle factors affecting psychological factors), it could be very difficult to decouple the importance of one factor from another in interventions. However, most current interventions do not seem to account for these interactions between factors and their individual nature. It has been proposed that an individual's reaction to an illness or diagnosis (e.g. NSCLBP) can be influenced by an interplay of physical symptoms, emotions, social influences and interactions with HCPs (Leventhal *et al.* 2003, Hale *et al.* 2007). The person's understanding will then influence their activities, emotional responses and actions. Most importantly, reactions seem highly personalised, in that people act and respond in ways that make sense to them and their situation, which can vary greatly from person to person or culture to culture. Therefore, what makes sense to one person or group may not to another (Leventhal *et al.* 2003). Interventions for NSCLBP may therefore need to reflect this variation.

Current interventions for NSCLBP

Notwithstanding the array of multidimensional factors and different pain mechanisms that can be involved in NSCLBP, the majority of interventions are generic in nature, focussed

primarily on changing patho-anatomical and/or physical aspects of NSCLBP, with limited effectiveness (Keller *et al.* 2007, Van Middelkoop *et al.* 2011, Artus *et al.* 2014). Pharmacological and surgical interventions have resulted in small or insignificant outcomes when compared to conservative management or placebo (Österman *et al.* 2006, Jacobs *et al.* 2010, Chaparro *et al.* 2013, Mannion *et al.* 2013, Staal *et al.* 2013, Kaye *et al.* 2015, Machado *et al.* 2015).

Conservative physical interventions such as manual therapy, exercise, education about biomechanics and back care have shown small effects in NSCLBP, with no form of exercise or manual therapy being superior to another (Assendelft *et al.* 2004, Hayden *et al.* 2005, Hurwitz *et al.* 2009, Macedo *et al.* 2009, Wang *et al.* 2012, Kumar *et al.* 2013, Marshall *et al.* 2013, Wells *et al.* 2013, Menke 2014, Ainpradub *et al.* 2015).

Behavioural and psychological interventions such as cognitive-behavioural therapy (CBT), mindfulness-based stress reduction (MBSR) and acceptance and commitment therapy (ACT) have also been used to focus more on psychological and/or behavioural factors. However, the results show a similar trend to the physical interventions, yielding small effects, with no one intervention being superior to the other (van Tulder *et al.* 2000, Engers *et al.* 2008, Wicksell *et al.* 2008, Henschke *et al.* 2010, Cramer *et al.* 2012, Oliveira *et al.* 2012a, Sveinsdottir *et al.* 2012, Veehof *et al.* 2016).

Combined physical and behavioural interventions such as multidisciplinary programmes and combined exercise and CBT interventions have been applied in NSCLBP populations (Guzman *et al.* 2002, van Hooff *et al.* 2010, Cramer *et al.* 2013, Richards *et al.* 2013). Again, like the physical and behavioural interventions in isolation, they only show slight superiority over minimal interventions, placebo or waiting list control groups and yield small effects (Van der Giessen *et al.* 2012, Kamper *et al.* 2014, Michaleff *et al.* 2014, Rantonen *et al.* 2014).

Interestingly however, research is not clear on which conservative intervention (physical, behavioural/psychological or combined) is superior for NSCLBP. This is worth investigating in order to guide the content of future interventions for NSCLBP. Furthermore, these interventions can be delivered on an individual or group basis. While individual physiotherapy is more commonly provided, group interventions for a range of musculoskeletal conditions have shown encouraging results (Russell *et al.* 2014, Cherkin *et al.* 2016, Wilson *et al.* 2016). Given the complex interaction of factors that can be involved in NSCLBP and their variability across individuals, patients with NSCLBP may require comprehensive one-to-one assessments and interventions (Vibe Fersum *et al.* 2013).

However, group interventions have also been associated with benefits such as social support (Wilson *et al.* 2016) and reduced costs (Critchley *et al.* 2007). Currently, it is unclear which mode of delivery is superior for NSCLBP interventions, and if individual physiotherapy is worth the potential extra time and costs involved. This would be an important area to examine in order to inform the future delivery of interventions for NSCLBP.

Why do interventions for NSCLBP have limited long-term effectiveness?

One possible reason for the poor effectiveness of existing current interventions is their unidimensional focus, with a failure to adequately address the multidimensional nature of NSCLBP. This is crucial considering that NSCLBP is associated with many different factors across the biopsychosocial spectrum (Gatchel *et al.* 2007, O'Sullivan 2012). Another potential reason is that interventions are “one-size fits all” in nature and so are insufficiently tailored to an individual’s own needs. Given the high variability of contributing factors and their unique interactions across each individual with NSCLBP (O'Sullivan 2012), a person-centred approach that deals with the heterogeneity of presentations may be needed (Foster *et al.* 2013). In fact, a body of qualitative research displays the various impact that NSCLBP can have on different individuals (e.g. hobbies, mood, work, stigma, “my life is on hold”), the different functional limitations patients may have (e.g. not able to play with children, not able to run), the different beliefs and fears that people hold (e.g. disc damage, “I may end up in a wheelchair”, “rest is needed”, “I need surgery”), and the different needs individuals want from interventions (e.g. their preferences taken into account, to be listened to) (Slade *et al.* 2009c, Slade *et al.* 2009b, Slade *et al.* 2009a, Bunzli *et al.* 2013b, Darlow *et al.* 2013, Darlow *et al.* 2015, Testa and Rossetini 2016). Based on this, it could be suggested that HCPs may need to explore all of these avenues on an individual basis, before designing an appropriate management plan with the individual.

“One-size fits all” interventions often seem to deliver contradictory messages. For example, while one aspect of an intervention may aim to change beliefs and fears around NSCLBP through education or encouraging physical activity, a second aspect could provide a physical intervention (e.g. advice not to bend) which reinforces the negative beliefs and fears (Ryan *et al.* 2010). Another example could be using breathing exercises to reduce a person’s lower back muscle tension, while at the same time providing information that the back is a vulnerable structure, requiring stability exercises. Such information and exercises could of course then increase a person’s muscle tension in order to protect the spine. A further

instance could be provision of mindfulness practice in lying down to aid stress management, while at the same time not observing for a person's mindfulness of movement (e.g. body awareness) or their response to facing feared activities (e.g. breath-holding and bracing before bending). These contradictions may easily happen if HCPs are not aware of the interaction of factors in NSCLBP. It also potentially conveys that many current interventions are not designed to target the complex inter-relationships of factors in NSCLBP.

Similarly, current interventions may not adequately target important mediators of change in NSCLBP. Interestingly, seemingly different interventions may work by similar mechanisms. This is based on trials showing that successful outcomes, even after a purely physical intervention are often mediated by changes in psychological factors (e.g. reduced fear-avoidance beliefs, increased self-efficacy) (Mannion *et al.* 2001b, Smeets *et al.* 2006, Lee *et al.* 2015). Therefore, it is important that future intervention trials for NSCLBP measure and explicitly target these factors if present.

Furthermore, current interventions may not harness non-specific factors, such as a positive patient-therapist interaction (Hall *et al.* 2010). Having a positive interaction with people with NSCLBP may be important in changing beliefs and facilitating behaviour change, with research showing that education needs to be made relevant to the individual (Robinson *et al.* 2015). In fact, increasing evidence demonstrates that a positive patient-therapist interaction has a positive effect on outcomes such as pain, disability and patient satisfaction across many different health conditions, including NSCLBP (Hall *et al.* 2010, Ferreira *et al.* 2013b, Fuentes *et al.* 2014, Testa and Rossetini 2016). As a result, it is crucial that future interventions are delivered within a positive therapeutic interaction to optimise outcomes. However, it remains unclear on what factors are needed to harness a positive patient-therapist interaction. Given the complexity of NSCLBP and the patient-therapist interaction, qualitative methods may need to be incorporated, to gain a holistic perspective from patients. Investigating the factors that influence interaction may therefore be very important to improve delivery of interventions for NSCLBP.

Based on this, interventions which target the interaction between multiple pain dimensions across the biopsychosocial spectrum, through a positive patient-therapist interaction are being proposed (Gatchel *et al.* 2007, Ramond-Roquin *et al.* 2014). It is postulated that tailoring to the needs of the patient within the broad NSCLBP population would aid this multidimensional approach (Foster *et al.* 2011).

Tailored management for NSCLBP

In order to improve the success of interventions for NSCLBP, there has been a move by some researchers to tailor management (Foster *et al.* 2011, Karayannis *et al.* 2012, Huijnen *et al.* 2015). Approaches include subgrouping people with NSCLBP based on their expected response to physical interventions (e.g. targeted exercises or manipulation) (Delitto *et al.* 1995, Childs and Cleland 2006, Fritz *et al.* 2007, Kent *et al.* 2010, Haskins *et al.* 2012), patho-anatomical features (Petersen *et al.* 2003), physical features (e.g. movement behaviour) (Karayannis *et al.* 2012), psychosocial features (Johansson and Lindberg 2000, Rusu and Hasenbring 2008, Beneciuk *et al.* 2012, Huijnen *et al.* 2015), and risk of ongoing disability (i.e. matching treatment based on low, moderate, high risk of disability) (Hill *et al.* 2008, Linton *et al.* 2011). Notwithstanding the wide range of classification systems available for attempting to deal with the heterogeneity of NSCLBP and enhance treatment matching, no system has so far been demonstrated to be superior (Fairbank *et al.* 2011). In fact, matching treatment based on physical and patho-anatomical factors alone has only demonstrated similar small effects to unmatched interventions (Kent *et al.* 2010, Saner *et al.* 2011, Karayannis *et al.* 2012, Laird *et al.* 2012, Henry *et al.* 2014, Saner *et al.* 2015, Haskins and Cook 2016). Similarly, targeting treatment on cognitive and psychosocial factors alone has shown small effects (Kent and Kjaer 2012, Ramond-Roquin *et al.* 2014). This highlights that targeting treatment based on one factor alone appears to be no more effective than other therapies for people with NSCLBP.

These small effects have led to classification and subgrouping systems being criticised for being unidimensional and failing to reflect the biopsychosocial nature of NSCLBP (Karayannis *et al.* 2012). Similar to non-targeted interventions, they neither target multiple aspects of an individual's pain experience nor individualise the targeting of such factors for each patient. With research displaying that the multiple factors at play in NSCLBP co-exist (Geisser *et al.* 2004, Elfving *et al.* 2007, Patel and Hu 2008, Thomas *et al.* 2008, Hulst *et al.* 2010, Costa *et al.* 2011, Scholich *et al.* 2012, Plaas *et al.* 2014, Massé-Alarie *et al.* 2016), and are not separate entities, "boxing" patients into rigid subgroups could miss the crucial inter-relationships between factors. In fact, a small number of studies which have tried to base interventions on multiple factors have shown encouraging results (Asenlof *et al.* 2005, Hill *et al.* 2011, Vibe Fersum *et al.* 2013).

Developing interventions based on Individualised, Multidimensional management of NSCLBP

In response to the shortcomings of current unidimensional subgrouping approaches, a flexible, multidimensional clinical reasoning framework that directs person-centred conservative care, called Cognitive Functional Therapy (CFT) has been developed (O'Sullivan 2012). CFT is described in detail in Chapter 3 and the multidimensional clinical reasoning framework and a sample case study using CFT are outlined in Appendices 1a. and 1c. It incorporates a contemporary biopsychosocial understanding of NSCLBP in order to identify the modifiable and non-modifiable factors and underlying pain mechanisms associated with a person's NSCLBP, and associated distress and disability. In this way, it can target multiple factors together, in an individualised manner, acknowledging the complex inter-relationships between factors. CFT provides a personalised multidimensional understanding of pain in the context of the person's own unique life story, normalises movement (where relevant), enhances pain controllability, and targets behavioural and lifestyle change where deemed important. Inter-tester reliability of some aspects of the framework has shown substantial agreement between trained HCPs (Vibe Fersum *et al.* 2009). In a recent physiotherapist led RCT among people with NSCLBP, this approach was significantly more effective than combining manual therapy and exercise for reducing disability and pain (Vibe Fersum *et al.* 2013). Similar results were demonstrated for a high-risk group of patients with NSCLBP treated with CFT in a recent single centre cohort study in Ireland (O'Sullivan *et al.* 2015). However, as this intervention is both (1) multidimensional and (2) individualised, it is unclear which component of CFT is responsible for the improved outcomes. Given the complex individual nature of NSCLBP and the importance of the patient-therapist interaction, it is postulated that giving patients one-to-one attention in the form of assessment and treatment may be needed. This may be particularly important when using an intervention like CFT, which explores particularly sensitive issues (e.g. life events, depression) and often challenges a person's back pain beliefs. If this is not managed well, it could result in the patient feeling stigmatized, dismissed and rejecting the advice provided. Therefore, providing a safe, individualised environment may be critical. On the other hand, a generic group intervention that reflects the multidimensional nature of pain may be enough to result in positive outcomes, and facilitate peer support from other patients, while avoiding the costs and complexity of individualised care. With research demonstrating positive outcomes after group interventions (Critchley *et al.* 2007, Russell *et al.* 2014, Cherkin *et al.* 2016), it is

worth comparing the effect of an individualised, multidimensional intervention (CFT) with a group, multidimensional intervention.

Key points: Chapter 1

- NSCLBP is a multidimensional disorder, individual in nature and associated with an interaction of physical, psychological, lifestyle, social and additional non-modifiable factors (e.g. genetics).
- Tailoring treatment based on the dominant contributing factors, and associated pain mechanisms involved in the pain experience of each individual patient with NSCLBP has been suggested.
- Despite this, most current interventions for NSCLBP remain generic in nature, do not target multiple factors in an individual's experience, do not explicitly demonstrate the inter-relationship between factors to patients nor individualise the targeting of these factors for each patient with NSCLBP.
- Current conservative physical, behavioural/psychological and combined interventions seem to yield small effects. However, little is known about the most effective intervention for NSCLBP and whether it should be delivered on an individual or group basis.
- Non-specific factors (e.g. patient-therapist interaction) affect outcome in NSCLBP. However, little is known about how to harness the patient-therapist interaction, which is important in maximising patient adherence and outcomes.
- Given the shortcomings of current interventions, and the importance of specific and non-specific factors in mediating outcomes, treatments which address multiple factors in the pain experience and individualise this to the patient are being proposed. A small number of studies which have attempted to base treatment on multiple factors have shown encouraging results.
- Cognitive Functional Therapy (CFT) is a novel, patient-centred intervention for NSCLBP. It targets multiple factors in NSCLBP, in an individualised manner, acknowledging the complex inter-relationships between factors. A previous RCT has demonstrated its effectiveness over manual therapy and exercise. It remains unclear however whether it is the (1) multidimensional or the (2) individualised nature of CFT that is responsible for the positive outcomes. Therefore, this individualised multidimensional intervention needs to be compared to a group multidimensional intervention.

Aims of thesis

A review of the literature highlights the lack of clarity on the most effective content and mode of delivery of NSCLBP interventions, and the potential role of an individualised, multidimensional intervention for NSCLBP. This doctoral thesis aims to provide a deeper insight into the required content and delivery of interventions for NSCLBP.

This will be done in four parts:

1. Systematically review the literature on the comparative effectiveness of physical, behavioural/psychological and combined interventions for non-specific chronic spinal pain (NSCSP).
2. Systematically review the literature on the comparative effectiveness of individual and group physiotherapy interventions that incorporate exercise for musculoskeletal pain conditions.
3. Systematically review the literature on physiotherapists' and patients' perceptions of factors that influence the patient-therapist interaction in musculoskeletal settings.
4. Investigate the effectiveness of an individualised, multidimensional intervention (CFT) compared to a group, multidimensional exercise and education intervention in people with NSCLBP.

CHAPTER 2: Investigating the most effective content and mode of delivery for non-specific chronic low back pain interventions

The overall layout of this chapter in this doctoral thesis is outlined in Table 1. This chapter contains three studies, all of which have been published in peer-reviewed journals (Study I- Study III) (O'Keeffe *et al.* 2015a, O'Keeffe *et al.* 2016a, O'Keeffe *et al.* 2016b). Other than formatting changes to make each paper consistently match the University of Limerick thesis submission requirements, these papers have not been altered in any way from the published versions. Each review was not specifically limited to NSCLBP because (1) the review may have been too small and/or (2) some relevant studies included a mix of pain conditions and/or (3) there is a large overlap in pain mechanisms between NSCLBP and other pain conditions. In the two quantitative reviews (Study I and Study II), subgroup analyses on the different pain conditions were completed.

Table 1. Research questions examined in Chapter 2

CHAPTER TITLE	RESEARCH QUESTIONS
Effective content and mode of delivery for NSCLBP interventions	<ul style="list-style-type: none"> • <u>Study I:</u> What is the most effective type of intervention for NSCLBP: Physical, behavioural/psychological or combined? • <u>Study II:</u> What is the most effective mode of delivery for physiotherapy interventions incorporating exercise for MSK conditions: Individual or group? • <u>Study III:</u> What factors are perceived to influence the patient-therapist interaction in musculoskeletal settings?

STUDY I: Comparative effectiveness of conservative interventions for non-specific chronic spinal pain: Physical, behavioural/psychologically informed or combined? A systematic review and meta-analysis

O’Keeffe, M., Purtill, H., Kennedy, N., Conneely, M., Hurley, J., O’Sullivan, P., Dankaerts, W. and O’Sullivan, K. (2016) *Journal of Pain*. 17(7), 755-74. (**Impact Factor** = 4.010)
[http://www.jpain.org/article/S1526-5900\(16\)00504-6/abstract](http://www.jpain.org/article/S1526-5900(16)00504-6/abstract)

Abstract

Background: Non-specific chronic spinal pain (NSCSP) is highly disabling. Current conservative rehabilitation commonly includes physical and behavioural interventions, or a combination of these approaches. Physical interventions aim to enhance physical capacity by using methods such as exercise, manual therapy and ergonomics. Behavioural/psychologically informed interventions aim to enhance behaviours, cognitions or mood by using methods such as relaxation and cognitive behavioural therapy (CBT). Combined interventions aim to target both physical and behavioural/psychological factors contributing to patients’ pain by using methods such as multidisciplinary pain management programmes. Since it remains unclear whether any of these approaches are superior, this review aimed to assess the comparative effectiveness of physical, behavioural/psychologically informed, and combined interventions on pain and disability in patients with NSCSP.

Methods: Nine electronic databases were searched for randomised controlled trials (RCTs) including participants reporting NSCSP. Studies were required to have an “active” conservative treatment control group for comparison. Studies were not eligible if the interventions were from the same domain (e.g. if the study compared two physical interventions). Study quality was assessed using the Cochrane Back Review Group risk of bias criteria. The treatment effects of physical, behavioural/psychologically informed, and combined interventions were assessed using meta-analyses.

Results: Twenty-four studies were included. No clinically significant differences were found for pain and disability between physical, behavioural/psychologically informed and combined interventions.

Conclusion: The simple categorisation of interventions into physical, behavioural/psychologically informed and combined could be considered a limitation of this review, as

these interventions may not be easily differentiated to allow accurate comparisons to be made. Further work should consider investigating whether tailoring rehabilitation to individual patients and their perceived risk of chronicity, as seen in recent RCTs for low back pain (LBP), can enhance outcomes in NSCSP.

Introduction

Non-specific chronic spinal pain (NSCSP), particularly low back and neck pain, remains a common musculoskeletal disorder, resulting in significant personal, social and economic burden (Vos *et al.* 2013, Ma *et al.* 2014, Hoy *et al.* 2015). While low back pain (LBP) and neck pain (NP) occupy different body regions, strong evidence exists that both are best considered multidimensional disorders, associated with a complex interaction of contributory factors (Sterling *et al.* 2003b, Sterling *et al.* 2006, Kasch *et al.* 2008, O'Sullivan 2012). While a plethora of interventions for NSCSP have been tested, heralding similar short-term outcomes (Deyo *et al.* 2009, Teasell *et al.* 2010, Artus *et al.* 2014), positive long-term outcomes are infrequent. One explanation for this relative ineffectiveness is the fact that many interventions used are uni-dimensional, either focusing on physical or behavioural factors, rather than combining these approaches and/or tailoring them to the individual needs of the person with NSCSP (O'Sullivan 2012, Mafi *et al.* 2013). Considering the increase in the number of randomised controlled trials (RCTs) conducted on NSCSP there is a need for a systematic review to determine which of these interventions has the greatest level of evidence.

Physical factors which have been described among people with NSCSP include maladaptive postures (Dankaerts *et al.* 2006, Yip *et al.* 2008), movement patterns associated with altered levels of muscle activity (Hodges and Tucker 2011, Falla *et al.* 2014), altered body perception (Sjölander *et al.* 2008, Bray and Moseley 2011), pain behaviours (e.g propping, breath-holding, bracing) (Martel *et al.* 2010) and muscular deconditioning (Ylinen *et al.* 2004, Dankaerts *et al.* 2009). Behavioural/psychological factors which have been described among people with NSCSP include fear (Nederhand *et al.* 2004, Myhre *et al.* 2013), maladaptive beliefs (Buitenhuis and de Jong 2011, Rainville *et al.* 2011), catastrophic thoughts (Bostick *et al.* 2013, Wertli *et al.* 2014a), hypervigilance (Peters *et al.* 2002, Woby *et al.* 2007a), anxiety, depression, stress (Carroll *et al.* 2004, Vereckei *et al.* 2013), poor pacing, maladaptive coping strategies (Andrews *et al.* 2012, Carroll *et al.* 2014), poor self-efficacy (Thompson *et al.* 2010), physical inactivity (Woby *et al.* 2007b, Griffin *et al.* 2012) and sleep problems (Kelly *et al.* 2011). Therefore, current rehabilitation for NSCSP comprises a range of interventions, primarily aimed at addressing physical, behavioural/psychological or both of these factors.

Physical interventions aim to enhance physical capacity by using methods such as exercise, manual therapy and ergonomics (Van Middelkoop *et al.* 2011). Despite many

treatment options, numerous trials have shown that most physical interventions have similar modest levels of effectiveness in the treatment of NSCSP (Assendelft *et al.* 2004, Hurwitz *et al.* 2009, Macedo *et al.* 2009, Wang *et al.* 2012, Marshall *et al.* 2013). Furthermore, positive results for these physical interventions are small and short-lived and are mostly only evident when compared to minimal interventions, placebo or waiting list control groups (Furlan *et al.* 2005, Hayden *et al.* 2005, Bertozzi *et al.* 2013, Kumar *et al.* 2013, Menke 2014).

Behavioural/psychologically informed interventions use educational, cognitive or psychological strategies to enhance behaviours, cognitions or moods. These include relaxation, biofeedback, cognitive-behavioural therapy (CBT), mindfulness-based stress reduction (MBSR) as well as acceptance and commitment therapy (ACT) (Hoffman *et al.* 2007). Similar to the evidence for physical interventions, no behavioural/psychological intervention has been found to be superior to another (van Tulder *et al.* 2000, Henschke *et al.* 2010, Veehof *et al.* 2011, Tan *et al.* 2015). In addition, positive effects (albeit small) are once again most often yielded for behavioural/psychologically informed interventions when compared to minimal interventions, placebo or waiting list control groups (Engers *et al.* 2008, Wicksell *et al.* 2008, Henschke *et al.* 2010, Cramer *et al.* 2012, Oliveira *et al.* 2012a, Sveinsdottir *et al.* 2012).

Combined interventions aim to target both physical and behavioural/psychological factors contributing to a patients' pain. These include multidisciplinary pain management programmes, functional restoration programmes (FRP), yoga, graded activity, graded exposure, behaviourally-informed physiotherapy or exercise combined with behavioural interventions such as relaxation or CBT (Söderlund and Lindberg 2001, van Hooff *et al.* 2010, Cramer *et al.* 2013, Richards *et al.* 2013). However, combined interventions have been shown to be only slightly superior to minimal interventions, placebo or waiting list control groups (Guzman *et al.* 2002, Van der Giessen *et al.* 2012, Michaleff *et al.* 2014, Rantonen *et al.* 2014). Consequently, it has been suggested also that any positive outcomes from combined interventions may not be worth the additional cost and effort (Kamper *et al.* 2014).

While it seems clear that physical, behavioural/psychologically informed and combined interventions are superior to minimal or no treatment (Keller *et al.* 2007, Artus *et al.* 2010, Oliveira *et al.* 2012a), it remains unclear whether either is superior to the other. No systematic review has compared the effectiveness of these interventions in a NSCSP population. Therefore, the primary objective of this systematic review was to assess the comparative effectiveness of physical, behavioural/psychologically informed, and combined interventions on pain and disability in patients with NSCSP.

Methods

Literature Search Strategy

The review was registered on the PROSPERO database (Registration number CRD42013005757) and has been reported in accordance with the PRISMA statement (Moher *et al.* 2009). All relevant RCTs and cluster randomised trials meeting the inclusion criteria (see the section on Inclusion and Exclusion criteria) were identified by;

- A computer aided search of the Academic Search Complete, MEDLINE, CINAHL, SPORTDiscus, Biomedical Reference Collection, AMED, PsycINFO, PsycARTICLES, EMBASE and Web of Science databases from the period of inception to January 2013 using the search strategy recommended by the Cochrane Back Review Group. The search was restricted to include trials that involved humans and which were published in English.
- Scanning the reference lists of previous systematic reviews and included studies for further references.

Two independent reviewers (MOK and KOS) conducted the electronic searches. The strategy had four components which were combined: (1) physical/behavioural/combined intervention, (2) spinal pain, (3) chronic and (4) RCT. The exact search strings utilized are shown in Figure 4.

Figure 4. Study I Literature Search Strategy

Psych* OR CBT OR cognitive* OR behavior* OR behaviour* OR graded activity OR graded exposure OR problem-solving OR problem solving OR goal* OR counseling OR counselling OR acceptance OR commitment OR pacing OR exposure OR classical conditioning OR operant OR relaxation OR coping OR biofeedback OR stress OR talk therapy OR interpersonal OR group OR motivation* OR meditation OR disclosure OR hypno* OR education OR advi* OR person-centered OR client-centered OR person-centred OR client-centred OR mindfulness OR yoga OR tai chi OR assertive* OR avers* OR gestalt OR autogenic OR dance OR suggest* OR imagery OR personal OR color OR colour OR art OR music OR implos* OR aromatherap* OR play OR reality OR balint OR zen OR free association OR mindbody OR visual OR flooding OR bibliotherap* OR transactional analysis OR roleplay* OR role play* OR desensitisation OR desensitization OR socioenvironmental OR directive OR nondirective OR non-directive OR milieu OR sociotherap* OR manual OR manip* OR physical OR conservative OR pain management OR osteo* OR chiro* OR massage OR exercise* OR mobil* OR hydrotherap* OR traction OR electr* OR hot OR heat OR cold OR cool OR training* OR therap* OR strength* OR stretch* OR aerobic OR acupuncture OR active* OR work OR occupation* OR back school OR orthotic* OR orthos* OR insoles* OR muscle OR multidis* OR functional restor* OR counter-transference OR countertransference OR residential OR outpatient OR inpatient (Abstract)
AND
low back OR lumbar OR neck OR cervical OR thoracic OR pelvic OR pelvis OR spinal OR spine OR back OR lumbo-pelvic OR spino-pelvic OR dorsal OR LBP OR low-back (Title)
AND
chronic OR persistent OR disabling OR recurrent (Full text)
AND
random* OR RCT (Full text)

Inclusion and exclusion criteria

Study design

Only published reports of completed RCTs published in peer-reviewed journals were included. Studies were required to have a minimum follow-up period of 12 weeks after completion of treatment.

Population

Studies including participants with NSCSP (neck, thoracic, low back, or pelvic) greater than 12 weeks duration and between 18 and 65 years of age, were eligible. Participants with previous spinal surgery (>6 months previously) were eligible. Studies that involved participants with specific pathologies/conditions (e.g. pregnancy, fibromyalgia, rheumatoid arthritis, ankylosing spondylitis, stenosis, psoriatic arthritis, lupus erythematosus, scheurmann's disease, spondylolisthesis or "red flag" disorders (e.g. spinal cord compression/cauda equina, spinal cord injury, neoplasm, fracture) were excluded.

Interventions

Studies were required to involve a head-to-head comparison between two of our three chosen categories of interest (i.e. active physical or behavioural/psychologically informed or combined interventions). Therefore, studies that had "no treatment", "waiting list" "treatment as usual" or usual medications as a control group were excluded. If however, "usual treatment" involved some form of therapy other than GP/medications (e.g. usual outpatient physiotherapy/pain clinic rehabilitation), a study was eligible for inclusion. Comparisons to surgery, percutaneous procedures or pharmacology were excluded, as these were not deemed to be active physical or behavioural/psychologically informed interventions. Studies deemed to have a minimalist control group only (e.g. short duration education sessions/seminars or merely provision of education or advice booklets) were excluded, based on data highlighting that physical, behavioural/psychologically informed and combined interventions have established superiority over minimalist intervention efforts (Van Middelkoop *et al.* 2011, Oliveira *et al.* 2012a). Studies were not eligible if the interventions were from the same domain (e.g. if the study compared physical to physical). Education was defined as physical if it was pertaining to physical aspects such as posture, anatomy, exercise or biomechanics. Education was defined as behavioural/psychologically informed if it was pertaining to cognitive and psychological aspects such as beliefs, fear, stress, relaxation. An intervention was only deemed to have an education component if it was a major aspect of the intervention provided. For example, if an intervention had a large physical component and had an educational leaflet that was behaviour focussed, such an educational leaflet was not adequate to be defined as behavioural. Therefore this intervention would still be defined as physical, not combined.

Clinical Outcomes

Studies had to report results from one or more outcome measures in the domains of pain intensity and/or level of functional disability. Since research highlights that interventions for NSCSP have similar outcomes immediately after treatment (Artus *et al.* 2010), eligible studies were required to have data at least 12 weeks after the completion of treatment. Outcome data were then only abstracted for three time periods: short-term follow-up (12 weeks to <6 months), medium-term follow-up (6 months to <12 months) and long-term follow-up (12 months or more).

Selection of studies

A standard protocol was followed for study selection and data abstraction (Van Tulder *et al.* 2003a). After the removal of duplicates, two reviewers (MOK and JH) independently screened the titles and abstracts from the articles found and discarded the irrelevant citations according to the selection criteria. If no abstract was available, or when it was not clear if the study should be included, full-text articles were retrieved in order to determine inclusion or exclusion. Both reviewers kept a record of their reasons for the inclusion or the exclusion of articles. The screened lists were compared between the two reviewers. To minimize the risk of discarding studies incorrectly, articles that were initially chosen by only one reviewer were included for the next stage of the review. The full-text version of an article was obtained if the title and abstract seemed to fulfil the inclusion criteria or if the eligibility of the study was unclear. Any disagreements on study eligibility were resolved by discussion and a consensus meeting. Original study authors were emailed if clarification was needed on interventions provided.

Data extraction

Data regarding each study were extracted and cross-checked by two reviewers (MOK and JH). The following data were extracted from the studies: (1) characteristics of the studies: number of participants, sex, age, area of pain and inclusion/exclusion criteria (2) characteristics of the interventions: the type and content of interventions; (3) characteristics of the outcomes: pain and disability outcome measures, length of follow-up and (4) results summary of each study. Similarities in the outcome measures used, the subjects included and

the interventions examined allowed for pooled analysis of most of the data. The data extracted from all studies are shown in Table 2.

Quality assessment

Two reviewers (MOK and MC) conducted the quality assessment independently, using the risk of bias criteria advised by the Cochrane Back Review Group (CBRG) (Furlan *et al.* 2009) which consists of 12 items: random sequence generation; allocation concealment; blinding of participants; blinding of personnel/care providers; blinding of outcome assessor; incomplete outcome data; selective reporting; group similarity at baseline; co-interventions; intention-to-treat analysis; timing of outcome assessment; and any other bias not covered elsewhere. Each item was scored as “+” if it fulfilled the criteria, as “-” when there was a risk of bias and as “?” if there was insufficient information. When it was unclear whether a study did or did not meet an item, or if no clear information regarding the item was stated, the author of the original study was contacted for clarification. A total score was calculated by using the number of items scored as “+”. Differences in assessment were discussed during a consensus meeting. A total score was computed, and high quality was defined as fulfilling six or more (>50%) of the internal validity criteria (range 0–12). The quality assessment scores for all studies are shown in Table 3.

Table 2. Study I Overview of characteristics of included studies

Study	Sample size	Sex	Mean age	Pain site	Interventions	Pain intensity measure	Disability Measure	Length of follow-up	Inclusion & exclusion criteria	Results summary
Christiansen et al. 2010	60	38F 22M	47.7	CLBP	1.Exercise therapy and education plus goal setting, CBT and a goal pursuit strategy (Combined) 2.Exercise therapy and education (Physical)	NRS (0-10)	Hannover ADL instrument (0-100)	3mths	LBP>6mths	No significant difference in pain between groups Significant difference observed in disability between groups, favouring group 1
Critchley et al. 2007	212	136F 76M	44	CLBP	1.Individual physiotherapy (exercise, joint mobilization, massage) (Physical) 2.Spinal stabilisation classes (Physical) 3.Pain management classes (education, exercise, CBT) (Combined)	NRS (0-100)	RMDQ (0-24)	6mths 12mths 18mths	LBP>12wks	No significant difference in pain and disability between groups

Dellve et al. 2011	73	73F 0M		Chronic NP	1.Exercise (Muscular strength training) (Physical) 2. Myofeedback (Behavioural)	NRS (0-10)		3mths	NP>12mths	No significant difference in pain and disability between groups
Ferreira et al. 2007	240	165F 74M	53.5	CLBP	1.Spinal manipulation (Physical) 2.General exercise plus CBT (Combined) 3.Motor control exercises plus CBT (Combined)	VAS (0-10)	RMDQ (0-24)	6mths 12mths	LBP>3mths	No significant differences in pain and disability between groups
Friedrich et al. 1998	93	47F 46M	44	CLBP	1.Combined exercise and motivation program (Combined) 2.Exercise program (Physical)	NRS (0-100)	Low back outcome scale (0-75)	4mths 12mths	LBP>4mths	Significant difference observed in both pain and disability, favouring group 1
Friedrich et al. 2005	93	47F 46M	44	CLBP	1.Combined exercise and motivation program (Combined) 2.Exercise program (Physical)	NRS (0-100)	Low back outcome scale (0-75)	5years	LBP>4mths	Significant difference observed both in pain and disability between groups, favouring group 1

Gustavsson and von Koch 2006	37	28F 1M	39.5	Chronic NP	1.Pain and stress management group intervention with relaxation (Combined) 2.Individual physiotherapy (electrotherapy, exercise, massage, acupuncture, heat) (Physical)	NRS (0-10)	NDI (0-50)	20wks	NP>3mths	No significant difference in pain and disability between groups
Gustavsson et al. 2010	156	139F 17M	45.7	Chronic NP	1.A multi-component pain and stress self-management group intervention (Combined) 2.Individual physiotherapy (electrotherapy, exercise, massage, acupuncture, heat) (Physical)	NRS (0-10)	NDI (0-100)	20wks	NP>3mths	No significant difference in pain and disability between groups
Gustavsson et al. 2011	156	139F 17M	45.7	Chronic NP	1.A multi-component pain and stress self-management group intervention (Combined) 2.Individual physiotherapy (electrotherapy, exercise,	NRS (0-10)	NDI (0-100)	1year 2years	NP>3mths	No significant difference in pain and disability between groups

					massage, acupuncture, heat) (Physical)					
Kaapa et al. 2006	120	120F 0M	46.3	CLBP	1.Multidisciplinary group rehabilitation (exercise, CBT, relaxation, back school education) (Combined) 2.Individual physiotherapy (exercise, massage, spinal traction, mobilisation, ultrasound) (Physical)	NRS (0-10)	ODI (0-100)	6mths 12mths 2years	LBP>3mths	No significant difference in pain and disability between groups
Kankaanpää et al. 1999	59	22F 37M	39.6	CLBP	1.Exercise and behavioural support (Combined) 2.Individual physiotherapy (Physical)	VAS (0-100)	The Pain and Disability Index (0-70)	6mths 12mths	LBP>3mths	Significant difference observed both in pain and disability between groups, favouring group 1
Macedo et al. 2012	172	102F 70M	49	CLBP	1.Graded activity (Combined) 2.Motor control exercises (Physical)	NRS (0-10)	RMDQ (0-24)	6mths 12mths	LBP>3mths	No significant difference in pain and disability between groups
Machado et al. 2007	33	23F 10M	43.5	CLBP	1.Exercise (walking, stretching, strengthening) (Physical)	VAS (0-10)	RMDQ (0-24)	6mths	LBP>3mths	At short-term follow-up, significant difference

					2.Client-centered therapy (Behavioural)					observed in disability between groups, favouring group 1. At long-term, no significant difference in pain or disability between groups
Mehling et al. 2005	36	26F 10M	49.2	CLBP	1.Breath therapy (Behavioural) 2.Individual physiotherapy (exercise, education, soft tissue and joint mobilisation) (Physical)	VAS (0-10)	RMDQ (0-24)	6mths	LBP>3mths	No significant difference in pain and disability between groups
Monticone et al. 2012	80	60F 20M	49.5	CLBP	1.Neck exercises plus CBT (Combined) 2.Neck exercises (Physical)	NRS (0-10)	Neck pain and disability scale (0-100)	12mths	NP>3mths	No significant difference in pain and disability between groups
Rendant et al. 2011	123	107F 15M	45.6	CLBP	1.Qigong (Combined) 2.Exercise therapy (Physical)	VAS (0-100)	Neck pain and disability scale (0-100)	3mths 6mths	NP>6mths	No significant difference in pain and disability between groups
Roche Leboucher	132	46F 86M	39.8	CLBP	1.Functional restoration (exercise, occupational	VAS (0-10)		12mths	LBP>3mths	No significant difference in pain

et al. 2011					therapy, psychology) (Combined) 2. Individual physiotherapy (exercise, pain management) (Physical)					and disability between groups
Sahin et al. 2011	146	112F 34M	49.3	CLBP	1. Back school, plus exercise plus TENS, US and heat (Combined) 2. Exercise plus TENS, US and heat (Physical)	VAS (0-10)	ODI (0-100)	3mths	LBP>12wks	Significant difference observed in pain and disability between groups, favouring group 1
Sherman et al. 2011	228	146F 82M	48.4	CLBP	1. Yoga (Combined) 2. Stretching (Physical)	NRS (0-10)	RMDQ (0-23)	12wks 26wks	LBP>3mths	No significant difference in pain and disability between groups
Sorensen et al. 2010	207	108F 99M	39	CLBP	1. Exercise and Educational programme (Combined) 2. Individual exercise therapy (Physical)	NRS (0-10)	RMDQ (0-23)	6mths 12mths	LBP>4mths	No significant difference in pain and disability between groups
Smeets et al. 2008	223	105F 118M	41.6	CLBP	1. Exercise (Physical) 2. Graded activity plus problem solving (Combined)	VAS (0-100)	RMDQ (0-24)	6mths 12mths	LBP>3mths	No significant difference in pain and disability between groups

					3.Exercise plus graded activity and problem solving (Combined)					
Turner et al. 1990	96	46F 50M	44	CLBP	1.Group behavioural therapy plus aerobic exercise (Combined) 2.Behavioural therapy only (Behavioural) 3.Aerobic exercise only (Physical)	McGill pain rating index (0-78)		6mths 12mths	LBP>6mths	No significant difference in pain and disability between groups
Viljanen et al. 2003	393	393F 0M	45	Chronic NP	1.Dynamic muscle training (Physical) 2.Relaxation (Behavioural) 3.Ordinary activity (Physical)	NRS (0-10)	NDI (0-80)	3mths 6mths	NP>12wks	No significant difference in pain and disability between groups
Vonk et al. 2009	30	9F 21M	45.7	Chronic NP	1.Behaviour graded activity (Combined) 2.Individual physiotherapy (exercise, massage, mobilizations) (Physical)	NRS (0-10)	NDI (0-100)	26wks 12mths	NP>3mths	No significant difference in pain and disability between groups

mths: months; CBT: cognitive behavioural therapy; LBP: low back pain; APT: active physical training; NP: neck pain; MET: motivational enhancement treatment; TENS: transcutaneous electrical nerve stimulation; US: ultrasound

Data analysis

Data analysis was performed by a statistician (HP). The treatment effects of physical interventions were compared to (1) behavioural/psychologically informed interventions and (2) combined interventions using meta-analyses. The primary outcomes of interest were pain intensity and functional disability. Pain intensity was measured using a visual analogue scale (VAS) or a numeric rating scale (NRS). The reported pain intensity scores were converted to a 10 point scale, where necessary, and a mean difference (MD) was computed. The analysis of functional disability required a standardised mean difference (SMD) to be computed as studies used a number of different measures to report disability including; Roland-Morris Disability Questionnaire (RMDQ), Oswestry Disability Index (ODI), Pain and Disability Index (PDI), Hannover Activities of Daily Living (ADL) instrument, Neck Pain and Disability Index, Low Back Outcome Scale and Neck Disability Index (NDI). Analyses were carried out at three assessment points, with data from studies included according to the time closest to these intervals: (1) Short-term follow-up (minimum of 12 weeks and <6 months), (2) Medium-term follow-up (minimum of 6 months and <12 months and (3) Long-term follow-up (minimum of 12 months).

A random-effects model was selected for all analyses a priori, as recommended by CBRG (Higgins and Green 2008) and heterogeneity between treatment studies was reported using the I^2 statistic. Substantial heterogeneity was determined using the cut-off; $I^2 \geq 50\%$. In studies where multiple contrasts were examined (e.g. physical intervention vs. behavioural/psychologically informed intervention 1 vs. behavioural/psychologically informed intervention 2), the sample size in the shared comparison was halved in order to avoid double-counting of participants in the analyses.

In cases where standard deviations were not reported at follow-up times, the baseline standard deviation was used in the analysis (Higgins and Green 2008). In studies where data were summarised using median and interquartile range (IQR) values, the mean was approximated using the median and the width of the IQR was used as an approximation of 1.35 times the standard deviation (Higgins and Green 2008). Pooled 95% confidence intervals were computed for MD and SMD and confidence intervals excluding zero were considered statistically significant. Clinical relevance was determined using the following effect size classifications: (1) Small: MD <1 (i.e. less than 10% of the 10-cm VAS); SMD (Cohen's d) of 0.2; (2) Medium: MD <2, SMD (Cohen's d) of 0.5; (3) Large: MD ≥ 2 , SMD (Cohen's d) of 0.8.) (Cohen 2013). The heterogeneity between studies was assessed visually

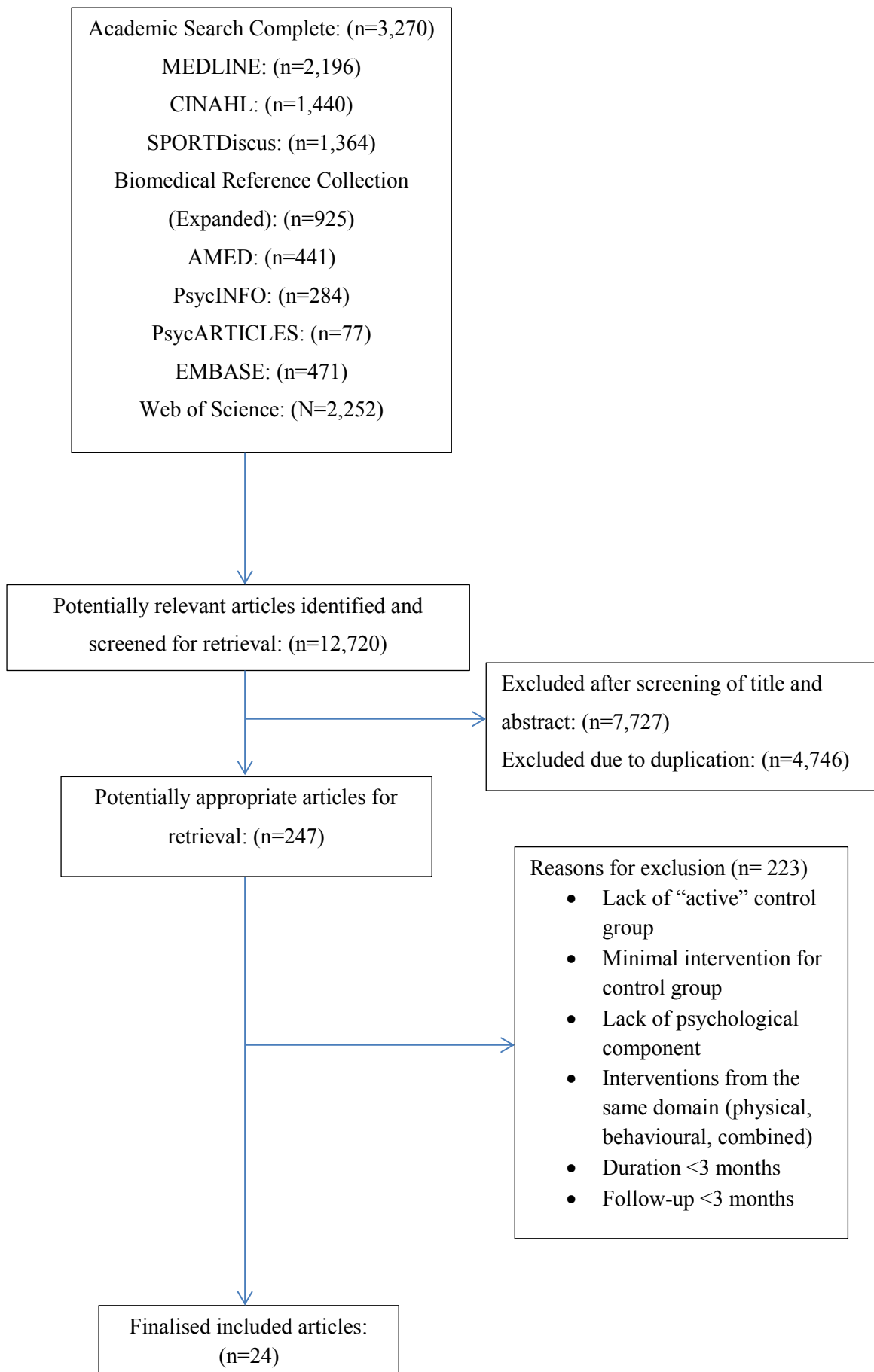
from the forest plots, using formal Q-tests (chi-square test statistic and p-value) and the I^2 statistic. In this review, a negative effect size indicates that physical interventions are more beneficial than the comparison. All analyses were conducted in Review Manager (Revman) software (version 5.2; The Nordic Cochrane Centre, Copenhagen, Denmark) (Team 2014).

Results

Literature search

Study identification is summarised in Figure 5. The literature search of databases yielded 12,720 potentially relevant articles. 4,746 duplicates were removed and 7,974 titles and abstracts were scanned. 247 full-text studies were retrieved with 223 studies being excluded as they did not meet the eligibility criteria. Searching the reference lists of these articles did not yield any further articles. The major reasons for exclusion were of lack of an “active” control group and comparison of interventions from the same domain (physical, behavioural/psychologically informed or combined). 24 articles met the selection criteria (Turner *et al.* 1990, Friedrich *et al.* 1998, Kankaanpää *et al.* 1999, Viljanen *et al.* 2003, Friedrich *et al.* 2005, Mehling *et al.* 2005, Gustavsson and von Koch 2006, Käpä *et al.* 2006, Critchley *et al.* 2007, Ferreira *et al.* 2007, Machado *et al.* 2007, Smeets *et al.* 2008, Vonk *et al.* 2009, Christiansen *et al.* 2010, Gustavsson *et al.* 2010, Sorensen *et al.* 2010, Dellve *et al.* 2011, Gustavsson *et al.* 2011, Rendant *et al.* 2011, Roche-Leboucher *et al.* 2011, Sahin *et al.* 2011, Sherman *et al.* 2011, Macedo *et al.* 2012, Monticone *et al.* 2012).

Figure 5. Study I Flow Diagram



Quality Assessment

The quality assessment scores are shown in Table 3. Forty-eight study authors were emailed about their studies (about treatment content and quality) and to clarify whether they were eligible to be included in this review. Twenty-six authors replied. Studies were excluded if no reply was received from the study author. Twenty-one studies included in this systematic review were deemed to have a low risk of bias ($>6/12$) when scored using the CBRG bias assessment tool, with four studies (Mehling *et al.* 2005, Smeets *et al.* 2008, Christiansen *et al.* 2010, Monticone *et al.* 2012) scoring the highest (10/12). Three studies (Turner *et al.* 1990, Friedrich *et al.* 2005, Roche-Leboucher *et al.* 2011) were deemed to have a high risk of bias ($<6/12$). Common methodological limitations identified across studies included lack of information on co-interventions and compliance to treatment.

Table 3. Study I Quality assessment scores

Study	1	2	3	4	5	6	7	8	9	10	11	12	Total
Christensen et al. 2010	+	+	-	-	-	+	+	+	+	+	+	+	9/12
Critchley et al. 2007	+	+	-	-	-	-	+	+	+	-	+	+	7/12
Dellve et al. 2011	+	+	-	-	-	+	+	+	?	+	+	+	8/12
Ferreira et al. 2007	+	+	-	-	-	+	+	+	?	+	+	+	8/12
Friedrich et al. 2005	+	?	-	-	-	-	+	+	?	-	+	+	5/12
Friedrich et al.1998	+	?	-	-	-	-	+	+	?	+	+	+	6/12
Gustavsson et al. 2006	+	+	-	-	-	?	+	+	?	?	+	+	6/12
Gustavsson et al. 2010	+	+	-	-	-	-	+	+	?	?	+	+	6/12
Gustavsson et al. 2011	+	+	-	-	-	-	+	+	?	?	+	+	6/12
Kankaanpaa et al. 1999	+	?	-	-	-	+	+	+	?	+	+	+	7/12
Kaapa et al 2006	+	+	-	-	-	+	+	+	?	?	+	+	7/12
Macedo et al. 2012	+	+	-	-	-	+	+	+	?	+	+	+	8/12
Machado et al. 2007	+	+	-	-	-	+	+	+	?	+	+	+	8/12
Mehling et al. 2005	+	+	-	-	-	+	+	+	+	+	+	+	9/12
Monticone et al. 2012	+	+	-	-	-	+	+	+	+	+	+	+	9/12
Rendant et al. 2011	+	+	-	-	-	+	+	+	?	+	+	+	8/12
Roche-Leboucher et al. 2011	+	+	-	-	-	-	+	+	?	?	?	+	5/12
Sahin et al. 2011	+	+	-	-	-	+	+	+	+	+	?	+	8/12
Sherman et al. 2011	+	+	-	-	-	+	+	+	+	?	+	+	8/12
Smeets et al. 2008	+	+	-	-	-	+	+	+	+	+	+	+	9/12
Sorenson et al 2010	+	+	-	-	-	+	+	+	-	-	+	+	7/12
Turner et al. 1990	+	?	-	-	?	-	+	+	?	+	?	+	5/12
Viljanen et al. 2003	+	+	-	-	-	+	+	+	+	?	+	+	8/12
Vonk et al. 2009	+	+	-	-	-	-	+	+	+	+	+	+	8/12

NOTE. +, criterion fulfilled; -, criterion unfulfilled; ?, unclear if criterion fulfilled

Population

The sample sizes of the included studies ranged from 30 to 393 participants. The average age of the participants in these studies ranged from 39 to 53.5 years. Eighteen studies investigated patients with CLBP, while six studies investigated participants with chronic NP. None of the studies involved patients with acute/subacute pain.

Intervention characteristics

The content and characteristics of the various physical, behavioural/psychologically informed and combined interventions can be seen in Table 2. Five studies compared physical and behavioural/psychologically informed interventions. Twenty studies compared physical and combined interventions. Only one study compared a behavioural/psychologically informed and combined intervention (Turner *et al.* 1990).

Clinical outcome measures

All studies reported results for pain intensity. Twenty-three of the 24 studies employed the VAS or NRS to measure pain intensity, while one study (Turner *et al.* 1990) utilised the McGill Pain Rating Index. Three studies did not report results for functional disability (Turner *et al.* 1990, Dellve *et al.* 2011, Roche-Leboucher *et al.* 2011). The ODI, NDI and RMDQ were the commonly adopted functional disability assessment scales, being used in 18 studies. One study employed the PDI (Kankaanpää *et al.* 1999). Another study employed the Hannover ADL instrument (Christiansen *et al.* 2010). Furthermore, two studies chose the Low Back Outcome Scale (Friedrich *et al.* 1998, Friedrich *et al.* 2005) and another two utilised the Neck Pain and Disability Scale (Rendant *et al.* 2011, Monticone *et al.* 2012).

Meta-analysis

Twenty-two of the 24 studies were included in the meta-analysis of pain and disability. Therefore, two studies (Turner *et al.* 1990, Friedrich *et al.* 2005) were excluded from the analysis. The first study (Friedrich *et al.* 2005) was a five year follow-up and was excluded from the meta-analysis since the remaining studies all had a long-term follow-up of a maximum of 24 months. The second study (Turner *et al.* 1990) used an outcome measure (McGill Pain Rating Index) that was too heterogeneous to be pooled with the remaining studies in the physical versus behavioural/psychologically informed and physical vs combined analyses. This was also the only study (Turner *et al.* 1990) to compare a behavioural/psychologically informed and combined intervention meaning that pooling of data was not possible and consequently there is no comparison between behavioural/psychologically informed versus combined interventions in the meta-analysis. These two studies (Turner *et al.* 1990, Friedrich *et al.* 2005) also had a high risk of bias (<6/12).

Subgroup and sensitivity analyses

Subgroup analyses were conducted by testing pooled differences in pain and disability between NP and LBP studies at each follow-up time. No significant differences were found between subgroups in the effects on pain or disability ($p>0.05$).

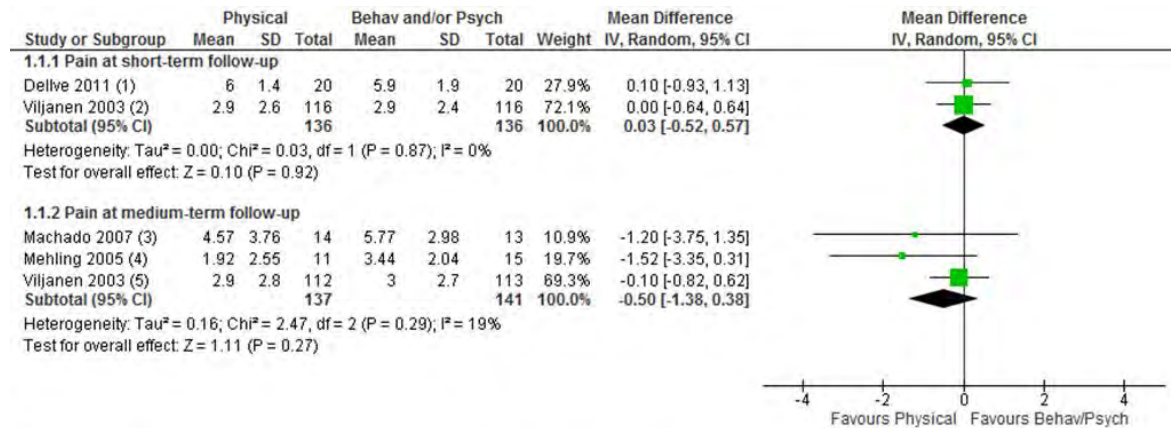
A sensitivity analysis was conducted by limiting to studies with a low risk of bias. Twenty-one studies were included in the sensitivity analysis after those at high risk of bias (Turner *et al.* 1990, Friedrich *et al.* 2005, Roche-Leboucher *et al.* 2011) were excluded. No significant differences between interventions in the effects on pain and disability were found ($p>0.05$).

Effects of Physical versus Behavioural/Psychologically informed interventions on pain intensity

No statistically significant difference was found for pain intensity between the physical and behavioural/psychologically informed groups at short term (two studies, $n=272$, MD= 0.03, 95% CI -0.52 to 0.57, $I^2=0\%$) and at medium term (three studies, $n=278$, MD= -0.50, 95% CI -1.38 to 0.38, $I^2=19\%$) follow-up (Figure 6).

Because only one study (Viljanen *et al.* 2003) measured pain in the long-term in the physical versus behavioural/psychologically informed groups, there is no long-term plot in this section of meta-analysis. This study found no statistically significant difference for pain intensity between the physical and behavioural/psychologically informed groups.

Figure 6. Effect of Physical versus Behavioural/Psychologically informed interventions on pain intensity



Footnotes

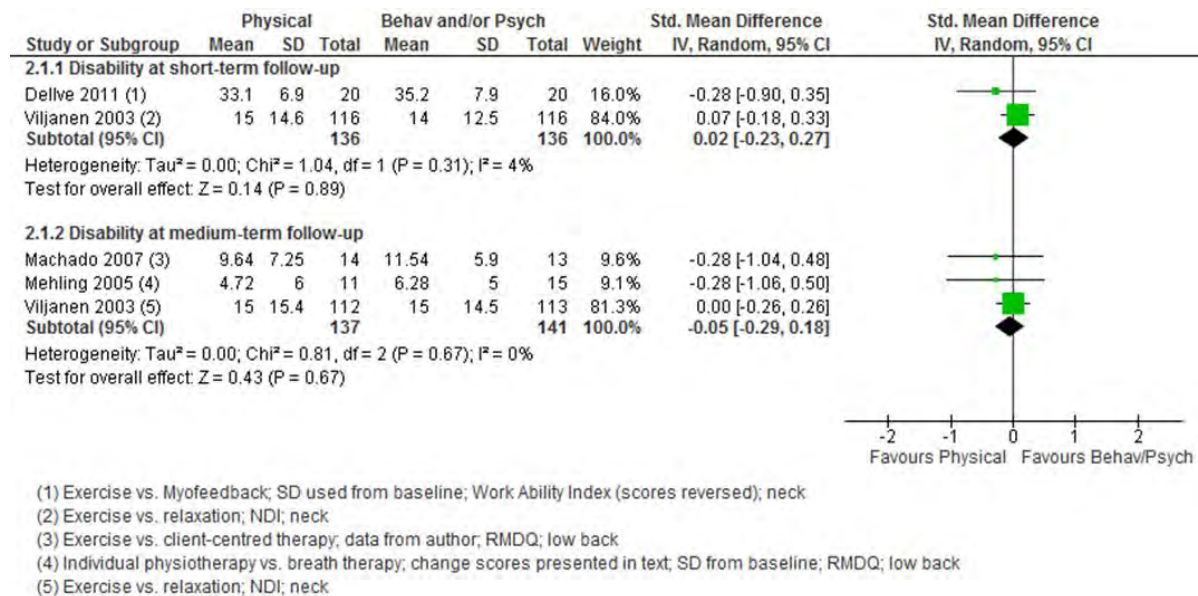
- (1) Exercise vs. Myofeedback; change scores presented in text; SD used from baseline; neck
- (2) Exercise vs. relaxation; neck
- (3) Exercise vs. client-centred therapy; data from author; low back
- (4) Individual physiotherapy vs. breath therapy; change scores presented in text; SD from baseline; low back
- (5) Exercise vs. relaxation; neck

Effects of Physical versus Behavioural/Psychologically informed interventions on disability

No statistically significant difference was found for disability between the physical and behavioural/psychologically informed groups at short term (two studies, n=272, MD= 0.02, 95% CI -0.23 to 0.27, I²= 4%) and at medium term (three studies, n=278, SMD= -0.05, 95% CI -0.29 to 0.18, I²=0%) follow-up (Figure 7).

Because only one study (Viljanen *et al.* 2003) measured disability in the long-term in the physical versus behavioural/psychologically informed groups, there is no long-term plot in this section of meta-analysis. This study found no statistically significant difference for disability between the physical and behavioural/psychologically informed groups.

Figure 7. Effect of Physical versus Behavioural/Psychologically informed interventions on disability

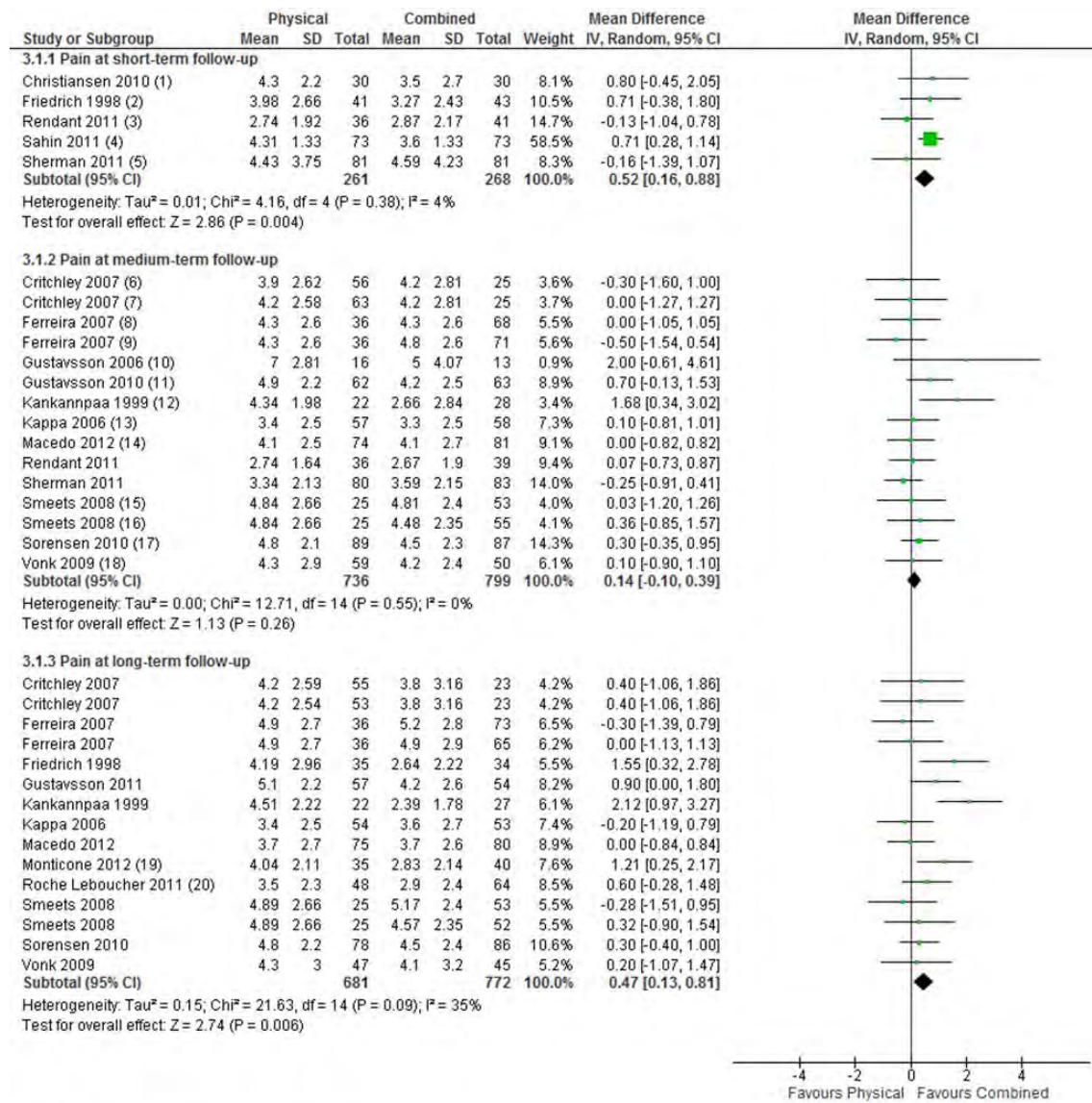


Effect of Physical versus Combined interventions on pain intensity

A statistically significant difference was found for pain between groups (favouring the combined group) at short term (five studies, n=529, MD= 0.52, 95% CI 0.16 to 0.88, I²= 4%) and at long term (15 studies, n=1453, MD= 0.47, 95% CI 0.13 to 0.81, I²=35%) follow-up (Figure 8).

No statistically significant difference was found for pain between physical and combined at medium term follow-up (15 studies, n=1535, MD= 0.14 95% CI -0.10 to 0.39, I²=0%) (Figure 8).

Figure 8. Effect of Physical versus Combined interventions on pain intensity



Footnotes

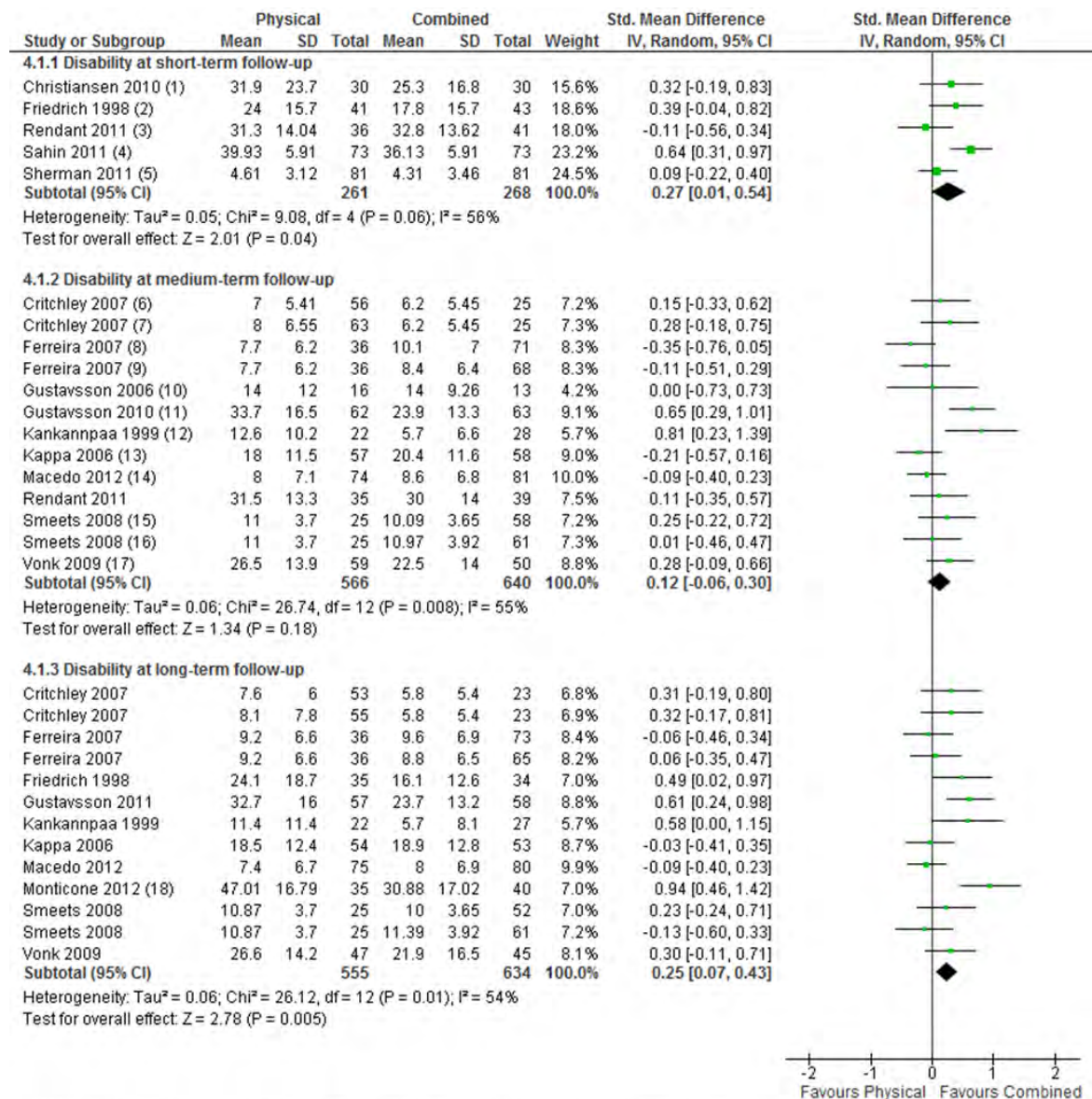
- (1) Exercise vs. exercise + goal setting; low back
- (2) Exercise vs. exercise + motivation; low back
- (3) Exercise vs. qigong; neck
- (4) Individual physiotherapy vs. individual physiotherapy + back school; low back
- (5) Exercise vs. yoga; adjusted scores from regression; low back
- (6) Spinal stabilisation vs. physiotherapy pain management; number of pain management subjects was halved; low back
- (7) Individual physiotherapy vs. physiotherapy pain management; number of pain management subjects was halved; low back
- (8) SMT vs. motor control exercises + CBT; number of subjects in SMT was halved; neck
- (9) SMT vs. general exercises + CBT; number of subjects in SMT was halved; neck
- (10) Individual physiotherapy vs. pain management + stress management; mean and SD estimated from median and IQR; neck
- (11) Individual physiotherapy vs. pain management + stress management; neck
- (12) Individual physiotherapy vs. exercise + behavioural support; low back
- (13) Individual physiotherapy vs. exercise + relaxation + CBT + education; low back
- (14) Motor control exercises vs. graded activity; low back
- (15) Exercise vs. exercise + graded activity + problem solving; number of subjects in exercise was halved; SD from baseline; low back
- (16) Exercise vs. graded activity + problem solving; number of subjects in exercise was halved; SD from baseline; low back
- (17) Exercise vs. education; low back
- (18) Exercise vs. graded activity; neck
- (19) Neck exercises vs. neck exercises + CBT; neck
- (20) Exercise vs. exercise + relaxation + psychology; low back

Effect of Physical versus Combined interventions on disability

A statistically significant difference was found for disability between groups (favouring the combined group) at short term (five studies, n=529, SMD= 0.27 95% CI 0.01 to 0.54, $I^2=56\%$) and at long term (13 studies, n=1189, SMD= 0.25 95% CI 0.07 to 0.43, $I^2=54\%$) follow-up (Figure 9).

No statistically significant difference was found for disability between physical and combined at medium term follow-up (13 studies, n=1206, SMD= 0.12 95% CI -0.06 to 0.30, $I^2=55\%$) (Figure 9).

Figure 9. Effect of Physical versus Combined interventions on disability



- (1) Exercise vs. exercise + goal setting; Hannover ADL Instrument (scores reversed); low back
- (2) Exercise vs. exercise + motivation; low back outcome scale (scores reversed); low back
- (3) Exercise vs. qigong; pain and neck disability scale; neck
- (4) Individual physiotherapy vs. individual physiotherapy + back school; ODI; low back
- (5) Exercise vs. yoga; adjusted scores from regression; RMDQ; low back
- (6) Spinal stabilisation vs. physiotherapy pain management; number of pain management subjects was halved; RMDQ; low back
- (7) Individual physiotherapy vs. physiotherapy pain management; number of pain management subjects was halved; RMDQ; low back
- (8) SMT vs. general exercises + CBT; number of subjects in SMT was halved; RMDQ; neck
- (9) SMT vs. motor control exercises + CBT; number of subjects in SMT was halved; RMDQ; neck
- (10) Individual physiotherapy vs. pain management + stress management; mean and SD estimated from median and IQR; NDI; neck
- (11) Individual physiotherapy vs. pain management + stress management; NDI; neck
- (12) Individual physiotherapy vs. exercise + behavioural support; PDI; low back
- (13) Individual physiotherapy vs. exercise + relaxation + CBT + education; ODI; low back
- (14) Motor control exercises vs. graded activity; RMDQ; low back
- (15) Exercise vs. graded activity + problem solving; number of subjects in exercise was halved; SD from baseline; RMDQ; low back
- (16) Exercise vs. exercise + graded activity + problem solving; number of subjects in exercise was halved; SD from baseline; RMDQ; low back
- (17) Exercise vs. graded activity; NDI; neck
- (18) Neck exercises vs. neck exercises + CBT; neck pain and disability scale; neck

Effect of Behavioural/Psychologically informed versus Combined interventions on pain intensity and disability

Because only one study (Turner *et al.* 1990) compared a behavioural/psychologically informed and combined intervention, no meta-analysis for this category was completed. No statistically significant differences were found for pain and disability between behavioural/psychologically informed and combined groups.

Discussion

This systematic review and meta-analysis investigated the comparative effectiveness of physical, behavioural/psychologically informed and combined interventions for pain and disability in NSCSP populations. No statistically significant differences were found for pain and disability between physical and behavioural/psychologically informed groups in the medium and long-term. No statistically significant differences were found for pain and disability in the single study (Turner *et al.* 1990) comparing behavioural/psychologically informed and combined interventions. While a small statistically significant difference was found for both pain and disability between the physical and combined group, favouring the combined group, this difference was small (Bombardier *et al.* 2001). This suggests that there are only small differences between physical, behavioural/psychologically informed and combined interventions for reducing pain and disability in NSCSP patients.

Although it may appear surprising that these very different interventions demonstrate such similar effects for NSCSP, it is clear that simply combining them offers only a small additional benefit. Consequently, choosing the most cost-efficient, rehabilitation choice which is both acceptable to patients and feasible for a healthcare service to provide should be considered. Similarly, Kamper *et al.* found that combined multidisciplinary programmes are significantly more effective than physical therapies for CLBP, but given the small effect, the decision to choose a combined intervention should be balanced against the time and resources available.

One possible reason for the lack of differences is that both physical and behavioural/psychologically informed interventions may in fact have similar mechanisms of effect. This is based on trials showing that successful outcomes, even after a purely physical intervention, are often mediated by changes in cognitive and psychological factors (e.g. fear, catastrophizing, self-efficacy, beliefs) (Mannion *et al.* 2001b, Smeets *et al.* 2006, Angst *et al.*

2014, Monticone *et al.* 2014, van Hooff *et al.* 2014). Another possibility is that other important “non-specific factors” such as clinician support, empathy, ability to motivate and encourage and accommodate patients’ treatment preferences and expectations may be common to these seemingly different interventions (Foster *et al.* 2011). This is supported by data demonstrating that a positive patient-therapist interaction is linked to reduced pain and disability (Hall *et al.* 2010).

It has been proposed that most RCTs have not adequately dealt with the multi-dimensional nature of NSCSP (Sterling *et al.* 2005, O'Sullivan 2012, Michaleff *et al.* 2014). This is significant considering the growing evidence that NSCSP is associated with a complex interplay of biopsychosocial factors. These may include patho-anatomical factors (e.g. disc prolapse with radiculopathy, spondylolysis/spondylolisthesis, lateral recess/central stenosis) (Sheng-yun *et al.* 2014), physical factors (e.g. maladaptive postures and movement patterns, altered body perception, pain behaviours and deconditioning) (Laird *et al.* 2014), cognitive factors (e.g. unhelpful beliefs, catastrophizing, hypervigilance, maladaptive coping strategies, poor self-efficacy) (Linton 2000), psychological factors (e.g. fear, anxiety, depression) (Blozik *et al.* 2009, Bener *et al.* 2013), lifestyle factors (e.g. physical inactivity, sleep problems, chronic life stress) (Viikari-Juntura *et al.* 2001, Bjorek-van Dijken *et al.* 2008, Kelly *et al.* 2011), neuro-physiological factors (e.g. peripheral and central nervous system sensitisation) (Curatolo *et al.* 2004, Nijs *et al.* 2014), social factors (e.g. socio-economic status, family, work and culture) (Bouter and van der Wal 2001, Lallukka *et al.* 2014) and genetic factors (MacGregor *et al.* 2004). Even the “combined” treatment approaches did not target this wide range of factors, for example commonly excluding factors such as sleep (Kelly *et al.* 2011, Valenza *et al.* 2012) and life stress (Linton 2000).

Another potential reason for the limited effectiveness of these conservative interventions is that the interventions are insufficiently tailored to the needs of patients (O'Sullivan 2012, Mafi *et al.* 2013, Huijnen *et al.* 2015). For example, one large RCT (Hill *et al.* 2011) demonstrated that people with LBP could be categorised into three different “risk” profiles, each with different natural histories for their LBP. Consequently, some groups may benefit from combined physical and psychological support more than others, and identification of these patients could be facilitated by using suitable screening measures (Hill *et al.* 2011, Linton *et al.* 2011, Dagfinrud *et al.* 2013, Kamper *et al.* 2014). However, when the type (physical or combined) and amount of rehabilitation was matched to the perceived needs of each group, outcomes were improved. The effect sizes for this trial were small however, and in line with the effect sizes displayed in this review. Attempts to individualise

rehabilitation in a biopsychosocial manner according to the needs of LBP patients, as opposed to targeting broad “risk” groups, resulted in significantly pain and disability in another recent RCT (Vibe Fersum *et al.* 2013). However, since both of these RCTs offered combined rehabilitation in both interventions arms, they were ineligible for this review. It is important however to acknowledge that individualising rehabilitation based on purely biomedical and physical factors alone does not appear likely to enhance outcomes (Brennan *et al.* 2006, Vibe Fersum *et al.* 2009, Apeldoorn *et al.* 2012, Henry *et al.* 2014). Therefore, while the findings of this review demonstrate that simply combining physical and behavioural/psychologically informed interventions does not increase effectiveness very much, there is a need for further studies investigating whether tailoring these rehabilitation options to the needs of patients can enhance effectiveness. The possibility that NSCSP will remain highly resistant to treatment in some patients, even when an individualised biopsychosocial approach is used, cannot be discounted. Additionally, the similar effects seen across interventions may also reflect the use of outcome measures which are influenced by the types of bias present in the included studies.

Future Research and Clinical implications

Given the strong evidence that NSCSP is associated with a complex interplay of biopsychosocial factors, the challenge is to determine whether individualised care based on targeting these factors offers greater benefits over other current approaches (McCarthy *et al.* 2004a, Hill *et al.* 2011, O'Sullivan 2012, Huijnen *et al.* 2015). Future RCTs should also incorporate mediation analysis to investigate and better understand particular patient profiles who respond best to specific treatment approaches, and the mechanisms underlying different interventions (Smeets *et al.* 2006, Mansell *et al.* 2014) including consideration of the role of “non-specific” factors such as therapeutic alliance, and the use of qualitative approaches where necessary.

Strength and limitations

To our knowledge, this is the first comprehensive systematic review and meta-analysis to compare the effectiveness of physical, behavioural/psychologically informed, and combined interventions in NSCSP. Most studies that were included were of high methodological quality. Kamper *et al.* published a systematic review during the completion of the current review,

investigating physical versus combined interventions in CLBP. From this perspective, our physical versus combined comparison is a repeat (and therefore confirmation) of the Kamper comparison. The current review had also initially aimed to investigate behavioural/psychologically informed versus combined comparisons, but because only one study was found, a meta-analysis could not be completed on this comparison. Furthermore, our review expanded on the Kamper review by including NSCSP, not just CLBP and investigated physical versus behavioural/psychologically informed interventions, as well as physical versus combined interventions.

However, there are significant issues in our review methodology which need to be acknowledged. Only RCTs published in English were included, therefore potentially relevant high quality studies in other languages may have been excluded. In addition, searches were limited to published studies only, which introduce a risk of publication bias. Not all studies could be included in the meta-analysis. For example, there was no plot showing the effect of behavioural versus combined rehabilitation since there was only one study comparing these interventions (Turner *et al.* 1990). This may indicate a preference for always including a physical component in interventions instead of a behavioural component, possibly displaying the dominance of the biomedical model in practice and that most treatments assume peripheral nociception is the primary driver of NSCSP. Furthermore, review procedures have evolved since the current authors submitted the original review protocol. The current authors used a summary score out of 12 and specific cut-off values to distinguish high from low quality studies. Using this system means that a study that fulfils any six of the 12 criteria is deemed high quality. This approach has limitations however as meta-epidemiological evidence suggests that failure on any one of the 12 criteria might alone explain a small positive effect on a subjective self-reported outcome.

Some study authors did not reply to emails regarding their study interventions and methodology. This may have resulted in errors of eligibility and risk of bias rating. Furthermore, while this approach was previously recommended by Cochrane, it is no longer advocated for risk of bias assessment. Also, in the current review all the primary outcome measures were subjective self-report scales (pain or disability) and the primary outcome data assessors were the patients themselves: hence high risk of bias for both of the above considerations for all studies. The current authors did not award a point for blinded assessment. This might be considered strict as the scoring is an arbitrary process, and it is simply not possible to get this point in studies of pain.

A further significant limitation of this review is the method used to group interventions; physical versus behavioural/psychologically informed versus combined. The authors chose these groupings based on their interpretation of the biopsychosocial model and their experience of different interventions. Therefore, the groupings are purely subjective, creating major difficulties for interpretation of the data. In reality, interventions cannot be easily differentiated and separated which introduces a lot of heterogeneity, making meaningful comparisons very difficult.

Only studies featuring an active control group were included which may have contributed to the small effect sizes. This was deemed appropriate however given the consistent evidence that physical, behavioural/psychologically informed and combined interventions are superior to minimal interventions, placebo or waiting list control groups (Teasell *et al.* 2010, Artus *et al.* 2014). The meta-analysis pooled the results for NP and LBP together. It could be argued that the results may have been different if plots were formed separately. However, the subgroup and sensitivity analyses performed showed no difference, further supporting the contention that LBP and NP both involve an interaction of multiple factors across the biopsychosocial spectrum (Sterling *et al.* 2006, O'Sullivan 2012, Nijs *et al.* 2014).

Conclusion

No clinically significant differences were found for pain and disability between physical, behavioural/psychologically informed and combined interventions for NSCSP. As a result, choosing the most cost-efficient, feasible rehabilitation option may be reasonable. Further work may be needed to investigate whether tailoring rehabilitation to the needs of individual patients, which has been seen in recent RCTs for LBP, can enhance outcomes in NSCSP.

STUDY II: Are group-based and individual physiotherapy exercise programmes equally effective for musculoskeletal conditions? A systematic review and meta-analysis

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<http://bjsm.bmj.com/content/early/2016/06/24/bjsports-2015-095410.abstract>

Abstract

Background: Musculoskeletal pain is common and its treatment costly. Both group and individual physiotherapy interventions which incorporate exercise aim to reduce pain and disability. Do the additional time and costs of individual physiotherapy result in superior outcomes?

Objective: To compare the effectiveness of group and individual physiotherapy including exercise on musculoskeletal pain and disability.

Methods: Eleven electronic databases were searched by two independent reviewers. Randomised controlled trials (RCTs) including participants with musculoskeletal conditions which compared group and individual physiotherapy interventions that incorporated exercise were eligible. Study quality was assessed using the PEDro scale by two independent reviewers, and treatment effects were compared by meta-analyses.

Results: Fourteen RCTs were eligible, including patients with low back pain (7 studies), neck pain (4), knee pain (2) and shoulder pain (1). We found no clinically significant differences in pain and disability between group and individual physiotherapy involving exercise.

Conclusions: Only small, clinically irrelevant differences in pain or disability outcomes were found between group and individual physiotherapy incorporating exercise. Since all but one study included other interventions together with exercise in either the group or individual arm, deciphering the unique effect of the way in which exercise is delivered is difficult. Group interventions may need to be considered more often, given their similar effectiveness and potentially lower healthcare costs.

WHAT ARE THE FINDINGS?

- Only small differences, clinically irrelevant differences were found between group and individual physiotherapy incorporating exercise and, where present, these differences favoured group interventions.
- Physiotherapy incorporating exercise for musculoskeletal pain delivered on an individual basis is no better than the equivalent treatment in a group. Future research should investigate the effect of individual physiotherapy involving exercise that better matches an individual's capacity and needs, and/or considers other barriers to recovery from pain across the biopsychosocial spectrum.

HOW MIGHT IT IMPACT ON CLINICAL PRACTICE IN THE FUTURE?

- Group interventions may need to be considered more often, given their similar effectiveness and lower healthcare costs.

Introduction

Musculoskeletal (MSK) conditions are a common and costly source of pain and functional disability, resulting in significant personal, social and economic burden (Mäntyselkä *et al.* 2002, Woolf *et al.* 2012, Palazzo *et al.* 2014). Collectively they cause 21.3% of the total years lived with disability in the world, affecting one in four adults in Europe alone (Hoy *et al.* 2015). Low back pain (LBP) has the highest global burden of disease, with neck pain ranking fourth, and other MSK conditions ranking fifth (Yelin and Callahan 1995, Hoy *et al.* 2015). Finding effective interventions for the management of MSK conditions is therefore of utmost importance.

Physiotherapy management of MSK conditions commonly consists of exercise and passive adjuncts including manual therapy, electrotherapy and thermal modalities (Smidt *et al.* 2005, Hurley and Bearne 2008). However, passive therapies provide only short-term benefits (Ho *et al.* 2009, Menke 2014). Exercise is probably the most effective component of physiotherapy for a range of MSK conditions; many systematic reviews and randomised controlled trials (RCTs) corroborate its benefit in reducing pain and disability (Verhagen *et*

al. 2007, Kuhn 2009, Bennell and Hinman 2011, Petersen *et al.* 2011, Hanratty *et al.* 2012, Bertozzi *et al.* 2013, Barker *et al.* 2014, Calatayud *et al.* 2014, O'Riordan *et al.* 2014).

Physiotherapy that includes exercise can be supervised individually or in groups. Both modes have been shown to be more effective than waiting list control groups and non-supervised programmes (e.g. home exercise programmes) (Binder *et al.* 2004, McCarthy *et al.* 2004b, Keller *et al.* 2007, Dundar *et al.* 2009, Oliveira *et al.* 2012b, Salacinski *et al.* 2012, Kudo *et al.* 2013). Individual physiotherapy is the most widely adopted approach for MSK conditions (Tiffreau *et al.* 2007). However, group physiotherapy may be as effective (Bennell and Hinman 2011, Russell *et al.* 2014). Advantages of group physiotherapy include the social interaction for participants and the lower cost compared with individualised care (Bennell and Hinman 2011). Although it is clear that group and individual physiotherapy interventions that incorporate exercise are better than minimal or no treatment, it remains unclear whether either is better than the other. In addition, many people with MSK conditions appear to be either overtreated or treated inefficiently, without improving their outcome (Artus *et al.* 2010, Henry *et al.* 2014, Michaleff *et al.* 2014, Rantonen *et al.* 2014).

A recent rapid review (Toomey *et al.* 2015) of five databases investigated the effectiveness of group education and exercise interventions in osteoarthritis and chronic LBP. Interventions that included group education were as effective as individual physiotherapy and medical management. In that review (Toomey *et al.* 2015) group interventions were not required to be delivered by a physiotherapist and the authors included group education interventions that contained some individual sessions. The group interventions were compared with several different treatments (individual physiotherapy, usual medical management, booklets and no intervention), while the control interventions were not required to have an exercise component.

No systematic review has compared physiotherapist delivered group-only and individual-only programmes that incorporate exercise across all MSK conditions. Therefore, the primary objective of this systematic review was to assess the comparative effectiveness of group and individual physiotherapy programmes that incorporate exercise on pain and disability in patients with MSK conditions.

Methods

Search Strategy

This review was registered on the PROSPERO database (CRD42014014486) and has been reported in accordance with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement (Moher *et al.* 2009). All relevant RCTs meeting the inclusion criteria were identified by a computer-aided search of the MEDLINE, CINAHL, Academic Search Complete, AMED, SPORTDiscus, PsycINFO, Biomedical Reference Collection, PsycARTICLES, Embase, Scopus and Web of Science databases during August 2014 from the period of inception. The search was restricted to include only trials that involved humans and were published in English. Two reviewers (MOK and AH) conducted the electronic searches independently. The strategy had four components which were combined: (1) physiotherapy AND (2) individual/group AND (3) RCT and NOT (4) non-MSK conditions. The exact search strings utilized are shown in Figure 10.

Figure 10. Study II Literature Search Strategy

physiotherap* OR "physical therap*" (Abstract)
AND
individ* OR person* OR "one to one" OR "one-to-one" OR class* OR group* OR program* OR school* (Abstract)
AND
random* OR RCT (Abstract)
NOT
pulmonary OR lung* OR renal OR kidney* OR cancer OR "multiple sclerosis" OR parkinson* OR brain OR incontinen* OR stroke OR CVA OR neuro* OR heart OR cardiac* (Abstract)

Inclusion/Exclusion Criteria

Study design

Only reports of completed RCTs published in peer-reviewed journals were included.

Population

Studies with participants with MSK conditions (e.g. low back, neck, hip, knee, ankle, shoulder, elbow or wrist pain) were included. Studies that involved participants with specific pathologies/conditions (e.g. pregnancy, incontinence, “red flag” disorders (e.g. spinal cord compression/cauda equina, spinal cord injury, cancer, fracture) or neurological, cardiac, renal or respiratory, rheumatological conditions) were excluded.

Interventions

Studies were required to compare group and individual physiotherapy. Both were required to include exercise. Individual physiotherapy was eligible for inclusion whether or not it also involved a passive therapy. The addition, or absence, of other co-interventions (e.g. manual therapy, education, relaxation) did not affect the eligibility of studies but, where present, these were noted. Studies were not eligible if they compared group physiotherapy with group physiotherapy or compared individual physiotherapy with individual physiotherapy. Similarly, if interventions contained a combination of group and individual components, they were excluded. Studies were also excluded if interventions had multidisciplinary team involvement (e.g. psychology, occupational therapy or dietician). Studies that compared group or individual physiotherapy with a minimalist control group only (e.g. simply providing education/advice booklets or a self-directed home exercise programme which did not involve regular tailoring and/or progression) were excluded. These were deemed irrelevant, as both group and individual physiotherapy incorporating exercise have established superiority over them (Binder *et al.* 2004, Team 2004, Keller *et al.* 2007, Dunder *et al.* 2009, Oliveira *et al.* 2012a, Kudo *et al.* 2013).

Clinical Outcomes

Studies had to report results from one or more outcome measures in the domains of pain intensity and/or functional disability.

Study selection

Two authors (MOK and AH) followed the same procedure for study selection and data extraction. After the removal of duplicates, the authors (MOK and AH) independently

screened the titles and abstracts from among the articles found and excluded articles not meeting the eligibility criteria. If no abstract was available, or when it was not clear if the study should be included, full-text articles were retrieved in order to determine inclusion or exclusion. The full text version of an article was obtained if the title and abstract seemed to fulfil the inclusion criteria or if the eligibility of the study was unclear. If any disagreements on study eligibility took place, the planned procedure was to hold a consensus meeting with two other authors (KMC and KOS). As no disagreements took place, this procedure was not required for this review. Original study authors were emailed, where required, to provide clarity on interventions or methodology. The reference lists of the selected articles were also manually searched for any further relevant articles.

Data extraction

Data for each study were extracted and cross-checked by two authors (MOK and AH). The following data were extracted: (1) characteristics of the participants: sample size, sex, age, area of pain; (2) inclusion criteria; (3) characteristics of the interventions: the type, frequency and duration of group and individual physiotherapy and (4) characteristics of the outcomes: pain and disability outcome measures, follow-up times. Similarities in the outcome measures used, the MSK conditions involved, the participants included and the physiotherapy interventions examined allowed for pooled analysis of the data. The data extracted from all studies are shown in Table 4.

Quality assessment

Methodological quality of the included studies was rated independently by two assessors (MOK and AH) using the reliable (Maher *et al.* 2003) and valid (de Morton 2009) PEDro scale. The scale has 11 criteria, 10 of which are scored. When it was unclear whether a study met a criterion, or if no clear information regarding the item was stated, the author of the original study was contacted for clarity. If the two assessors disagreed about an individual study, a consensus decision was reached. Each item was scored as “Yes” if it fulfilled the criteria, and “No” when there was a risk of bias or a lack of clarity. The quality was classified as ‘high’ ($\geq 6/10$), ‘fair’ ($\geq 4-6/10$) or ‘poor’ ($< 4/10$), according to PEDro scores (Ye *et al.* 2011) to aid interpretation of study quality if the findings were inconsistent. The quality assessment scores for all studies are shown in Table 5.

Table 4. Study II Overview of characteristics of included studies

Study	Sample Size & Sex	Age Mean (SD)	Pain area & inclusion criteria	Group intervention	Individual intervention	Frequency & duration	Outcome Measure and follow-up times
Carr et al. 2005	N=237 (G=118; I=119) G=69F/49M I=74F/45M	G=42 (10.61) I=42.5 (11.18)	Low back LBP >6 wks	A CBT approach underpinned this intervention. <ul style="list-style-type: none"> Exercise (aerobics, strengthening, stretching) Other (relaxation) 	Choice of treatment varied and was at discretion of physio. <ul style="list-style-type: none"> Exercise (Mc Kenzie -68%; strengthening -15%; stretching -18%; stabilisation -11%; other exercises -12%) Education (unspecified) Manual therapy (manipulation - 2%; mobilisations -39%), Modalities (traction -9%; SWD -11%; US -5%; IFT -17%; TENS -6%). 	G: 8 x 1 hour each. I: At discretion of physio	RMDQ (0-24) 3 mths 12 mths
Cecchi et al. 2010	N=210* (G=70; I=70) G=49F/21M I=43F/27M	G=57.9 (15.1) I=60.5 (15.8)	Low back LBP >6 mths	<ul style="list-style-type: none"> Exercises (postural, respiratory, and individually tailored back exercises). 	Choice of treatment varied and was at discretion of physio. <ul style="list-style-type: none"> Exercise (passive and assisted mobilization, active exercise, PNF). Education (posture, 	G: 15 x 1 hour sessions, 5 days a week. I: 15 x 1 hour sessions, 5 times a week, for 3	RMDQ (0-24) NRS (0-6) 3 mths

				<ul style="list-style-type: none"> • Education (ergonomics, pathophysiology, benign character of LBP). • Other (relaxation). 	<p>ergonomics, pathophysiology, anatomy).</p> <ul style="list-style-type: none"> • Manual therapy (massage/ treatment of the soft tissues). 	consecutive wks.	6 mths 12 mths
Chown et al. 2008	N=239* (G=80; I=80) G=44F/36M I=50F/30M	G=42.5 (11.9) I=44.3 (12.3)	Low back LBP >3 mths	<ul style="list-style-type: none"> • Exercise (HEP of stretching, basic postural setting (transversus abdominus multifidus), circuits). • Education (pathophysiology/ anatomy/ biomechanics). 	<p>Choice of treatment varied and was at discretion of physio.</p> <ul style="list-style-type: none"> • Exercise (McKenzie, neural tension, muscle imbalance, postural correction, isometric stabilisation exercises, global exercise for mobility). • Education (unspecified). • Manual therapy (traction, joint and soft tissue mobilisation). • Modalities (electrotherapy). 	G: 5 x 30 minute sessions. I: 5 x 30 minute sessions.	ODI (0-100) VAS (0-100) 6 wks 12 mths
Critchley et al. 2007	N=212* (G=69; I=71) G=43F/M	G=44 (12) I=45 (12)	Low back LBP >12 wks	<ul style="list-style-type: none"> • Exercise (strengthening, stretching and aerobic). 	<p>Choice of treatment varied and was at discretion of physio.</p> <ul style="list-style-type: none"> • Exercise (specific trunk muscle retraining, stretches, and 	G: 8 x 90 minute sessions. I: Up to 12 x 30 minute sessions.	RMDQ (0-24) NRS (0-100)

	I=42F/M			<ul style="list-style-type: none"> • Education (self-management, graded return to activities with goal-setting, positive coping strategies, pacing). 	<ul style="list-style-type: none"> • general spinal mobility • Education (back-care advice). • Manual therapy (joint mobilizations, joint manipulation and massage). 		<p>6 mths</p> <p>12 mths</p> <p>18 mths</p>
Eadie et al. 2013	<p>N=60* (G=20; I=20)</p> <p>G= 12F/8M I= 13F/7M</p>	<p>G= 41.3 (11.9)</p> <p>I= 47.1 (14.3)</p>	<p>Low back LBP >3 mths</p>	<ul style="list-style-type: none"> • Exercise (aerobic, stretching and strengthening) • Goal setting (according to their individual goal and exercise capabilities). 	<ul style="list-style-type: none"> • Exercise (100%) • Education (100%) • Manual therapy (manipulation-66.7%) 	<p>G:8 sessions</p> <p>I: Attended a mean (SD) of 3.5 (2.2) sessions</p>	<p>ODI (0-100)</p> <p>NRS (0-10)</p> <p>3 mths</p> <p>6 mths</p>
Fransen et al. 2001	<p>N=126* (G=40; I=43)</p> <p>G=31F/9M</p>	<p>G=65.3 (7.1)</p> <p>I=68.5 (8.7)</p>	<p>Knee Knee pain on most of the days of</p>	<ul style="list-style-type: none"> • Exercise (aerobic, stretching and strengthening). 	<ul style="list-style-type: none"> • Exercise (strengthening) • Manual therapy • Modalities (heat, US, IFT or laser). 	<p>G: Twice a week, one-hour each, for 8 wks.</p> <p>I: Mean of 7 x 30 minute</p>	<p>WOMAC function (0-100)</p> <p>WOMAC pain</p>

	I= 32F/11M		the past month			sessions.	(0-100) 2 mths
Gustavsson et al. 2010	N=156 (G=77; I=79) G=69F/8M I=70F/9M	G=45.7 (11.15) I=45.7 (11.6)	Neck NP >3 mths	<ul style="list-style-type: none"> • Exercise (body awareness). • Education • Other (relaxation). 	<ul style="list-style-type: none"> • Exercise (individually tailored: home-exercise-65%, gym-based- 26%, water-based- 16%). • Education (relaxation- only a few received this). • Manual therapy (spinal manipulation/mobilization techniques, e.g. cervical traction- 51%, acupuncture- 38%). • Modalities (heat-20%, TENS- 20%, US-5%). 	G: 7 x 1.5 hour sessions, and additional booster session at 20 weeks. I: Mean of 11 sessions (range 1–52)	NDI (0-100) NRS (0-10) 10 wks 20 wks
Hudson et al. 2010	N=12 (G=6; I=6) G=5F/1M I=3F/3M	G=42.3 (19.8) I=42.7 (16.1)	Neck NP >3 mths	<ul style="list-style-type: none"> • Exercise (progressive cervicothoracic stability training, postural control, 	Choice of treatment varied and was at discretion of physio. <ul style="list-style-type: none"> • Exercise • Education • Manual therapy (mobilisations, 	G: 5-6 x 1 hour sessions, once a week for 6 wks and initial 40 minute	NDI (0-100) NRS (0-10)

				<p>proprioceptive training).</p> <ul style="list-style-type: none"> • Education (neck anatomy and pathology, pain management, benefits of exercise and pacing, posture, ergonomics, and relaxation). • Other (relaxation). 	<p>massage, acupuncture)</p> <ul style="list-style-type: none"> • Other (relaxation) 	<p>assessment</p> <p>I: 6-7 x 20 minute sessions and initial 40 minute assessment</p>	<p>Discharge</p>
<p>Ko et al. 2013</p>	<p>N=249* (G=84; I=85) G=N/S I= N/S</p>	<p>G= N/S I= N/S</p>	<p>Knee</p> <p>>2 wks post TKR</p>	<ul style="list-style-type: none"> • Exercise (stairs and balance retraining, specific muscle group exercises (knee flexion, mini-squats, step-ups, and upper-limb weights), and 	<ul style="list-style-type: none"> • Exercise (VMO retraining or ITB stretches). • Manual therapy (joint mobilization or massage). • Modalities (cryotherapy, IFT, taping, or prescription of orthotics). 	<p>G: 12 sessions I: 12 sessions</p>	<p>OKS (0-60)</p> <p>WOMAC pain and function (0-100)</p> <p>10 wks 12 mths</p>

				aerobic activities (arm ergometry in standing and stationary cycling).			
Lansinger et al. 2013	N=122 (G=60; I=62) G=44F/16M I=42F/20M	G=44.9 (12.3) I=42.8 (1.4)	Neck NP >3 mths	<ul style="list-style-type: none"> • Exercise (qigong) • Relaxation (qigong) 	<ul style="list-style-type: none"> • Exercise (active neck movements, endurance and strength. The amount of load was individualized, modified and progressed where appropriate. 	G: 10-12 x 1 hour sessions I: 10-12 x 1 hour sessions.	SF-36 (0-100) VAS (0-100) 12 mths
Mannion et al. 2001	N=148* (G=50; I=49) G=27F/23M I= 29F/20M	G=45.2 (9.7) G=43.7 (10.1) I= 46.3 (10.1)	Low back LBP >3 mths	<p>Group intervention 1</p> <ul style="list-style-type: none"> • Exercise (trunk and leg strengthening, stretching) • Other (relaxation). <p>Group intervention 2</p> <ul style="list-style-type: none"> • Exercise (strengthening on 	<ul style="list-style-type: none"> • Exercise (strengthening, coordination, HEP). • Education (ergonomics). 	G: 1 hour sessions. I: 30 minute sessions.	RMDQ (0-24) VAS (0-10) 6 mths 12 mths

				<p>machines, stretching</p> <ul style="list-style-type: none"> • Other (relaxation) 			
Mc Lean et al. 2013	<p>N=151 (G=75; I=76)</p> <p>G=44F/31M I=46F/30M</p>	<p>G=54.2 (13.8)</p> <p>I=53.5 (15.1)</p>	<p>Neck</p> <p>Subacute or chronic NP</p>	<ul style="list-style-type: none"> • Exercise (range of movement exercises for neck, trunk and upper limb, endurance training for the upper limb, trunk and lower limbs). Exercise was modified individualized, and progressed where appropriate. 	<p>Choice of treatment varied and was at discretion of physio.</p> <ul style="list-style-type: none"> • Exercise (McKenzie n=31, Stretches n=25, cervical stabilisation n=24, upper limb strengthening n=4, specific exercises n=33, general exercise n=3). • Education (ergonomics n=1) • Manual therapy (mobilization n=42, neural biased n=4, muscle biased=20, massage n=1) • Modalities (traction n=3, SWD n=7, US=3, TENS N=2, ice/heat n=15, acupuncture n=4, collar n=1, taping n=1). 	<p>G: 6-12 x 30-60 minute sessions over 6 wks.</p> <p>I: Average 6 sessions. Initial assessment between 40- 60 minutes and follow-up sessions between 20-30 minutes.</p>	<p>NPQ (0-100)</p> <p>DASH (0-100)</p> <p>VAS (0-100)</p> <p>6 wks</p> <p>6 mths</p> <p>12 mths</p>
Russell et al. 2014	<p>N=75* (G=25; I=24)</p>	<p>G=51.1 (12.3)</p> <p>I=51.1</p>	<p>Shoulder</p> <p>Shoulder</p>	<ul style="list-style-type: none"> • Exercise (range of motion exercises for the shoulder) 	<p>Choice of treatment varied and was at discretion of physio.</p> <ul style="list-style-type: none"> • Exercise (HEP of neck, 	<p>G: 12 x50 minute sessions, twice a week for</p>	<p>Constant Score (0-100)</p>

	Female to-male ratio was 1:1.14.	(12)	pain with marked loss of active and passive ROM > 3 mths	and thoracic spine. Stick, pulley, and ball techniques, scapula setting, trunk rotation, side flexion exercises and HEP). <ul style="list-style-type: none"> • Education (pathophysiology, treatment options, “good” sitting posture). 	shoulder and thoracic ROM exercises and stretches). <ul style="list-style-type: none"> • Education (pathophysiology, treatment options, “good” sitting posture). • Manual therapy (Maitland mobilizations, soft tissue massage, myofascial trigger point release) • Modalities (heat) 	6 wks. I: 12 sessions, twice a week, for 6 wks.	OSS (0-60) 6 wks 6 mths 12 mths
Unsgaard-Tondel et al. 2010	N=109 (G=37; I=36; I=36) G=24F/13M I=29F/7M I=23F/13M	G=36 (10.3) I=40.9 (11.5) I=43.4 (10.2)	Low back LBP >3 mths	<ul style="list-style-type: none"> • Exercise (general trunk strengthening involving trunk flexion, extension and rotation with resistance and stretching of trunk and extremity muscles). 	Individual intervention 1 <ul style="list-style-type: none"> • Exercise (Motor control): Isolated control and activity of the transversus abdominus, multifidus and obliques during the ADIM. Exercises were progressed where appropriate. Individual intervention 2 <ul style="list-style-type: none"> • Exercise (Sling exercise): Unloading elastic bands were 	G: 8 x 1 hour sessions, once a week for 8 wks. I: Both had 8 x 40 minute sessions, once a week, for 8 wks.	ODI (0-100) NRS (0-10) 8 wks 12 mths

					attached to the pelvis to help participants maintain the neutral spine position through a range of leg and arm positions and movements. Exercise progression was achieved by gradually reducing the elastic band support.		
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* = Remainder of sample size allocated to an inactive/non-exercise control group

G-Group; I-Individual; mths-months; LBP-low back pain; NP-neck pain; TKR-total knee replacement; RMDQ-Roland Morris Disability Questionnaire; ODI-Oswestry Disability Index; NRS-Numerical Rating Scale; VAS-Visual Analogue Scale; DASH-Disabilities of the Arm, Shoulder and Hand; NPQ-The Northwick Park Neck Pain Questionnaire; NDI-Neck Disability Index; WOMAC-Western Ontario and McMaster Universities Arthritis Index; OKS-Oxford Knee Score; OSS-Oxford Shoulder Score; SF-36-Short Form Health Survey; ADIM-Abdominal drawing-in maneuver; IFT-Interferential therapy; SWD-Short wave diathermy; VMO-vastus medialis oblique; US-Ultrasound; TENS-Transcutaneous electrical nerve stimulation; CBT-cognitive behavioural therapy; HEP-home exercise programme; ITB-iliotibial band; N/S-not stated.

Data analysis

Data analysis was performed by a statistician (HP). The effects of group and individual physiotherapy incorporating exercise were compared using meta-analyses. The primary outcomes of interest were pain intensity and functional disability. Pain intensity was measured using the Visual Analogue Scale (VAS) or Numerical Rating Scale. The reported pain intensity scores were converted to a 0–100 point scale, where necessary, and a mean difference (MD) was computed. The analysis of functional disability required a standardised MD (SMD) to be computed as studies used a number of different measures to report disability, including the Roland–Morris Disability Questionnaire, Oswestry Disability Index, Northwick Park Neck Pain Questionnaire, Neck Disability Index and Western Ontario and McMaster Universities Arthritis Index (WOMAC).

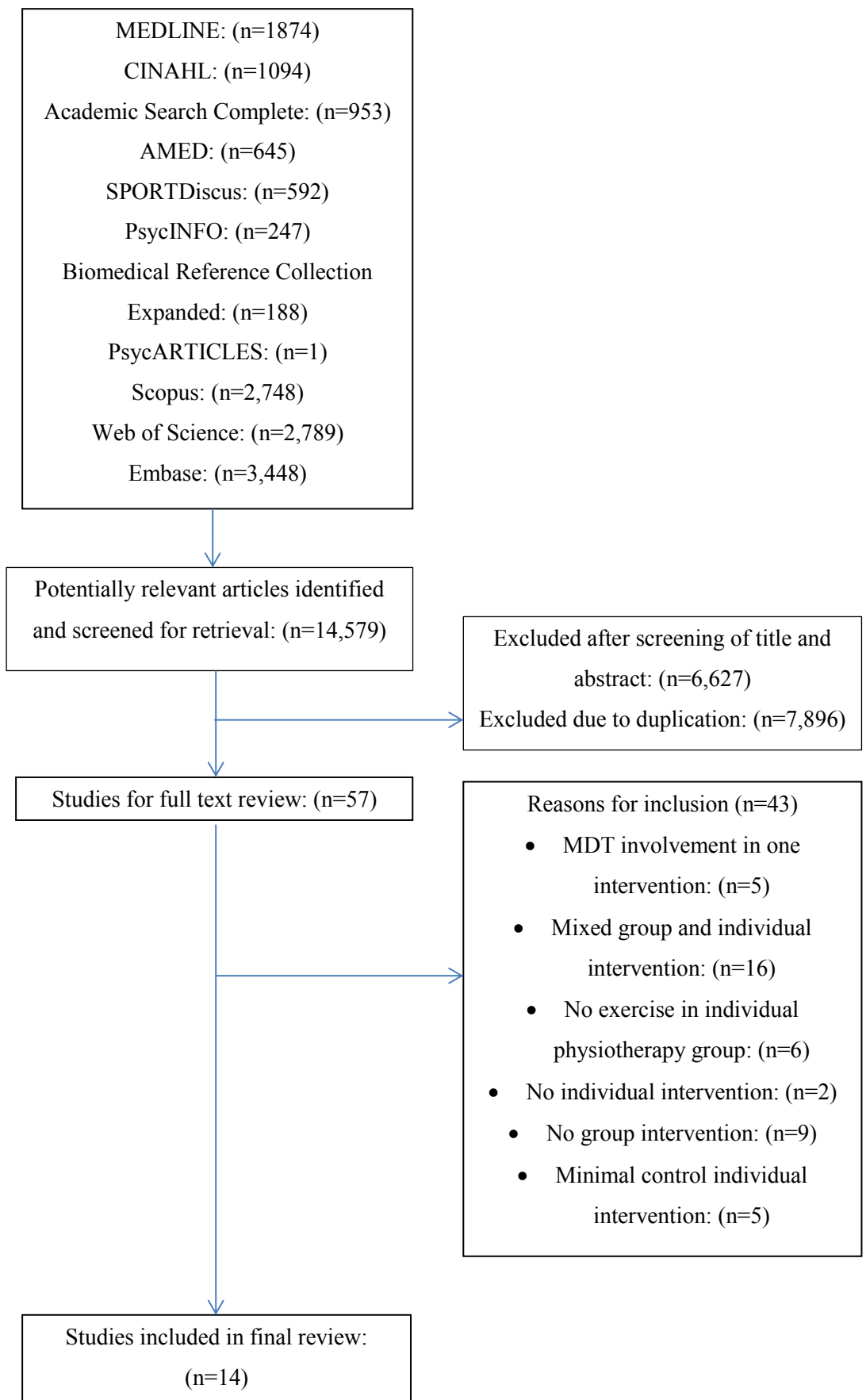
Analyses were carried out at three assessment points: (1) short-term follow-up (up to 3 months), (2) medium-term follow-up (>3 months and <12 months) and (3) long-term follow-up (≥ 12 months). The meta-analysis analysed all the studies together. Subgroup analyses were also conducted by testing differences in pain and disability between neck pain, low back pain and knee pain separately. A sensitivity analysis was conducted to determine whether limiting the analysis to high-quality studies changed the results. A random-effects model was selected for all analyses a priori (Higgins and Green 2008), and heterogeneity between treatment studies was reported using the I^2 statistic. In studies where multiple contrasts were examined (e.g. Individual Physiotherapy vs. Group Physiotherapy A vs. Group Physiotherapy B), the sample size in the shared comparison was halved in order to avoid double-counting of participants in the analyses. In studies where standard deviations were not reported at follow-up times, the baseline standard deviation (SD) was used in the analysis. Where data were summarised using median and interquartile range (IQR) values, the mean was approximated using the median and the width of the IQR was used as an approximation of 1.35 times the SD (Higgins and Green 2008). Pooled 95% confidence intervals (CIs) were computed for MD and SMD and CIs excluding zero were considered statistically significant. Clinical relevance was determined using the following effect size classifications: (1) Small: MD < 1 (i.e. less than 10% of the 100-mm VAS); SMD (Cohen's d) of 0.2; (2) Medium: MD < 2, SMD (Cohen's d) of 0.5; (3) Large: MD ≥ 2 , SMD (Cohen's d) of 0.8 (Cohen 2013). Heterogeneity between studies was assessed visually from the forest plots, using formal Q-tests (chi-square test statistic and p-value) and the I^2 statistic. Substantial heterogeneity was determined using the cut-off; $I^2 \geq 50\%$. All analyses were conducted in Review Manager 5.2.

Results

Literature search

Study identification is summarised in Figure 11. The literature search of databases yielded 14,579 potentially relevant articles. Duplicates (7,896) were removed and 6,683 titles and abstracts were scanned. Fifty-seven full-text studies were retrieved, with 43 studies being excluded as ineligible. Searching the reference lists of these articles did not yield any further articles. The major reasons for exclusion were multidisciplinary team involvement in interventions, mixed group and individual physiotherapy being provided, no exercise being included in the physiotherapy, lack of individual or group physiotherapy and the individual intervention being minimal (e.g. solely providing an information leaflet). Fourteen articles met the selection criteria. Four authors were emailed to obtain further information for clarification and two of them replied.

Figure 11. Study II Flow Diagram



Quality assessment

The quality assessment scores are shown in Table 5. Thirteen studies were rated as ‘high quality’ and one study as ‘fair quality’ according to the PEDro scale. Four studies were awarded a score of 8/10 (Carr *et al.* 2005, Gustavsson *et al.* 2010, Ko *et al.* 2013, Russell *et al.* 2014) and one a score of 4/10 (Chown *et al.* 2008). Common methodological limitations included lack of therapist and patient blinding, which would be practically unavoidable in trials of exercise therapy, as well as large loss to follow-up.

Table 5. Study II Quality assessment scores

Study	1	2	3	4	5	6	7	8	9	10	Total
Carr et al. 2005	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8/11
Cecchi et al. 2010	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	6/11
Chown et al. 2008	Yes	No	Yes	No	No	Yes	No	No	No	Yes	4/11
Critchley et al. 2007	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	7/11
Eadie et al. 2013	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	7/11
Fransen et al. 2001	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	7/11
Gustavsson et al. 2010	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	6/11
Hudson et al. 2010	Yes	Yes	No	No	No	Yes	Yes	No	Yes	Yes	6/11
Ko et al. 2013	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8/11
Lansinger et al. 2013	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	6/11
Mannion et al. 2001	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	6/11
Mc Lean et al. 2013	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	6/11
Russell et al. 2014	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8/11
Unsgaard-Tondel et al. 2010	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	7/11

Population

Studies involved participants with LBP (Mannion *et al.* 2001b, Carr *et al.* 2005, Critchley *et al.* 2007, Chown *et al.* 2008, Cecchi *et al.* 2010, Unsgaard-Tondel *et al.* 2010, Eadie *et al.* 2013) (n=7), NP (Gustavsson *et al.* 2010, Hudson and Ryan 2010, Lansinger *et al.* 2013, McLean *et al.* 2013) (n=4), knee pain (Fransen *et al.* 2001, Ko *et al.* 2013) (n=2) and shoulder pain (Russell *et al.* 2014) (n=1). The majority of participants had chronic pain (ie, >3 months). The sample sizes of the included studies ranged from 12 to 249. The mean (SD) age across all studies was 48 (12) years.

Intervention characteristics

The characteristics of the various group and individual physiotherapy interventions can be seen in Table 4. Group physiotherapy mainly consisted of exercise, education and relaxation while individual physiotherapy mainly consisted of exercise, education and passive modalities. Only four studies (Fransen *et al.* 2001, Unsgaard-Tondel *et al.* 2010, Ko *et al.* 2013, McLean *et al.* 2013) had a group intervention consisting of exercise alone. Only two studies (Unsgaard-Tondel *et al.* 2010, McLean *et al.* 2013) had an individual intervention consisting of exercise alone. Only one study (Unsgaard-Tondel *et al.* 2010) had both a group and individual intervention providing exercise alone.

Clinical outcome measures

All studies reported a disability measure. The shoulder pain study (Russell *et al.* 2014) did not report a pain intensity measure. Ten of the other 13 studies used the NRS or VAS to measure pain intensity. Three common disability measures (ODI, NDI and RMDQ) were used in nine studies. The specific pain intensity and disability measures for each individual study can be seen in Table 4.

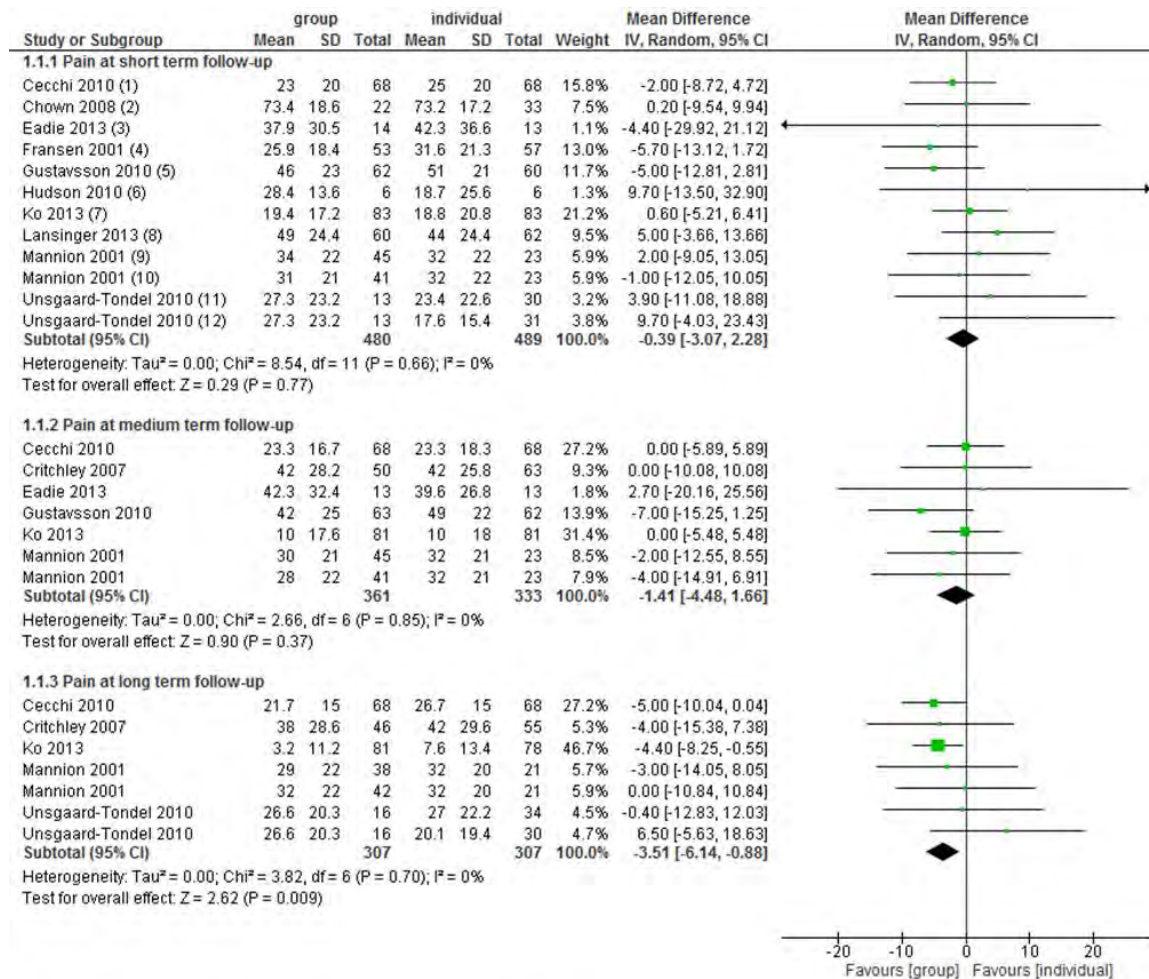
Meta-analysis studies

Twelve studies were included in the meta-analysis of pain and disability. One study on LBP (Carr *et al.* 2005) was excluded as there were significant differences in baseline disability between the groups. The one study on shoulder pain (Russell *et al.* 2014) was excluded as the original study authors were unable to provide the means and relevant SDs required for analysis. Subgroup analyses were conducted by testing pooled differences in pain and disability between LBP, NP and knee pain at each follow-up time; no significant differences were found ($p>0.05$). We conducted a sensitivity analysis limited to the 11 'high-quality' studies and no significant differences were found for pain or disability ($p>0.05$).

Effects of Individual versus Group physiotherapy on pain intensity

No statistically significant difference was found for pain intensity between individual and group physiotherapy including exercise at short-term (12 studies, n=480, MD=0.39, 95% CI -3.07 to 2.28) and medium-term (seven studies, n= 361, MD= -1.41, 95% CI -4.48 to 1.66) follow-up (Figure 12). A small, yet statistically significant, difference was found for pain intensity between individual and group physiotherapy interventions involving exercise at long-term (seven studies, n=307, MD= -3.51, 95% CI -6.14 to -0.88) follow-up, favouring group interventions (Figure 12).

Figure 12. Effect of Individual versus Group physiotherapy on pain intensity



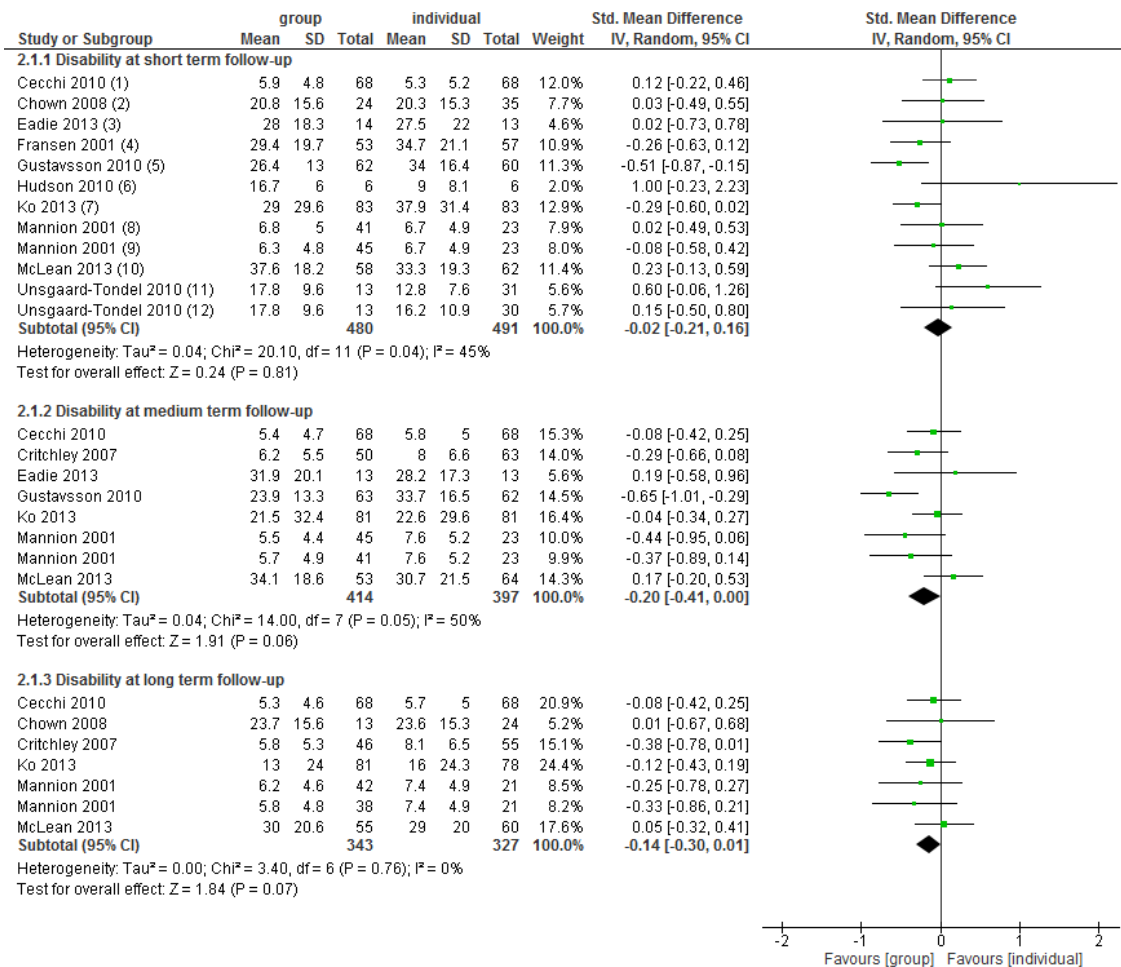
Footnotes

- (1) Exercise class vs. physiotherapy; NRS score transformed to 0-100; lower back
- (2) Exercise class vs. physiotherapy; change scores in text, SD from baseline; lower back
- (3) Exercise class vs. physiotherapy; change scores in text, data from author; lower back
- (4) Exercise class vs. physiotherapy; change scores in text, SD from baseline; scores reversed; knee
- (5) Pain + stress management vs. physiotherapy; neck
- (6) Exercise + education vs. physiotherapy; data estimated from graphs; neck
- (7) Exercise class vs. physiotherapy; data from author; median and IQR converted; knee
- (8) Qigong vs. physiotherapy; mean and SD estimated from median and IQR; scores reversed; neck
- (9) Exercise class vs. physiotherapy; number of individual subjects halved; lower back
- (10) Exercise on machines vs. physiotherapy; number of individual subjects halved; lower back
- (11) Exercise class vs. physiotherapy (sling); number of group subjects halved; lower back
- (12) Exercise class vs. physiotherapy (motor control); number of group subjects halved; lower back

Effects of Individual versus Group physiotherapy on disability

No statistically significant difference was found for disability between individual and group physiotherapy including exercise at short-term (12 studies, n=480, MD=-0.02, 95% CI -0.21 to 0.16) follow-up (Figure 13). A small, yet statistically significant, difference was found for disability between individual and group physiotherapy involving exercise at medium-term (eight studies, n=414, MD= -0.20, 95% CI -0.41 to 0.00) and long-term (seven studies, n=343, MD= -0.14, 95% CI -0.30 to 0.01) follow-up, favouring group interventions (Figure 13).

Figure 13. Effect of Individual versus Group physiotherapy on disability



Footnotes

- (1) Exercise class vs. physiotherapy; RMDQ (0-24); low back
- (2) Exercise class vs. physiotherapy; ODI (0-100); change scores in text, SD from baseline; low back
- (3) Exercise class vs. physiotherapy; ODI (0-100); change scores in text, data from author; low back
- (4) Exercise class vs. physiotherapy; WOMAC function (0-100); change scores in text, SD from baseline; scores reversed; knee
- (5) Pain + stress management vs. physiotherapy; NDI (0-100); neck
- (6) Exercise + education vs. physiotherapy; NDI (0-100); data estimated from graphs; neck
- (7) Exercise class vs. physiotherapy; 10 week follow-up; WOMAC function (0-100); data from author; median and IQR converted; knee
- (8) Exercise on machines vs. physiotherapy; RMDQ (0-24); number of physiotherapy subjects halved; low back
- (9) Exercise class vs. physiotherapy; RMDQ (0-24); number of physiotherapy subjects halved; low back
- (10) Exercise class vs. physiotherapy; NPQ (0-100); neck
- (11) Exercise class vs. physiotherapy (sling); ODI (0-100); number of exercise class subjects halved; low back
- (12) Exercise class vs. physiotherapy (motor control); ODI (0-100); number of exercise class subjects halved; low back

Studies excluded from meta-analysis

The one excluded study on LBP (Carr *et al.* 2005) found no statistically significant differences for pain and disability between individual and group physiotherapy including exercise at all follow-up periods. The one excluded study on shoulder pain (Russell *et al.* 2014) found a statistically significant difference for pain and disability between individual and group physiotherapy including exercise at all follow-up periods, favouring group interventions.

Discussion

Main findings

For pain and disability, no clinically significant differences were found between group and individual physiotherapy including exercise. For some of the comparisons performed, particularly in the long-term, group interventions were more effective, but these differences were small and not clinically relevant. The small and similar effects yielded by the two modes of physiotherapy support choosing more cost-efficient group interventions (Critchley *et al.* 2007), providing they are feasible and acceptable to patients. Our review extends previous findings (Barker *et al.* 2014, Abdulla *et al.* 2015, Searle *et al.* 2015) that show no superiority for one type of exercise over another in the management of MSK conditions. Our findings are also consistent with those of a recent review (Toomey *et al.* 2015) where self-management that included group physiotherapy was as effective as individual physiotherapy and medical management in those with LBP and osteoarthritis.

Why is individual physiotherapy including exercise not better than group physiotherapy?

Many clinicians may be surprised that individual physiotherapy was not better than group physiotherapy. This raises the question of whether we failed to find a ‘real’ difference or

whether there really is no difference. Is it possible that group programmes provide a similar but cheaper outcome? We provide several avenues for consideration.

One potential explanation for the lack of superiority of individual physiotherapy may be that the group physiotherapy interventions seem to have spent more time on exercise and education. Individual physiotherapy in 12 of the 14 included studies in this review involved other non-exercise-based, passive therapies which have limited evidence of effectiveness (Ho *et al.* 2009, Menke 2014, Parreira *et al.* 2014, van den Dolder *et al.* 2015). Only two individual physiotherapy interventions (Unsgaard-Tondel *et al.* 2010, Lansinger *et al.* 2013) involved exercise only. Individual physiotherapy involving passive therapies may not spend enough time on exercise in comparison with groups which have no passive therapies. Since dose as well as content of an intervention can influence outcome (Waterschoot *et al.* 2014), we speculate that group interventions may benefit from focusing mainly on evidence-based treatment, such as exercise and education, and excluding other passive therapies (eg, modalities, manual therapy) with limited evidence of efficacy (Russell *et al.* 2014).

A second possible explanation for the lack of additional benefit from individual physiotherapy might be that the exercise provided was not tailored to the individual needs of patients. For example, exercise used in the majority of studies did not appear to take into account the baseline exercise capacity of people with MSK conditions. This is not in line with evidence advocating the use of the FITT (Frequency, Intensity, Time, Type) principle for exercise (Pescatello *et al.* 2009, O'Riordan *et al.* 2014). In addition, patient needs might vary according to their MSK condition, with differences in strength, endurance, flexibility, sensory motor control, muscle recruitment, proprioception and movement patterns. Furthermore, most participants received the same dose and type of exercise. In addition, the exercise did not progress or was completed in such a way that all participants reached the same level, at the same time, with no account taken of variations in individual needs, pain, disability, progress or goals. These factors may explain why using a generic exercise programme is equally effective for a group as for an individual.

A third explanation for the lack of difference might result from not categorising MSK conditions using different risk profiles or clinical presentations to guide treatment (Smart *et al.* 2008, O'Sullivan 2012, Vibe Fersum *et al.* 2013). MSK conditions are biopsychosocial disorders, involving not just patho-anatomical (e.g. knee osteoarthritis) and physical factors

(e.g. deconditioning), but also cognitive (e.g. unhelpful beliefs), psychological (e.g. depression), lifestyle (e.g. physical inactivity, insomnia, stress) and social (e.g. work status) factors.

Exercise can influence a wide range of these factors, including mood (Rosenbaum *et al.* 2015), catastrophizing (Smeets *et al.* 2006), fear (Mannion *et al.* 2001a) and self-efficacy (O'Sullivan *et al.* 2015). However, there was no evidence that exercise interventions in the included studies aimed at dealing with cognitive, psychological and social factors. Furthermore, since few studies in this review measured non-physical factors, detailed analysis of the mechanisms involved in reducing pain in these studies is not possible. Given the multidimensional nature of MSK conditions, it is possible that exercise programmes which deal primarily with only one contributory domain (e.g. physical factors) will have small effects.

Possibly, some patients may benefit from more emphasis on some contributory factors than others (e.g. exercise prescription versus interventions to deal with depression or sleep, etc.). This could be facilitated by the use of screening tools and training. For instance, some studies have shown that for patients with LBP, matching the type and amount of treatment to the perceived needs of the patient improves outcomes (Hill *et al.* 2011, Vibe Fersum *et al.* 2013, O'Sullivan *et al.* 2015). These studies included more than just physical rehabilitation, reflecting the biopsychosocial nature of MSK conditions. It should be noted, however, that recent attempts to tailor LBP rehabilitation to individual patients, which deal only with physical factors, have failed to show any benefit of individualisation (Henry *et al.* 2014, Saner *et al.* 2015). This suggests that rehabilitation for MSK conditions may need to be both biopsychosocial and tailored to the individual needs of patients. Nevertheless, the possibility that MSK conditions will remain highly resistant to treatment in some patients, even when an individualised biopsychosocial approach is used, cannot be discounted.

Finally, the potential for better social interaction and social support in groups could be considered as an advantage of group-based rehabilitation (Tiffreau *et al.* 2007, Bennell and Hinman 2011).

Future Research and Clinical implications

Based on these findings, if exercise is to be delivered by physiotherapists in the management of MSK conditions, group interventions should be considered owing to the lower healthcare costs. While cost-benefit analysis was not the primary aim of this review, the one study (Critchley *et al.* 2007) carrying out an economic evaluation showed no differences in pain and disability between group and individual physiotherapy, but modest cost savings with a group intervention, in line with other literature (Garrett *et al.* 2011, Hurley *et al.* 2012). If exercise delivered through individual physiotherapy is to show clinical and cost-effectiveness, the exercise may need to be (i) tailored to the exercise capacity and individual needs (e.g. strength, flexibility, proprioception and movement patterns) of each patient and/or (ii) deal with the specific biopsychosocial needs of a patient. Furthermore, given the limited long-term ineffectiveness of passive therapies in MSK conditions (Ho *et al.* 2009, Menke 2014, Parreira *et al.* 2014, van den Dolder *et al.* 2015), individual and group physiotherapy interventions should perhaps eschew these treatments and place greater emphasis on evidence-based treatments (e.g. exercise). Providing non-evidence-based treatments might reduce the priority a patient places on exercise. As exercise may work via multiple mechanisms, future RCTs should also include analysis to better understand which patients would respond best to exercise, and the mechanisms underlying improvements in pain and disability after exercise. In addition, details of the type of education that accompanies exercise are often not given. As effectiveness depends on the type of education provided (Louw *et al.* 2011, Ainpradub *et al.* 2015), future RCTs should investigate whether supplementing exercise with education which highlights the safety and benefits of activity, together with the multidimensional nature of MSK conditions, results in better outcomes. Furthermore, certain people might be more suited to a group or individual intervention. For example, people with more complex pain disorders or language difficulties might be better suited to an individualised programme (Critchley *et al.* 2007). These factors and patient preference should be considered when the type of intervention.

Limitations

We acknowledge a number of limitations. (1) Only RCTs published in English were included, and relevant studies in other languages might have been excluded. (2) Both group and individual interventions usually included other co-interventions, with some individual interventions including education and passive modalities (e.g. manual therapy), and some group interventions including education and relaxation. All but one study (Unsgaard-Tondel *et al.* 2010) included other co-interventions with exercise in either the group or individual arm, so determining the independent effect of exercise is difficult. However, using a multi-modal approach to complement exercise is standard physiotherapy practice. Furthermore, the one study (Unsgaard-Tondel *et al.* 2010) that included exercise only in both arms, showed no differences between group and individual physiotherapy and underlies our overall conclusion. (3) As only RCTs were included, the very nature of these studies might have contributed to exercise being standardised in a manner that does not always reflect practice. (4) The studies differed in the amount of exercise provided, with some group physiotherapy interventions providing more exercise than the individual physiotherapy comparison. (5) Review procedures have evolved since we submitted the original review protocol. We used a summary score out of 10 and specific cut-off values to distinguish between high- and low-quality studies. With this system a study that fulfils any six of the 10 criteria is deemed high quality. This approach has limitations; however, as meta-epidemiological evidence suggests that failure in any one of the 10 criteria might alone explain a small positive effect on a subjective self-reported outcome. (6) Some study authors did not reply to emails asking about their study interventions and methodology, which might have resulted in errors in quality assessment and inclusion of some studies. However, if criteria were deemed unclear, they were scored accordingly on the PEDro critical appraisal measure. Furthermore, we performed a sensitivity analysis and a consistent study selection procedure, based on strict inclusion/exclusion criteria.

Conclusion

For pain and disability, no clinically significant differences were found between group and individual physiotherapy including exercise. Given the lower healthcare costs of group-based interventions, group physiotherapy for MSK conditions may need to be considered more often.

STUDY III: What Influences Patient-Therapist Interactions in Musculoskeletal Physiotherapy? A Qualitative Systematic Review and Meta-Synthesis

O’Keeffe, M., Cullinane, P., Hurley, J., Leahy, I., Bunzli, S., O’Sullivan, P. and O’Sullivan K. (2015) *Physical Therapy*, 96(5): 609-622. (**Impact Factor:** 2.526)

<http://www.ncbi.nlm.nih.gov/pubmed/26427530>

Abstract

Background: Musculoskeletal physiotherapy involves both “specific” and “non-specific” effects. “Non-specific” variables associated with the patient, therapist and setting may influence clinical outcomes. Recent quantitative research has shown that “non-specific” factors including patient-therapist interactions can influence treatment outcomes. It remains unclear however what factors influence patient-therapist interaction. This qualitative systematic review and meta-synthesis investigated patient and physiotherapist perceptions of factors that influence patient-therapist interaction.

Methods: Eleven databases (Academic Search Complete, AMED, Biomedical Reference Collection, CINAHL, MEDLINE, PsychARTICLES, PsycINFO, SPORTSDiscus, Web of Science, Embase and Scopus) were searched independently. Qualitative studies examining physiotherapists’ and/or patients’ perceptions of factors which influence patient-therapist interaction in musculoskeletal settings were included. Two reviewers independently selected articles, assessed methodological quality using the Critical Appraisal Skills Programme (CASP), and performed the three stages of analysis; extraction of findings, grouping of findings (codes), abstraction of findings.

Results: Thirteen studies were included. Four themes were perceived to influence patient-therapist interactions; (1) Physiotherapist interpersonal and communication skills: the presence of skills such as listening, encouragement, confidence, being empathetic and friendly and non-verbal communication; (2) Physiotherapist practical skills: physiotherapist expertise and level of training while the ability to provide good education was considered as

important only by patients; (3) Individualised patient-centred care: individualising the treatment to the patient and taking patient opinions into account and (4) Organisational and environmental factors: time and flexibility with care and appointments. Only studies published in English were included.

Conclusions: A mix of interpersonal, clinical and organisational factors are perceived to influence patient-therapist interactions, though research is needed to identify which of these factors do actually influence patient-therapist interactions. Physiotherapist awareness of these factors could enhance patient interactions and treatment outcomes. Mechanisms to best enhance these factors in clinical practice requires further study.

Introduction

Patients with musculoskeletal pain are commonly treated by physiotherapists, yet the mechanisms by which physiotherapy interventions influence clinically relevant outcomes such as pain and disability are complex (Crow *et al.* 1999, Lærum *et al.* 2006, Hall *et al.* 2010). Research shows that factors associated with the physiotherapist, patient and setting (Szybek *et al.* 2000, Del Re *et al.* 2012) may influence clinical outcomes in addition to the specific physical interventions provided. These factors make up the “context” and are often described as “non-specific” factors (Miciak *et al.* 2012). Therefore, it is being increasingly recognised that musculoskeletal physiotherapy involves both “specific” and “non-specific” factors (Miciak *et al.* 2012).

Abundant research has focused on the impact of the relationship between patients and therapists on treatment outcome. This concept is usually referred to as the patient-therapist interaction (Martin *et al.* 2000). This is an example of a “non-specific” factor and is fundamental to the therapeutic process. It is defined as the sense of collaboration, warmth, and support between the patient and therapist (Ackerman and Hilsenroth 2003, Hall *et al.* 2010). The three main components are proposed to consist of (1) patient-therapist agreement on goals, (2) patient-therapist agreement on interventions, and (3) the affective bond between patient and therapist (Bordin 1979). Physiotherapy relies on a complex interplay of technical skill, communicative ability and the reflective capacity of the therapist to respond to the patient (Hall *et al.* 2010). Other constructs, such as trust (Hall *et al.* 2012), empathy (Mercer *et al.* 2004) as well as verbal and non-verbal communication may be important prerequisites to positive interaction (Pinto *et al.* 2012).

Evidence has emerged that positive patient-therapist interactions in physiotherapy settings are linked with reduced pain, reduced disability, and higher treatment satisfaction (Lewin *et al.* 2001, Moore *et al.* 2004, McGilton *et al.* 2009, Hall *et al.* 2010, Ferreira *et al.* 2013b, Fuentes *et al.* 2014). The main systematic review in this area (Hall *et al.* 2010) provided rich quantitative data on the positive effect of the patient-therapist relationship on treatment outcome in physiotherapy, but not specifically in a musculoskeletal population.

No review has yet systematically investigated physiotherapists’ and patients’ views on factors important to the patient-therapist interaction. An investigation of the factors that may

facilitate or hinder its development is therefore appropriate. Given that patient-therapist interactions are unique, qualitative methods may be most suited to this investigation, as they would gather the perspectives of both physiotherapists and patients, giving a holistic understanding of interaction. Therefore, the aim of this review was to systematically investigate physiotherapists' and patients' perceptions of factors that influence patient-therapist interactions in musculoskeletal settings.

Methods

Data sources and searches

This review has been registered in the PROSPERO database (CRD42014014336) and has been reported in accordance with the ENTREQ guidelines (Tong *et al.* 2012). The electronic-databases Academic Search Complete, AMED, Biomedical Reference Collection, CINAHL, MEDLINE, PsychARTICLES, PsycINFO, SPORTSDiscus, Embase, Web of Science and Scopus were searched during March-July 2014 independently by three authors. The search strategy used several combinations of keywords; (1) qualitative research, (2) interaction, (3) pain and (4) physiotherapy. The complete list of keywords is listed in Figure 14. Titles were screened and abstracts read where appropriate initially. Relevant full-text versions were retrieved and evaluated if they fulfilled the inclusion criteria or if the abstract was insufficiently detailed to determine eligibility. Manual searches of reference lists of the identified studies were also completed.

Study selection

Studies were shortlisted by three authors independently, with any disagreements resolved using consensus. Studies were included if they examined the opinions, of patients or physiotherapists regarding facilitators and barriers to a positive interaction between the patient and the physiotherapist. Studies were excluded if they;

- Were solely quantitative in nature.
- Were not reported in English.

- Only measured the strength of the interaction between the patient and the physiotherapist, rather than the factors which influence it.
- Examined Physiotherapist perceptions only as part of a group of healthcare professionals.
- Did not specifically focus on musculoskeletal physiotherapy settings or conditions.
- Examined opinions prior to rehabilitation only.
- Focused on clinical reasoning decisions only.

Figure 14. Study III Literature Search Strategy

Interview* OR “focus group*” OR “focus-group*” OR thematic OR experience* OR narrative* OR qualit* OR perspective* OR percept* (Abstract)
AND
psych* OR rapport OR relat* OR educat* OR communicat* OR empath* OR interact* OR understand* OR listen* OR “non verbal” OR “non-verbal” OR “nonverbal” OR “eye-contact” OR “eye-contact” OR support* OR respons* OR trust* OR bond* OR intima* OR attach* OR genuine* OR alliance OR encounter* OR therapeutic OR connect* OR emotion* OR express* OR perspect* OR mutual* OR honest* OR “patient-centred” OR “patient-centered” OR “patient centred” OR “patient centered*” OR interrocept* OR cogniti* OR affect* OR regard* OR goal* OR “body language” OR “body-language” OR hear* OR care OR caring OR discuss* OR dialogue* OR judge* OR aware* OR feed* OR attent* OR acknowledge* OR facilitate* OR confiden* OR concern* OR compassion* OR appreciate* OR warm* OR comprehend* OR consider* OR prosocial* OR “pro-social” OR soci* OR close* OR respect* OR observ* OR encourag* OR friend* OR react* OR adopt* OR imitate* OR copy* OR context* OR feel* OR personal* OR trait* OR apprais* OR link* OR valu* OR motivat* OR expert* OR shar* OR engag* OR think* OR intern* OR explain* OR verbal* OR need* OR resonan* OR interplay* OR sensitive* OR recept* OR reflect* OR identif* OR subjective* OR tone* OR recognis* OR recogniz* OR interpersonal* OR comfort* OR mirror* OR harmon* OR unease* OR empower* OR cooperat* OR reassur* OR “re-assur*” OR assur* OR negotiat* OR collaborat* OR help* OR agree* OR adher* OR behav* OR satisf* (Abstract)
AND
pain OR musculo* OR orth* OR healthcare (Abstract)
AND
“physical therap*” OR physiotherap* (Abstract)

Quality Assessment

Trustworthiness of the studies included was determined by two authors independently using the CASP Qualitative Research Assessment Tool (Critical Appraisal Skills Programme 2013), with any disagreements resolved using consensus, and consultation with another

author . This tool was chosen due to its extensive use in other qualitative systematic reviews in musculoskeletal populations (Fullen *et al.* 2008, Kelly *et al.* 2011, Synnott *et al.* 2015).

Data extraction

Data extraction was performed using a purpose-designed format by one author and cross-checked by another author (Table 6). For two studies (Dean *et al.* 2005, Harman *et al.* 2011), the original authors were contacted to clarify information about study participants.

Table 6 Study III Overview of characteristics of included studies

Study	Population	Age (Years)	Sex (%)		Sample Size	Data Source	Study Aims	Key Findings on factors influencing interaction	CASP Criteria unmet
			Male	Female					
Cooper et al. 2008	CLBP patients	18-65	20%	80%	25	Semi-structured interviews	To explore the patient perspective on ‘patient-centeredness’ in physiotherapy for CLBP	<ul style="list-style-type: none"> • Communication (listening, understanding, explaining exercises) • Physiotherapist personality (caring, friendly, pleasant and professional, interested or abrupt) • Physiotherapist competence (knowledge, be specialised) • Individualised Care • Involvement in decision-making • Information-sharing and education • Organisation of Care (waiting times, rescheduling appointments, quick access, follow-up) 	3,5,6 & 7

Dean et al. 2005	Non-specific or intermittent LBP patients	28-59	24%	76%	17 (9 patients)	Focus group	To investigate patients' & physiotherapists' perceptions of why LBP patients choose to adopt, or not, the advice/exercises given in primary-care outpatient physiotherapy	<ul style="list-style-type: none"> • Managing time • Bargaining process (importance of physiotherapist listening, exploring beliefs and expectations around management of pain) • Reviewing future (identify fears about long term disability, highlight importance of recovery time) 	4 & 6
Del Bano-Aledo et al.2014	MSK patients	>18	58%	42%	57	Focus group	To identify elements of the physiotherapist-patient interaction considered by patients when evaluating care in outpatient rehabilitation	<ul style="list-style-type: none"> • Physiotherapist willingness to provide information and education • Physiotherapist technical expertise • Physiotherapist interpersonal manners (respect, emotional support and sensitivity changes in patient's status) 	None

Escolar-Reina et al 2010	CLBP and NP patients	25-70	32.%	68%	34	Focus group	To explore perceptions of CLBP and NP patients about how features of HEP and care-provider style during clinical encounters may affect adherence to exercises.	<ul style="list-style-type: none"> • Education about condition • Provision of feedback and encouragement during exercise • Reminders given to exercise • Motivation given by physiotherapist 	None
Gard 2007	Physiotherapists for patients who have undergone torture.	38-60	0%	100%	10	Semi-structured interviews	To identify factors important for a good interaction between physiotherapist and patients who have been tortured.	<ul style="list-style-type: none"> • Personal characteristics (respect, humour, empathy, honesty, flexibility, self-awareness, handle negative emotions) • Professional and therapeutic competence (seek help or supervision when required) • Language factors (interpret meaning, metaphors and 	3,5,6,7 & 8

								<p>humour used)</p> <ul style="list-style-type: none"> • Time and frames (structured treatment with adequate time) • Cultural factors (sensitivity to patient needs, norms and values) • Treatments tailored to the patient's needs • Confidence and trust • Religious factors (respect beliefs) 	
Gyllensten et al. 1999	Primary Care Physiotherapists	44-62	-	100%	10	Crosscase analysis/ Interview	To investigate expert physiotherapists' perceptions of important factors influencing the quality of the interaction in physiotherapeutic treatment in	<ul style="list-style-type: none"> • Practical professional skills & patient experiences • Physiotherapy own education and theoretical courses completed • Physiotherapist life experiences & values • Physiotherapist personal characteristics 	3,6 & 7

							primary care	<ul style="list-style-type: none"> • Teamwork • Work organisation & environment • Communication & interpersonal skills (being sensitive, intuitive, listening, holistic, acknowledging body language, motivating) • Identification of patient resources • Patient education and clear explanations of problem • Giving time • Patient participation in goal setting 	
Harman et al. 2011	Subacute LBP patients	Not stated	18%	82%	44	Focus group	To investigate client education provided by physiotherapists in private practice	<ul style="list-style-type: none"> • Education about pain and multiple aspects involved • Physiotherapist tacit knowledge • Active listening • Reassurance 	4 & 6

							to subacute LBP workers	<ul style="list-style-type: none"> • Individualised approach • Understanding body language • Support and encouragement provided • Understanding of patient needs • Involving patient in treatment plan 	
Hills et al. 2007	MSK patients	36-70	40%	60%	30	Focus Group	To investigate the factors that affect patients' satisfaction with MSK outpatient physiotherapy within the NHS system of care in the UK.	<ul style="list-style-type: none"> • Expectations addressed or not • Patient needs met/unmet • Communication and education about condition • Perceptions of the Therapist (knowledgeable, good/poor communicator, empathy perceived or not, encouragement given) • Treatment Process (content, frequency of sessions, follow-up, waiting time) 	None

Kidd et al. 2011	MSK outpatients	20-68	50%	50%	8	Semi-structured interviews	To investigate patient's perspectives of components of patient-centred physiotherapy and its essential elements.	<ul style="list-style-type: none"> • The ability to communicate (listening, reassure, educate) • Physiotherapist Confidence • Physiotherapist knowledge and professionalism • Physiotherapist understanding of people and an ability to relate (empathy, encouragement) • Taking patient opinions into account • Transparency of progress and outcome (focus on progress and measurement) 	3,5,6 & 7
May et al. 2007	LBP patients	29-77	41.2%	58.8%	34	Semi-structured interviews	To investigate patients' attitudes to and satisfaction with physiotherapy for LBP	<ul style="list-style-type: none"> • Physiotherapist personal and professional manner • Explanations, teaching and education provided • Patient involvement in process • Organisation (time and access to care) 	6 & 7

Oien et al. 2010	1. Physiotherapists specialising in NPMP. 2. CLBP or NP patients	1.44-68 2.22-47	1.17% 2.9%	1.83% 2.91%	17 (11 patients)	Semi-structured interviews, focus group, personal notes and repeated video recording	To analyse how do patients and physiotherapists communicate verbally and nonverbally during demanding situations	<ul style="list-style-type: none"> • Shared understanding • Taking patient opinions into account • Patience and understanding non-verbal activity • Physiotherapist sensitivity of and ability to negotiate tasks with patient 	5 & 7
Peiris et al. 2012	MSK patients	60-92	16%	84%	19	Semi-structured interviews	To explore how inpatients in a rehabilitation setting experience physiotherapy rehabilitation.	<ul style="list-style-type: none"> • Empathetic and caring physiotherapists (friendly, knowledgeable, and compassionate) • Physiotherapist encouragement and motivation 	None
Potter et al. 2003	MSK patients	20-79	39%	62%	26	Nominal Group Technique/ Interview	To identify the attributes of a 'good' physiotherapist and	<ul style="list-style-type: none"> • Good or poor physiotherapist communication and interpersonal skills (listening, empathy, builds trust, caring, friendly, inspires confidence) 	4 & 6

							characteristics of 'good' and 'bad' experiences in private practice physiotherapy from patient's perspective	<ul style="list-style-type: none"> • Education and explanations provided • Physiotherapist professional behaviour (appropriate skills and knowledge) • Physiotherapist organisational ability (punctuality) • Service characteristics (diagnostic and treatment expertise, pleasant and welcoming environment, convenience and accessibility) 	
--	--	--	--	--	--	--	--	---	--

CASP-Critical Appraisal Skills Program; CLBP-chronic low back pain; LBP-low back pain; MSK-musculoskeletal; NP-neck pain; HEP-home exercise program; NPMP-Norwegian psychomotor physiotherapy

Data synthesis and analysis

A thematic synthesis approach was used to gather information and identify all themes. It is the most appropriate approach for qualitative meta-synthesis. The inductive analysis by Sandelowski and Barroso (2007) was adapted and used three stages;

- I. Extraction of findings and coding of findings for each article.
- II. Grouping of findings (codes) according to their topical similarity to determine if findings confirm, extend, or refute each other.
- III. Abstraction of findings—Analysing the grouped findings to identify additional patterns, overlaps, comparisons, and redundancies to form a set of concise statements, which capture the content of findings.

All stages were performed simultaneously as opposed to sequentially, as recommended (Sandelowski and Barroso 2007). All data under the headings “results/conclusions” were read several times line by line to gain an idea of the topics. Relevant quotes were copied and pasted into a word document and these quotes were then analysed and organised into codes and groupings. By a process of constant comparative analysis (Corbin and Strauss 1994), emerging groupings from early codings were checked with ongoing coding and used to guide later coding. Final groupings were reviewed to ensure codings were similar in all groups and that no potential groupings were missed during the process. The aforementioned process was simultaneously performed by two authors independently in order to ensure against any biases influencing the analysis and coding of themes, with any disagreements resolved using consensus, and consultation with another author.

Consideration of Systematic Review’s Trustworthiness

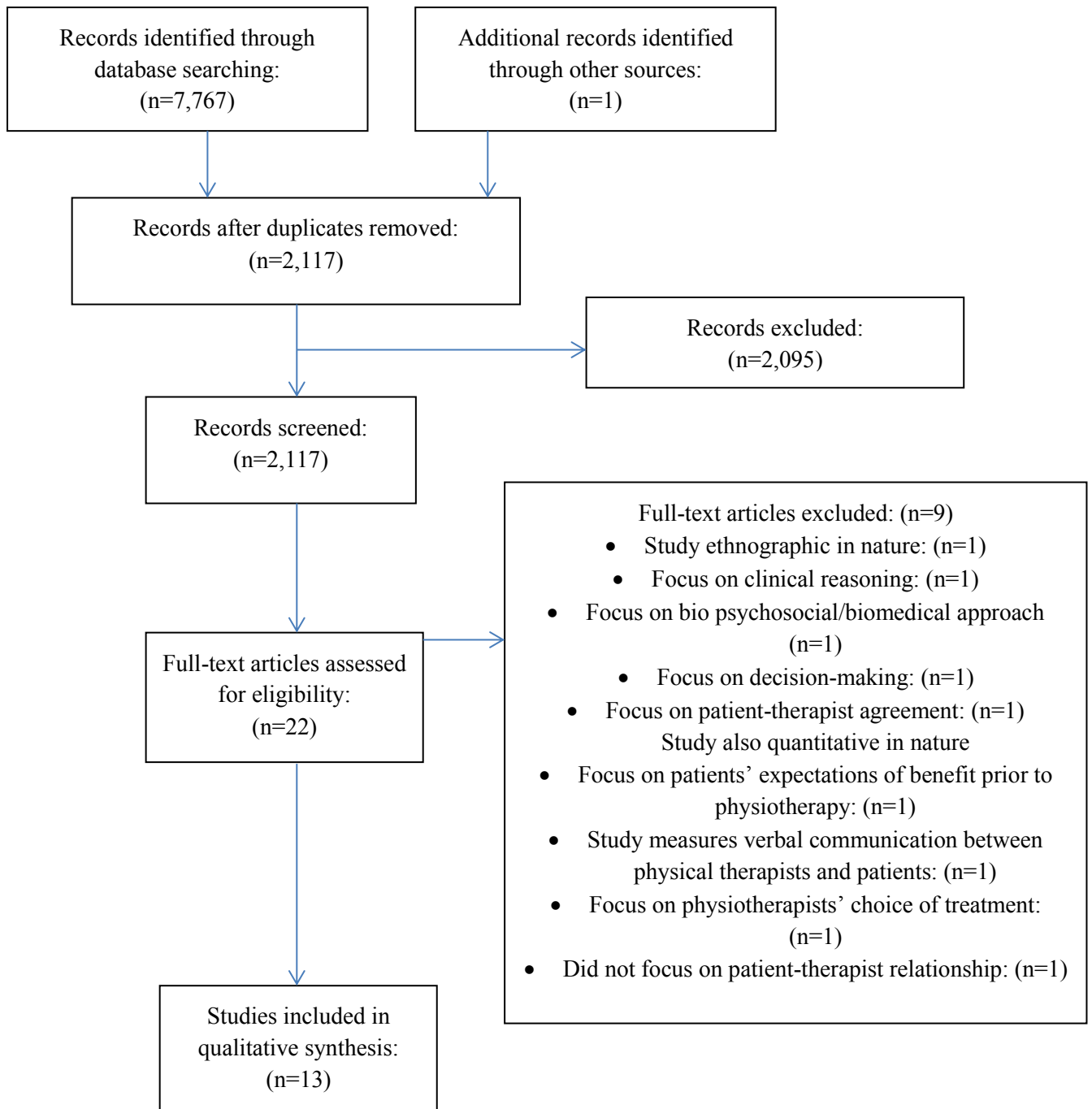
The authors of this study are clinical and research physiotherapists. Several different authors were involved in different stages of the review—from designing the initial search strategy, to the coding, grouping and abstraction processes. All authors have experience in performing qualitative research (Synnott *et al.* 2015).

Results

Identification of Studies

Figure 15 summarises study identification. 7,768 journal-articles were retrieved. One was retrieved from a reference list, while the remaining were retrieved from the databases. 5,651 duplicate journal-articles were removed. 2,117 journal-articles (titles and abstracts) were screened. Twenty-two journal-articles were retrieved after screening the abstracts, of which nine did not meet the inclusion-criteria. Thirteen journal-articles were included. A total of 253 patients and 78 physiotherapists were interviewed in the 13 studies. The authors were consistent in the number of studies retrieved and included.

Figure 15. Study III Flow Diagram



Quality Assessment

The CASP criteria of trustworthiness unmet by each study are presented in Table 6. The authors were consistent in the scoring of the CASP criteria for each study. Eight studies failed to meet criterion 6, for not considering the researcher-participant relationship. Six studies failed to meet criterion 7, for not considering ethical issues. Three studies failed to meet criterion 4, for not justifying the recruitment strategy. Four studies failed to meet criterion 3, for not justifying the research design, while another four studies failed to meet criterion 5, for not providing thorough information on data collection. One study failed to meet criterion 8, as the data analysis was not sufficiently rigorous. Therefore, due to some studies not meeting the criteria, the credibility, transferability and dependability of the results may have been affected.

Identification of Codes/Themes

Initial coding of the eligible journal articles resulted in 12 codes, which were reduced and organised into four themes (Table 7 and Table 8). These themes were: Physiotherapist Interpersonal and Communication Skills; Physiotherapist Practical Skills; Individualised Patient-Centred Care and Organisational and Environmental Factors (Figure 16).

Figure 16. Systematic Review Themes

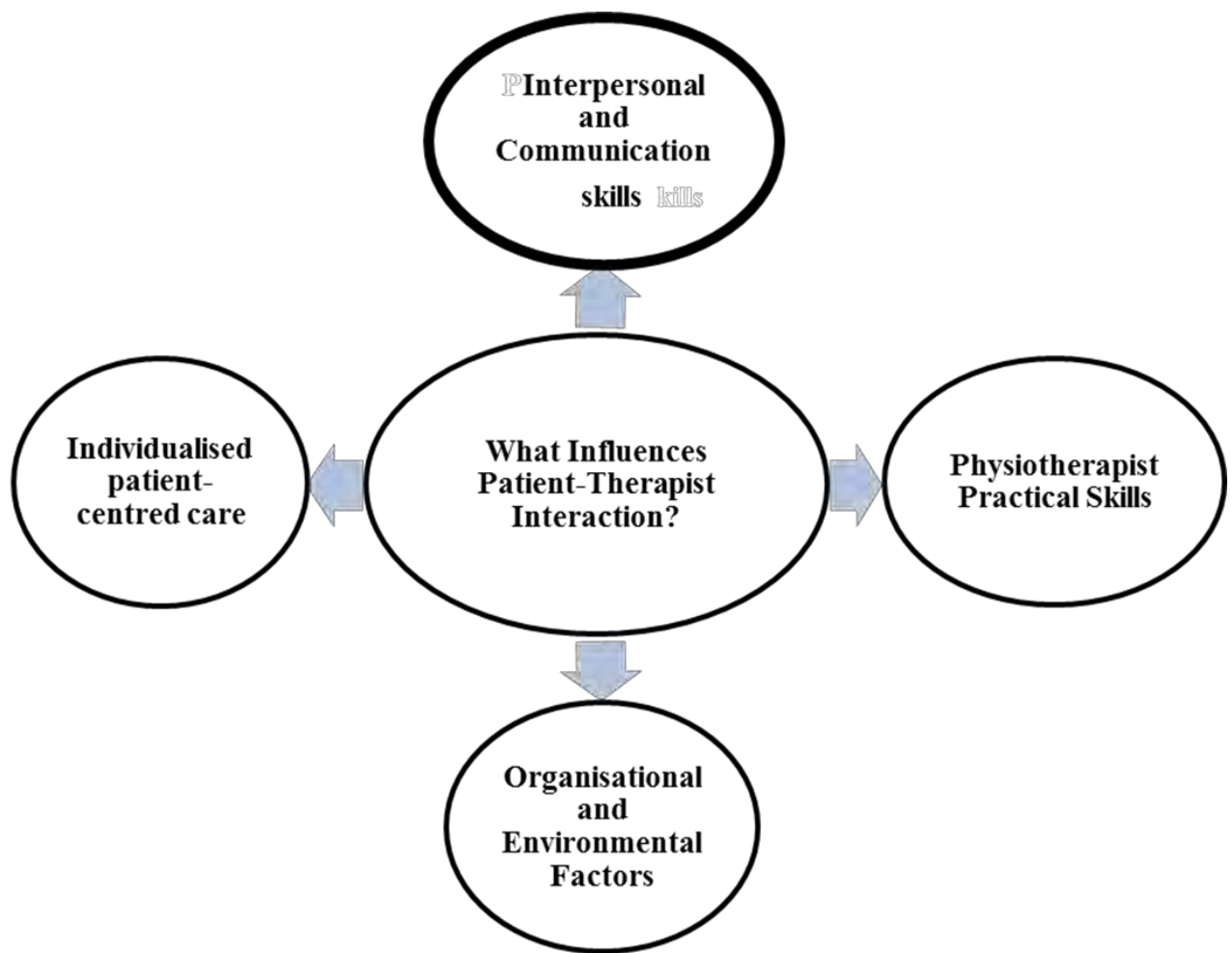


Table 7. Frequency with which themes and codes were identified across the studies

Themes	Codes	Physiotherapist/ Patient	No. of statements	No. of articles	
Physiotherapist interpersonal and communication skills	Listening	Physiotherapist	7	4	
		Patient	12	6	
	Empathy	Physiotherapist	6	3	
		Patient	7	5	
	Friendliness	Physiotherapist	4	3	
		Patient	8	5	
	Encouragement	Physiotherapist	0	0	
		Patient	9	4	
	Confidence	Physiotherapist	2	1	
		Patient	4	3	
	Non-verbal communication	Physiotherapist	2	2	
		Patient	2	2	
	Physiotherapist practical skills	Patient education	Physiotherapist	2	1
			Patient	25	8
Physiotherapist expertise and training		Physiotherapist	4	2	
		Patient	6	6	
Individualised patient-centred care	Individualised	Physiotherapist	11	2	
		Patient	15	6	
	Taking patient opinion and preference into consideration	Physiotherapist	3	1	
		Patient	0	0	
Organisational and environmental factors	Time	Physiotherapist	9	3	
		Patient	7	6	
	Flexibility with patient appointments & care	Physiotherapist	1	1	
		Patient	5	2	

Table 8. Identification of themes from initial coding

Themes	Codes
Physiotherapist Interpersonal and Communication Skills	1.Listening 2.Empathy 3.Friendliness 4.Encouragement 5.Confidence 6.Non-verbal communication
Physiotherapist Practical Skills	1.Patient education 2.Physiotherapist expertise and training
Individualised, Patient-Centred Care	1.Individualised care 2.Taking patient opinion and preference into consideration
Organisational and Environmental Factors	1.Time 2.Flexibility with patient appointments and care

Description of Results

Theme 1: Physiotherapist interpersonal and communication skills

Active Listening

One of the most common aspects to emerge regarding physiotherapists' communication skills was active listening (Gyllensten *et al.* 1999, Potter *et al.* 2003, Gard 2007, Hills and Kitchen 2007, Cooper *et al.* 2008, Harman *et al.* 2011, Kidd *et al.* 2011, Oien *et al.* 2011, Peiris *et al.* 2012). Both physiotherapists and patients felt that it was important for physiotherapists to listen and to allow patients to tell their stories (Gyllensten *et al.* 1999, Potter *et al.* 2003, Gard 2007, Hills and Kitchen 2007, Cooper *et al.* 2008, Harman *et al.* 2011, Kidd *et al.* 2011, Oien *et al.* 2011, Peiris *et al.* 2012). This allowed a bond to develop between the patient and the therapist as the patients felt that they were valued (Potter *et al.* 2003, Kidd *et al.* 2011, Oien *et al.* 2011, Peiris *et al.* 2012). Patients were unhappy when they were interrupted and could not tell their story (Potter *et al.* 2003, Hills and Kitchen 2007, Cooper *et al.* 2008). Patients also felt that not just listening, but understanding what the patient was saying was very

important (Potter *et al.* 2003, Oien *et al.* 2011, Peiris *et al.* 2012). Some physiotherapists felt that listening was such an important facilitator of a positive patient-therapist interaction that they should be taught to improve their listening skills (Harman *et al.* 2011).

Empathy

Another significant factor mentioned by physiotherapists and patients as necessary to develop a positive interaction was empathy (Gyllensten *et al.* 1999, May 2001, Gard 2007, Cooper *et al.* 2008, Kidd *et al.* 2011, Oien *et al.* 2011, Peiris *et al.* 2012, Del Bano-Aledo *et al.* 2014). Physiotherapists viewed empathy as a fundamental component of the patient-therapist relationship (Gyllensten *et al.* 1999, Gard 2007, Cherry-Bukowiec *et al.* 2011, Kidd *et al.* 2011). They felt that the treatment should take into consideration the pain and suffering the patient has endured (Gard 2007, Oien *et al.* 2011). Patients appreciated when the therapist understood what patients had to suffer and didn't just treat them as if the pain they had was a minor irritation. Patients felt it was important for therapists to realise how much of an impact pain could have on the patients' lives and for therapists to empathise with them about this (May 2001, Kidd *et al.* 2011, Del Bano-Aledo *et al.* 2014). Conversely, lack of empathy was a major barrier to a positive interaction and patients did not develop a bond with therapists who could not empathise with them (Cooper *et al.* 2008).

Friendliness

Patients believed that being able to chat to their physiotherapist in a friendly manner was important for positive interaction (Potter *et al.* 2003, Gard 2007, Kidd *et al.* 2011, Oien *et al.* 2011, Peiris *et al.* 2012, Del Bano-Aledo *et al.* 2014). Talking with the physiotherapist in an open way helped deepen the relationship between the patient and the therapist. Patients mentioned that a pleasant greeting from their therapist every day encouraged further interaction (Potter *et al.* 2003, Kidd *et al.* 2011). Both physiotherapists and patients mentioned that having a sense of humour was another way to develop a positive relationship (Gyllensten *et al.* 1999, Potter *et al.* 2003). Patients found it difficult to engage with therapists when they were not as friendly and the interaction suffered as a consequence (Hills and Kitchen 2007, Del Bano-Aledo *et al.* 2014).

Encouragement

Motivation and encouragement helped patients feel that the therapist cared about them and that they had a strong relationship with their therapist (Escolar-Reina *et al.* 2010, Oien *et al.* 2011, Peiris *et al.* 2012, Del Bano-Aledo *et al.* 2014). This was important for many reasons as the encouragement motivated some to comply with the prescribed rehabilitation and strive to improve (Escolar-Reina *et al.* 2010, Kidd *et al.* 2011, Peiris *et al.* 2012, Del Bano-Aledo *et al.* 2014). The reassurance also provided emotional support to patients, which further deepened the bond between the patient and the therapist as they shared personal feelings and experiences (Del Bano-Aledo *et al.* 2014).

Confidence

Patients reported that feeling confident in their therapist was an important factor and meant that they could respect their therapist and trust their opinion (May 2001, Potter *et al.* 2003, Gard 2007, Kidd *et al.* 2011). Physiotherapists stated that over time patients will become confident in their therapists and develop a sense of trust which will enhance the interaction between patients and therapists (May 2001, Gard 2007, Kidd *et al.* 2011). However, some patients felt that their physiotherapist was too confident and behaved in an arrogant manner, which was a significant barrier to a positive patient-therapist interaction (Potter *et al.* 2003).

Non-verbal communication

Patients and physiotherapists acknowledged that non-verbal communication was a vital part of communication skills (Gyllensten *et al.* 1999, May 2001, Potter *et al.* 2003, Harman *et al.* 2011). Patients expressed that the therapist acting in what they felt was an appropriate manner made them feel more comfortable with their therapist (May 2001, Potter *et al.* 2003). Physical contact between the patient and therapist also enhanced the patient-therapist interaction according to both physiotherapists and patients (Potter *et al.* 2003). Physiotherapists believed that it was very important to pay attention, not just to what the patient said, but the manner and behaviour of the patient as they were talking (Gyllensten *et al.* 1999, Harman *et al.* 2011).

Theme 2: Physiotherapist practical skills

Patient education

A physiotherapist skill that patients felt enhanced the patient therapist interaction was the ability to provide a simple, clear explanation (Gyllensten *et al.* 1999, May 2001, Potter *et al.* 2003, Gard 2007, Cooper *et al.* 2008, Escolar-Reina *et al.* 2010, Kidd *et al.* 2011, Peiris *et al.* 2012, Del Bano-Aledo *et al.* 2014). Patients valued an easy explanation of what their problem was, how they could help them and why the therapist was prescribing certain exercises (Gyllensten *et al.* 1999, May 2001, Cooper *et al.* 2008, Escolar-Reina *et al.* 2010, Kidd *et al.* 2011, Del Bano-Aledo *et al.* 2014). Patients felt more comfortable when they knew what their treatment plan was and felt interaction with their therapist was enhanced as a result (May 2001, Cooper *et al.* 2008, Escolar-Reina *et al.* 2010, Kidd *et al.* 2011, Del Bano-Aledo *et al.* 2014). On the other hand, patients did not like when the education given to them was technical and felt this impacted negatively on the relationship (Potter *et al.* 2003, Gard 2007, Hills and Kitchen 2007, Cooper *et al.* 2008, Escolar-Reina *et al.* 2010, Del Bano-Aledo *et al.* 2014).

Physiotherapist expertise and training

Patients believed it was vital that physiotherapists possessed excellent technical ability and skills (May 2001, Potter *et al.* 2003, Gard 2007, Cooper *et al.* 2008, Kidd *et al.* 2011, Peiris *et al.* 2012, Del Bano-Aledo *et al.* 2014). This enhanced the trust between the therapist and patient, and patients felt they could rely on their therapist which helped develop a positive interaction (May 2001, Cooper *et al.* 2008, Kidd *et al.* 2011, Peiris *et al.* 2012, Del Bano-Aledo *et al.* 2014). Physiotherapists echoed this belief and stated that it was imperative that they continue to develop their practical skills so that they can manage their patients effectively and continue to improve the relationship (Gyllensten *et al.* 1999, Gard 2007).

Theme 3: Individualised patient-centred care

Individualised

Patients reported that they felt a stronger bond with their therapist when their treatment was individualised and related specifically to their presentation (May 2001, Potter *et al.* 2003, Hills and Kitchen 2007, Del Bano-Aledo *et al.* 2014). Patients appreciated when their therapist made an effort to adjust the treatment when patients experienced problems and made it easier for them (May 2001, Potter *et al.* 2003, Hills and Kitchen 2007, Del Bano-Aledo *et al.* 2014). Patients who did not receive individual care and reported being treated like just another patient felt they did not have a positive interaction (Potter *et al.* 2003, Gard 2007, Hills and Kitchen 2007, Cooper *et al.* 2008, Escolar-Reina *et al.* 2010). Physiotherapists also acknowledged the need to provide individual care for each patient and to answer any specific questions they may have as opposed to providing generic information (Gard 2007, Harman *et al.* 2011).

Taking patient opinion and preference into consideration

Physiotherapists mentioned that it was important to consider the patient's point of view and opinions (Gyllensten *et al.* 1999). This encouraged patients to engage in the treatment process and interact with their therapist (Gard 2007). It also showed patients that their opinions were important to the therapist (Gyllensten *et al.* 1999). This encouraged a better interaction between the therapist and patient and helped form a stronger bond (Gyllensten *et al.* 1999). Patients found it annoying when their therapists ignored their preferences and abilities when prescribing exercises which negatively impacted on the interaction (Potter *et al.* 2003, Cooper *et al.* 2008, Peiris *et al.* 2012).

Theme 4: Organisational and Environmental Factors

Time

Many physiotherapists perceived that giving their patients time to describe their problem, and having the time to be listened to, as an essential factor in positive patient-therapist interaction

(Gyllensten *et al.* 1999, Dean *et al.* 2005, Gard 2007). Some patients did not feel that they had enough time with the physiotherapist and that they had to wait a long time to get an appointment (Potter *et al.* 2003, Hills and Kitchen 2007). Some patients mentioned that they would like more time with the physiotherapist to discuss their treatment as they were unsure about some aspects (Hills and Kitchen 2007, Cooper *et al.* 2008, Escolar-Reina *et al.* 2010). Patients appreciated having the time to sit down and interact with someone and not being rushed during appointments (Dean *et al.* 2005).

Flexibility with patient appointments and care

Patients appreciated when the physiotherapists were flexible when setting up patient appointments (Gyllensten *et al.* 1999, Potter *et al.* 2003, Hills and Kitchen 2007). Patients liked when they could arrange appointments which did not disrupt their days and felt grateful to their therapist for accommodating their needs (Potter *et al.* 2003, Hills and Kitchen 2007). Patients also felt that it was very useful being able to contact their physiotherapists following their treatment and get some advice (Potter *et al.* 2003, Hills and Kitchen 2007). Patients felt reassured that they could talk to their therapist when they were uncertain about some activities and this encouraged a stronger interaction between the therapist and patient (Hills and Kitchen 2007).

Discussion

This is the first systematic review to investigate physiotherapists' and patients' perceptions of factors that influence patient-therapist interaction in musculoskeletal settings. Four themes; Physiotherapist interpersonal and communication skills; physiotherapist practical skills; individualised patient-centred care; and organisational and environmental aspects were identified as the main factors thought to influence patient-therapist interactions. The presence or absence of these factors may act to positively or negatively influence interactions.

Physiotherapists and patients both acknowledged the importance of the physiotherapists' communication and interpersonal skills. Patients appreciated a physiotherapist who listened, who was empathetic, friendly, humorous, confident, encouraging and had a good 'bedside manner'. These findings are in line with other qualitative studies on healthcare professionals (HCPs) relationships with patients (Lærum *et al.* 2006, Strutt *et al.* 2008, Lin *et al.* 2014, Oosterhof *et al.* 2014). For example, Laerum *et al.*

which investigated patients' opinions of medical specialists found that being "seen, heard and believed" was crucial to the quality of the interaction. In particular, patients wanted professionals that expressed interest in what they said and who showed signs of empathy, active listening and understanding of their problem. Similarly, Oosterhof et al. which explored factors that are associated with a successful treatment outcome in chronic pain patients and professionals participating in a multidisciplinary rehabilitation program, reported that patients wanted to be taken seriously and have an open interaction with HCPs. An open interaction was explained as the professional having a calm, personal manner and being able to listen well. The lack of these two components was reported to be associated with a failure in rehabilitation (Oosterhof *et al.* 2014). This was strongly evident in the studies included in the current review. In addition, a clinical ethnographic study (Lin *et al.* 2014) revealed that CLBP patients felt communication with HCPs was enhanced by factors such as friendliness, empathy, respect and a more conversational and relaxed style of communication. Furthermore, Strutt et al. revealed similar themes in an osteopathic training clinic with patients considering empathy (caring, reassuring, listening, and continuity), atmosphere (friendly, relaxed, courteous) and manner (gentle, holistic) as crucial to their interaction with HCPs and their treatment satisfaction. Therefore, across numerous qualitative studies in different healthcare settings, communication and good interpersonal skills are perceived as vitally important to interaction, treatment success and satisfaction. In fact, Williams (1997) reported that within the medical-field, approximately 80% of patient-complaints are thought to arise secondary to a breakdown in communication. Interestingly, no study in this review explored causes of such breakdown in communication. For example, no study mentioned traits of patients that may prevent interaction, (e.g. patients thought to be annoying or angry) (Synnott *et al.* 2015). It is no surprise that there is increasing emphasis placed on communication skills training in physiotherapy (Shannon and Hillsdon 2007, Parry and Brown 2009, Lonsdale *et al.* 2012). This review shows that good communication should be a fundamental part of every treatment encounter.

Physiotherapist practical skills were also highlighted to be of importance. Patient education (what the physiotherapist says) and expertise and training (what the physiotherapist does) were the main practical skills perceived to be significant. The importance of patient education is in line with other qualitative and quantitative literature. A recent systematic review (Pincus *et al.* 2013) concluded that cognitive reassurance (giving knowledge) is important for treatment outcomes and satisfaction in primary care settings. However, while

patient education was viewed as important by patients in this review, physiotherapists did not refer to its importance for interaction. Similarly, Laerum et al. found that explanations and knowledge was important to patients. In particular, it was important for patients to receive an understandable explanation of their condition. Effective education was deemed to be achieved when the patients got clear information in the form of simple explanations and metaphors. Such methods have been recommended by quantitative data (Gallagher *et al.* 2013, Stewart 2014) revealing the importance of analogies and metaphors in explaining pain to patients. Oosterhof et al. similarly outlined that patients appreciated a thorough explanation of any assessments or investigations from HCPs. Patients were satisfied when they had a similar shared understanding of their pain with their HCPs. A clear recognisable explanation enabled understanding of pain and the ability to explain it to others. Patients also required information about how to manage their pain and ways to cope to improve function. In addition, in another study (Lin *et al.* 2014), patients in an osteopathic clinic were dissatisfied with information about their pain if it did not meet their expectations of a good explanation or when information was provided with excessive medical terminology. Both were viewed as barriers to good communication. The same studies (Lærum *et al.* 2006, Lin *et al.* 2014, Oosterhof *et al.* 2014) revealed that education using complex medical jargon hindered interaction and successful rehabilitation. Discrepancies in the explanation of factors involved in pain between professionals and patients were not deemed to be advantageous to interaction and outcome. Furthermore, physiotherapists felt that their own limited knowledge of pain was a barrier to providing good patient education. While they mentioned knowledge as a barrier to communication, as mentioned earlier they did not see education as important for interaction. This may raise the issue of physiotherapist role and scope of practice and how physiotherapists think they cannot charge for education and need to use their skills to treat something else. This area has not been explored enough however and it is difficult to differentiate this from the review findings. Overall, given that patient understanding of pain is related to changing beliefs and better self-efficacy (Louw *et al.* 2011), good quality patient education is of crucial importance.

The finding that physiotherapist training and expertise is important is also in line with the literature. Peersman et al. which investigated patient's priorities in outpatient physiotherapy revealed that the physiotherapist being an expert in their professional field was the most important aspect for patients. Similarly, Strutt et al. found that physiotherapists have to be competent in their treatment approach and be thorough, knowledgeable and dedicated.

It is not possible to differentiate from the findings of this review whether it is actually greater technical expertise and technical skills which are needed, or merely the perception that physiotherapists are technical experts which is important.

This review found that it was also important that physiotherapists individualise treatment to the patient and take patient opinions and preferences into account. This is in line with literature showing that patient health outcome and patients' satisfaction benefits from a patient-centred approach. Laerum *et al.* which explored patients' opinions of a good consultation with medical HCPs highlighted that patients appreciated patient-centred management where the professional actively sought the patients' perspective in terms of thoughts and expectations. Similarly, Oosterhof *et al.* found that patients were dissatisfied when they were not involved in the treatment planning with HCPs. Quantitative data has also displayed that identification of patient needs, goals and expectations affects outcome (Mondloch *et al.* 2001, Verbeek *et al.* 2004, Linde *et al.* 2007). Interestingly, while physiotherapists mentioned the importance of taking patient preferences into account, no study in this review mentioned patients valuing this component. This is contrary to guidelines encouraging patient preferences for treatment in management. It may be indicate that patients are happy if the treatment chosen makes sense in terms of their main problems and presentation. In fact, some recent trials focussing on individualising and tailoring treatment to the patient presentation and needs have shown positive findings (Asenlof *et al.* 2005, Hill *et al.* 2011, Vibe Fersum *et al.* 2013). Since quantitative and qualitative data highlight the potential importance of individualising treatment, musculoskeletal physiotherapy may benefit from greater emphasis on delivering an individualised approach together with good communication and education.

Organisational and environmental aspects of physiotherapy were also a main theme in this review. Patients were generally dissatisfied about a lack of organisation regarding time, appointments and appropriate resources/facilities. This is in line with other literature on patient-therapist interactions (Lærum *et al.* 2006, Oosterhof *et al.* 2014). For instance, Oosterhof *et al.* revealed that patients reported cancelled appointments, professionals arriving late, changes in the treatment programme which were not implemented or explained adequately hindered interactions and outcomes. Similarly, Laerum *et al.* found that patients were dissatisfied when there was a lack of information provided about the layout of the treatment session. In a large survey (Potter *et al.* 2003) of HCPs, including 2,793 physiotherapists, 60% reported they did not have enough time to 'treat patients to their

satisfaction'. Other patients commented that the physiotherapist was 'rushed' which might be interpreted by patients as a lack of interest in them (Harrison and Williams 2000). Patient-satisfaction has been previously related to accessibility, availability and convenience (Fox and Storms 1981).

Strengths and Limitations

A key strength of this review is that the research question is highly relevant to the physiotherapy profession. With the emerging international consensus that musculoskeletal pain is a multidimensional disorder associated with a complex interaction of factors across the biopsychosocial spectrum that can be resistant to change (Karjalainen *et al.* 2003, Nijs *et al.* 2013), research is increasingly encouraging clinicians to harness both "specific" and "non-specific" aspects of treatment to improve outcome, with patient-therapist interactions among the most important of these "non-specific" factors. High quality quantitative data reveal that a positive patient-therapist interaction can positively influence treatment outcomes (Hall *et al.* 2010, Pinto *et al.* 2012, Ferreira *et al.* 2013b, Fuentes *et al.* 2014). The findings of this review will inform physiotherapists about important factors that may need consideration when enhancing interaction.

Only studies published in English were included. Grey literature was excluded from the review as we wanted to include only studies which have been peer-reviewed. We acknowledge that potentially relevant studies could have been missed, however this method has been used by us in a similar qualitative systematic review (Synnott *et al.* 2015). The CASP quality assessment was not assessed for reliability, however studies were rated independently and agreement was reached for all. This review did not consider the "specific" interventions provided during treatment, as this was not the focus of this review. There is no suggestion that the specific treatment used is irrelevant, merely that the effectiveness of any specific treatment may be enhanced by better patient-therapist interactions. It must be acknowledged that this review has only identified factors which are perceived to be related to patient-therapist interaction. Further research is needed to examine whether these factors are actually related to the quality of these interactions or indeed patient outcomes.

Clinical Implications

Addressing factors that are thought to influence patient-physiotherapist interactions may enhance the experience of musculoskeletal physiotherapy for patients and improve adherence and outcomes. Physiotherapists should be aware that these factors can act as facilitators of, and barriers to, positive interaction. While it could be argued that using these factors effectively could be time consuming and thus costly in the short-term due to longer waiting lists, adopting these factors could be beneficial in the long-term through promoting better adherence and better patient outcomes. Ultimately, the responsibility lies with the physiotherapist, healthcare service providers, and wider society, to make time available to listen to patients' stories and provide the resources necessary to successfully treat patients. Given the higher number of patients to be seen by physiotherapists, they may need to adopt creative methods of dealing with long waiting-lists or organisational aspects which affect patient-therapist interaction. This could involve the use of telephone triaging (Taylor *et al.* 2002) or the use of tools that assess the quality of patient-therapist interaction such as the Working Alliance Inventory and Communication Assessment Tool (Hatcher and Gillaspay 2006, Makoul *et al.* 2007).

This review revealed a disparity between physiotherapist and patient views towards the importance of education, with patients rating it as highly important and physiotherapists failing to see its benefit as a determinant of interaction quality. This is a potential concern in management and may reveal physiotherapists' view of their profession; that they need to deliver a particular intervention, as opposed to a greater emphasis on listening and educating patients. Given the high importance placed on education by patients, physiotherapists need to prioritise this in their management as a strategy to enhance adherence and outcomes. The provision of training courses in the cognitive and affective domains of patient-physiotherapist interactions, improving physiotherapist communication skills and the ability to educate and take an individualised approach to treatment may enhance patient-physiotherapist interactions.

Further research in clinical settings is required to observe whether physiotherapists account for these factors in their interactions. It would be also interesting to evaluate whether training programmes specifically targeting the factors identified in this review can have an effect on treatment delivery and outcome, when compared to an intervention that does not acknowledge these factors.

Conclusion

Physiotherapists and patients believe physiotherapist communication and interpersonal skills, physiotherapist practical skills, individualised care and organisational and environmental factors have a key influence on patient-therapist interaction in musculoskeletal settings. The presence or absence of any of these factors may act as a facilitator of, or barrier to, the patient-therapist interaction. Further study is needed to examine which of these factors are best related to patient-therapist interactions and clinical outcomes. However, increased emphasis on communication, education, individualised care and attention to organisational and environmental factors could at the very least enhance the perceived interaction between patients and physiotherapists.

Key points: Chapter 2

The general aim of the three studies discussed in Chapter 2 was to examine the most effective type of content and mode of delivery for NSCLBP interventions. Study I examined intervention content, while Study II and III examined mode of delivery. Study I was a systematic review and meta-analysis that examined the comparative effectiveness of physical, behavioural/psychologically informed and combined interventions for reducing pain and disability in NSCSP. Eighteen of the 24 included studies were on NSCLBP. The results revealed no clinically significant differences between interventions for reducing pain and disability neither in NSCSP nor separately for NSCLBP or chronic NP. Study II was a systematic review and meta-analysis that examined the comparative effectiveness of individual and group physiotherapy interventions that incorporated exercise for reducing pain and disability in MSCs. Seven of the 14 included studies were on NSCLBP. While group interventions were slightly more effective, overall there were no clinically significant differences between group and individual interventions in the meta-analysis. Study III was a systematic review and qualitative meta-synthesis that examined patient and physiotherapist perceptions of factors that influence patient-therapist interaction in musculoskeletal settings. Eleven of the 13 eligible studies included people with NSCLBP. The results revealed that physiotherapist communication and interpersonal skills, physiotherapist practical skills, individualised patient-centred care and organisational and environmental factors were perceived as important in influencing the patient-therapist interaction.

Some specific implications of the studies in this chapter, are worthy of consideration;

- Given that NSCLBP is a multidimensional disorder, associated with a complex interaction of factors across the biopsychosocial spectrum and that current conservative interventions display similar small effects (Study I), there may be a need for interventions to target multiple factors based on the unique individual needs of patients with NSCLBP.
- Since exercise-based interventions delivered on a group basis display similar effects to individual interventions (Study II), it is worth investigating whether a multidimensional intervention delivered on a group basis would be as effective as an individualised multidimensional intervention. The first RCT on individualised CFT

demonstrated statistically and clinically superior outcomes over manual therapy and exercise provided on an individual basis. However, comparing to an intervention more multidimensional in nature, for example a group multidimensional intervention may allow us elicit whether it is the (1) multidimensional content or (2) individualised component that is more important.

- Since physiotherapist interpersonal and communication skills, physiotherapist practical skills, the ability to provide individualised patient-centred care and organisational and environmental factors may influence the patient-therapist interaction (Study III), which in itself affects outcome; it may be worth maximising these factors to examine if they enhance outcomes.

Based on the results of this chapter, an RCT comparing the effectiveness of an individualised, multidimensional intervention to a group, multidimensional intervention was considered appropriate.

CHAPTER 3: An Individualised, Multidimensional intervention for managing non-specific chronic low back pain

This chapter includes two studies. One has been published in a peer reviewed journal (O'Keeffe *et al.* 2015b). The primary research question for this chapter is outlined in Table 9;

Table 9. Research question examined in Chapter 3

CHAPTER TITLE	RESEARCH QUESTION
Individualised, Multidimensional intervention (CFT) to manage NSCLBP	<u>Study V</u> : What is the clinical effectiveness of CFT compared to a group multidimensional intervention for NSCLBP?

STUDY IV: Individualised Cognitive Functional Therapy compared with a combined exercise and pain education class for patients with non-specific chronic low back pain: study protocol for a multicentre randomised controlled trial

O’Keeffe, M., Purtill, H., Kennedy, N., O’Sullivan, P., Dankaerts, W., Tighe, A., Allworthy, L., Dolan, L., Bargary, N. and O’Sullivan, K. (2015) British Medical Journal Open; 5(6):e007156. (Impact Factor: 2.271) <http://bmjopen.bmj.com/content/5/6/e007156.abstract>

Abstract

Introduction: Non-specific chronic low back pain (NSCLBP) is a very common and costly musculoskeletal disorder associated with a complex interplay of biopsychosocial factors. Cognitive Functional Therapy (CFT) represents a novel, patient-centred intervention which directly challenges pain related behaviours in a cognitively integrated, functionally specific and graduated manner. CFT aims to target all biopsychosocial factors which are deemed to be barriers to recovery for an individual patient with NSCLBP. A recent randomised controlled trial (RCT) demonstrated the superiority of individualised CFT for NSCLBP compared to manual therapy combined with exercise. However, several previous RCTs have suggested that class-based interventions are as effective as individualised interventions. Therefore, it is important to examine whether an individualised intervention such as CFT demonstrates clinical effectiveness compared to a relatively cheaper exercise and education class. The current study will compare the clinical effectiveness of individualised CFT with a combined exercise and pain education class in people with NSCLBP.

Methods and analysis: This study is a multicentre RCT. 214 participants aged 18-75 years, with NSCLBP for at least six months will be randomised to one of two interventions across three sites. The experimental group will receive individualised CFT and the length of the intervention will be varied in a pragmatic manner based on the clinical progression of participants. The control group will attend six classes which will be provided over a six-eight week period. Participants will be assessed pre-intervention, post-intervention and after six and 12 months. The primary outcomes will be functional disability and pain intensity. Non-specific predictors, moderators and mediators of outcome will also be analysed.

Ethics and dissemination: Ethical approval has been obtained from the Mayo General Hospital Research Ethics Committee (MGH-14-UL). Outcomes will be disseminated through publication according to the SPIRIT statement and will be presented at scientific conferences.

Trial registration: (ClinicalTrials.gov NCT02145728).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This will be the first randomised controlled trial (RCT) to compare the clinical effectiveness of a novel individualised treatment called cognitive functional therapy (CFT) with a combined exercise and pain education class in people with non-specific chronic low back pain (NSCLBP).
- Methodological qualities of the trial include; three intervention sites, blinded assessment and concealed allocation, an active comparison group, long-term follow-up, appropriate sample size calculation, treatment fidelity measures and a planned intention-to-treat analysis.
- Only patients with NSCLBP greater than six months will be included, and while inclusion and exclusion criteria are broad, the study results will not be generalizable to all people with low back pain (LBP).
- Therapist and patient blinding is not possible.

Introduction

Non-specific chronic low back pain (NSCLBP) is a very common and costly musculoskeletal disorder, resulting in a significant personal, social and economic burden (Hoy *et al.* 2012, Vos *et al.* 2013, Ma *et al.* 2014). There is strong evidence that NSCLBP is associated with a complex interaction of factors. These include physical factors (e.g. maladaptive postures and movement patterns, altered body perception, pain behaviours and deconditioning) (Dankaerts *et al.* 2006, Dankaerts *et al.* 2009, MacDonald *et al.* 2009, Martel *et al.* 2010, Bray and Moseley 2011), cognitive factors (e.g. unhelpful beliefs, catastrophizing, hypervigilance, maladaptive coping strategies, poor self-efficacy) (Sullivan *et al.* 2001, Woby *et al.* 2007b, Main *et al.* 2010, Darlow *et al.* 2012, Campbell *et al.* 2013, Wertli *et al.* 2014a), psychological factors (e.g. fear, anxiety, depression) (Bener *et al.* 2013, Vereckei *et al.* 2013, Zale *et al.* 2013, Wertli *et al.* 2014b), lifestyle factors (e.g. physical inactivity, sleep problems, chronic life stress) (Bjorck-van Dijken *et al.* 2008, Briggs *et al.* 2011, Kelly *et al.* 2011, Griffin *et al.* 2012), neuro-physiological factors (e.g. peripheral and central nervous system sensitisation) (Tsao *et al.* 2008, Luomajoki and Moseley 2011, Wand *et al.* 2011, Nijs *et al.* 2014, O'Sullivan *et al.* 2014) and social factors (e.g. socio-economic status, family, work, culture) (Mitchell *et al.* 2010, Lallukka *et al.* 2014). Despite this complex interaction of factors in NSCLBP, with many of these factors being potentially modifiable, most current interventions neither target multiple aspects of an individual's pain experience nor individualise the targeting of such factors for each patient (O'Sullivan 2012, Mafi *et al.* 2013). Therefore, it is not surprising that treatments such as manual therapy, exercise, medications, relaxation, cognitive behavioural therapy and acceptance and commitment therapy, while reducing disability and enhance quality of life to an extent, are not superior to each other and have a limited impact on pain in the long-term (Furlan *et al.* 2005, Hayden *et al.* 2005, Henschke *et al.* 2010, Sveinsdottir *et al.* 2012, Wang *et al.* 2012, Chaparro *et al.* 2013, Menke 2014).

Cognitive Functional Therapy (CFT) is a novel, patient-centred behavioural intervention which addresses multiple aspects in NSCLBP. This approach focusses on changing patient beliefs, confronting their fears, educating them about pain mechanisms, enhancing mindfulness of the control of their body during pain provocative functional tasks, training them to reduce excessive trunk muscle activity and change behaviours related to pain provocative movements and postures (O'Sullivan 2012). In a recent RCT among people with

moderate NSCLBP, this approach was significantly more effective than combining manual therapy and exercise (Vibe Fersum *et al.* 2013). Similar results were demonstrated for a high-risk group of patients with NSCLBP treated with CFT in a recent single-centre cohort study in Ireland (O'Sullivan *et al.* 2015). However, a range of RCTs have suggested that class-based treatments are as effective as individualised treatment in musculoskeletal pain populations (Fransen *et al.* 2001, Mannion *et al.* 2001b, Carr *et al.* 2005, Critchley *et al.* 2007, Chown *et al.* 2008, Cecchi *et al.* 2010, Gustavsson *et al.* 2010, Hudson and Ryan 2010, Unsgaard-Tondel *et al.* 2010, Ko *et al.* 2013, Lansinger *et al.* 2013, McLean *et al.* 2013), including NSCLBP. In addition, many people with chronic musculoskeletal pain, including NSCLBP, appear to be either over-treated or treated inefficiently, without this additional one-to-one intervention necessarily improving their outcome (Hill *et al.* 2011, Artus *et al.* 2014, Henry *et al.* 2014, Michaleff *et al.* 2014, Rantonen *et al.* 2014). Therefore, it is important to examine whether an individualised intervention such as CFT is demonstrative of clinical-effectiveness as compared to a relatively cheap comparison treatment such as a combined exercise and pain education class.

Objectives

Primary objective

The primary objective is to examine the clinical effectiveness of CFT, based on whether participants in the CFT arm report significant improvements in the short-, medium- and long-term on measures of functional disability and pain intensity, relative to those allocated to combined exercise and pain education classes.

Secondary objectives

The secondary objectives include examining whether CFT has a significant effect on costs relative to classes in the short-, medium- and long-term and examining mediators (back pain beliefs, fear, coping, self-efficacy, sleep, depression, anxiety, stress and treatment satisfaction) as well as moderators and predictors (demographic information (age, sex, duration of NSCLBP), socio-economic status, baseline risk of chronicity, number of pain areas and general health complaints) of treatment effect across both interventions.

Methods and analysis

Design and Setting

The design is a three site RCT comparing individualised CFT and a class-based intervention. The sites are two primary care centres (Ballina Primary Care Centre and Claremorris Primary Care Centre) and one public hospital (Mayo General Hospital) that receives referrals from both medical consultants in secondary care and primary care general practitioners (GPs) in Ireland. Any modifications to the protocol which may impact on the conduct of the study will require a formal amendment to the protocol. Such amendment will be agreed on by the project management committee (MOK, KOS, NK, POS, HP and NB), and approved by the relevant ethics committee prior to the implementation of the modifications. Minor administrative changes to the protocol will be agreed on by the project management committee, and will be documented in a memorandum.

Ethical Considerations

Ethical approval has been granted by the relevant hospital research ethics committee (MGH-14-UL). Written informed consent will be obtained from all participants included in the study. Participants will be informed that they are not obliged to take part in the study and are free to withdraw at any time, without any negative consequences on their future care. All efforts will be made to protect the privacy of the participants and to keep their names and personal information confidential at all times. This will be achieved by referring to all participant records and information only by their assigned research code. No significant adverse reactions are anticipated in the study, but these will be monitored. Both interventions will involve some exercise. This involves a very small risk of increased stiffness and soreness initially. However, all exercise will be performed at a speed and intensity under the participants own control. The suitability of exercise for the participants will be assessed at entry to the study by the treating physiotherapist.

Recruitment and Participants

Participants who are referred to the physiotherapy service in each site will be screened individually for 15-20 minutes. Participants meeting the eligibility criteria will be recruited. All participants will be given the option of receiving usual care physiotherapy (individual) or taking part in the study. Those interested in participating will be presented with written information about the study, including its aims and procedures. Here, it is clearly stated that there are two active intervention arms, and that based on current knowledge, it is not known which intervention is superior. The patients will provide written informed consent prior to randomisation. The inclusion/exclusion criteria are described in Table 10.

Table 10. Inclusion and exclusion criteria for study participation

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Aged between 18 and 75 • Chronic low back pain for at least six months duration • Score of 14% or more for disability on the Oswestry Disability Index (ODI) • Independently mobile (with or without aids), to be capable of participating in a rehabilitation programme • Be able to speak and understand English well enough to be able to complete the questionnaires independently 	<ul style="list-style-type: none"> • Primary pain area is not the lumbar spine (from T12- buttocks) • Leg pain as the primary problem (e.g. nerve root compression or disc prolapse with true radicular pain/radiculopathy, lateral recess or central spinal stenosis) • Less than six months after lumbar spine, lower limb or abdominal surgery • Pain relieving procedures such as injection based therapy (e.g. epidurals) and day case procedures (e.g. rhizotomy) in the last three months • Pregnancy • Rheumatologic/inflammatory disease (e.g. rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, lupus erythematosus, scheuermann’s disease) • Progressive neurological disease (e.g. multiple sclerosis, parkinsons disease, motor neuron disease) • Scoliosis (if considered the primary driver of pain) • Unstable cardiac conditions • Red flag disorders like malignancy/cancer, acute

	traumas like fracture (less than six months ago) or infection, spinal cord compression/cauda equine
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Treatment allocation and randomisation

To ensure concealment of allocation, patients will only be randomised to receive the individualised CFT or the class-based intervention after it is clear that they meet the inclusion criteria. Allocation will be picked from an opaque envelope. The envelope will contain two pieces of paper only. Participants will be asked to pick one piece of paper from the envelope. One piece of paper will have the letter “C” for class and the letter “I” for individual CFT. The number of participants who choose to withdraw from the study at this, or any other, stage will be recorded. Participant progress through the study is shown in Figure 17.

Baseline assessments

At the initial screening assessment when patients are screened for eligibility, all complete the ODI (Fairbank and Pynsent 2000) to ensure they meet the criteria for inclusion. If eligible, and participants consent to participate after random allocation, they then complete the remaining sections of the questionnaire before their first intervention session which is within two weeks of the date of screening. In the event that their appointment is longer than two weeks after the initial screening session, they will re-complete all the questionnaires on the day of the first intervention session. The second of these baseline assessments will be used as baseline. In the event an individual’s ODI is less than 14%, they will remain in study since they have already been randomised.

Interventions

All interventions will be provided by three physiotherapists (AT, LD, LA), with one physiotherapist working in each location. The treating physiotherapists have been trained to deliver the interventions to enhance standardisation of interventions. Training involved a blended learning approach, including interactive lectures and seminars, as well as clinical workshops where the management of NSCLBP as a multidimensional biopsychosocial disorder was discussed. Both interventions use a biopsychosocial approach. The specific training for the CFT intervention involved the treating physiotherapists (i) observing CFT-trained tutors (www.pain-ed.com) assess and treat real patients with NSCLBP using CFT, and (ii) assessing and treating patients with NSCLBP in front of the same CFT tutors. The specific training for the class-based intervention involved the development of a series of six classes, each including exercise and education. Discussions between the three treating physiotherapists and two of the study authors (KOS, MOK) will take place to ensure effective and consistent delivery across sites.

For both intervention arms, treating physiotherapists piloted the interventions until they were deemed competent to deliver the interventions. Treating physiotherapists were also provided with additional resources to support both the interventions, including written and web-based resources (e.g. www.pain-ed.com) regarding the biopsychosocial nature of pain, the limited role of imaging in NSCLBP, and the role of behaviour changes such as activity, stress management and sleep hygiene in managing NSCLBP.

Experimental intervention: Individualised Cognitive Functional Therapy (CFT)

The CFT intervention will be one-to-one, will involve hearing the full patient story regarding their pain, and the intervention will be targeted to meet the participants' individual needs. All participants randomised to this group will undergo a comprehensive one-to-one interview and physical examination by the treating physiotherapist. This detailed examination will be essential in order to broadly identify the modifiable multidimensional drivers of pain and disability (pain provocative cognitive, movement and lifestyle behaviours) for each participant (O'Sullivan 2005, Vibe Fersum *et al.* 2013, O'Sullivan *et al.* 2015).

During the interview, participants will be asked to provide information about their history of pain, pain area and nature, pain behaviour (aggravating/easing movements and

activities), their primary functional impairments, disability, activity levels, lifestyle behaviours and sleep patterns. Participants will be also questioned about their level of fear of pain and any avoidance of activities, work and social engagement. Their degree of pain focus, pain coping strategies, stress response and its relationship to pain, and their pain beliefs will also be established as will be any history of anxiety and depression. Finally, their beliefs and goals regarding management of their disorder will be ascertained (O'Sullivan 2005, Vibe Fersum *et al.* 2013, O'Sullivan *et al.* 2015).

The physical examination will involve analysis of the participants' primary functional impairments (e.g. pain provocative, feared and/or avoided movements and functional tasks as reported during the interview), in order to identify maladaptive behaviours including muscle guarding, 'abnormal' movements and postures, avoidant patterns and pain behaviours. They will also be assessed regarding their level of body control and awareness (body perception), as well as their ability to relax their trunk muscles and normalise pain provocative postural and movement behaviours, and the effect this has on their pain (O'Sullivan 2005, Vibe Fersum *et al.* 2013, O'Sullivan *et al.* 2015).

Treatment will be provided in the local physiotherapy department at each site. The initial session will last approximately one hour and follow-up sessions will range from 30 minutes to one hour. Treatment frequency will vary pragmatically with each patient, though it is expected that appointments will start weekly and reduce in frequency over time. Similarly, treatment duration will vary from approximately four to 16 sessions. While 16 is the anticipated upper limit of sessions, eight is the expected average. The duration, and number, of treatments will be recorded. Each patient will receive an individualised targeted intervention directed at changing their individual cognitive, movement and lifestyle behaviours considered to be provocative and maladaptive of their disorder (Dankaerts *et al.* 2007, Dankaerts *et al.* 2009, O'Sullivan 2012). There will be four main components to the intervention. These will be;

(1) A cognitive component will focus on the factors identified from the examination that are considered to contribute to their pain disorder. This will include discussing the multidimensional nature of persistent pain as it pertains to the individual, and how beliefs, emotions and behaviours (movement and lifestyle) can reinforce a vicious cycle of pain sensitisation and disability. The various factors of the vicious cycle will be outlined in a personalised diagram for each participant based on their findings from the examination. Where considered appropriate, patients will be advised to read resources and watch patient

videos on www.pain-ed.com and will be given leaflets on sleep, relaxation and mindfulness, the role of spinal imaging such as MRI scans and regarding exercise and physical activity if these are considered relevant to their pain presentation by the treating physiotherapist.

(2) Specific functional training will be designed to normalise maladaptive and provocative postural and movement behaviours as directed by the patient's individual presentation. This will involve a behavioural modification approach to rehabilitation where patients will be taught strategies aimed to enhance their body awareness and control in order to relax and modify postures and tasks they report as being pain provocative. Where considered appropriate, patients will be given audio resources (e.g. mindfulness cds) to facilitate this process.

(3) Targeted functional integration into daily life of activities which are avoided by, and/or provocative for, the patient. This will vary between individuals, but will likely include targeting activities such as rolling in bed, sitting, standing up from sitting, walking, bending and lifting.

(4) Physical activity and lifestyle advice. This will include promotion of gradually increasing physical activity based on their preference and presentation, advice on sleep hygiene, stress management strategies, and social re-engagement (O'Sullivan 2005, Vibe Fersum *et al.* 2013, O'Sullivan *et al.* 2015).

A key component underlying each of these four stages which may facilitate patients achieving a positive outcome will be maximising the contextual or “non-specific” aspects of treatment. This will include using motivational interviewing techniques (Chilton *et al.* 2012), as well as establishing and demonstrating empathy with the patient to enhance patient-therapist rapport and interaction (Fuentes *et al.* 2014). All instructions for participants will be written when deemed appropriate by the physiotherapist and/or requested by participants.

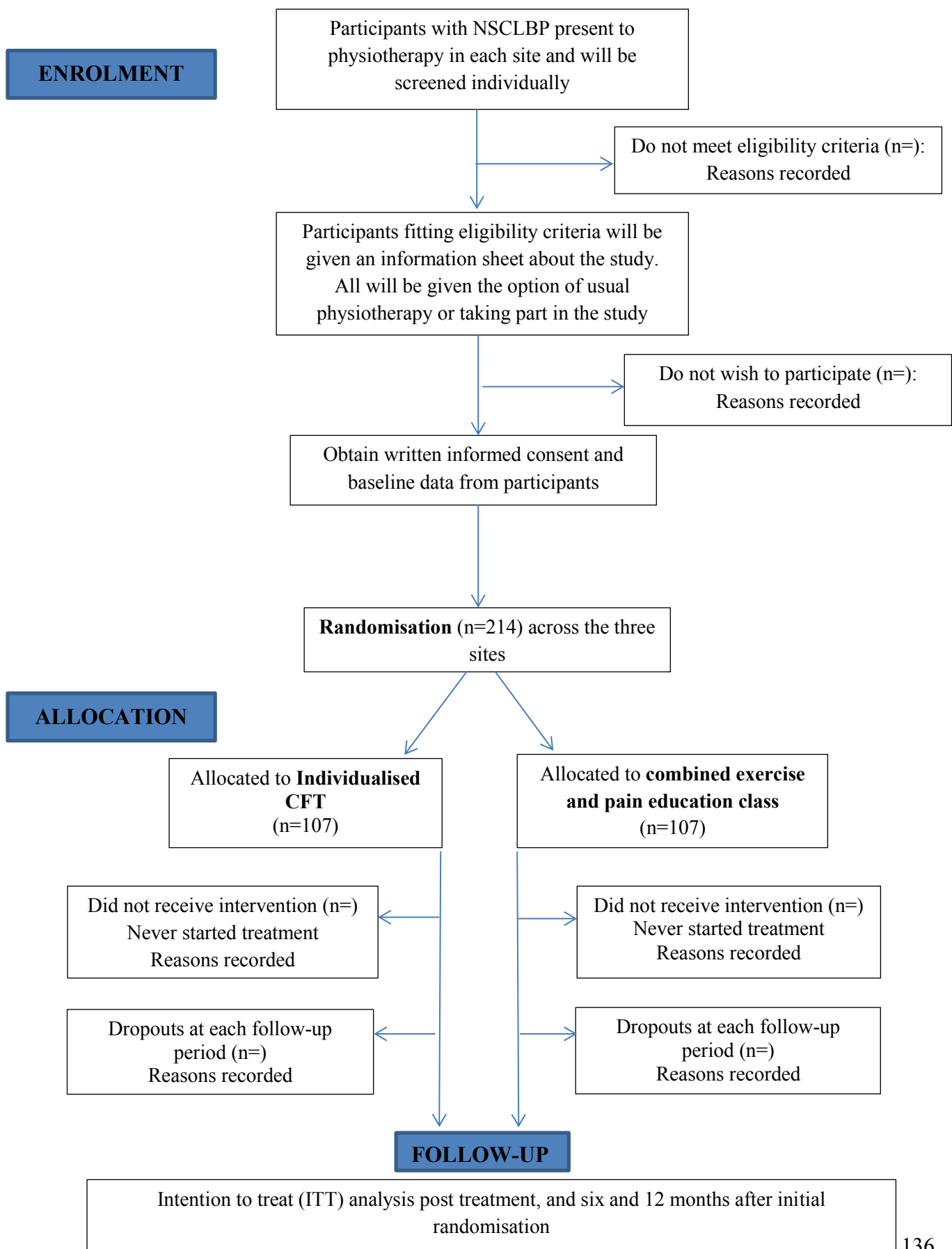
Control intervention: Combined exercise and pain education class

This class-based intervention will not involve individual assessment or consideration of the patient story. All participants in this class will receive the same intervention and it will not be specifically targeted to their individual needs.

The class-based intervention will consist of six classes over six to eight weeks, each lasting approximately one hour and 15 minutes, with up to ten participants in each class. It will have biopsychosocially orientated sessions involving education, exercise and relaxation/mindfulness. Everybody will have the opportunity to ask questions and answers will be provided for the whole class. It differs from the individualised CFT in that is not targeted to the individual, it does not involve one-to-one attention, and everybody gets the same advice and functional activation exercises. Each class will start with a 30 minute discussion, using a different focus/topic each week. The topics to be covered will include explaining contemporary understanding of pain and the role of the nervous system (Nijs *et al.* 2011), the multidimensional nature of NSCLBP and common myths about NSCLBP, posture and ergonomics, exercise, relaxation and sleep. All talks will involve the use of visual aids (e.g. slides, flipcharts) and a copy of the slides from every class will be provided to participants. The second part of the class will be a 40 minute gradually progressive exercise circuit, involving aerobic, flexibility and strengthening exercises, similar to the class-based intervention delivered in a previous RCT (Klaber Moffett *et al.* 1999). The exercises will be step-ups, squats, sit to stands, marching/jogging on spot, wall push-ups, hip lift/bridging, knees to chest/lumbar flexion, rolling knee to side/lumbar rotation, the cat stretch and the hip flexor lunge stretch. Participants will be instructed to do the exercises at their own desired pace. No special equipment will be needed. All participants will be given a copy of these exercises to do at home and will be encouraged to do them once a day. Finally, a five minute relaxation/mindfulness component will take place at the end of each class.

In addition, all participants will be advised to watch patient videos and read resources on www.pain-ed.com and will receive the aforementioned leaflets on sleep, relaxation and mindfulness, the role of spinal imaging such as MRI scans and on exercise and physical activity. Efforts will be made to enhance the “non-specific” aspects of treatment by creating an open atmosphere, encouraging patient interaction, engagement and opportunity for questions and input.

Figure 17. Study IV Flow Diagram



Outcome measures

All outcome measures will be self-reported and will be conducted pre-intervention, post-intervention as well as six and 12 months after randomisation. The primary outcome measures selected for this study are based on the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations for outcome measures for chronic pain clinical trials. The rate of attrition among the participants during their completion of the intervention will be recorded.

Primary outcomes

The two primary outcomes of interest will be functional disability and pain intensity. Functional disability will be measured using the ODI, a validated 10-item questionnaire (Fairbank and Pynsent 2000). Pain intensity will be assessed using the Numeric Rating Scale, a validated 0-10 scale (Jensen *et al.* 1999). Participants will be asked to rate their pain on average during the last week; 0 representing no pain and 10 representing pain as bad as you can imagine. Both will be assessed at all time-points (baseline, post-intervention, as well as six and 12 months after randomisation).

Secondary outcomes

The secondary outcome of interest will be costs. Treatments and tests received, hospitalisations and tests, medications, equipment, aids and informal care, travel costs, employment status and work absenteeism will be assessed. The number and length of treatment sessions will also be documented by the treating physiotherapists. This will be assessed at six and 12 months.

Mediators of outcome

- **Beliefs:** Beliefs about back pain will be assessed using the nine-item Back Beliefs Questionnaire (Bostick *et al.* 2013).
- **Fear:** this will be measured using the four item physical activity subscale of the Fear-Avoidance Beliefs Questionnaire (Waddell *et al.* 1993).

- **Coping:** this will be measured using the five item coping subscale of the Coping Strategies Questionnaire (Harland and Georgieff 2003).
- **Self-efficacy:** this will be assessed using the 10 item Pain Self-Efficacy Questionnaire (Di Pietro *et al.* 2014).
- **Sleep, depression and anxiety:** these will be assessed using the single item questions regarding these measures on the Subjective Health Complaints Inventory (Eriksen *et al.* 1999).
- **Stress:** this will be measured using the seven item stress subscale of the Depression, Anxiety and Stress Scale (Lovibond and Lovibond 2014).
- **Satisfaction:** participant satisfaction with treatment will be assessed using a single item from the 18-item Patient Satisfaction Questionnaire. “The care that I have been receiving here is just about perfect”. 1=Strongly Agree, 2=Agree, 3=Unsure, 4=Disagree, 5=Strongly Disagree (Marshall and Hays 1994).

Satisfaction will be assessed at post-intervention only while the remaining mediators will be assessed at all time-points (baseline, post-intervention, six, and 12 months follow-up).

Non-specific predictors and moderators of outcome

- **Demographic information:** Participants’ age, sex, duration of NSCLBP will be obtained.
- **Socio-economic status:** this will be assessed using the Socio-Economic Index (Rannestad and Skjeldestad 2012). This questionnaire provides information about education, employment status, income, ability to pay bills, self-perceived health and satisfaction with number of friends. While aspects of this (e.g. education) are unlikely to change, some of them (e.g. work status, self-perceived health) may actually be targets of treatment.
- **Risk of chronicity:** this will be measured using the 10 item short-form Orebro musculoskeletal screening questionnaire (Linton *et al.* 2011).
- **Number of pain areas:** this will be assessed using the Nordic Musculoskeletal Screening Questionnaire (Crawford 2007).

- **General Health:** general health complaints will be assessed using the 13-item, version of the Subjective Health Complaints Inventory (Eriksen *et al.* 1999) scored as simply the presence or absence of the 13 items.

Demographic information will be obtained at baseline only, while the remaining predictors and moderators will be assessed at all time-points.

Timing of outcome measurement

The aforementioned patient self-report outcomes will be collected at baseline (except satisfaction and costs) and immediately after the intervention by the treating physiotherapist. Costs will only be assessed six and 12 months after randomisation. Participants will then be sent copies of the same questionnaires by a blinded assessor (MOK) six and 12 months after their randomisation. If a participant does not respond to follow-up, they will be telephoned on up to two occasions each time to ask if they wish to complete the questionnaires.

Blinding

Questionnaires at all time-points will be self-completed by the patient. Single blinding will be achieved by having an independent blinded assessor perform the follow-up assessments after six and 12 months. Questionnaires will be posted back to the blinded assessor. The blinded assessor will not be treating any of the participants, nor be aware of their group allocation. The statistician conducting the primary data analysis will also be blinded to group allocation. Blinding of the treating physiotherapists and participants will not be possible because they will know the intervention arm to which they have been allocated.

Data and treatment fidelity

A fidelity evaluation where the treating physiotherapists are observed while assessing and treating actual patients from the RCT will be conducted. For every participant in the study, the type and number of treatments received will be recorded. In addition, there will be session-by-session documentation of treatment content for the CFT arm by the treating physiotherapist. Standardised and regular training, monitoring and feedback will be given to the

physiotherapists to facilitate successful delivery of both treatments. Physiotherapists will complete a series of standardised questionnaires assessing their beliefs and attitudes towards NSCLBP and pain presentations (Health Care Professionals Pain and Impairment Relationship Scale (Houben *et al.* 2005), The Pain Attitudes and Beliefs Scale For Physiotherapists (Mutsaers *et al.* 2012), The Practitioner Confidence Scale (Smucker *et al.* 1998), The Attitudes to Back Pain Scale in Musculoskeletal Practitioners (Pincus *et al.* 2006b) and The Neurophysiology of Pain Questionnaire) (Catley *et al.* 2013). The physiotherapists will also be asked to complete a clinical vignette (Bishop *et al.* 2008) and to provide demographic details, information about their physiotherapy training and general health. To assess quality of communication and interaction, some sessions from both intervention arms will be observed and audio recorded. These recorded sessions will also involve the physiotherapist, patient(s) and an observer completing the Working Alliance Theory of Change Inventory (Hall *et al.* 2012) and physiotherapists will complete the Communication Assessment Tool (Makoul *et al.* 2007).

Qualitative interviews will be done with 8-15 participants from each treatment arm, depending on data saturation. Stratified sampling for these patient interviews will take place and be based on reaching the minimal clinically important difference (MCID) of ODI (30%) (Bombardier *et al.* 2001) at six month follow-up. Participants will then be randomly selected and interviews will be conducted six to 12 months following randomisation to get their views on the care they received.

Statistical analysis

Descriptive statistics will be used to summarise participant characteristics in the individualised CFT and class-based intervention. An intention to treat analysis using linear mixed models will be used to compare pain intensity and functional disability between the intervention arms and account for the correlation within subject over time, while adjusting for differences in participant characteristics at baseline as appropriate. Sensitivity analyses and per protocol analysis will be used to explore whether adherence to the intervention influences the effect of the intervention on the primary outcomes. The analysis of the secondary outcomes will involve linear and nonlinear mixed models for continuous and categorical responses as appropriate. Variable selection techniques will be used to identify the most parsimonious set of participant characteristics for inclusion as explanatory variables in each

model. An analysis of the potential mediating effects of the secondary outcomes on treatment will be undertaken using the approach of Baron and Kenny (1986) (Baron and Kenny 1986). In addition, baseline variables will be assessed as non-specific predictors or moderators of treatment by including main and interaction terms in the models. The 5% level of statistical significance will be used throughout the analyses. In addition, the level of clinical significance will be also reported by comparing any changes in outcome measures to the recognized minimum clinically important difference (MCID) values (Bombardier *et al.* 2001) for standardized outcome measures. A responder to treatment is defined as a >30% improvement on the ODI (Bombardier *et al.* 2001). All data will be analysed using the IBM SPSS® Statistics V. 21 (Armonk, New York, USA) and R 3.1.1 (R Core Team, 2014). Data will be inputted by one researcher (MOK) and a second researcher will randomly double-check 10% of the inputted data to ensure accuracy.

A thematic analysis approach will be used to analyze the qualitative interviews. When all the audio recordings have been transcribed verbatim, the transcripts will be imported into NVIVO 10. The analytic process will be adapted from Sandelowski and Barroso (2007) (Sandelowski and Barroso 2007). It will involve the following 3 stages; (1) Extraction of findings and coding of findings for each interview, (2) Grouping of findings (codes) according to their topical similarity and (3) Abstraction of findings—analyzing the grouped findings to identify additional patterns, overlaps, comparisons, and redundancies to form a set of concise statements, which capture the content of all findings.

Analysis of costs to the participant after intervention

The cost analysis of participants after intervention will be undertaken at the follow-up times; six and 12 months after initial randomisation. The aims of the analysis will be to identify, measure and compare individual costs incurred by the participants in both groups. Concomitant care, interventions and tests received, hospitalisations and tests, medications, equipment, aids and informal care, travel costs, employment status and work absenteeism will be assessed by a postal questionnaire at these follow-up times and statistical analyses will compare differences between the treatment groups.

Sample size estimation

Based on the previous RCT using CFT (Vibe Fersum *et al.* 2013), a sample size calculation estimates that a sample size of 64 in each group will have 80% power to detect a difference in means of 5.0 (disability) and 1.0 (pain) between the two arms of the study, assuming that the common standard deviation is 10.0 (disability) and 2.0 (pain), and using a two-sided 5% significance test. Pilot data collection suggests a slightly larger drop-out rate from the class-based intervention. Consequently, allowing for a 40% dropout rate requires a sample size in each arm of 107, or an overall sample size of 214.

Data and safety monitoring

The Clinical Therapies Department at the University of Limerick, Ireland will serve as the data coordinating centre responsible for data collection forms, coordination of data transfer, and data analysis. Health of participants will be monitored through attending their interventions in the three sites. If any adverse events do take place, and in the unlikely event that harm is suffered, the project management team will liaise with local health service providers. All adverse events will be documented in the final written report of this study. All study data will be stored securely in the University of Limerick. All paper based documents and data will be stored in a secure filing cabinet. All electronic data will be secured on a password-protected laptop. All documents that contain names or personal identifying information will be stored separately from other study data identified by code number. Access to files will be limited to research staff involved in the study. The statistician for the final analysis will receive depersonalised data where the participants' identifying information will be replaced by an unrelated sequence of numbers. There are no current plans for granting public access to the full protocol, participant-level dataset or statistical code. However, if researchers wish to access the dataset (e.g. for conduct of secondary analysis or meta-analysis) the project management committee will try to facilitate this.

Dissemination

Results will be presented at international scientific conferences and in peer-reviewed publications. An open-access version of the study results will be made available through the

University of Limerick's institutional repository. Trial participants will also be offered an opportunity to obtain the anonymised, overall study results.

Conclusion

This will be the first RCT to compare the clinical effectiveness of individualised CFT and a combined exercise and education class for people with NSCLBP. The study results will provide valuable information about the role of these interventions and has the potential to inform the clinical management of NSCLBP.

STUDY V: Individualised cognitive functional therapy compared with a combined exercise and pain education class for patients with non-specific chronic low back pain: Preliminary results of a multicentre randomised controlled trial

Abstract

Non-specific chronic low back pain (NSCLBP) is associated with a complex interplay of biopsychosocial factors. Currently there is a lack of clear evidence for the superiority of one type of intervention content (physical or behavioural/psychologically informed or combined) or delivery (individual or group) above another. However there is promising, preliminary evidence that a more individualised, multidimensional intervention called Cognitive Functional Therapy (CFT) is associated with better outcomes. This multicentre randomised controlled trial (RCT) investigated the clinical effectiveness of CFT compared with a group multidimensional pain education and exercise intervention. 208 participants were randomised to one of the two interventions across three sites. The primary outcomes were functional disability (Oswestry Disability Index (ODI)) and pain intensity (numerical rating scale (NRS)), obtained at baseline, post-intervention, six months and 12 months after baseline. Data collection is still ongoing. Therefore, this study presents preliminary descriptive data based on the 171 participants who received the six month follow-up questionnaire and the 142 of whom also received the 12 month follow-up questionnaire. The descriptive analysis found lower levels of disability in the CFT arm compared to the group intervention arm at six months (Mean 21.40 (SD 16.38) vs Mean 30.03 (SD 17.04)) and at 12 months (Mean 21.96 (SD 12.96) vs Mean 29.68 (SD 16.45)). Furthermore, levels of pain were lower in the CFT arm compared to the group intervention arm at six months (Mean 3.88 (SD 2.87) vs Mean 4.65 (SD 2.36)) and at 12 months (Mean 4.33 (SD 2.36) vs (Mean 5.05 (SD 2.73))). These preliminary descriptive findings suggest that CFT may produce superior clinical outcomes for NSCLBP compared with a group, multidimensional intervention. On completion of the data collection an intention to treat analysis of all randomised participants will be completed to assess the significance of the intervention effects. Sensitivity analysis will test the robustness of the results to non-adherence to the protocol. Mediators, moderators and predictors will be

analysed to examine mechanisms of effect. Costs and qualitative interviews will also be analysed.

Introduction

Non-specific chronic low back pain (NSCLBP) is the leading cause of disability worldwide, and is associated with a significant personal, social and economic burden (Dagenais *et al.* 2008, Deyo *et al.* 2009, Gore *et al.* 2012, Buchbinder *et al.* 2013, Hoy *et al.* 2014, Ma *et al.* 2014). The exponential increase in its associated health care costs, the concurrent increase in its associated disability, together with the failure of current interventions, have led to calls for a change in the management of NSCLBP (Deyo *et al.* 2009, O'Sullivan 2012, Zusman 2013).

Strong evidence demonstrates that NSCLBP is a multidimensional disorder, involving different pain mechanisms (Rabey *et al.* 2015a, Rabey *et al.* 2015b), which can be influenced by a wide range of different interacting factors across the biopsychosocial spectrum (Gatchel *et al.* 2007, O'Sullivan 2012). These include patho-anatomical (Hancock *et al.* 2011), physical (Dankaerts *et al.* 2006, Laird *et al.* 2014), psychological (Linton 2000, Main *et al.* 2010, Vlaeyen and Linton 2012, Pinheiro *et al.* 2016), lifestyle (Kelly *et al.* 2011, Dean and Söderlund 2015), social (Hoogendoorn *et al.* 2000b, Lallukka *et al.* 2014) and other non-modifiable (genetics, life stages and sex) (Battié *et al.* 2004, Diatchenko *et al.* 2005, Dugan *et al.* 2006, Bartley and Fillingim 2013) factors. The relative contribution from these different factors is variable, fluctuating and unique to each individual with NSCLBP (O'Sullivan 2012, O'Sullivan *et al.* 2015). Of crucial importance, is the emerging evidence for the interactions between different factors (Linton and Fruzzetti 2014). This could indicate that it may be very difficult to decouple one factor from another in treatment.

Notwithstanding the breadth and unique interaction of these factors in each person with NSCLBP, current interventions are often unidimensional in nature, often focussed on changing one factor (e.g. physical or psychological) (Jacobs *et al.* 2013b, Menke 2014, Smith *et al.* 2014), and so not adequately acknowledging the multidimensional nature of pain. In addition, different components of the same intervention often seem to contradict each other. For example, one aspect of an intervention can aim to address unhelpful back pain beliefs and behaviours through education (e.g. exercise and movement are good), but then provide a physical intervention which serves to indirectly reinforce the beliefs that are unhelpful (e.g. avoiding bending and tensing your muscles before moving) (Ryan *et al.* 2010). Therefore, while a plethora of surgical (Brox *et al.* 2010, Jacobs *et al.* 2013b), pharmacological (Staal *et al.* 2009, Chaparro *et al.* 2013, Machado *et al.* 2015) and conservative physical, behavioural/psychologically informed and combined interventions (O'Keeffe *et al.* 2016b)

have been tested, it is unsurprising that all have similar small levels of effectiveness, with limited long-term benefits for pain and disability.

Many other potential reasons for the similar small effects yielded by current interventions have been proposed. Emerging evidence contends that similar mechanisms are responsible for improvements after seemingly different interventions (e.g. physical and psychological interventions). Changes in cognitive and psychological factors (e.g. reduced fear, increased self-efficacy) mediate outcome across many intervention types (Mannion *et al.* 2001b, Smeets *et al.* 2006, Jackson *et al.* 2014, Lee *et al.* 2015), and may need to be explicitly targeted in interventions.

Non-specific factors, namely a positive patient-therapist interaction have also been linked to reduced pain and disability in NSCLBP and other MSCs (Hall *et al.* 2010, Farin *et al.* 2013, Testa and Rossettini 2016). While a whole host of good interpersonal and communication skills, practical skills, individualised patient-centred care, and organisational and environmental factors are perceived as important in developing a positive patient-therapist interaction (O'Keeffe *et al.* 2015a), current interventions do not always appear to explicitly foster these factors (Testa and Rossettini 2016).

Another potential reason for the similar small effectiveness of interventions is that they are often generic or “one-size fits all” in nature, and so seem insufficiently tailored to the specific needs of patients (O'Sullivan 2012). While tailored interventions based on one factor (e.g. physical or psychological factors or likely response to treatment) have shown limited effectiveness for NSCLBP (Kent *et al.* 2010, Saner *et al.* 2011, Haskins *et al.* 2012, Karayannis *et al.* 2012, Kent and Kjaer 2012, Henry *et al.* 2014, Ramond-Roquin *et al.* 2014), the small number of studies that have attempted to tailor treatment based on multiple factors for MSCs, including NSCLBP, have shown encouraging results (Asenlof *et al.* 2005, Hill *et al.* 2011, Vibe Fersum *et al.* 2013). These studies differed significantly however, with one involving relatively simple stratification into homogenous groups based on risk of disability (Hill *et al.* 2011), and the others involving more individualised and multidimensional care (Asenlof *et al.* 2005, Vibe Fersum *et al.* 2013).

Cognitive Functional Therapy (CFT) is an individualised, patient-centred intervention which addresses multiple aspects in NSCLBP and the inter-relationships between them (O'Sullivan 2005, Vibe Fersum *et al.* 2013). This approach fosters a positive patient-therapist interaction to reconceptualise patients' understanding of their pain, challenge unhelpful beliefs, confront fears and encourage behaviour change. It places a large emphasis on

reflection and behavioural experimentation and learning (e.g. new ways of bending, sitting) to enhance the patients' perceived pain controllability and self-efficacy in achieving their functional goals. A previous RCT (Vibe Fersum *et al.* 2013) demonstrated that CFT was significantly more effective than physiotherapist-led manual therapy and exercise. With a recent systematic review and meta-analysis (O'Keeffe *et al.* 2016a) revealing no significant differences between individual and group interventions for reducing pain and disability across range of MSCs, including NSCLBP, it remains unclear whether it is the multidimensional or individualised component of CFT that is most responsible for the positive outcomes observed in that RCT (Vibe Fersum *et al.* 2013). Given the complex individual nature of NSCLBP and the importance of the patient-therapist interaction, it is postulated that giving patients one-to-one attention in the form of assessment and treatment may be needed, even when a treatment is suitably multidimensional. On the other hand, a generic intervention that reflects the multidimensional nature of pain may alone be enough to result in positive outcome and be more cost-effective to deliver. Therefore, the aim of this study was to investigate the clinical effectiveness of an individualised, multidimensional intervention (CFT) compared to a multidimensional exercise and education intervention delivered in a group format in people with NSCLBP.

Methods

Study population

The methods are reported in full in the protocol in Chapter 3 Study IV (O'Keeffe *et al.* 2015b). Between April 2014 and February 2016, patients that were referred from medical consultants in secondary care and primary care general practitioners (GPs) to the physiotherapy departments in two primary care centres and one public hospital in Ireland were invited by their consulting physiotherapist (AT, LA, LD) to participate. Inclusion criteria were: between 18 and 75 years of age, NSCLBP for at least six months duration, a score of 14% or more on the ODI, independently mobile (with or without aids), to be capable of participating in a rehabilitation programme, be able to speak and understand English well enough to be able to complete the questionnaires independently.

Exclusion criteria were: primary pain area not the lower back (from T12 to buttocks), leg pain as the primary problem (e.g. nerve root compression or disc prolapse with true

radicular pain/radiculopathy, lateral recess or central spinal stenosis), less than 6 months after lumbar spine, lower limb or abdominal surgery, pain relieving procedures such as injection-based therapy (e.g. epidurals) and day case procedures (e.g. rhizotomy) in the past 3 months, pregnancy, rheumatological/inflammatory disease (e.g. rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, lupus erythematosus, Scheuermann's disease), progressive neurological disease (e.g. multiple sclerosis, Parkinson's disease, motor neuron disease), scoliosis (if considered the primary driver of pain), unstable cardiac conditions, red flag disorders like malignancy/cancer, acute traumas like fracture (less than 6 months ago) or infection, spinal cord compression/cauda equina. To control for expectation bias, participants were told that the study was being performed to compare two interventions for NSCLBP, and that based on current knowledge, it was not known which intervention is superior. The RCT was approved by the Mayo General Hospital research ethics committee (MGH-14-UL).

Randomisation and blinding

Sealed opaque envelopes created by the University of Limerick were sent to each site. Allocation was picked by each participant from a sealed opaque envelope, given by the consulting physiotherapist. The envelope contained only two pieces of paper. Participants were asked to pick one piece of paper from the envelope. One piece of paper had the letter 'C' for class and the other, letter 'I' for individualised CFT. Participants and physiotherapists could not be masked to randomisation because the physiotherapists were administering the active intervention. The researcher who retrieved outcome data and posted the questionnaires at six months and 12 months after baseline was blinded to randomisation.

Interventions

All interventions were provided by three physiotherapists, with one physiotherapist working in each location. The treating physiotherapists were trained to deliver the interventions to enhance standardisation of interventions. Detailed information on the interventions is provided elsewhere (Chapter 3 Study IV) (O'Keeffe *et al.* 2015b).

Individualised CFT

All participants randomised to this intervention underwent a comprehensive one-to-one interview and physical examination by the physiotherapist, to identify relevant multidimensional factors considered key drivers of their pain and disability (See Appendix 1a. for the multidimensional clinical reasoning framework). These factors then became the targets for the individualised management. The initial session was approximately 60 minutes in duration and follow-up sessions ranged from 30 minutes to 60 minutes. Treatment frequency varied pragmatically with each participant. There were four main components to the intervention:

1. **Cognitive component/Making sense of pain:** A personalised understanding of the multidimensional drivers of pain sensitisation and disability relevant to the person's story and clinical presentation was outlined for each individual. For example, in the event that their NSCLBP was exacerbated at a time of high stress in their life, the link between NSCLBP and stress in general, and in their particular case was explored (See Appendix 1c. for patient case study).
2. **Normalisation of specific movements and pain control:** This provided patients with strategies to normalise postural and movement behaviours that they nominated as painful, feared or that they avoided. Only patients that presented with aggravating postural and movement behaviours that contributed to their disorder got this component of treatment. This approach followed a 'graded exposure' model where the patient was gradually exposed to valued and previously pain provocative tasks. For example, if lifting children was painful but important for the person with NSCLBP, this stage would have practiced components of that task in a graduated manner, such as practicing bending in sitting and standing without any external load to develop confidence and capacity. In addition they were provided with targeted strategies to relax and control their body, as dictated by their pain provocation pattern (O'Sullivan 2005). This process was reinforced with feedback (visual with the use of mirrors and video, manual palpation, mental imagery and awareness of body responses such as breath-holding, muscle guarding) (See Appendix 1c. for case study).
3. **Targeted functional integration:** Once the patient had developed mastery over postural and movement behaviours, they were integrated into each persons nominated

pain provocative activities and directed at their valued functional goals. Each patient nominated activities of daily living that provoked their pain or that they feared and these were rehearsed with the therapist, so that they were confident and mindful of normalising their movement behaviours whilst performing these tasks in activities of daily living. For example, if lifting children was painful, this stage involves gradually practicing this task while being mindful of pain behaviours which are maladaptive (e.g. excess tension, breath-holding, propping).

4. **Lifestyle advice:** This included promotion of gradually increasing physical activity based on their preference and presentation 3-5 days a week if they were not previously doing so. Participants were given exercise, sleep and stress management advice, if relevant to their presentation, through information leaflets (Appendix 1b) or relaxation cds and encouraged to engage in physical and social activities they enjoyed if not already doing so. If relevant to the individual presentation, participants were advised to watch specific patient videos that were similar to their story and read resources on <http://www.pain-ed.com>.

Group multidimensional exercise and education intervention

This group intervention did not involve individual assessment or consideration of the patient's story. All participants received the same intervention and it was not specifically targeted to their individual needs. It consisted of six classes over six–eight weeks, each lasting approximately one hour and 15 min, with up to 10 participants allowed in each class. There were three main components to the intervention:

1. **Pain education:** each class started with a 30 minute discussion, using a different focus/topic each week. The topics were explaining a contemporary understanding of pain and the role of the nervous system, the multidimensional nature of NSCLBP and common myths about NSCLBP, posture and ergonomics, the role of exercise and relaxation and sleep.
2. **Exercise:** This involved a 40 minute gradually progressive exercise circuit involving aerobic, flexibility and strengthening exercises (Klaber Moffett *et al.* 1999). All participants were given a copy of these exercises and were encouraged to do them at home (See Chapter 3 Study IV for more details on the exercises).

3. **Relaxation:** Each class finished with five minutes of relaxation (diaphragmatic breathing) exercises. All participants were given a mindfulness cd for home practice.

All participants were advised to watch patient videos and read resources on <http://www.pain-ed.com>, and received leaflets on sleep, relaxation and mindfulness, the role of spinal imaging (i.e. MRI, x-ray), and exercise and physical activity.

Treatment fidelity

Several strategies were applied to enhance treatment fidelity. The treating physiotherapists received extensive training in CFT and were observed by a researcher (KOS) trained in the delivery of CFT and were given feedback on assessing and treating actual patients. There was session-by session documentation of intervention content, as well as individual working sheets by each therapist. The physiotherapists provided demographic details, as well as information about their physiotherapy training, general health and back pain beliefs. These will be reported, and considered as covariates, when data collection is completed.

Sample size estimation

A priori sample size calculation indicated that a sample of 128 (64 in each arm) was required to detect a difference in means of 5.0 (disability) and 1.0 (pain) between the two arms of the study, assuming a common SD of 10 for disability and a common SD of 2.0 for pain. To allow for a 40% dropout, it was calculated that 214 participants should be recruited. However, due to a lower than anticipated dropout rate (30% at six and 12 months thus far), 208 participants have been recruited and this will be the final sample size. The following is a preliminary descriptive analysis of 171 participants who received the six month questionnaire and 142 of whom have also received the 12 month questionnaire. The remaining participants are not yet six months or 12 months post-randomisation. Full analysis of all the participants six and 12 month data will be available and analysed in December 2017.

Outcomes

Participants provided a range of demographic information, including age, duration of NSCLBP, and duration of recent episode of NSCLBP and SES (Table 11). Outcome measures were self-reported and were conducted at baseline, post-intervention, as well as six and 12 months post-randomisation.

Primary outcomes

The two primary outcomes of interest were functional disability, measured using the ODI (Fairbank and Pynsent 2000), and pain intensity, measured using the NRS (Jensen *et al.* 1999).

Secondary outcomes

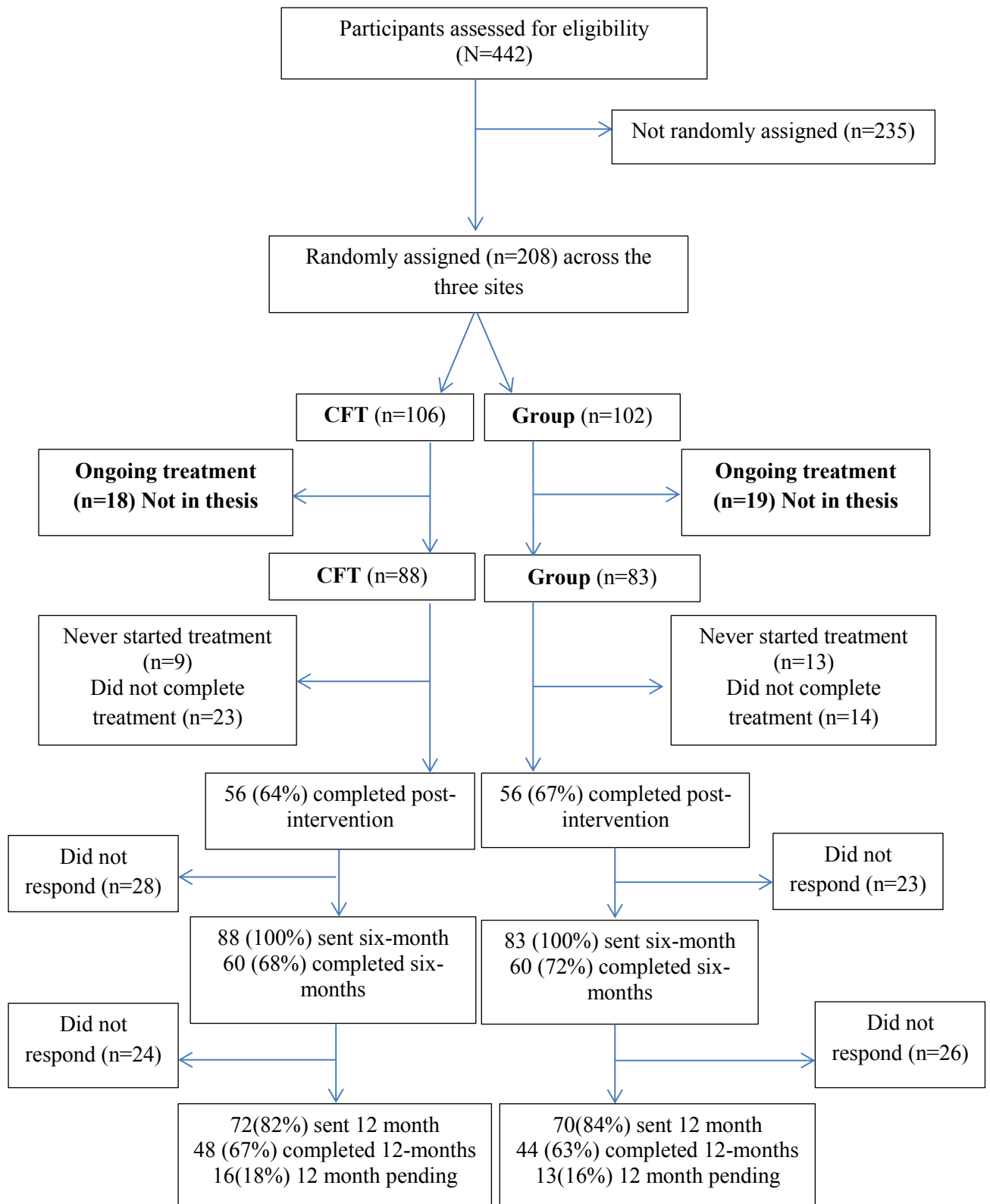
A range of secondary outcomes were collected. Stress using the stress subscale of the Depression, Stress and Anxiety Scale (DASS) (Lovibond and Lovibond 2014), risk of chronicity using the Short Form Orebro Questionnaire (Linton *et al.* 2011), number of pain sites using the Nordic Musculoskeletal Screening Questionnaire (NMSQ) (Crawford 2007), socio-economic status (SES) using the Socio-Economic Index (Rannestad and Skjeldestad 2012), general health complaints, anxiety, sleep and depression using the Subjective Health Complaints Inventory (SHCI) (Eriksen *et al.* 1999), fear of physical activity using the physical activity subscale of the Fear Avoidance Beliefs Questionnaire (FABQ) (Waddell *et al.* 1993), coping using the Coping Strategies Questionnaire (CSQ) (Harland and Georgieff 2003), self-efficacy using the Pain Self-Efficacy Questionnaire (PSEQ) (Di Pietro *et al.* 2014) and satisfaction with treatment using a single item question from the Patient Satisfaction Questionnaire (Marshall and Hays 1994). A blinded research assistant completed a maximum of two telephone follow-ups of non-responders at six month and 12 month follow-ups to remind participants to complete the questionnaires if possible.

Data analysis

Descriptive statistics were used to summarise participant characteristics for the 171 participants who received the six month follow-up. Primary and secondary outcome measures

were summarised at baseline, post-intervention and six months for these participants and at 12 months for the 142 participants who received the 12 month follow-up. Continuous variables were assessed for normality using the Shapiro-Wilk normality test and by visual inspection of histograms. Data were summarised using mean (SD), median (interquartile range) or percentage as appropriate. Descriptive analyses were conducted using IBM SPSS Statistics V. 21 (Armonk, New York, USA). De-personalised and coded data was inputted by one researcher (MOK). On advice from three statisticians, a full preliminary intention to treat (ITT) analysis was not completed at this stage. On completion of the data collection (April 2017) an ITT analysis of the primary and secondary outcome measures will examine the significance of the treatment interventions in accordance with the statistical analysis plan reported in full in the protocol in Chapter 3 Study IV (O'Keeffe *et al.* 2015b).

Figure 18. Study V Flow Diagram



Results

This paper reports the preliminary descriptive statistics for the post-intervention, six month and 12 month follow-up results. Figure 18 details the flow of participants through the trial. Three physiotherapists delivered the trial interventions across three physiotherapy departments (One public hospital physiotherapy department and two primary care physiotherapy centres).

Table 11 shows the baseline characteristics of participants. Participants were mainly female (76%), had a mean age of 48.61 (SD 14.58) and had experienced NSCLBP for 24 (SD 12-60) months. SES appears slightly lower in the group intervention, though both were of an average to good SES. Differences at baseline will be tested for significance on completion of data collection. No serious adverse events were reported. 56 participants completed treatment in both intervention groups. In total, the mean (SD) number of classes attended was 4.8(1.3), lasting 369 (125) minutes and the mean (SD) number of individual treatments provided was 5.5 (2.5), lasting 220 (94) minutes.

Primary Outcomes

Both interventions resulted in improvements in pain and disability. Overall, the descriptive analysis suggests that the individualised CFT intervention delivers superior outcomes when compared with the group multidimensional exercise and education intervention. This was evident at all follow-up points (Table 12). Differences at post-intervention, six and 12 months will be tested for statistical and clinical significance on completion of data collection.

Secondary outcomes

The descriptive analysis of secondary outcomes (Table 13 and Table 14) suggest that CFT yields higher satisfaction ratings, lower risk of ongoing chronicity and higher pain self-efficacy at follow-up points when compared to the group intervention. The number of pain sites, general health, depression, sleep and coping also seem to improve more in the CFT intervention, but the differences seem modest. Fear appears to improve at a similar, large rate in both interventions. Stress and anxiety do not appear to change significantly in either

intervention. Differences at post-intervention, six and 12 months will be tested for statistical and clinical significance on completion of data collection.

Table 11. Baseline characteristics of study participants

	Individualised CFT	Group intervention
Age (years) Mean (SD)	47.27 (14.01)	49.95 (15.14)
Sex (M/F)	18M= 20.5% 70F= 79.5%	23M=27.7% 60F=72.3%
Duration of NSCLBP (months) Median (IQR)	24.0 (12.0-48.0)	24.0 (12.0-60.0)
Socio-economic status Mean (SD)	60.71 (20.50)	51.13 (17.05)

Table 12. Baseline, post-intervention, six month and 12 month descriptive statistics for continuous primary and secondary outcome measures

		Individualised CFT			Group intervention		
		Mean	SD	N	Mean	SD	N
Disability	Baseline	32.93	12.73	88	34.47	12.86	83
	Post-intervention	16.11	9.77	55	26.88	14.13	56
	Six months	21.40	16.38	60	30.03	17.04	60
	12 months	21.96	12.96	48	29.68	16.45	44
Pain	Baseline	6.22	2.08	85	5.89	2.15	76
	Post-intervention	2.95	2.55	55	4.78	2.35	55
	Six months	3.88	2.87	60	4.65	2.36	60
	12 months	4.33	2.36	48	5.05	2.73	44
Risk of chronicity	Baseline	54.04	14.50	84	54.15	15.60	74
	Post-intervention	33.56	15.32	54	47.04	15.18	56
	Six months	40.28	21.37	60	50.10	17.95	59
	12 months	40.49	17.88	47	47.15	18.80	41
Number of pain sites	Baseline	3.59	1.86	81	4.32	2.04	71
	Post-intervention	1.93	1.27	54	3.20	2.06	55
	Six months	2.63	1.74	59	3.42	2.31	59
	12 months	2.91	1.89	47	2.93	1.56	43
Stress	Baseline	15.11	10.80	81	16.60	11.55	70
	Post-intervention	12.20	8.69	51	15.69	9.43	52
	Six months	14.71	11.31	59	15.26	11.18	54
	12 months	14.34	11.88	47	16.05	12.85	43
Fear	Baseline	14.18	5.78	77	15.72	5.48	64
	Post-intervention	6.21	6.39	53	8.80	5.44	51
	Six months	9.64	7.25	56	11.06	6.16	52
	12 months	8.51	6.06	45	10.34	7.23	41

Coping	Baseline	17.00	6.03	75	16.18	7.53	62
	Post-intervention	19.89	6.86	54	17.66	6.61	50
	Six months	19.88	6.33	58	17.38	6.22	53
	12 months	19.53	6.36	47	16.34	6.22	44
Pain Self-Efficacy	Baseline	33.89	12.55	81	33.59	12.46	70
	Post-intervention	48.65	10.45	54	39.69	12.33	55
	Six months	45.57	13.16	60	37.63	15.21	59
	12 months	44.33	13.91	48	38.00	14.43	44
General Health	Baseline	8.54	4.82	83	9.92	6.49	72
	Post-intervention	6.75	4.92	52	9.27	5.88	56
	Six months	7.51	5.88	59	10.36	6.77	58
	12 months	7.71	5.53	49	9.88	7.57	43

Table 13. Post-intervention satisfaction

		Individualised CFT	Group intervention
		%	%
Satisfaction with intervention	Strongly agree	94.3%	71.4%
	Agree	5.7%	26.5%
	Unsure	0.0%	2.0%
	Disagree	0.0%	0.0%
	Strongly disagree	0.0%	0.0%

Table 14. Post-intervention, six month and 12 month data for categorical measures (anxiety, depression and sleep)

	Individualised CFT				Group intervention			
	None	A little	Some	Severe	None	A little	Some	Severe
Anxiety Baseline	123 (51.3)	69 (28.8%)	36 (15%)	12 (5.0%)	111 (52.1%)	39 (18.3%)	42 (19.7%)	21 (9.9%)
Anxiety Post-intervention	72 (48%)	51 (34%)	24 (16%)	3 (2%)	78 (47.3%)	30 (18.2%)	33 (20%)	24 (14.5%)
Anxiety 6 months	90 (51.7%)	42 (24.1%)	30 (17.2%)	12 (6.9%)	72 (41.4%)	42 (24.1%)	51 (29.3%)	9 (5.2%)
Anxiety 12 months	23 (50%)	17 (37.0%)	3 (6.5%)	3 (6.5%)	19 (47.5%)	8 (20.0%)	8 (20.0%)	5 (12.5%)
Depression Baseline	132 (54.3%)	48 (19.8%)	42 (17.3%)	21 (8.6%)	105 (49.3%)	48 (22.5%)	42 (19.7%)	18 (8.5%)
Depression Post-intervention	93 (60.8%)	36 (23.5%)	21 (13.7%)	3 (2.0%)	81 (50.0%)	33 (20.4%)	33 (20.4%)	15 (9.3%)
Depression Six months	90 (51.7%)	45 (25.9%)	27 (15.5%)	12 (6.9%)	75 (43.1%)	48 (27.6%)	39 (22.4%)	12 (6.9%)
Depression 12 months	26 (56.5%)	13 (28.3%)	5 (10.9%)	2 (4.3%)	22 (52.4%)	8 (19.0%)	6 (14.3%)	6 (14.3%)
Sleep Baseline	45 (18.1%)	51 (20.5%)	90 (36.1%)	63 (25.3%)	48 (22.2%)	30 (13.9%)	84 (38.9%)	54 (25.0%)
Sleep Post-intervention	57 (35.8%)	45 (28.3%)	36 (22.6%)	21 (13.2%)	42 (25.0%)	45 (26.8%)	39 (23.2%)	42 (25.0%)
Sleep Six months	60 (34.5%)	51 (29.3%)	39 (22.4%)	24 (13.8%)	51 (29.3%)	36 (20.7%)	45 (25.9%)	42 (24.1%)
Sleep 12 months	11 (22.9%)	15 (31.3%)	16 (33.3%)	6 (12.5%)	14 (33.3%)	7 (16.7%)	11 (26.2%)	10 (23.8%)

Discussion

The preliminary descriptive analysis of this RCT suggests that an individualised multidimensional intervention (CFT) results in superior outcomes when compared to a group multidimensional intervention in people with NSCLBP. Both interventions yielded improvements in pain and disability at post-intervention, as well as six and 12 months post-randomisation. However, the individualised CFT intervention appears to be more effective, exceeding the proposed minimally important change (MIC) value of 30% for both disability and pain at post-intervention, six months and 12 months (Ostelo *et al.* 2008). The MICs achieved by the individualised CFT intervention in this preliminary analysis are consistent with another RCT (Vibe Fersum *et al.* 2013) utilising CFT in a less disabled population with NSCLBP.

In the individualised CFT arm, the mean reductions in functional disability at six months (36% reduction from baseline) and 12 months (33% reduction from baseline) exceeded the MIC value reported in the literature of 30%. Furthermore, the mean reductions in pain at six months (38% reduction from baseline) and at 12 months (30% reduction from baseline) also meet the proposed MIC reduction of 30% (Ostelo *et al.* 2008). This degree of reduction in functional disability using the ODI is considerably greater than that observed in Study II of Chapter 2 for individual interventions for NSCLBP when using the same questionnaire (6%-21%).

In the group intervention, the mean reductions in disability at six months (13% reduction from baseline) and at 12 months (14% reduction from baseline), as well as pain at six months (21% reduction from baseline) and at 12 months (14% reduction from baseline) are similar to the small effects yielded by the majority of conservative physical, behavioural and group and individual treatments for NSCLBP. This degree of reduction in functional disability using the ODI is consistent with that observed in Study II of Chapter 2 for group interventions for NSCLBP when using the same questionnaire (6%-14%).

Why was individualised CFT more effective?

While both interventions tested in this RCT were multidimensional in nature, and placed a major focus on evidence-based education about the complex biopsychosocial nature of pain, myths surrounding NSCLBP, the shortcomings of imaging (i.e. MRI, x-ray), and the benefits

of active coping strategies (e.g. exercise), the individual intervention had unique characteristics which may be responsible for the superior outcomes.

Comprehensive initial assessment of NSCLBP

Participants in the group intervention did not undergo a one-to-one interview and assessment prior to commencing their intervention. In contrast, all participants in the CFT intervention all received a one-to-one multidimensional assessment, consisting of a comprehensive interview and physical examination that was tailored to their individual concerns and functional limitations. Since the relevance of different factors is highly variable, and that factors commonly interact with each other, each person with NSCLBP will possess their own interacting profile of factors contributing to their disorder. For instance, physical factors may be dominant in some people with NSCLBP, and psychological factors in others. Having a flexible clinical reasoning framework that allows for this heterogeneity in presentation (O'Sullivan 2012, O'Sullivan *et al.* 2015), by screening for multiple factors, may have led to better management.

Furthermore, the dominance of certain factors (e.g. physical versus lifestyle or combined) may affect the dominant pain mechanism at play, and so influence the complexity of the NSCLBP disorder. This is in line with research displaying that people with pain disorders can present with dominant peripheral mechanisms (Smart *et al.* 2012b, Rabey *et al.* 2015a, Rabey *et al.* 2015b), aggravated and eased by physical factors, and others presenting with more dominant central mechanisms (Smart *et al.* 2012a, Rabey *et al.* 2015a), aggravated by a range of psychological, social and lifestyle factors. However, emerging research shows that many people with NSCLBP possess a spectrum of factors, with mixed pain mechanisms at play (Rabey *et al.* 2015a). As a result, specific questions about physical (aggravating postures, movements, activities), lifestyle (sleep, physical activity, diet), psychological (beliefs about what is wrong, fears, mood, coping, self-efficacy), social (family, work, life events, culture) factors may be important to elicit modifiable contributing factors to the person's NSCLBP. Furthermore, the inclusion of a physical examination may have led to greater validation, with therapeutic touch being a fundamental element of the interpersonal interaction (Testa and Rossetini 2016). This assessment, which allows for individualised, instead of generic intervention, may partly explain why the CFT intervention was more effective.

Individualised education based on multidimensional assessment of NSCLBP versus generic education

All participants in the group intervention received the same education on posture, exercise, sleep, relaxation, imaging for NSCLBP, the role of the nervous system and the multidimensional nature of NSCLBP. In contrast, participants in the CFT intervention received personalised education on the multidimensional factors believed to contribute to their pain and disability, in the context of their story and clinical presentation. Particular attention was placed on what was happening around the time the person's NSCLBP began or during flare-ups, in an attempt to establish a pattern to that individual's pain (e.g. changes in sleep, stress, life events, training load, a bending incident, a lifting accident). Emphasis was also placed on what the patient had been told about the cause of their NSCLBP, their own beliefs and how they may have altered life or body movements in response to these. The treating CFT physiotherapist drew a diagram for each patient with NSCLBP explaining the series of events leading up to and/or maintaining each patient's NSCLBP (e.g. not bending since a lifting accident, lack of sleep, mood, stress, life events, beliefs etc.). This is based on evidence showing that all pain is an individual and multidimensional experience, with different interacting factors relevant for different people (O'Sullivan 2012). In this way, providing generic or contradictory education about different factors, which may not be of relevance to each person's unique story, may contribute to misconceptions about pain (Ryan *et al.* 2010, Stewart 2014) and a lack of uptake of the information provided.

Emerging evidence demonstrates that individuals with NSCLBP view education as effective when it is made relevant to the individual (Robinson *et al.* 2015), given in the form of simple explanations and metaphors, gives a thorough understanding of pain and the ability to explain it to others, and provides strategies to manage pain (Lærum *et al.* 2006, Lin *et al.* 2014, Oosterhof *et al.* 2014, Testa and Rossettini 2016). CFT used simple language and types of metaphors/analogies unique to each individual, to help individuals make sense of their pain. It involved written, visual (e.g. videos of the patient sitting, moving on phone, iPad) and online (e.g. www.pain-ed.com, podcasts) explanations, depending on the patient preferences. Furthermore, patients were often given videos to watch of other patients talking about how they got better with this approach, which boosts observational learning (Colloca 2014). Having many methods of education to choose from has been recommended to facilitate understanding (Gallagher *et al.* 2013, Stewart 2014). The education content and provision of coping strategies was highly variable, depending on the factors contributing to the person's

disorder (physical or psychological or lifestyle or social or combinations of each) and the individual's hobbies and goals. It included epidemiological evidence about MRI findings, that movement is good, that emotions, sleep and lack of exercise affect nervous system sensitivity, and made links between changes in life and the onset of pain. This personalised education to the patient's unique contributing factors may be partly responsible for the larger changes in satisfaction and self-efficacy at follow-up.

This personalised multidimensional education contrasts with unidimensional education focussed on biomedical findings and biomechanics in NSCLBP, which has shown limited effectiveness (Maier-Riehle and Härter 2001, Ainpradub *et al.* 2015). However, other forms of education that have explained the biopsychosocial nature of pain (Moseley 2004, Moseley *et al.* 2004, Clarke *et al.* 2011, George *et al.* 2011, Louw *et al.* 2011, Pincus *et al.* 2013, Traeger *et al.* 2015) in a similar manner to CFT have shown positive results.

Individualised physical rehabilitation and lifestyle advice versus generic exercise and lifestyle advice

All participants in the group completed a generic set of exercises and relaxation. While all participants were encouraged during the completion of the exercises, no tailoring to the individual took place, and individual's movement or postural patterns were not corrected during the exercise. For example, if the person was moving in a very rigid, slow manner or not bending through their lower back, this was not corrected or changed. Participants were encouraged to engage in physical activity and relaxation, but this was not tailored or designed to fit patient goals.

In contrast, where maladaptive movements and postures were seen to contribute to a person's NSCLBP, the CFT intervention provided physical rehabilitation that was tailored to the needs of each individual. This is in line with evidence that patients with NSCLBP will have different functional limitations, task-specific fears, and avoid different activities (e.g. sitting, bending, lifting, standing, rolling) (Dankaerts *et al.* 2006, Vlaeyen and Linton 2012, Laird *et al.* 2014). Research has demonstrated that people with NSCLBP adopt different movements and postures in response to pain that may be maladaptive or provocative of their disorder (Dankaerts *et al.* 2006, Van Hoof *et al.* 2012, Sheeran *et al.* 2013, Laird *et al.* 2014). For instance, some people's pain may be aggravated by sitting or bending in flexion, while others may be aggravated by extension (O'Sullivan 2005). Furthermore, individuals may

present with hand propping, breath-holding and avoidance of loading their spine or limbs, which may act to maintain pain by abnormal tissue loading (O'Sullivan 2005).

Depending on the individual's clinical presentation, CFT targeted specific activities, exposed individuals to movements and postures that were feared and avoided, and provided active management strategies (e.g. specific exercises, breathing during movement). Given the intricate mind-body relationships in pain disorders, such as NSCLBP (Vlaeyen and Linton 2000, O'Sullivan 2012, Linton *et al.* 2016), observation of how a person moved, reflection on why a person was moving in that way (e.g. why they were breath-holding, propping, not bending through back, being cautious moving) and why it might be aggravating their NSCLBP was a key feature throughout assessment and treatment. These protective behaviours in NSCLBP are often linked to cognitive factors like fear and catastrophizing (de Jong *et al.* 2005, Smeets *et al.* 2006, Meulders and Vlaeyen 2012, Vlaeyen and Linton 2012, Karayannis *et al.* 2013), and so targeting them may have indirectly targeted patient cognitions (e.g. fear and self-efficacy) and optimise the personalised education and learning. Since research shows the benefits of exposing individuals to feared activities (Linton *et al.* 2007, Meulders and Vlaeyen 2012, Vlaeyen *et al.* 2012), CFT is strongly behavioural in nature, challenging beliefs and encouraging changes in physical behaviour (e.g. moving more relaxed, not avoiding lumbar flexion). This was done in a graded manner, but unlike other exposure intervention like ACT, CFT targets pain control strategies where possible and pays attention to what is happening when a person is moving in pain (e.g. breathing, reduce protective guarding, cues to use legs and relax back etc.) and aims to reduce pain intensity as well as disability. Visual feedback through therapist demonstration and mirrors are used to optimise the vicarious learning needed to shift maladaptive behaviours. In fact, patients that looked at their back when moving during exercises reported less increases in pain and a faster resolution of their dysfunction in other studies (Wand *et al.* 2012, Diers *et al.* 2016). Given that individuals fear and lack confidence to do specific movements and activities, CFT by individualising physical rehabilitation, may partly explain the large changes in fear, self-efficacy and risk of ongoing disability that were achieved at follow-up.

Crucially, if physical behaviours are not a contributing factor to a person's NSCLBP, emphasis was not placed on them. This may explain why generic physical and/or exercise interventions that are not targeted to the individual presentation have resulted in small effects in the NSCLBP population (Hayden *et al.* 2005, Driessen *et al.* 2010, Kent *et al.* 2010, Saner *et al.* 2011, Haskins *et al.* 2012). However, targeting specific physical factors when they are

dominant contributors to a person's NSCLBP has resulted in positive results (Van Hoof *et al.* 2011, Cañeiro *et al.* 2013, O'Keeffe *et al.* 2013, Sheeran *et al.* 2013).

The one-to-one patient-therapist interaction

Emerging evidence is demonstrating that a positive interaction with the patient is associated with reductions in pain, disability and increased treatment satisfaction (Hall *et al.* 2010, Del Re *et al.* 2012, Farin *et al.* 2013, Ferreira *et al.* 2013b, Kelley *et al.* 2014). Both the CFT and group interventions involved encouragement, engagement with patients in a warm and friendly manner, time to express opinions, empathy, education, and humour where appropriate, and an opportunity to ask questions. However, CFT differed to the group in that it provided one-to-one attention, flexibility in the time provided, a comprehensive interview and assessment of multiple factors, facilitated the disclosure of personal information in a patient's life, personalised education, took patient preferences into account and targeted specific goals. Given the complexity of NSCLBP (O'Sullivan 2012), that more sensitive factors can be contributing to a person's NSCLBP (e.g. stress, mood, life events) and the long-term impact of NSCLBP on a person's life (e.g. hobbies, family, quality of life) (Bunzli *et al.* 2013b, Osborn and Smith 2015, Damsgaard *et al.* 2016), providing one-to-one attention and privacy to validate a person's experience and allow them to disclose and discuss personal information and feelings could be important. Interestingly, lack of privacy and a reduction of patient-physiotherapist time has been linked to more negative therapy outcomes (Hush *et al.* 2011, Oliveira *et al.* 2012b) This may explain the greater satisfaction levels after CFT. Furthermore, a motivational interviewing (MI) style of communication to provide hope and encouragement, while challenging individuals to reflect on their NSCLBP was used throughout. It reinforces positive health behaviours, discourages maladaptive behaviours and promotes active coping strategies (Resnicow *et al.* 2002), highlighting that each individual can self-manage, successfully control and reduce their NSCLBP. This may explain the large increases in self-efficacy after this intervention. There is a body of research showing the patients want a physiotherapist to spend time assessing them, have good communication and interpersonal skills, such as listening, empathy, humour, encouragement and have the ability to individualise and modify treatment based on their preferences and goals (O'Keeffe *et al.* 2015a).

The MI component of CFT could have been crucial in determining outcome. Given the evidence that behaviours (e.g. avoidance, physical inactivity, etc.) are complex and difficult to change, having a multidimensional approach that requires patients to reflect on barriers and facilitators to change, set goals, and elicit what patients see as important and required for change may be warranted. In interventions for other health conditions that address multiple aspects in an individual's presentation, behaviour change and motivational techniques are now being encouraged (Chilton *et al.* 2012, Michie *et al.* 2014).

Limitations

This paper features a descriptive analysis of the RCT. 37 participants still have to receive their six month follow-up and 66 their 12 month follow-up. Therefore, definitive assertions regarding efficacy cannot be made until the full data set is available.

A limitation of this study was the number of participants that did not start or complete the interventions after randomisation. Reasons for this included; being unable to attend due to logistical/time constraints and needing to seek other medical care. Other reasons may possibly include; not wanting the intervention that they were allocated to, recovery during the intervention, or not responding to the intervention. However, this non-adherence to intervention has been demonstrated in other NSCLBP trials (Chown *et al.* 2008, Cherkin *et al.* 2016). Furthermore, the number of non-starters was similar across both interventions.

Some other measures which have been shown to be related to NSCLBP outcomes (e.g. catastrophizing, back pain beliefs questionnaire) were not measured in the current trial. Having these two outcome measures may have allowed better explanations of treatment effect, with both been consistently shown to relate to improvements in pain and disability in other NSCLBP trials (Mannion *et al.* 2001b, Smeets *et al.* 2006, Main *et al.* 2010, O'Sullivan *et al.* 2015, Hall *et al.* 2016). However, many important mediators of treatment outcome (e.g. self-efficacy and fear) (Woby *et al.* 2004, Jackson *et al.* 2014, Wertli *et al.* 2014b) were measured. Furthermore, the Orebro Musculoskeletal Questionnaire was used as a measure of risk of chronicity (Linton *et al.* 2011). Given the role of multiple risk factors in NSCLBP (O'Sullivan 2012), cumulative risk outcome measures assessing multiple factors, instead of unidimensional measures are now being increasingly encouraged (Wideman *et al.* 2012, Wideman and Sullivan 2012). Furthermore, the authors wanted to examine factors not as

commonly investigated in NSCLBP (e.g. general health, coping and stress) and sought to avoid the use of too many measures, to reduce patient burden and optimise response rates.

Physical factors such as posture, back muscle activity and physical activity levels were not objectively measured in this study, which may have helped explain changes in outcome. However, research has shown that these physical factors do not always explain changes in pain and disability after treatment in people with NSCLBP (Steiger *et al.* 2012, Wong *et al.* 2014, O'Sullivan *et al.* 2015). Furthermore, emerging evidence supports the association between psychological and physical factors (Geisser *et al.* 2004, Hulst *et al.* 2010, Karayannis *et al.* 2013, Lewis *et al.* 2014), and that psychological factors are more important mediators of pain and disability in NSCLBP (Pincus *et al.* 2006a, Chou and Shekelle 2010, Main *et al.* 2010, Lee *et al.* 2015). In addition, changes in psychological factors explain changes in pain and disability after treatment in people with NSCLBP (Mannion *et al.* 2001b, Smeets *et al.* 2006, Jackson *et al.* 2014, O'Sullivan *et al.* 2015), justifying the inclusion of these type of measures.

Future work

This paper presents the preliminary results for 171 participants at six month follow-up and 142 participants at 12 month follow-up. Follow-ups are ongoing for the remaining participants. The data for all participants will be analysed at all time points to confirm these promising results. Costs relating to the individual and society have been collected at six and 12 months for both interventions. Given the potential of group interventions to reduce healthcare costs (Critchley *et al.* 2007), it is necessary to analyse this data to examine whether CFT is a cost-effective, as well as clinically-effective intervention option.

Qualitative interviews of 20 participants from both interventions have been conducted after six month follow-up. Given the major effect of NSCLBP on a person's life (Bunzli *et al.* 2013b), getting patient perspectives may generate knowledge that could be useful in future intervention planning and execution. A recent qualitative study (Bunzli *et al.* 2016) exploring participant experiences after CFT revealed that improvements or lack thereof were related to the uptake of biopsychosocial pain beliefs versus maintaining biomedical beliefs, changes in fear, self-efficacy and independence. Therefore, analysis of the interviews from the current study could provide very important information. Levels of stress and anxiety were not changed following the CFT intervention in this study. This is in line with a recent case series

examining CFT in highly disabled people with NSCLBP (O'Sullivan *et al.* 2015). Given that maladaptive stress and anxiety are associated with increased pain and disability in some people with pain/NSCLBP (Linton 2000, Gatchel *et al.* 2007, Hasenbring and Verbunt 2010, Andrews *et al.* 2012, Hannibal and Bishop 2014, Plaas *et al.* 2014, Generaal *et al.* 2015, Østerås *et al.* 2015), future studies should try to optimise CFT to better target these. Other secondary outcomes (e.g. coping, depression, sleep) only seemed to change modestly after the intervention, so it may also be worth looking at these in more detail.

Given that participants were satisfied with the group intervention, together with the proposed benefits of group settings (Wilson *et al.* 2016), it may be worth examining ways of optimising the group, through greater individualisation or a greater emphasis on certain components.

Conclusion

This descriptive analysis of a multicentre RCT suggests that an individualised multidimensional intervention (CFT) produces superior outcomes for pain and disability when compared to a group multidimensional intervention. On completion of the data collection an ITT analysis of all randomised participants will be completed to assess the significance of the intervention effects. Future work will involve performing a cost analysis of the interventions, analysing mediators, moderators and predictors of outcome, analysing qualitative patient interviews, and the development of strategies to more effectively target those secondary outcomes which appear most resistant to change, to further optimise long-term outcomes.

Chapter 3: Key points

The general aim of Chapter 3 was to investigate the clinical effectiveness of an individualised, multidimensional intervention (CFT) compared with a group multidimensional exercise and education intervention in people with NSCLBP. Data collection is still ongoing and therefore preliminary descriptive data for post-intervention, six months and 12 months were presented. The descriptive analysis found lower levels of disability and pain in the individualised CFT intervention compared to the group intervention at post-intervention, six months and 12 months. Satisfaction, risk of ongoing disability and self-efficacy were better in the CFT intervention compared to the group intervention at all time points. The number of pain sites, general health, depression, sleep and coping also seem to improve more in the CFT intervention, but the differences seem modest. Reductions in fear were large, and similar, across both interventions. Stress and anxiety did not change after either intervention.

These preliminary descriptive findings suggest that CFT may produce superior clinical outcomes for NSCLBP compared with a group, multidimensional intervention. On completion of the data collection an ITT analysis of all randomised participants will be completed to assess the significance of the intervention effects. Sensitivity analysis will test the robustness of the results to non-adherence to the protocol. Mediators, moderators and predictors will be analysed to examine mechanisms of effect. Costs and qualitative interviews will also be analysed.

CHAPTER 4: Discussion

The aim of Chapter 4 is to review the studies from each chapter in this doctoral thesis, and link the results of each study to the current scientific literature on NSCLBP. This chapter will display how the findings of this doctoral thesis contribute to the current knowledge regarding NSCLBP and the effectiveness of an individualised, multidimensional intervention for NSCLBP. Finally, the limitations of this thesis, and its implications for practice, will be discussed.

Key findings

- A systematic review and meta-analysis demonstrated no clinically significant differences in pain and disability between physical, behavioural/psychologically informed and combined conservative interventions at short-, medium-, and long-term follow-up in people with NSCSP. All interventions had similar, small effects on pain and disability.
- A systematic review and meta-analysis demonstrated no clinically significant differences in pain and disability between individual and group physiotherapy interventions incorporating exercise at short-, medium-, and long-term follow-up in people with MSCs. All interventions had similar, small effects on pain and disability.
- A systematic qualitative review and meta-synthesis demonstrated that a range of (1) physiotherapist interpersonal and communication skills, (2) physiotherapist practical skills, (3) individualised patient-centred care and (4) organizational and environmental factors influence the patient-therapist interaction in musculoskeletal settings.
- Preliminary results from a multicentre RCT suggest that an individualised multidimensional intervention (CFT) has superior outcomes for pain and disability when compared to a group multidimensional intervention at post intervention, and six and 12 months post-randomisation in people with NSCLBP.

Why do most current interventions have similar small effects on clinical outcomes?

Chapter 2 of this thesis revealed no significant differences in pain and disability between commonly used interventions for NSCLBP, and other painful MSCs. Despite variations in the content (physical versus behavioural/psychologically informed versus combined) (Study I) and the mode of delivery (individual versus group) (Study II), most interventions yielded similar small effects on pain and disability. This is in line with other systematic reviews reporting that NSCLBP symptoms follow the same trajectory, regardless of the intervention applied (Keller *et al.* 2007, Van Middelkoop *et al.* 2011, Artus *et al.* 2014). Chapter 2 also fits with a huge body of literature that reveals no differences in outcomes for NSCLBP between surgery and conservative interventions (Brox *et al.* 2003, Fairbank *et al.* 2005, Froholdt *et al.* 2011, Mannion *et al.* 2013), different types of surgery (Jacobs *et al.* 2013b,

Försth *et al.* 2016), different pharmacological interventions (van Tulder *et al.* 2003b, Urquhart *et al.* 2008, Staal *et al.* 2009, Kuijpers *et al.* 2011, Chaparro *et al.* 2013), different physical interventions (e.g. exercise, manual therapy) (Hayden *et al.* 2005, Wang *et al.* 2012, Wells *et al.* 2013, Menke 2014, Saragiotto *et al.* 2016), different psychological interventions (e.g. CBT, graded exposure, ACT) (van Tulder *et al.* 2000, Sveinsdottir *et al.* 2012, Veehof *et al.* 2016), or different combined treatments (exercise with CBT principles, MDT, graded activity) (Michaleff *et al.* 2014, Rantonen *et al.* 2014). Therefore, surgical, pharmacological and conservative interventions all typically yield small effects, with the vast majority showing no clear superiority over the other. Many reasons could be responsible for this;

1. NSCLBP is individual and multidimensional, but interventions are often generic and unidimensional: There is strong evidence that NSCLBP is a **multidimensional** disorder, involving a complex interaction of factors across the biopsychosocial spectrum (Gatchel *et al.* 2007, O'Sullivan 2012). Given the high variability of contributing factors and their unique interactions across each **individual** with NSCLBP, interventions may need to be tailored to the individual presentation and acknowledge the interactions between multiple factors (e.g. physical, psychological, lifestyle, social) among individual patients. Unfortunately, it appears interventions are often **unidimensional** or only target some factors, and are often **generic** or “one-size fits all” in nature, providing the same type of intervention to each patient, no matter the presentation. These approaches have the advantage of being easily standardised and easily replicated, which can be advantageous in RCT designs (Hoffmann *et al.* 2014), but do not reflect the individual nature of NSCLBP, nor typical clinical practice. For example, surgery typically targets the excision of patho-anatomical factors (e.g. disc prolapse) which have been shown to have a poor relationship with pain and disability in the majority of people (Jarvik *et al.* 2005, Brinjikji *et al.* 2015b). Similarly, specific exercises are commonly used to try to change a person’s posture or muscular strength, while general exercise is used to improve fitness or physical activity levels (Hoffmann *et al.* 2016), but both do not explicitly target other factors like beliefs, sleep, fear of pain, pain related distress or an individual’s exercise preference.

Traditionally CBT for NSCLBP while addressing unhelpful beliefs and encouraging movement and activity, does not explicitly address how a person moves (e.g. moving with protective behaviours such as breath-holding and bracing their tummy and adopting tense postures) or assess for/address maladaptive movement patterns (e.g. movement control impairment into flexion or excessive extension loading). Exposure interventions while

instructing patients to engage in specific activities (e.g. lifting, bending) do not explicitly address protective (as described) and safety behaviours during feared activities (e.g. propping, avoidance of loading a leg) and emotion regulation during the activity (e.g. fear responses such as breathing patterns) (Linton and Fruzzetti 2014). This may be due to psychological interventions (CBT, exposure, ACT) often being delivered by psychologists alone, who have limited skills in examining and addressing physical behaviours. Education interventions most often target biomechanics, lifting techniques or patho-anatomy alone in NSCLBP, with a recent review (Ainpradub *et al.* 2015) displaying unsurprisingly poor effects for such education programmes. In fact, our group submitted a letter to the editor (Hurley *et al.* 2016) regarding this review, detailing our opinions on why education may currently be ineffective. Neuroscience education may be more effective, but even then the effect sizes are small and no better than other active interventions like CBT and exercise (Louw *et al.* 2011). Furthermore, even combined interventions such as multidisciplinary treatment (Guzman *et al.* 2002, Kamper *et al.* 2015), may not assess for and target the full range of factors contributing to a person's pain, for example sleep (Kelly *et al.* 2011) and life stress (Gatchel *et al.* 2007).

Another common feature of interventions for NSCLBP is the targeting of one factor (e.g. physical), the management of which in turn may have a negative effect on another factor (e.g. psychological). As an illustration, one study (Ryan *et al.* 2010) found that the addition of a back class in addition to neuroscience education actually reduced the benefit gained from the neuroscience education initially. The authors speculated that this was related to the contradictory information provided by the two components of this combined intervention. Interventions for NSCLBP often involve spinal stability retraining and back care advice to avoid certain postures and movements in an effort to target physical factors. This is despite the lack of strong evidence of a causal link between 'poor' postures, deficits in spine stabilising muscles and NSCLBP (Gubler *et al.* 2010, Roffey *et al.* 2010c, Wong *et al.* 2013). Furthermore, there is a lack of evidence for interventions targeting these factors being superior to other interventions (Smith *et al.* 2014, Saragiotto *et al.* 2016). These interventions may in fact reinforce the idea that the spine is vulnerable to injury and contribute to fear which has been associated with reduced movement (Geisser *et al.* 2004, Thomas and France 2007, Trost *et al.* 2012, Karayannis *et al.* 2013, Archer *et al.* 2014) and back muscle hyperactivity (Vlaeyen *et al.* 1999, Massé-Alarie *et al.* 2016). This is significant, given poor back beliefs and fear are strongly associated with poorer recovery in NSCLBP (Main *et al.* 2010, Wertli *et al.* 2014a, Wertli *et al.* 2014c). The multidimensional and individual nature of

NSCLBP is similar to other complex disorders, such as anxiety, depression and phobias, which also involve interactions of multiple factors (Teychenne *et al.* 2008, Uher 2008, Rosenberg and Hickie 2013), and often respond poorly to generic, unidimensional interventions (Lawlor and Hopker 2001, Gilbody *et al.* 2003, Cuijpers *et al.* 2010).

2. Overassessment and/or overtreatment using passive therapies: NSCLBP is a common experience with studies reporting that up to 84% of people will report LBP at some point over their lifetime (Walker *et al.* 2003, Hoy *et al.* 2014). Guidelines for NSCLBP (Airaksinen *et al.* 2006, Koes *et al.* 2010) encourage reassurance and a return to normal activities as soon as possible following an episode of pain. However, guidelines appear to be not adhered to (Fullen *et al.* 2007, Williams *et al.* 2010), with **over-imaging** endemic across the world (Deyo *et al.* 2009, Mafi *et al.* 2013). This trend is on the increase (Mafi *et al.* 2013), despite the poor evidence for early imaging (Chou *et al.* 2009, Webster and Cifuentes 2010, Steffens *et al.* 2014). Furthermore, excessive time is often spent on performing “objective” tests to assess for so called “abnormalities” in movement, posture, spinal alignment and timing of muscle activation. This is problematic, given the poor reliability and validity of current objective tests to identify a cause of NSCLBP (May *et al.* 2006, van der Wurff *et al.* 2006, Hancock *et al.* 2007) and the lack of causal relationships between joint hyper and hypomobility, spinal and pelvic alignment, muscle timing patterns and the development of NSCLBP (Mikkelsen *et al.* 1996, Christensen and Hartvigsen 2008, Roffey *et al.* 2010a, Roffey *et al.* 2010c, Wai *et al.* 2010a, Wai *et al.* 2010b, Wong *et al.* 2013). This assessment approach may reflect practitioner back pain beliefs, which could then influence their management of patients (Darlow *et al.* 2012). Unsurprisingly as a result, overtreatment is often standard, despite poor evidence for early and intensive treatment (Fritz *et al.* 2015). A biomedical orientation to NSCLBP has also been linked to greater advice to limit work and physical activity (Darlow *et al.* 2013), and potentially to an assumption that **passive therapies** are required to “fix abnormalities”, or else that pain cannot be modified given the presence of “abnormalities”. Examples include the provision of rest, manual therapy, surgery or injections, which are either not in line with guidelines or show poor results (Waddell *et al.* 1997, Airaksinen *et al.* 2006, Staal *et al.* 2009, Koes *et al.* 2010, NICE 2016) or informing patients that their pain will never change. This could fuel negative back beliefs (Darlow *et al.* 2013, Darlow *et al.* 2015), passive coping strategies, low recovery expectations and low self-efficacy, all of which have been linked to greater disability due to NSCLBP (Mercado *et al.* 2005, Iles *et al.* 2009, Jackson *et al.* 2014). Emerging evidence supports that low risk patients

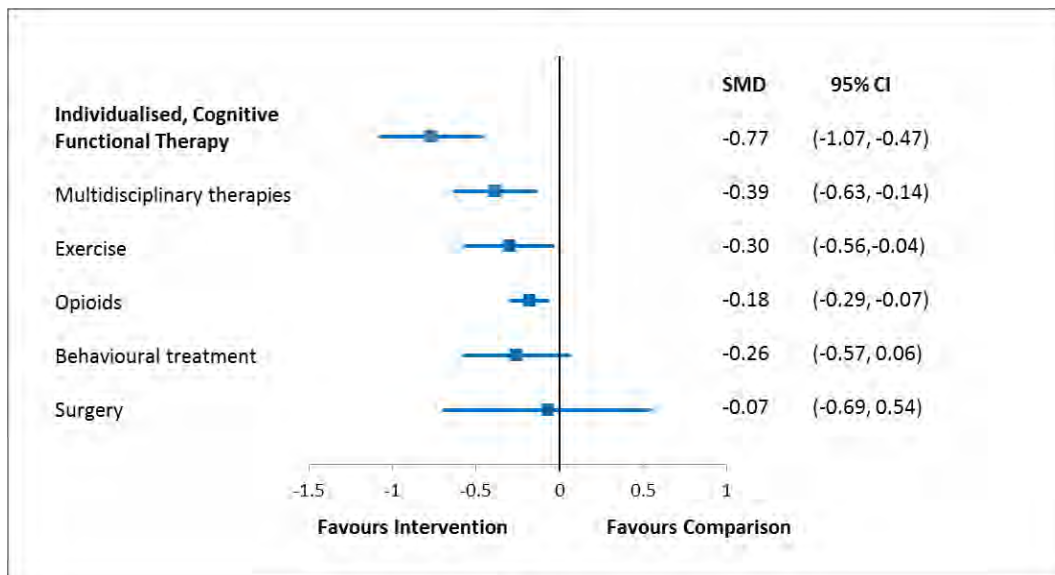
with NSCLBP can achieve good outcomes with minimal treatment if provided in an evidence-based manner (Hill *et al.* 2011). This approach could save money that could then be used to treat more high-risk patients more intensively (Hill *et al.* 2011).

3. Not explicitly fostering a positive patient-therapist interaction: Most interventions **do not appear to explicitly harness a positive patient-therapist interaction** which is shown to be important to clinical outcomes in NSCLBP and a range of other clinical conditions (Hall *et al.* 2010, Ferreira *et al.* 2013b, Fuentes *et al.* 2014). Study III (O'Keeffe *et al.* 2015a) in Chapter 2 of this thesis demonstrated that patients want to be listened to, receive empathy and encouragement, to receive good education and want their opinions and preferences to be acknowledged. However, emerging qualitative data show that patients feel that education is often either absent in treatment or not made relevant to their story (Robinson *et al.* 2015). Furthermore, patients often interpret education on the biopsychosocial nature of NSCLBP as implying that the pain is “in their head”, leading to feelings of stigmatisation, insecurity and their pain not being validated (Bunzli *et al.* 2013b, Linton 2015, Osborn and Smith 2015). This could lead to patients having a poor understanding of their NSCLBP and how to manage it. It should be acknowledged that a good therapeutic interaction in isolation has small effects on pain and disability (Kelley *et al.* 2014). Therefore, there is a critical need that any enhancement in the patient-therapist interaction facilitates better communication of evidence-based information and treatment, as opposed to harmful, outdated principles, in order to get more effective results. It is worth acknowledging that any intervention, including CFT, which specifically challenges both the unhelpful beliefs and behaviours of patients, runs the risk of being rejected, and this risk could potentially be magnified if the patient-therapist interaction is not very strong.

How does CFT build on current interventions?

The design of the CFT intervention outlined in Chapter 3 Study IV and Study V reflects the contemporary evidence on pain and addresses the aforementioned limitations in current approaches, in an attempt to yield clinically meaningful changes in pain and disability. Figure 19 illustrates the increased effect sizes of CFT on disability, based on the results of Study V and the existing Norwegian trial (Vibe Fersum *et al.* 2013), compared to a range of other commonly used therapies for NSCLBP.

Figure 19. Effect of sizes of CFT versus current interventions



CFT: (Vibe Fersum *et al.* 2013) and my preliminary RCT results; **MDT:** (Kamper *et al.* 2015); **Exercise:** (Hayden *et al.* 2005); **Opioids:** (Chaparro *et al.* 2013); **Behavioural treatment:** (van Tulder *et al.* 2000); **Surgery:** (Jacobs *et al.* 2013a).

CFT involves a broad and flexible multidimensional assessment system to allow the identification of the factors that may be contributing to an individual’s NSCLBP (Vibe Fersum *et al.* 2013, O’Sullivan *et al.* 2015). It then individualises the intervention to target the modifiable factors that are considered to be contributing to each individual’s NSCLBP. This is different to most interventions that are either generic in nature (Hayden *et al.* 2005, Driessen *et al.* 2010, Van Middelkoop *et al.* 2011, Menke 2014) or tailor interventions based on one dimension only (physical or psychological), which have shown limited effectiveness (Kent *et al.* 2010, Saner *et al.* 2011, Haskins *et al.* 2012, Henry *et al.* 2014, Ramond-Roquin *et al.* 2014). Some tailored interventions that have tried to target treatment, by stratifying into more homogenous groups (Hill *et al.* 2011), or individualising treatment based on multiple factors (Asenlof *et al.* 2005, Vibe Fersum *et al.* 2013), have shown more positive results.

CFT prioritises the unique interactions between seemingly different factors in NSCLBP. This is a key focus of the personalised education given to the patient, which “joins the dots” between all the different factors that can be taking place in a person’s life, their cognitions, emotional responses, loss of valued life activities, pain responses to movement as well as lifestyle factors and link them together. In this way, it aims to avoid contradictory messages and encourage individuals to appreciate the body-mind interactions in NSCLBP, with physical, lifestyle and psychosocial co-existing and heavily influencing one another

(Geisser *et al.* 2004, Elfving *et al.* 2007, Woby *et al.* 2007b, Karayannis *et al.* 2013). It is acknowledged that people interpret education differently, and so uses a myriad of educational tools, including using patients own words, analogies, personal metaphors, written material, podcasts and videos. Individuals are encouraged to reflect on their understanding of their pain disorder and barriers to recovery at the end of each session.

It is acknowledged that NSCLBP can be modified and controlled by the individual. CFT does this by providing information on the myths surrounding NSCLBP, discouraging the prominent role of passive therapies and rest in line with guidelines, and giving active coping strategies and goal setting. It acknowledges that the provision of advice alone is not adequate for behaviour change and so puts a substantial emphasis on behavioural experimentation in the clinical setting. In line with other fields of research (phobias, anxiety, post-traumatic stress disorder) where individuals are exposed to feared activities on a one-to-one basis with successful outcomes (Koch *et al.* 2004, Powers and Emmelkamp 2008, Kashdan *et al.* 2012, Rauch *et al.* 2012), CFT exposes individuals to their specific fears and avoided tasks (if relevant) within the safe environment of the clinic, and then translates this to varied activities to reflect life outside of the clinic. It shows individuals how to perform feared and aggravating activities and movements in an adaptive manner with pain control where relevant (e.g. relaxing, breathing, moving more through the spine, with a shift of attention away from their pain and towards their body control e.g. using legs). It then encourages the individual to practice these movements and activities repeatedly, until mastery is achieved. Individuals are frequently given videos to watch featuring other people that recovered from NSCLBP using this approach. This vicarious and experiential learning together with feedback (mirrors, tactile, oral, videos on phone/iPad) and subsequent reflection by the individual is a key feature of CFT. This goal to directly target and enhance pain control during provocative and feared functional tasks is in direct contrast to commonly advocated treatments such as ACT for NSCLBP, where there is no aim to target pain control, but rather to accept pain and move on with a better life (McCracken and Vowles 2008, Vowles *et al.* 2014). It must be acknowledged that the patient in pain is concerned most obviously about their pain and what it means, so to 'ignore' it in an intervention may only make sense if the patient understands the protective action model of pain (Lotze and Moseley 2015). While there are useful elements of ACT that are incorporated into CFT, such as the importance of a patient not "fighting" their pain or their body and goal setting towards valued activities, in CFT it is proposed that enhancing pain controllability can be a powerful

mechanism to reduce fear and enhance functional capacity. This important role for pain control is supported by qualitative research by international collaborators of ours (Bunzli *et al.* 2015a, Bunzli *et al.* 2015b, Bunzli *et al.* 2016).

CFT places a major emphasis on having a positive interaction with the individual. While this idea has always been important in fields of psychotherapy and psychology (Horvath and Symonds 1991, Lambert and Barley 2001), its importance is still emerging in treating musculoskeletal pain (Pinto *et al.* 2012). CFT provides the necessary one-to-one time and attention needed to validate a patient's pain, their experience, thoughts related to their pain, and so allows patients to disclose their pain story and the impact of it on their life. Effective validation involves conveying acceptance and understanding of pain-related thoughts and feelings, while also discouraging maladaptive behaviours (Edmond and Keefe 2015, Linton 2015). CFT harnesses the important factors (listening, empathy, humour, personalised education, simple language, patient preferences, time) outlined in Study III Chapter 2 to aid this and optimise the comfort with disclosure, and so create trust and a good relationship with each individual with NSCLBP. This is important as confiding personal information to another person has been identified as a building block to a good relationship, and disclosure of distressing events has been associated with better adjustment and health (Linton *et al.* 2016). CFT also involves a MI style of communication, which is increasingly being used to facilitate behaviour change, problem-solving and shared decision-making (Chilton *et al.* 2012). Through this open and flexible style of communication, it encourages individuals to engage in change, reflect on their pain experience and discourage maladaptive behaviours. MI helps identify discrepancies in patient beliefs and challenge patients in an empathetic, but assertive manner to provide the patient with the skills to master their situation (Resnicow *et al.* 2002). This communication style is ongoing throughout each session to facilitate patient reflection on their treatment. This also builds trust and allows the therapist to take the individual back to feared activities, directed to their valued goals. With increasing emphasis being placed on the patient narrative as a potential driver of rehabilitation and facilitator of conceptual and behavioural change (Lotze and Moseley 2015), this component of individualised CFT is considered very important.

How does CFT help?

As outlined in Chapter 1, multiple systems (nervous, immune and endocrine) (Marchand *et al.* 2005, Moseley 2007, Wand *et al.* 2011, Vachon-Preseu *et al.* 2013) are involved in NSCLBP and can be influenced by a wide spectrum of factors. It is only in relatively recent times that the role of these systems, particularly the role of the brain, has been more consistently acknowledged in NSCLBP (Moseley and Butler 2015). It has been hypothesised that any input that provides credible evidence of a perceived danger or threat to the individual (e.g. information about minding your back, scan findings, depression, pain is forever, stressful home life) can increase the protective response of the individual and so construct or increase pain, and any input that provides credible evidence for safety to the individual (e.g. reassurance, good sleep, exercise, relaxation, understanding pain) can reduce the protective response of the individual and so decrease pain (Lotze and Moseley 2015). The key features of CFT outlined above aim to reduce threat and promote safety, and this could be reducing pain and disability through multiple mechanisms.

Chapter 3 Study IV demonstrated that CFT led to large increases in pain self-efficacy. This has also been demonstrated in previous research on CFT (O'Sullivan *et al.* 2015). Self-efficacy has been defined as the confidence that one can successfully execute a course of action to produce a desired outcome in a given situation (Bandura 1977). Previous research across domains of psychology, sport and pain has shown that high self-efficacy is fostered by cognitive reconceptualization, education, physical activity, mindfulness, witnessing mastery experiences of similar others, persuasion from credible others to engage in particular activities, graded mastery experiences that are applicable to daily life and structured so that success is achieved, building awareness of physiological and affective states before and after performing desired activities (Feltz *et al.* 2008, Wu *et al.* 2013, Jackson *et al.* 2014). These are fostered by CFT through; the provision of exercise based on individual preference, getting patients to be more mindful of the way they think and respond to pain, exposure to and practice of feared and avoided activities (e.g. bending) in a less painful manner, challenging all unhelpful beliefs and giving patients a personalised, multidimensional understanding of their pain. Low pain self-efficacy has been shown to mediate the relationship between pain and disability in NSCLBP (Arnstein *et al.* 1999, Costa *et al.* 2011). CFT has yielded large changes in self-efficacy when compared to other interventions such as CBT, graded exposure

and exercise (Nicholas *et al.* 1992, Frost *et al.* 1995, Koumantakis *et al.* 2005, Woods and Asmundson 2008, Lamb *et al.* 2010, Ryan *et al.* 2010, Hurley *et al.* 2015).

In Study IV, CFT also led to large reductions in fear, in line with previous CFT studies (Vibe Fersum *et al.* 2013, O'Sullivan *et al.* 2015). Fear tends to be task-specific and contextual (Meulders and Vlaeyen 2013) and can represent a fear of damage (e.g. disc damage, unstable spine) and/or fear of the pain itself (Vlaeyen and Linton 2000, Wertli *et al.* 2014c, Darlow *et al.* 2015). Fear has also been linked to a lack of controllability and predictability of pain and pain intensity (Bunzli *et al.* 2015a, Bunzli *et al.* 2015b). Pain-related fear is associated with increased activation of the amygdala and associated brain areas (Wand *et al.* 2011, Barke *et al.* 2012). Previous interventions involving pain education and one-to-one exposure interventions have led to reductions in fear in back pain patients (Linton *et al.* 2002, Leeuw *et al.* 2008, Wertli *et al.* 2014b). CFT also uses education and exposure to tackle fear. CFT reduces the threat of pain through reconceptualising pain, enhancing pain controllability and predictability, reducing pain experience with movement and using exposure techniques, especially to feared movements and activities. Reductions in fear are associated with reduced activation of brain areas involved in the pain experience (Wand *et al.* 2011).

CFT significantly reduced negative back pain beliefs, in line with previous CFT studies (Vibe Fersum *et al.* 2013, O'Sullivan *et al.* 2015). Negative beliefs and thoughts about back pain are very common, are unique in nature, and are related to greater disability due to NSCLBP (Main *et al.* 2010, Wertli *et al.* 2014a). By providing personalised education about pain and beliefs that specific individuals have, exploring myths and facts about NSCLBP, and showing individuals that they can control their NSCLBP; CFT potentially reduces individuals' perceived threat around their lower back and so promotes positive back beliefs. Other interventions involving biopsychosocially orientated pain education have led to significant changes in back pain beliefs (Burton *et al.* 1999, George *et al.* 2009, Louw *et al.* 2011), though interestingly not all studies reporting positive changes in beliefs reported accompanying positive changes in pain and disability (Moseley *et al.* 2004). This may suggest that changing thoughts and beliefs alone, without addressing other components such as returning to personally meaningful activities, is not enough (Bunzli *et al.* 2013b, Bunzli *et al.* 2016).

While CFT targets different factors depending on the individual presentation (e.g. physical factors), strong evidence demonstrates that successful outcomes, even after a purely

physical intervention, are often mediated by changes in the above cognitive and emotional factors (e.g. fear, self-efficacy, beliefs) (Mannion *et al.* 2001b, Spinhoven *et al.* 2004, Smeets *et al.* 2006, O'Sullivan *et al.* 2015). Overall, CFT reduces perceived threat around the lower back and promotes safety, which could be reducing the protective response of individuals' neuro-immuno-endocrine systems, through changes in fear, self-efficacy and beliefs.

Theoretical underpinnings of CFT

CFT is best considered a hybrid, integrative model. As it looks at the interplay between multiple factors, transcending rigid subgrouping or “one-size fits all” approaches; it is not based on any one model or theory. Instead, it builds on the theoretical constructs within other successful models, to allow a more flexible and liberal approach to the management of NSCLBP. Self-efficacy has already been discussed. Other important models are discussed below;

The Mature Organism Model emphasises the dynamic interplay between the nervous, immune, endocrine, and motor systems in promoting health and/or the development of poor health (e.g. NSCLBP and its associated disability) (Gifford 1998). It describes that tissue health (e.g. discs, muscles) is analysed and communicated along with contextual information about the individual's environment, via input mechanisms (i.e. all sensory pathways). It argues that the brain scrutinizes (both consciously and unconsciously) incoming information (Jones *et al.* 2002). If sensory inputs reach a conscious level they may be scrutinized alongside, and be influenced by, an individual's past experiences, expectations, beliefs and attributes. All this information is analysed in order to create a response via the output mechanisms (i.e. nervous, immune, endocrine, and motor systems) (Jones *et al.* 2002). The model states that how an individual thinks and feels about a given situation has major influence on the physiological, psychological and behavioural ‘output’ responses generated, which in turn affects how the person's health is manifest. In this way, the model challenges that factors (e.g. physical, psychological) are mutually exclusive; but instead exist on a continuum that varies from person to person. This challenges dualistic and peripheral thinking about NSCLBP and encourages more flexibility and creativity in management approaches. Clinically, this means allowing the person with pain the freedom, time and environment to express their thoughts, feelings, fears, perceptions and experiences, and encouragement to find self-motivated strategies to understand and manage their pain (Jones *et*

al. 2002, Gifford 2013). CFT embraces this model by not boxing people into rigid subgroups, letting the person's narrative guide management, and acknowledging the dynamic interplay between multiple factors in NSCLBP.

First-person neuroscience (Thacker and Moseley 2012) describes pain as an emergent property of the person that is suffering it. It argues that clinicians need an understanding of the interactions between neuroscience, immunology, endocrinology, psychology, sociology and philosophy to understand and effectively manage pain (Thacker and Moseley 2012). It highlights the importance of taking a first person perspective approach to assessment; investigating the experience of the person in pain. This challenges traditional methods, where clinicians ask a generic set of questions to make a diagnosis. This resulted in individual pain experiences not being heard. First-person neuroscience attempts to combine the subjective experience of an individual with physiological data obtained in the third-person domain (by the clinician) (Thacker and Moseley 2012). It aims to extract the feelings and experiences of the person with pain, together with the meaning for the person and its impact on his or her life. CFT embraces this model by letting the person's narrative guide the assessment and management.

The Common sense model of illness representation (Leventhal *et al.* 2003) suggests that individuals develop an understanding of their illness or diagnosis by formulating their own ideas of what the illness is, its causes, its consequences, and whether it can be cured or controlled. "Common sense", is highly personalized in that individuals act and display behaviours that make sense to them, which can vary greatly from individual to individual or culture to culture (Leventhal *et al.* 2003). What makes sense to one individual or group may not to another. Although members of a specific population or culture can have similar ideas and feelings about certain health issues and practices, every individual is unique in their own personal experiences, personality characteristics, and surroundings (Leventhal *et al.* 2003). CFT embraces this model by acknowledging that people will react and cope differently with pain (e.g. different movements, avoidance versus endurance, inactivity versus over activity). This creates a platform to provide an individualised management approach, instead of a "one-size fits all" approach.

Experiential learning theory emphasises the process of learning through experience, or learning through doing (Kolb 2014). The theory states that the individual must be willing to be actively involved in the experience; be able to reflect on the experience; must possess and use analytical skills to conceptualize the experience; and must possess decision making

and problem solving skills in order to use the new ideas gained from the experience (Kolb 2014). CFT implements experiential learning theory by getting people with NSCLBP to engage in different behavioral experiments in the clinic (e.g. new ways of bending, moving or responding to pain) and uses motivational interviewing strategies to get individuals to reflect on the experience.

CFT encompasses **exposure therapy** (Linton and Fruzzetti 2014) to expose individuals to feared, avoided or provocative activities (e.g. bending, playing with kids, socialising). It builds on traditional exposure which considers movement only, to considering and regulating emotional responses and goals during movement. Emotions, like fear can generate unhelpful safety behaviours (e.g. hand propping, breath holding, bracing) (Linton and Fruzzetti 2014). Providing **emotional regulation** during movement should encourage and empower individuals to engage in exposure (Linton and Fruzzetti 2014). **Personally relevant goals** during exposure also would seem to be essential from a motivational perspective (Wright 2016). Therefore, exposure in CFT focuses on goal pursuit in a task and context specific manner based on the individual's story, combined with emotional regulation throughout, to encourage and motivate individuals to engage in exposure and continue until their personal goals are achieved. This approach also builds on the **Fear Avoidance Model** of musculoskeletal pain and derived from procedures like Dialectical Behavioural therapy which highlights emotion regulation skills and incorporates goal pursuit (Linton and Fruzzetti 2014).

Crucially, no one model has been found to be superior to another (Michie *et al.* 2009, Jensen *et al.* 2016). Therefore, integrating components from different models into management may be a viable option.

Clinical Implications

1.Be aware of the multiple factors involved in pain: Given that multiple factors across the biopsychosocial spectrum are involved in NSCLBP (Gatchel *et al.* 2007, O'Sullivan 2012), and that generic, unidimensional interventions have small similar effects on NSCLBP outcomes (Chapter 2 Study I and II), HCPs treating people with NSCLBP may need to adopt a multidimensional framework of assessment and treatment to target the main contributing factors to a person's disorder in an individualised manner. Traditionally, physiotherapists may have a more "physical" bias aiming to "correct" postures, increase

flexibility, “release” muscle tension, through modalities like manual therapy or exercise. In contrast, psychologists may have a more “mind” bias aiming to change cognitions and improve psychological distress. It now seems vital that HCPs assess and target a multitude of physical, psychological, lifestyle and social factors, where relevant. Of importance, HCPs may need to interpret the links between these factors and then decide on an appropriate management plan based on evidence. However, a body of qualitative research has demonstrated that physiotherapists have a poor knowledge of “non-physical” factors in pain, express preference for dealing with the more “physical” aspects of NSCLBP, and stigmatize the behaviours suggestive of psychological and social contributions to NSCLBP (Singla *et al.* 2015, Synnott *et al.* 2015). Changing this is of crucial importance but could be challenging.

2. Remember that individualised physiotherapy is not the same as individual physiotherapy: Study II in Chapter 2 demonstrated that individual physiotherapy interventions where patients are seen on a one-to-one basis, but all receive the same intervention, have similar small effect sizes. In contrast, Study IV in Chapter 3 demonstrated that an individualised physiotherapy approach (CFT) tailored to the individual needs of the patient has produced superior effects, similar to the first RCT (Vibe Fersum *et al.* 2013) investigating this intervention. This may underscore the importance of tailoring treatment to an individual’s needs and preferences. In light of this, HCPs working clinically may need to tailor treatment to the individual patient.

3. Optimise the patient-therapist interaction: Study III in Chapter 2 displayed that a host of interpersonal and communication skills, practical skills, the ability to individualise care and organisational and environmental factors are perceived by both patients and physiotherapists to influence the patient-therapist interaction. This review builds on the existing evidence that a strong therapeutic alliance is associated with positive outcomes (Hall *et al.* 2010, Ferreira *et al.* 2013b, Fuentes *et al.* 2014), and may give us an insight into the factors that may need to be harnessed. This may highlight that HCPs need to be multi-skilled. They need to understand the multidimensional nature of NSCLBP, be skilled communicators, be able to perform a competent assessment, and critically be able to educate and motivate patients. An important finding from Study III in Chapter 2 was the lack of importance that physiotherapists placed on patient education. This may indicate that physiotherapists feel their role is more in doing “something”, whether it is an exercise programme or a passive modality, rather than listening or educating. All HCPs (e.g. physiotherapists) treating people with NSCLBP may need to put more value on what they say, how they say it, their overall

listening skills and possibly consider upskilling in these areas. Study III in Chapter 2 also demonstrated that organisational and environmental factors are perceived to influence the patient-therapist interaction (e.g. providing adequate time). This builds on other evidence displaying the importance of contextual factors like physiotherapist appearance and the physiotherapy environment (e.g. privacy, atmosphere) in outcome (Testa and Rossetini 2016). It must be acknowledged that enhancing the environment may require system changes. For example, the provision of more space for privacy, so patients feel comfortable to disclose sensitive information. Furthermore, the provision of longer appointments for some initial consultations which seem complex may be helpful. However, time and reimbursements has been proposed as barriers to this type of initiative in mind-body medicine approaches (McGuire *et al.* 2016).

4. Adopt an empowering, integrated approach to NSCLBP: Study IV in Chapter 3 demonstrated that an individualised, multidimensional approach to NSCLBP has superior outcomes for pain and disability compared to a generic group multidimensional intervention. This could indicate that clinical physiotherapists have a major role to play in modifying NSCLBP. The intervention yielded larger changes in self-efficacy, fear and risk of ongoing chronicity. The results may underscore the importance of empowering patients such that they can exert mastery over their problem. Physiotherapists, as well as other HCPs, may need to place more focus on these factors in the clinic. It could be possible that physiotherapists for example, need to reduce patient dependence on passive therapy and instead instil patients with an understanding of their NSCLBP and the coping skills required to self-manage and improve. This may require the ability to discuss emotions (e.g. depression, anxiety, stress) and to challenge the patient on maladaptive behaviours (e.g. not engaging in physical activity, avoidance of lifting). However, it is common for HCPs to feel “stressed” by negative emotions when dealing with patients or think it is outside of their scope of practice (Ptacek and Eberhardt 1996, Linton 2015). Their concerns for upsetting the patient with questions often culminate in the avoidance of emotionally sensitive topics altogether (Edmond and Keefe 2015, Linton 2015). This is a challenge, as patients’ perceptions of how well they are understood and validated will affect the success of the consultation (Zachariae *et al.* 2003, Linton 2015). Getting HCPs to be less avoidant of sensitive discussions may be a challenge.

5. Education through multiple methods: Study IV in Chapter 3 demonstrated the effectiveness of an individualised intervention that used a combination of educational strategies. It involved verbal education, written education, but also education through

behavioural experiments (e.g. exploring new ways of bending and lifting) combined with reflection on how their NSCLBP related to their personal life story. This builds on a body of evidence that shows that education can be delivered in a variety of forms (Louw *et al.* 2011, Stewart 2014) and ideally in a manner which is relevant to the individual (Robinson *et al.* 2015). This could indicate that HCPs need to be trained in various strategies in the clinic on how to educate a patient, and be flexible in the strategy they choose and how they deliver it, to optimise patient understanding.

Can CFT be further optimised?

While CFT has demonstrated clinically meaningful reductions in pain and disability in the preliminary analysis of this thesis and in a previous trial (Vibe Fersum *et al.* 2013), pain and disability levels still remain moderately high, indicating there is significant room to further improve outcomes. CFT has demonstrated improvements in self-efficacy and fear but these could be further optimised to ensure the large improvements post-intervention are maintained in the long-term. Depression, coping and sleep only changed modestly after CFT, while stress and anxiety remained relatively unchanged after the intervention. Given the individual nature of NSCLBP, these factors may be more important for certain people and improving their management may lead to better outcomes. It is possible that the current CFT intervention does not target these factors adequately. Some suggested modifications to the current CFT intervention are proposed:

1. Adopting a chronic care model: While this thesis has shown that NSCLBP and its associated disability are modifiable, there have been calls to label NSCLBP as a long term condition that is vulnerable to recurrence throughout the lifespan (Dunn *et al.* 2013). In fact, 25%-30% of individuals in another CFT study (O'Sullivan *et al.* 2015) experienced a relapse of symptoms at long-term follow-up. To optimise long-term self-management of a broad range of chronic diseases, a chronic care model has been advocated (Wagner *et al.* 1996). This model replaces generic, short-term, acute care models, with longer-term strategies. It typically provides periodic monitoring and support to maintain patient health, emphasise patient self-management, and include technological components where relevant. Interestingly, Study III in Chapter 2 displayed that patients felt that it was very useful to be able to contact their therapist following treatment and get some advice, reassurance and talk about uncertainties. This flexibility could possibly be achieved through a chronic care model.

Adopting this chronic care model has resulted in greater compliance with therapy and improved outcomes for patients with a range of chronic diseases (e.g. diabetes, obesity, cardiovascular disease, chronic obstructive pulmonary disease and mental health disorders) (Adams *et al.* 2007, Coleman *et al.* 2009, Jacobson and Gance - Cleveland 2011, Woltmann *et al.* 2012, Stellefson 2013, Baptista *et al.* 2016). Currently, the CFT intervention as tested in the two RCTs has involved one block of treatments after which patients are then discharged. However, strong evidence demonstrates that issues like stress, coping and anxiety are highly complex and require long-term behaviour changes to improve. Furthermore, long-term adherence to positive lifestyle behaviours like physical activity which benefits sleep and mental health (Ströhle 2009, Yang *et al.* 2012, Rosenbaum *et al.* 2015) tend to be poor (Adams and White 2003), and better adherence may be advantageous to outcome. Giving patients the option of booster sessions (either by telephone or face to face) may be helpful to realign goals, track progress or seek clarification. Boosters have previously been shown to be beneficial in a NSCLBP population (Monticone *et al.* 2013). Monitoring certain patients' self-efficacy levels via short message service or email might be useful, and could be used to organise a possible booster if needed. This type of service is being increasingly used in other conditions (Kayyali *et al.* 2008, Sicotte *et al.* 2011, Kent and Kongsted 2012). Incorporating technology such as activity and sleep monitors (e.g. fitbit) (Bravata *et al.* 2007, Kayyali *et al.* 2008, Adam Noah *et al.* 2013, Diaz *et al.* 2015), stress management applications (Dickerson *et al.* 2011, Donker *et al.* 2013, Plaza *et al.* 2013) or internet coping skills applications (Carpenter *et al.* 2012, Bring *et al.* 2015), depending on the individual's needs may also boost the benefits of CFT, through providing motivation and long-term self-management strategies. While these types of applications are in their infancy and so currently lack strong scientific evidence, their combination with evidence-based treatments could prove beneficial.

2. Integration of other HCPs and organisations: CFT represents an integrative approach delivered by a single physiotherapist. Certain people with NSCLBP have complex presentations, involving high levels of depression, sleep problems or a strong contribution from social factors (e.g. family and work issues, compensation). Therefore, any clinic based intervention may be limited in its capacity to change these factors (e.g. work and family relationships). Patients who are unresponsive may require multidisciplinary care (Kamper *et al.* 2015). Greater communication and involvement of other HCPs (e.g. general practitioner, psychiatry, and psychology) and partner organisations (e.g. workplace) could be helpful. However, achieving this could be a very difficult task. The possibility that NSCLBP will

remain highly resistant to treatment in some patients, even with an integrated approach, cannot be discounted, given the complexity of these factors and the poor effect sizes reported (Kamper *et al.* 2015). In addition, getting all HCPs involved in a person's care agreeing on the mechanisms at play, delivering a consistent message and an integrated treatment approach would also pose a challenge to successful multidisciplinary care. This may explain the current small effects for multidisciplinary care for NSCLBP (Kamper *et al.* 2015), and so its expense may not be justified. Involving family members (e.g. parent, spouse) (Swift *et al.* 2014) in rehabilitation may also be helpful and could potentially provide support and encouragement. Greater involvement of other non-clinical partners (e.g. employers, insurance companies, social welfare) may also be of benefit where feasible.

3. Tackling societal beliefs about pain: While modern research has debunked many erroneous beliefs about NSCLBP (e.g. need for scans, structures being out of place, bed rest) in favour of a more biopsychosocial view of NSCLBP, the shift does not seem to be reflected in societal thinking, with members of the public still seeming to believe many myths about NSCLBP, and associate their pain primarily with biomedical and biomechanical factors (Steffens *et al.* 2015). Therefore, biopsychosocially oriented interventions, like CFT; have to spend a significant amount of time and resources (e.g. leaflets, videos) on debunking common myths about pain. If a single physiotherapist is the only person debunking these myths, while patients still receive contradictory messages from family, media or other HCPs, the task of changing patient beliefs represents a huge challenge. Furthermore, the chance of rejection of the role of other factors (e.g. psychological) is high given a lack of understanding of how these factors relate to pain. A potential aid could be the running of public campaigns about the contemporary understanding of NSCLBP. Engaging with the public in this way may help with beliefs. I completed a piece called "15 things you didn't know about back pain" for a national newspaper in Ireland, <http://www.independent.ie/life/health-wellbeing/15-things-you-didnt-know-about-back-pain-31367264.html> which received a significant numbers of shares and reads on social media. Furthermore, my supervisor (Dr. Kieran O'Sullivan) chaired an Irish campaign called "Challenging Back Pain Myths", whose materials have been adopted by the World Confederation of Physical Therapy (WCPT) http://www.wcpt.org/sites/wcpt.org/files/files/Publicity_materials-ISCP-Booklet.pdf. A population based intervention in Australia led to significant improvements in back pain beliefs (Buchbinder *et al.* 2001). However, a similar initiative in Canada did not replicate these improvements (Gross *et al.* 2006). This may be related to the greater levels of funding

and more widespread advertising achieved in Australia. For example, a musculoskeletal research group in Australia have recently received a grant to reduce unnecessary imaging in musculoskeletal pain, like NSCLBP. Initiatives like these could optimise the impact of CFT and other NSCLBP interventions. However, they are very expensive and could require the involvement of media and industry to help funding.

Can the group intervention be further optimised?

The group intervention in this thesis yielded effects in line with the small to moderate effects of conservative interventions (physical, behavioural, combined, group, individual) that were examined in Chapter 2 of this thesis. The group intervention examined in this thesis displayed encouraging improvements in self-efficacy and fear. However, in the last few months, research on group interventions has been published showing better effects than the current group intervention (Cherkin *et al.* 2016). This may have been related to the participants being relatively affluent and were referred from a group health facility, suggesting possible preference for a group intervention. This recent RCT (Cherkin *et al.* 2016) examined the effect of group mindfulness, group yoga versus usual care on NSCLBP and yielded clinically significant improvements in disability in favour of the two interventions. Many HCPs acknowledge the group effect in the treatment of chronic pain (Russell *et al.* 2014, Murphy *et al.* 2015, Wilson *et al.* 2016), and group physiotherapy has been associated with reduced costs (albeit modest) over individual physiotherapy (Critchley *et al.* 2007). Some suggestions on how to optimise the group are proposed:

1. Patients with NSCLBP could be individually assessed before entering the group to allow better understanding of the relevant contributing factors and allow them to tell their story. Based on this, patients could be stratified into more homogenous groups. For example, patients with similar factors at play could be put in the same group (e.g. similar physical factors, similar psychological distress). However, given the interaction between multiple factors in NSCLBP and that each person's NSCLBP is individual; splitting into these arbitrary groups could be very difficult. Group homogeneity has also been hypothesised in terms of having people of a similar age, sex, culture and socio-economic status in the same group (Wilson *et al.* 2016). Another suggestion could be to give patients some individual physiotherapy first, to specifically target certain factors (e.g. beliefs, establish a positive interaction) and then transfer them to a group for other factors (e.g. maintaining physical

activity). Conversely, patients could begin treatment within a group, and if not responding, they could receive some individualised physiotherapy. If patients received a baseline individual assessment before starting the group, they could be encouraged to do more of certain activities in the group (e.g. more relaxation, more of a certain exercise). On the other hand, patients could also be given the option to pick whatever type of activity they want to do within the class, given that patients like their preferences to be accounted for (O'Keeffe *et al.* 2015a). Preference for, and perceived value of, group work are strong predictors of outcome in teamwork unrelated to pain (Bell 2007), so it may be worth examining whether a person with NSCLBP wants to receive a group intervention.

2. The total number and frequency of classes could be increased, with some evidence from the psychotherapy literature demonstrating that greater than 12 classes may be needed to increase group cohesiveness (Burlingame *et al.* 2011). Furthermore, it may be worth ensuring that the number in the group is not too large, with evidence showing that smaller groups perform better (Lei *et al.* 2010).

3. The group could be more led by the patients, giving them more time for open discussion, problem-solving and discussing goals and views (Wilson *et al.* 2016). However, this potentially could be detrimental to the group, if the individuals clash (e.g. personality type, opinions on pain, dominant person or negative person). While the benefit of modelling others behaviours could be beneficial and motivational, modelling unhelpful beliefs or unhelpful movement patterns could result in worse outcomes.

Strengths and limitations of thesis

This doctoral thesis has many strengths. The three systematic reviews and RCT protocol have already been published in reputable journals. The three reviews have been presented at prestigious conferences such as WCPT 2015. The study methodologies are strong. The reviews and RCT were prospectively registered. The database searching and critical appraisal was completed by two independent reviewers for each review. The RCT is the first to evaluate whether it is the individualised nature of CFT, or its multidimensional nature, which is key to the promising results previously reported. The RCT was powered adequately, assessor blinded, included a wide array of outcome measures based on the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) recommendations for chronic pain clinical trials (Dworkin *et al.* 2008) and involved

strategies to enhance treatment fidelity. It had broader inclusion criteria than the previous CFT trial, and most NSCLBP trials, enhancing generalisability. The RCT abstract meets the CONSORT guidelines for RCT abstract content. Furthermore, the thesis contained a mix of quantitative and qualitative methods, which is strongly recommended in the design of complex interventions.

The thesis also has limitations. The simple categorisation of interventions into physical, behavioural and/or psychologically informed and combined in Study I in Chapter 2 is a limitation of this review, as these interventions may not be easily differentiated to allow accurate comparisons to be made. In reality, interventions cannot be easily differentiated and separated which introduces a lot of heterogeneity, making meaningful comparisons very difficult.

Studies in Study II in Chapter 2 displayed differences in the type of intervention provided within group and individual physiotherapy, with some individual interventions including passive therapies (e.g. manual therapy), and some group interventions including relaxation. This limits the ability to decipher the true effectiveness of exercise and its effect could be diluted through the provision of other modalities, though the interventions probably did reflect what typically happens in clinical practice. While Study III in Chapter 2 has identified factors that are perceived to be related to the patient-therapist relationship, this does not mean that these perceived factors are actually related to the quality of these interactions or patient outcomes. The three studies in Chapter 2 do not investigate NSCLBP in isolation. Study I is on NSCSP, while Studies II and III include multiple MSCs, including NSCLBP. However, subgroup analyses did not reveal any differences in outcomes between NSCLBP and the other MSCs.

Only studies published in English were included in the reviews, therefore other relevant studies in other languages may have been excluded. Procedures to rate study quality have evolved since the completion of the reviews. The thesis used a summary score and specific cut-off values to distinguish high from low quality studies. This approach has limitations however, as meta-epidemiological evidence suggests that failure on any one of the criteria might alone explain a small positive effect on a subjective self-reported outcome.

A descriptive analysis of the RCT is provided. Definite conclusions about efficacy therefore cannot be made at this point. The full dataset must be analysed to confirm these preliminary results. A limitation of this study was the number of participants that did not start or complete the interventions after randomisation, though the rates of retention and follow-up

are in line with other trials involving similarly disabled cohorts of people with NSCLBP, where follow-ups range from 60%-88% (Critchley *et al.* 2007, Ferreira *et al.* 2007, Chown *et al.* 2008, Vibe Fersum *et al.* 2013, Cherkin *et al.* 2016).

Future research

Study IV in Chapter 3 of this thesis presented the preliminary six month follow-up for 171 participants and 12 month follow-up for 142 participants. Follow-ups are ongoing for the remaining participants. On completion of the data collection an ITT analysis of all randomised participants will be completed to assess the significance of the intervention effects.

Costs relating to the individual and society have been collected at six and 12 months for both interventions in the RCT. Given the potential of group interventions to reduce healthcare costs (Critchley *et al.* 2007); it is necessary to analyse this data to examine whether CFT is a cost-effective, as well as clinically-effective intervention option.

Qualitative interviews of 20 participants from both interventions have been conducted after completion of their six month follow-up questionnaires. Given the major effect of NSCLBP on a person's life (Bunzli *et al.* 2013b), and that previous qualitative interviews after a CFT intervention revealed a lot of rich information about patient experiences and beliefs (Bunzli *et al.* 2013a, Bunzli *et al.* 2016), analysing patient perspectives after the RCT in this thesis may generate knowledge that could be useful in future intervention planning and execution.

Future studies should try to better optimise CFT to target stress and sleep and maintain long-term improvements in self-efficacy and fear. Conducting interdisciplinary research in conjunction with general practitioners, psychologists, workplaces, and patient advocacy groups could ensure that different HCPs have a consistent message about NSCLBP. Furthermore, different expertise could better help target complex factors like stress, coping and social factors. Comparing the effect of CFT with boosters to CFT alone would be useful to examine if there is long term benefit of providing continued support to NSCLBP if needed. Picking the patients that may benefit from boosters and the patients that may not (e.g. chance of dependency) would be also worth investigating. The emerging field of e-health may provide opportunities for future research. Researching the added value of devices like activity or sleep trackers, stress management applications or internet delivered programmes to CFT

compared to CFT alone would be useful, to see if such adjuncts could help with outcomes like self-efficacy, coping, physical activity and sleep.

Given the established benefits of group interventions for pain disorders, future research on optimising the group through greater individualisation, greater patient choice, a greater emphasis on certain components of therapy (e.g. relaxation) and a combination of group and individual physiotherapy where appropriate could be worthwhile.

Given the emerging evidence that the same multidimensional factors and mechanisms underlie many persistent MSCs (e.g. shoulder pain, neck pain, knee pain, arthritis, widespread pain) (Söderlund and Lindberg 2003, Sterling *et al.* 2003a, Sterling *et al.* 2006, Gupta *et al.* 2007, Arendt-Nielsen *et al.* 2010, Guermazi *et al.* 2012, Bring *et al.* 2013, Carroll *et al.* 2014, McBeth *et al.* 2014, Mundal *et al.* 2014, Carriere *et al.* 2015, Hart *et al.* 2015, Falla *et al.* 2016, George *et al.* 2016, Wylie *et al.* 2016) and the small effects of current interventions in these populations too (Chapter 2 Study II), it may be worth piloting the effect of CFT on pain and disability in these other populations.

It has been proposed that musculoskeletal disorders like NSCLBP begin early in the lifespan (e.g. adolescence), and frequently recur and relapse throughout the lifespan (Dunn *et al.* 2011, Dunn *et al.* 2013). Future research into understanding the determinants of musculoskeletal pain and disability earlier in the lifespan (e.g. adolescents) may increase our understanding of pain and develop preventative strategies at an earlier stage to reduce disability related to MSCs.

Conclusion

Generic, “one-size fits all” interventions have small effects on NSCLBP, irrespective of content (physical, behavioural/psychological, combined) or mode of delivery (individual or group). Having a good patient-therapist interaction is important and harnessing interpersonal and communication skills, practical skills and patient-centred care may improve the interaction and outcomes, if used to deliver evidence-based information. Preliminary results of an RCT suggest that superior outcomes can be yielded by adopting an individualised multidimensional approach to NSCLBP over a generic multidimensional group intervention.

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Appendices

Will be presented in four main parts:

- 1. Doctoral thesis resources**
- 2. Public engagement and blogs**
- 3. Co-authored publications**
- 4. Letters to the editor**

Appendix 1: Doctoral thesis resources

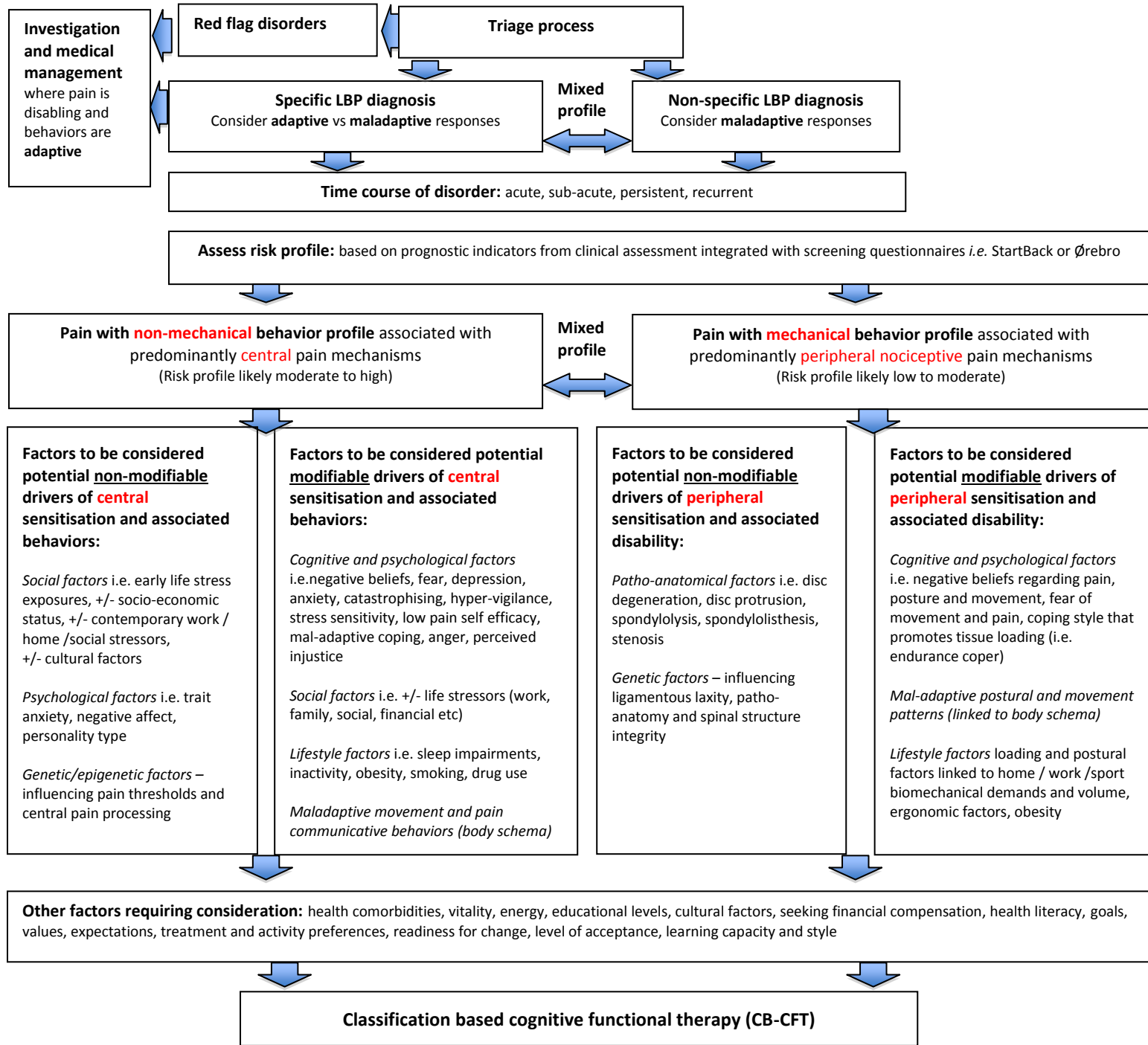
1a. Cognitive Functional Therapy Clinical Reasoning Framework for targeted management of low back pain

1b. Randomised controlled trial (Study V) patient information leaflets: Sleep, X-rays and MRIs, Mindfulness and Relaxation and Exercise and Physical Activity

1c. Cognitive Functional Therapy in action: A patient case study

Clinical reasoning framework for targeted management of LBP

In the context of a strong therapeutic relationship emphasizing person-centred care, utilising motivational communication approach



Flexible multidimensional intervention directing care at the modifiable drivers of pain and disability in order to deliver targeted person centred care.

Four components are targeted based on the various levels of the MDCS and linked to the patient's goals;

- 1. Cognitive** – bio-psycho-social understanding of pain, cognitive reframing, developing adaptive pain coping strategies
- 2. Functional training** – training body schema, functional postural and movement behaviors and abolishing pain behaviors specific where present
- 3. Functional integration** - integrate new behaviors into activities of daily living +/- targeted conditioning
- 4. Lifestyle change** as indicated

CB-CFT targeted to reduce central sensitisation

1. Explain the role cognitive, psychological, social, behavioral and lifestyle factors play, setting up vicious cycle of central sensitisation and disability. Develop adaptive pain coping strategies, mindfulness, fear reduction, stress management, acceptance where indicated.
 2. Body relaxation +/- body scanning / mindfulness integrated into provocative functional tasks, address maladaptive functional and pain communicative behaviors if present, pacing, exposure training if high levels of fear avoidance.
 - 3 Activity pacing, general conditioning, social, work and home engagement.
 4. Sleep hygiene, activity levels, sedentary behaviors, diet, smoking, alcohol and drug use etc.
- Integrated with *medical* and *psychological* management where indicated

Mixed profile

CB-CFT targeted to reduce peripheral sensitisation

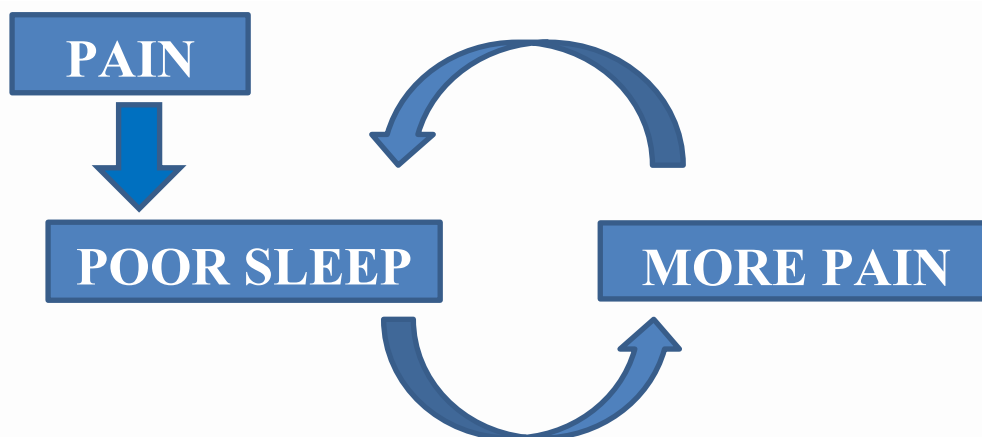
1. Explain factors linked to peripheral sensitisation, address beliefs
2. Address maladaptive functional behaviors (postures and movement patterns) based on movement classification, linked with primary functional impairments and pain provocation. Manual therapies may be integrated where movement impairments provides a barrier for behavior change.
3. New functional behaviors are incorporated into activities of daily living, sports, work and social settings previously reported to be provocative. Ergonomic adjustments are made where necessary to facilitate new behavior. Targeted conditioning and pacing of activity / loading are integrated where appropriate.
4. Address lifestyle factors such as activity, sedentary behaviors and weight loss where they are linked to increased spinal loading. Integrated with *medical* management where indicated

Sleep

Sleep like diet and exercise, is closely linked to health and well-being. Sleep quality and duration affect a person's health in many different ways. If left untreated, sleep problems and chronic short sleep are associated with:

- Pain and muscle tension
- Increased inflammation in our body
- Reduced immune system function, which is linked to greater vulnerability to pains and stiffness, as well as getting “burned out”, cold sores, colds, flus, dry skin, changes in breathing, sinus problems, stomach discomfort and changes in bladder/bowel function.
- Stress, anxiety and depression, all of which lead to increased pain and muscle tension.
- Tiredness, lack of energy and reduced interest in activities and performing exercise
- Increased risk of conditions like heart disease, high blood pressure, obesity

Therefore, improving one's sleep can help with reducing pain, reducing muscle tension, improving immune function, mood, energy and overall general health. No other activity delivers so many benefits with so little effort.



Why do I have problems with my sleep?

Many things can affect a person's sleep time and quality. When you are in pain, you may feel restless, it can be hard to get comfortable and relaxed to go to sleep. While it was mentioned above that poor sleep can lead to stress, anxiety, depression, these things can also cause you to have a sleep problem. Low mood or negative, worrying or stressful thinking during the day and particularly before going to bed has been shown to directly have an effect on sleeping and the number of times you wake up during the night. Eating and drinking too late which is discussed below, will also impact on your sleeping ability. Therefore, things like pain, stress, worry, exposure to screens (laptop/TV) and eating and drinking keep the body “switched” on. Therefore, the meditation and visualisation mentioned below along with the other tips may be very helpful with achieving this state of relaxation.



How do I know if I have enough sleep?

Most healthy adults need between 7.5 to 9 hours of sleep per night to function at their best. Less than 6 hours can cause back and or neck pain. Sometimes (e.g. pregnancy, puberty, stress) we need even more! As well as the duration of sleep, there are other considerations e.g. Do you feel refreshed in the morning, and throughout the day? Do you not always need an alarm clock to wake in the morning? Do you have enough energy throughout the day? Do people tell you that you look refreshed? If you answered yes to these, you have enough sleep!

Tips to improve your sleep include;

Maintain a Sleep Schedule:

You should try to go to bed at the same time every day (the same goes for waking up). This rhythm will help keep you refreshed throughout the day. Sometimes people in pain spend long periods in bed, yet not sleeping. So we suggest you stay out of bed at times other than when sleeping (or doing mindfulness/meditation), so that the bed is closely linked to sleep.

Eat and Drink Responsibly:

Remember not to eat less than two hours before going to bed, to help prevent discomfort such as indigestion. However, you also shouldn't go to sleep hungry, as that will also provide you with a lot of unnecessary discomfort. Also, control how much you drink before going to bed. Keep caffeine and alcohol consumption low – and especially before bed time.

Exercise more often:

Doing any type of exercise/physical activity during the day will help you sleep more calmly at night. Walking, using the stairs, jogging, cycling, swimming, gardening, stretching are all good and help relax all the tense muscles in your body. When you are tired because of physical activities, you are sure to fall asleep faster. Always pick an exercise you enjoy, and start gradually!



Create a Bedtime Ritual:

A bedtime ritual, such as reading a book, or doing some mindfulness/meditation, will help your body prepare to sleep. A regular bedtime ritual will make you feel tired around the same time every day, and fall asleep quicker. This goes hand in hand with your regular sleeping schedule.

Relaxation and Clear Your Mind:

Meditation and visualisation will help you prepare for make you prepared to go into a deep sleep. This is recommended also if you wake up during the night and can't get back to sleep. Try the breathing, clear your mind and try not to think about everything that awaits you the next day. Make a deal with yourself that you will leave those things to the next day (imagine putting your concerns and jobs into a box and locking them away until the next day!) If this is not working, maybe get up for a while, then go back to bed and try your relaxation and breathing again. If you are not relaxed, then you won't get the rejuvenation you need, and you won't be able to do everything that you planned for the next day. Refer to relaxation sheet for tips.

Visit www.pain-ed.com for more information

X-rays and MRIs

We used to think that if we got a good picture of the spine with x-rays or scans that it would be a big help in dealing with pain. However, we now know that this is most often not the case! When people have MRIs and x-rays for low back pain, the scans often show up things that are poorly linked with pain. In fact, studies have shown that even people who don't have back pain have things like bulging discs (52% of people), degenerated or black discs (90%), herniated discs (28%) and 'arthritic' changes to their joints/bones (38%). Remember these people do NOT have pain! All relevant studies find NO DIFFERENCES in bony and disc alignment in people with and WITHOUT back pain. In other words, pain is rarely explained by the things we see on scans.



The likelihood of finding something showing up on scans increases with age. We show age on the outside like developing wrinkles and grey hair. Scans show signs of aging on the inside, which doesn't mean there is anything seriously wrong. In other words, degenerative and bulging discs are similar to a grey hair or wrinkles – they don't necessarily cause pain!

If we see the same things on scans among both people with and without pain, it can be hard to know what is actually relevant to your pain. For this reason, scans like x-rays and MRIs can provide misleading information which isn't good for you. Being told that you have “wear and tear” or have something “out of place” or “bulging” like a bone or disc can lead to fears about the structure of the back, promote you to avoid activities, and increase dependence on others for help. All these fears can make you cautious and lead to you protecting your back, which can lead to lots of muscle guarding, stiffness and discomfort.



Scans could lead to recommendation for interventions like surgery which is rarely needed and isn't superior to approaches like exercise, movement and relaxation. It is worth noting that many people feel better after undergoing massage and manipulation. However, this improvement is due to short-term reductions in pain, muscle tone/tension and fear, **NOT** due to realigning of body structures.

So REMEMBER:

- The back is a strong, robust structure which is designed to move to keep it healthy.
- Serious or permanent damage is rare.
- Finding things on scans such as disc bulges and degenerative discs are common in people with and without back pain, with NO DIFFERENCES between the scans of people with and without pain!
- Pain is driven by lots of factors and therefore the best treatment is an approach that involves keeping active, adopting a healthy lifestyle and thinking positively about your back.
- X-rays and MRIs are rarely needed therefore it is best to focus on improving your health and lifestyle, like exercise, sleep, stress management and relaxation.

Further information:

watch this video <http://www.youtube.com/watch?v=OjZaN0s26xo>

Or type “**should you have an mri for low back pain**” into Youtube to watch the above short video

visit www.pain-ed.com for more information

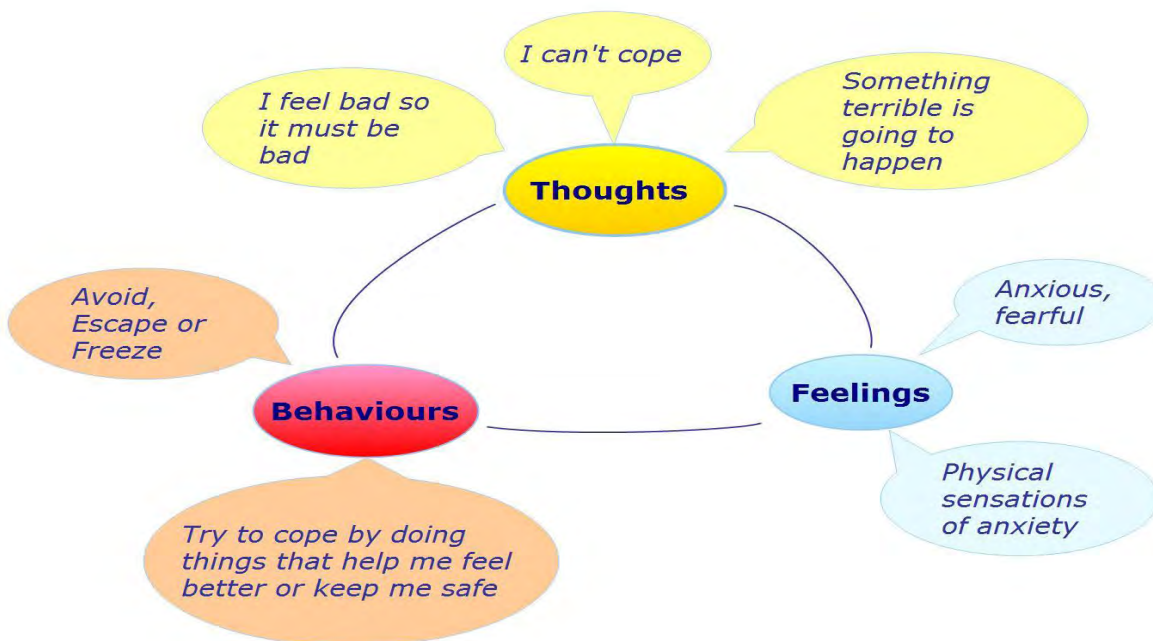
Mindfulness and Relaxation

It is very difficult to relax and stay calm when you are in pain. Pain can affect our body's ability to "shut down" such as being able to sleep at night and to relax during the day. An important part of dealing with pain is learning how to relax both body and mind, to allow better sleep, more painfree movement and reduce stress. The practice of mindfulness develops our ability to control our attention and emotions to help with relaxation. It has been shown to lead to significant **pain relief**, **reduced muscle tension** and **reduced stress** levels. Typically our mind wanders (like a child straying from the path) and needs encouragement to return. This may be a thought, a noise or body sensation. All are normal and we are not seeking to stop these stimuli but instead to develop control over what happens next, i.e. where our attention goes and consequently how we respond emotionally and physically.

For example;

Situation → feeling → automatic thoughts → physical response → behaviour

Trigger - real or imagined danger



For example: Back/neck pain on moving → **feel anxious, frustrated, fearful of movement** → **think about how long the pain has been there, will it ever go? It means that I cannot do X ...** → **tension, pain, altered movement** → **continue to avoid moving, bending, turning....**

As well as helping with pain, mindfulness practice has been shown to **lessen stress, depression and anxiety levels**. Our reactions to stressful events of our lives (can you think of people/things/events in your own life?) can become so common that they occur essentially without awareness, until they manifest in physical, emotional or psychological distress that we cannot ignore any longer. These reactions include **tensing the body**, experiencing painful emotional states like panic, agitation, anxiety and depression/low mood. Given that stress, low mood and anxiety make our body more “sensitive”, tense and sore, managing our stress, mood and anxiety levels through practicing mindfulness and relaxation can be really beneficial in helping your pain.



Using mindfulness to change the outcome means that you become aware of the thought that is driving the physical responses and behaviours. We have the ability to think about our own thinking and to be able to play out scenarios in our head. The problem is that the brain may not differentiate between a thought and actually being in a situation. This means that the emotional and physical responses are the same: anxiety, tension, pain etc.



Instructions

- Sit or lie in a relaxed posture, close your eyes, bring your awareness to body sensations, by connecting with the “touch points” or sensations of pressure where your body makes contact with the floor or whatever you are sitting on.
- Bring your attention to the belly, feeling it rise and expand gently on the in-breath and feeling it fall slightly on the out-breath. How do you feel?
- Keep the focus on your breathing, “being with” each in-breath for its full duration and with each out-breath for its full duration.



- Be aware of any areas of tightness in your body. Breathe into the tight areas and as you exhale let go of excess tension.
- Every time that you notice that your mind has wandered off the breath, note what it was that took you away and then gently bring your attention back to the breath.
- When you wake up and before you go to sleep, take a few minutes and bring your attention to your breath. Observe your breathing and the feeling of being relaxed.
- During the day, take moments to bring your attention to your breathing, even while driving, eating and moving. It makes you stay in the present and promotes relaxation.
- Notice changes in your posture during the day. Be aware of how your body and mind feel when you change position, observe your breathing, are you breath holding/tense?

More information

<http://www.youtube.com/watch?v=XwiiWrt3Ld8>

<http://www.youtube.com/watch?v=1sQ0DTF2tAM>

<http://www.youtube.com/watch?v=aS5QpPRFdbg>

For more examples, type “**guided mindfulness meditation body scan**” into YouTube, where there are lots of links available

Your physiotherapist can also give you a mindfulness CD that you can use.

visit the website www.pain-ed.com for more information

Exercise and Physical Activity

Many people with pain are afraid of exercise and avoid it as they think it may cause them more problems. However this is not true! We now know that regular exercise helps to keep you and your body fit and healthy. All types of exercise are good, with no major differences between them. Walking, using the stairs, cycling, jogging, running and stretching are all good and help relax all the tense muscles in your body. It is important that you find an activity that you enjoy and start gradually!



Low fitness levels have been shown to be worse for your health than smoking, diabetes and obesity combined together, showing that fitness is important for your health. Regular exercise can actually decrease pain and discomfort. It prepares the body for other activities. It can strengthen weak muscles and it will help you feel better in yourself.

When you are in pain, starting exercise can be very hard. Underused muscles feel more pain than healthy muscles. Therefore, if you are feeling sore after exercise, this does not indicate harm or damage to your body. Always pick an exercise you enjoy, and start gradually! You can start by doing some gentle light activity and then increase your levels when you feel confident to do so. Your physiotherapist will help you form an exercise plan, which will involve increasing your activity levels gradually and only when you are happy to do so. Regular exercise has the following benefits:

- Reduces pain and muscle tension. Exercise relaxes the muscles and increases natural pain killers (called endorphins) in the body to help control pain
- Strengthens your immune system and overall general health
- Helps with weight control
- Strengthens the cardiovascular system - heart, lungs and blood vessels. Regular exercise reduces blood pressure, cholesterol and heart disease



- Increases muscle strength, flexibility, endurance and stamina

- Helps to improve sleep quality. When you are tired because of physical activities, you fall asleep faster and your mind will be more calm and relaxed
- Reduces fatigue, tiredness and increases energy levels
- Prevents and reduces stress, depression and anxiety, all of which can aggravate pain and muscle tension.



More information: you can watch these two short videos on exercise and physical activity
<http://www.youtube.com/watch?v=aUaInS6HIGo&feature=share>

<http://www.youtube.com/watch?v=whPuRLil4c0>

visit the website www.pain-ed.com for more information

Or type in “**Let’s make our day harder by Mike Evans**” and “**23 and a half hours: What is the single best thing we can do for our health**” into Youtube to watch these short videos.

Cognitive Functional Therapy in action: A patient case study

Interview:

Harry, a 35-year-old male employed in manual work reported a five year history of disabling NSCLBP that had developed following a lifting injury at work. He was advised to stay off from work for four weeks as he had “put a disc out of place”. He was told that he had to keep his back straight from now on to avoid damaging discs and needed a more stable and stronger spine to prevent future injury from lifting activities. Harry was worried, but under financial strain at the time and could not afford to take time off from work. He continued to work but made every effort to “mind” his back. Harry reported that he had never recovered from the first incident of LBP, and experienced frequent muscle spasms, finding all bending, lifting and sitting activities very painful. He felt that he was getting increasingly stiff. He continued to make himself work but started to miss days recently due to considerable pain and increasing stiffness.

Physical: Harry reported severe pain when he had to sit, bend or lift. He reported feeling “looser” after massage and heat. He remained active, with golf being his hobby of choice, but experienced high levels of pain following golf, which would exacerbate his pain for up to three days.

Psychological: Harry believed he had a disc out of place that would always be vulnerable to injury. His MRI revealed disc degeneration, leading him to think that he needed to change job as he shouldn't be bending or lifting. Since he had the pain for five years, he didn't feel that it was going to improve, but he was adamant for it not to get worse. Harry never avoided physical activities but minded his back while doing all activities. He noticed a reduction in his overall mood since it happened as he couldn't work as hard, and while he continued to socialise, he found sitting in social settings very painful, reducing his enjoyment of these occasions. The pain has made him more “cranky”.

Lifestyle: Harry has always been active. He works as a builder, walks a lot and plays golf once a week. His activity levels did not reduce since the pain started, but all the activities were very painful. He thought he would feel worse if he didn't engage in these so continued to persist with them. Sleep was generally good but occasionally he reported lying awake worrying about how his back could affect his future employment. He has a good diet and does not smoke.

Social: Harry is married and has two children. They have a good relationship, but Harry felt increasingly annoyed with pain, and sometimes took it out on the family. Harry used to love his manual job and being physically active but then developed a dread of facing work as he felt it was bad for him. He played golf but felt very sore and stiff after it. He had no history of serious life traumas or events.

Treatment history:

Physiotherapy: He has received heat and massage which he finds helpful in the short term, but the pain always returns within a short period of time (hours). He was told to avoid lumbar flexion and move with his tummy braced to protect his spine when working and playing golf.

To help with this, he was given core stability exercises and “McKenzie” extension exercises to straighten his spine.

Medical: Received two injections for the disc being “out of place”. Told to rest and lie down after the injections.

Cognitive Behavioural Therapy: Told that movement is good and that thinking negatively about his back was bad for him, told not to be fearful, avoid bed rest and keep active. Harry has remained active and continues to move.

Pacing: Harry was told to limit the amount of bending and lifting during the day. Harry then became very aware of all the physical work he did and knew when he was overdoing it/doing too much. This often resulted in Harry doing less activity than planned.

Acceptance and Commitment Therapy: Harry was told not to fear pain, but to accept it and make sure to engage in valued activities. Therefore, Harry continued to bend, lift and go out to social events but remained in pain.

Surgery: Harry went for a surgical review and was told he had the “back of a 70 year old”. He was told to take it easy with any physical work and that he will eventually need surgery on the disc.

Mindfulness: Harry’s wife noticed his stress levels and he was sent for mindfulness to relax. Harry didn’t like the mindfulness and it made him think more about his muscles and spine.

Investigations: MRI scan revealed disc degeneration at L5/S1. No other major findings.

General health: Very good. No other pain sites. No subjective health complaints.

Physical examination:

Observation: Harry sat and walked with a rigid upright posture. Harry was asked why he was moving and sitting this way. Attempts were made to get Harry to relax more into the chair and sit less straight. He was then asked to reflect on how this felt in comparison to his usual way.

Range of movement: Harry had very little movement through his lower back. He kept his back straight while bending with a lot of abdominal muscle guarding. He was also breath-holding and propping his hand on one leg. This was very painful. Harry was asked to reflect on why he was moving this way and was this normal for him. He said he had been told to do this. The physiotherapist experimented with getting Harry to move differently and was asked to compare the two ways and how they felt.

Bending and lifting: Harry bent and lifted items with a straight back, propping and tensing his tummy muscles. Again Harry was asked why he was bracing and breath-holding. He was not aware that he was doing this. The physiotherapist experimented with getting him to breathe and relax while moving and discouraging propping. Harry was asked to reflect on what was happening in his body every time he was asked to bend (i.e. getting fearful, then bracing, holding breath, getting more tense).

Palpation: Harry had very tense muscles throughout his lower back and his abdominals were very tense and switched on. Harry’s pain was reproduced on palpation of his lower back muscles.

Treatment: Individualised CFT (6 sessions over 9 weeks)

Cognitive component/Making sense of pain: Harry avoided bending due to the knowledge that flexion could provoke pain and the belief (reinforced by treatment providers) that this movement causes ‘further damage’. Harry continued to engage in activity (e.g. walking) and not avoid physical work (e.g. lifting), but the manner in which he did these activities was very provocative and maladaptive. Trying to learn a less painful manner to do these activities was the basis of Harry’s treatment. The evidence about disc degeneration on scans being poorly related to NSCLBP was explained, and supplemented with information leaflets. He was educated that movement is good for the lower back and was informed that being fearful, keeping the back straight and holding your breath increases muscle tension. It was then explained that doing all the core stability work was making him more tense, and that the massage might be helping him feel “looser” through reducing his muscle tension. He was reassured that the back is a strong structure and not vulnerable. This was supplemented by getting Harry to practice moving in both a tense and then less tense manner, and reflecting on what felt better.

Normalisation of specific movements and pain control: Harry had particular problems with lumbar flexion activities like sitting, bending, and lifting so achieving normal and pain-free lumbar flexion was a target of treatment. Harry was given a range of specific exercises to achieve better lumbar flexion. For example, Harry learned how to do these in a relaxed manner, while breathing, not propping and not tensing his tummy. Visual aids such as mirrors, phone videos facilitated this. All core stability exercises were stopped.

Targeted functional integration: After achieving less painful lumbar flexion and feeling more confident to bend through his lower back, this new lumbar flexion was tested in bending, and while lifting things that Harry perceived as difficult or which he feared. He was asked to progress to movements and tasks more similar to his provocative tasks, such as sitting on stools to resemble a night out and golf. Particular emphasis was placed on how Harry moved doing these activities, so that all propping, bracing and breath-holding was discouraged for more normal ways.

Lifestyle advice: Harry was already active. Therefore, emphasis was placed on making his activity more comfortable. Practice was done with Harry on how to walk and move more comfortably without “minding” his back excessively. This included focussing on external cues, rather than internal cues, as he appeared to be too focussed on internal cues (e.g. keep muscles tight) previously.

Harry’s sleep was disturbed by worries about the future. These were addressed by giving him education that his spine was a strong structure and that manual work was not bad for it.

Outcome: Harry now reports very mild, intermittent pain and no disability. He is less fearful, more confident and has developed more positive back pain beliefs. He is flexing through his lower back in a relaxed manner and feels the benefits from sitting and moving in a less straight way. After lots of bending and lifting practice, Harry is now confident at doing these activities and most importantly, he does them in a more relaxed way (e.g. moving faster, not breath-holding, letting his back move) as he no longer believes that he is damaging his spine. He reports that his mind set around his back has changed and he no longer feels like he has to mind his back. This has resulted in Harry sleeping better from reduced worry and enjoying his social activities and golf again.

Appendix 2: Public engagement and blogs

2a. Mary O’Keeffe, Dr Kieran O’Sullivan and Dr Derek Griffin. ‘15 things you did not know about back pain’. Published by the Irish Independent newspaper:

<http://www.independent.ie/life/health-wellbeing/15-things-you-didnt-know-about-back-pain-31367264.html> (Now available in seven languages)

2b. Mary O’Keeffe and Dr Kieran O’Sullivan. ‘What’s best for chronic spinal back pain? Physical, behavioural/psychologically or combined interventions?’ Body in Mind website.

<http://www.bodyinmind.org/spinal-back-pain-interventions/#comment-525285>

2c. Mary O’Keeffe and Dr Kieran O’Sullivan. ‘Body-mind interactions in low back pain’. TalkBack Magazine, BackCare: UK’s national back pain charity.

<http://www.backcare.org.uk/wp-content/uploads/2015/04/Body-Mind-Interactions.pdf>

2d. Mary O’Keeffe and Dr Kieran O’Sullivan. ‘I have back pain, what should I do?’

TalkBack Magazine, BackCare: UK’s national back pain charity.

<https://issuu.com/backcare/docs/backcare-talkback-3-2015/16>

2e. Mary O’Keeffe. ‘Physical, psychological or combined interventions: what’s best for treating pain?’ Pain-ed website.

<http://www.pain-ed.com/blog/2016/02/28/physical-psychological-or-combined-interventions-whats-best-for-treating-pain/>

2f. Mary O’Keeffe. ‘Interaction is Intervention, but how do we foster it?’ Pain-ed website.

<http://www.pain-ed.com/blog/2016/02/22/interaction-is-intervention-but-how-do-we-foster-it/>

2g. Mary O’Keeffe. ‘Brace yourself’. Body in Mind website.

<http://www.bodyinmind.org/evidence-for-bracing-in-lbp/>

MIND YOURSELF

15 *things
you didn't
know about*
BACK PAIN



Back pain is so prevalent that it costs the country more than cancer and diabetes treatment combined, but there are many myths circulating about the condition. We asked some of Ireland's leading experts to shed some light on the common ailment

Managing back pain costs the State more than cancer and diabetes combined. Most of these costs are related to treating people with ongoing pain.

Scientific research in the area of back pain has progressed in recent times and it is challenging widespread beliefs held about the condition that seems to plague so many people.

1 BACK PAIN IS COMMON AND NORMAL

Eighty percent of people will experience an episode of back pain during their lifetime. Experiencing back pain is like getting tired or becoming sad; we don't necessarily like it, but it occurs to almost everybody at some point. What isn't common, however, is not recovering from back pain.

Most acute back pain is the result of simple strains or sprains and the prognosis is excellent. Within the first two weeks of an acute episode of pain, most people will report a significant improvement in their symptoms with almost 85pc of people fully recovered by three months. Only a very small number of people develop long-standing, disabling problems.

2 SCANS ARE RARELY NEEDED

Both healthcare professionals and members of the public often consider getting a scan "just in case" there is something serious involved in their pain. However, all the evidence suggests scans only show something truly important in a tiny minority (<5pc) of people with back pain.

A brief consultation with a healthcare professional (eg GP, chartered physiotherapist) would usually be able to identify if a scan was really needed based on a person's symptoms and medical history.

3 INTERPRETING SCANS SHOULD COME WITH A HEALTH WARNING

We used to think that if we got a good enough picture of the spine with scans that it would be a big help in solving back pain. However, we now know that this is most often not the case.

When people have scans for back pain, the scans often show up things that are poorly linked with pain. In fact, studies have shown that even people who don't have back pain have things like bulging discs (52pc of people), degenerated or black discs (90pc), herniated discs (28pc) and 'arthritic' changes visible (38pc).

Remember, these people do NOT have pain! Unfortunately, people with back pain are often told that these things indicate their back is damaged, and this can lead to further fear, distress and avoidance of activity. The fact is that many of these things reported on scans are more like baldness — an indication of ageing and genetics that do not have to be painful.

4 BACK PAIN IS NOT CAUSED BY SOMETHING BEING OUT OF PLACE

There is no evidence that back pain is caused by a bone or joint in the back being out of place, or your pelvis being out of alignment. For most people with back pain, scans do not show any evidence of discs, bones or joints being 'out of place'. In the very small number of people with some change in their spinal alignment, this does not appear to be strongly related to back pain.

Of course, it is worth noting that many people feel better after undergoing treatments like manipulation.

However, this improvement is due to short-term reductions in pain, muscle tone/tension and fear, NOT due to realigning of body structures.

5 BED REST IS NOT HELPFUL

In the first few days after the initial injury, avoiding aggravating activities may help to relieve pain, similar to pain in any other part of the body, such as a sprained ankle. However, there is very strong evidence that keeping active and returning to all usual activities gradually, including work and hobbies, is important in aiding recovery.

In contrast, prolonged bed rest is unhelpful, and is associated with higher levels of pain, greater disability, poorer recovery and longer absence from work. In fact, it appears that the longer a person stays in bed because of back pain, the worse the pain becomes.

6 MORE BACK PAIN DOES NOT MEAN MORE BACK DAMAGE

This may seem strange, but we now know that more pain does not always mean more damage. Ultimately, two individuals with the same injury can feel different amounts of pain. The degree of pain felt can vary according to a number of factors, including the situation in which the pain occurs, previous pain experiences, your mood, fears, fitness, stress levels and coping style. For example, an athlete or soldier may not experience much pain after injury until later when they are in a less intense environment.

Furthermore, our nervous system has the ability to regulate how much pain a person feels at any given time. If a person has back pain it might be that their nervous system has become hypersensitive and is causing the person to experience pain, even though the initial strain or sprain has healed.

This can mean the person feels more pain when they move or try to do something, even though they are not damaging their spine.

Once people with back pain can distinguish between the 'hurt' they are feeling from any concerns about 'harm' being done to their back, it is easier to participate in treatment.

7 SURGERY IS RARELY NEEDED

Only a tiny proportion of people with back pain require surgery. Most people with back pain can manage it by staying active, developing a better understanding about what pain means, and identifying the factors which are involved in their pain. This should help them continue their usual daily tasks, without having to resort to surgery.

On average, the results for spinal surgery are no better in the medium and long-term than non-surgical interventions, such as exercise.

8 SCHOOLBAGS ARE SAFE — WORRYING ABOUT SCHOOLBAGS MIGHT NOT BE

Many people believe that children carrying a heavy schoolbag might cause back pain. However, research studies have not found this link, revealing no differences in schoolbag weight between those children who do and do not go on to develop back pain. However, if a child — or their parent — believes that their schoolbag is too heavy, the child is more likely to develop back pain, highlighting the importance of fear in the development of back pain.

Given concerns about inactivity and obesity in children, carrying a schoolbag may actually be a simple healthy way for children to get some exercise.



School bags are safe

9 THE PERFECT SITTING POSTURE MAY NOT EXIST

Should we all sit up straight? Contrary to popular belief, no specific static sitting posture has been shown to prevent or reduce back pain. Different sitting postures suit different people, with some people reporting more pain from sitting straight, others from slouching. So while slouching gets a bad press, there is no scientific evidence to support this. In fact, many people with back pain can adopt very rigid postures (eg sitting extremely upright) with little variation.

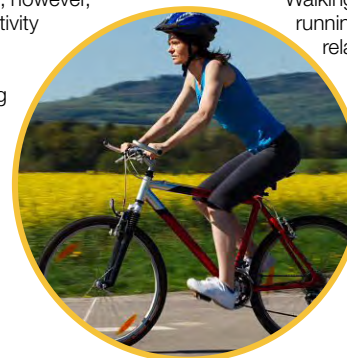
The ability to vary our posture, instead of maintaining the same posture, together with learning to move in a confident, relaxed and variable manner is important for people with back pain.

10 LIFTING AND BENDING ARE SAFE

People with back pain often believe that activities such as lifting, bending and twisting are dangerous and should be avoided. However, contrary to common belief, the research to date has not supported a consistent association between any of these factors and back pain.

Of course, a person can strain their back if they lift something awkwardly or lifting something that is heavier than they would usually lift. Similarly, if a person has back pain, these activities might be more sore than usual. This, however, does not mean that the activity is dangerous or should be avoided.

While a lifting or bending incident could initially give a person back pain, bending and lifting is normal and should be practiced to help strengthen the back, similar to returning to running and sport after spraining an ankle.



11 AVOIDING ACTIVITIES AND MOVING CAREFULLY DOES NOT HELP IN THE LONG-TERM

It is common, especially during the first few days of back pain, that

your movement can be significantly altered. This is similar to limping after spraining your ankle, and generally resolves as the pain settles. While initially hard, getting back doing valued activities which are painful, or feared, is important. Many people, after an episode of back pain, can begin to move differently due to a fear of pain or a belief that the activity is dangerous. Such altered movement can be unhealthy in the long term and can actually increase the strain on your back.

12 POOR SLEEP INFLUENCES BACK PAIN

When someone has pain, a good night's sleep can be hard to get. However, it works both ways as sleep problems can lead to back pain in the future. In the same way that poor sleep can make us more stressed, give us a headache, make us tired or feel down, it can also cause or prolong back pain. So, improving sleeping routine and habits can be very helpful in reducing pain.

13 STRESS, LOW MOOD AND WORRY INFLUENCE BACK PAIN

How we feel can influence the amount of pain we feel. Back pain can be triggered following changes in life stress, mood or anxiety levels.

In the same way that these factors are linked to other health conditions like cold sores, irritable bowel syndrome and tiredness, they have a very large effect on back pain. As a result, managing our stress, mood and anxiety levels through doing things we enjoy, and engaging in relaxation can be really beneficial in helping back pain.

14 EXERCISE IS GOOD AND SAFE

Many people with pain are afraid of exercise and avoid it as they think it may cause them more problems. However this is not true! We now know that regular exercise helps to keep you and your body fit and healthy, and actually reduces pain and discomfort. It relaxes muscle tension, helps mood and strengthens the immune system once started gradually.

All types of exercise are good, with no major differences in effectiveness between them — so pick one you enjoy, can afford and which is convenient.

Walking, using the stairs, cycling, jogging, running and stretching are all good and help relax all the tense muscles in your body.

When you are in pain, starting exercise can be very hard. Under-used muscles feel more pain than healthy muscles. Therefore, if feeling sore after exercise, this does not indicate harm or damage to the body.

15 PERSISTENT BACK PAIN CAN GET BETTER

Since back pain is associated with many factors that vary between individuals, treatments that address the relevant factors for each individual can be effective. Failing to get pain relief after lots of different treatments is very frustrating and cause people to lose hope.

However, this is very common as most treatments only address one factor, for example someone goes for a massage for their sore muscles, but doesn't address their sleep or fitness or stress levels.

By identifying the different contributing factors for each individual and trying to address them, pain can be significantly reduced and people can live a happier and healthier life.

How we feel can influence the amount of pain we feel. Back pain can be triggered following changes in life stress, mood or anxiety levels

■ **Mary O'Keeffe (University of Limerick), Dr Kieran O'Sullivan (University of Limerick), Dr Derek Griffin (Tralee Physiotherapy Clinic)**

What's best for chronic spinal back pain? Physical, behavioural/psychologically or combined interventions?

Non-specific chronic spinal pain (NSCSP), particularly low back pain (LBP) and neck pain (NP), results in significant personal, social and economic burden ([here](#) and [here](#)).^{1,2}

Our research group has recently published a [systematic review and meta-analysis](#)³ in the Journal of Pain comparing the effectiveness of conservative interventions for NSCSP. The reason we undertook this review was that despite many interventions being available for treating spinal pain, it is unclear which intervention has the greatest level of supporting evidence. Current conservative interventions can be broadly divided into (i) physical, (ii) behavioural and/or psychological and (iii) interventions which combine these approaches. Physical interventions include using exercise, manual therapy and ergonomic advice. Behavioural and/or psychologically informed interventions aim to improve behaviours, cognitions or mood by using methods such as relaxation and cognitive behavioural therapy (CBT). Combined interventions aim to improve physical and psychological factors contributing to patients' pain by using some combination of both approaches, up to an including multidisciplinary pain management programmes. Therefore, by conducting this systematic review and meta-analysis we wanted to answer the question: What is the relative effectiveness of different conservative interventions for reducing pain and disability in people with NSCSP: physical, behavioural/psychological or combined?

We included RCTs involving participants with NSCSP (neck, thoracic, low back, or pelvic) for greater than 12 weeks duration. RCTs had to measure pain and/or disability and have a minimum follow-up period of 12 weeks. We only included RCTs that had an "active" conservative treatment control group for comparison (i.e. no treatment or waiting list comparisons were excluded). We excluded RCTs if the interventions were from the same domain (e.g. if the study compared two physical interventions like aerobic exercise versus strength training). We excluded RCTs that involved participants with specific pathologies/conditions (e.g. pregnancy, rheumatoid arthritis) or "red flag" disorders.

So what did we find?

We included 24 RCTs. 22 of these RCTs could be included in the meta-analysis, with the remaining two studies being too heterogeneous to be pooled for analysis. The sample sizes of the included studies ranged from 30 to 393 participants. The average age of the participants in these studies ranged from 39 to 54 years. 18 RCTs investigated patients with LBP, while six studies investigated participants with NP.

No statistically significant differences were found for pain and disability between (i) physical and behavioural and/or psychologically informed or between (ii) behavioural and/or psychologically informed and combined groups. While a small statistically significant difference was found for both pain and disability between the physical and combined treatment groups (favouring the combined group), this difference was small and likely to be of limited clinical significance. Therefore, we found only small differences between physical,

behavioural and/or psychologically informed and combined interventions for reducing pain and disability in NSCSP patients.

What do these findings tell us?

Current interventions for NSCSP result have similarly small effectiveness on pain and disability. Choosing the most cost-efficient and feasible may be reasonable, based on the evidence to date. There is still a lot of work to be done to find a long-term clinically effective intervention for NSCSP. **While the more multi-dimensional combined therapies examined in this review offer a slightly greater effect, the increased costs are not easy to justify for large groups of people with NSCSP. It is possible, though far from certain, that attempts to better combine different components of therapy for people with NSCSP might show better results.**

About Mary O’Keeffe



Mary O’Keeffe is a PhD student at the University of Limerick (UL). Her PhD research is examining whether tailoring multidimensional rehabilitation to the individual chronic LBP patient enhances effectiveness, and is worth the additional time (and costs!) involved. Her supervisors are Dr Kieran O’Sullivan and Dr Norelee Kennedy from UL and Prof Peter O’Sullivan from Curtin University, Perth.

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2. Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of common conditions requiring rehabilitation in the United States: stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and back pain. (2014) *Arch Phys Med Rehabil.* 95:986-995.
3. O’Keeffe M, Purtill H, Kennedy N, et al. Comparative effectiveness of conservative interventions for non-specific chronic spinal pain: Physical, behavioural/psychologically informed or combined? A systematic review and meta-analysis. (2016) *The Journal of Pain.* In Press.

Body-mind interactions in low back pain

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Mary O’Keeffe



Kieran O’Sullivan

Invited contributors Mary and Kieran have a keen interest in challenging widely-held low back pain beliefs. In this feature, they tackle one of the most common – that low back pain is either physical or psychological, but cannot be both. Drawing on parallels from other health conditions, they illustrate why back pain management remains too focused on the physical anatomy of the back.

Low back pain (LBP) is exceptionally common. In fact, not to experience LBP at some point of your life would be abnormal. Many healthcare professionals have been trained to view the high incidence of LBP as either a terrible sign of the way we live in modern society (e.g. prolonged sitting) and/or the inherent fragility of our spine. Instead, LBP is like becoming tired or sad, which is perfectly natural to experience at some point in our lives. Usually, it only lasts a short period and people recover and go on to live a full and healthy life.

Unfortunately, a small proportion of people experience LBP that either never goes away or returns so frequently that it has a big impact on their quality of life. In these cases, like among people with clinical depression or chronic fatigue, there is a need to step back and consider why this person has not recovered, as opposed to why most of us develop LBP at some point in our lives. Therefore, we are not convinced that we should be trying to “prevent” LBP in terms of aiming to get to a point where almost nobody in society gets LBP.

Almost all of us will experience LBP at some point in our lives – as Nortin Hadler has said,² LBP is one of the common “predicaments” of life which most of us will face. The more important question is how to ensure when someone gets LBP that it only lasts a very short period and doesn’t affect a person’s life long term. Key to this is the body-mind relationship in people with LBP, which LBP management has usually not addressed.

How is low back pain typically treated?

Healthcare – and society in general – has spent decades thinking that once we find an accurate diagnosis of a local tissue that is causing LBP, treatment of that specific local tissue will eliminate the pain. Unfortunately, what this has led to is more scans, more rehabilitation, more medications and more surgery.¹

There is no denying that the approaches we have taken to manage LBP in recent decades have had little benefit.¹ This is not because LBP has become more prevalent – rather we have more unhelpful methods of frightening people in recent years, e.g. through using high-tech imaging such as MRI scans inappropriately. In fact, it is likely that it is the interpretation of such tests which is the biggest problem. For example, it is very rare for an MRI of someone’s back not to show something such as disc degeneration.⁶ We used to think these things were always important, but it now looks like the things we see on MRI scans are a lot like finding some grey hair on your head or some wrinkles on your face. In other words, they may not be cosmetically appealing, but they are themselves not dangerous and just signify a combination of genetics and ageing.

The pain is still there – and the pain is “real” – which makes the situation frustrating for patients. However, it is critical that we dispel inaccurate notions of serious back degeneration in most people with LBP.

Society has overwhelmingly accepted the idea

...the things we see on MRI scans are a lot like finding some grey hair on your head or some wrinkles on your face

that LBP and injury are very closely connected. Furthermore, there's an assumption that if a person's stress levels or mood are involved then that person's pain is psychological or "all in their head". However, even if LBP commonly starts with injury,⁵ its persistence is not related to the degree of injury or damage.⁴ Consequently, treating LBP solely as an injury is misguided and has not led to impressive clinical outcomes.⁴

If we compare LBP management to other healthcare areas, it has not given the taxpayer the same value for money. For example, the risk of being disabled by cardiovascular disease or breast cancer has decreased, but the risk of being disabled by LBP has increased.¹

We are not saying that typical treatments have nothing to offer, but we are concerned they tend to look at "fixing" one aspect of a person with LBP (e.g. their facet joint, or a tender point in their muscle, or a disc, or their posture) and not considering the entire person. Even psychologically informed treatments such as CBT are not immune to such criticisms – tending to be almost exclusively psychological, such that their effectiveness is similar to physical treatments.^{3,7}

With patients, we obviously need to examine their back, but we also need to look at the whole person – their sleep, their stress, their fears, and what they think is wrong with their back.

How is low back pain similar to other health conditions?

It is well accepted that high blood pressure can be linked to physical factors (e.g. cholesterol or diabetes) as well as psychological factors like stress. There is no suggestion that patients with high blood pressure should be divided into "real" and "imaginary" cases depending on whether stress is involved. I think sensible management would address acute symptoms and then focus on each person's own contributing factors – be that obesity, stress or whatever.

Cold sores provide another useful comparison. They have a "real" biological trigger (a virus). However, the virus typically only becomes symptomatic when a person is "run down", e.g. stressed, sleep deprived, poor diet, lack of exercise. Once overall health improves, the cold sore resolves, despite the virus remaining. We see the virus being a lot like a sensitive tissue in the back (e.g. muscle, disc, ligament). When overall health is good, the back is much less symptomatic. Cold sores are typically managed through (i) short-term local treatment and (ii) enhancing the person's overall health in the medium term.

Unfortunately, LBP is not as visible as a cold sore – patients can feel reluctant to accept

something like stress is part of their pain and fear being judged by others. Consequently, treatment then focuses almost exclusively on the back and not the big picture of their overall health. This possibly increases risk of recurrent pain as an accurate understanding is critical to long-term self-management.

We have personally both had cold sores in the past. We have similarly both had LBP, headaches and other various aches and pains at points in our lives. We see managing such infrequent episodes of pain as being very similar to the management of intermittent cold sores – get some symptomatic relief if needed in the short term and work on boosting our overall health in the medium term.

● Mary O'Keeffe is a PhD student at the University of Limerick. Her PhD research is examining whether tailoring multidimensional rehabilitation to the individual chronic LBP patient enhances effectiveness, and is worth the additional time (and costs!) involved. Her supervisors are Dr Kieran O'Sullivan and Dr Norelee Kennedy from UL and Prof Peter O'Sullivan from Curtin University, Perth.

● Dr Kieran O'Sullivan is a lecturer at the University of Limerick and has been awarded specialist status by the Irish Society of Chartered Physiotherapists. He is also a researcher with over fifty peer-reviewed publications, whose work has attracted €1 million in funding, including a multi-centre randomised controlled trial of LBP treatment.

Further resources:

www.pained.com – public health information on chronic pain

www.ulresearchimpact.com/category/health – 'Building Resilience' initiative

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...even if LBP commonly starts with injury, its persistence is not related to the degree of injury or damage

When overall health is good, the back is much less symptomatic

I have back pain... what should I do?



Mary O'Keeffe and Dr Kieran O'Sullivan, Department of Clinical Therapies, University of Limerick, Ireland

We have a particular interest in challenging common, yet unhelpful beliefs which exist about low back pain (LBP) and delivering evidenced-based messages on how to manage it. In a previous issue of *TalkBack* (Issue 1, 2015), we discussed how the body and mind are interconnected in back pain, similar to many other health conditions. For this issue, we will explore some options for a person who is in pain, based on some common questions posed by patients.



What should I do when I initially hurt my back, or if the pain is severe?

The evidence shows it is best to start simple. From a medication perspective, while the effectiveness of non-prescription painkillers (e.g. paracetamol) is limited, they are as effective as stronger medications (e.g. nonsteroidal anti-inflammatory drugs, opioids) which have more side effects.¹

From an activity perspective, in the first few days after the initial injury, avoiding aggravating activities may help to relieve pain, similar to pain in any other part of the body, such as a sprained ankle.

However, there is strong evidence that keeping active and returning to all usual activities gradually, including work and hobbies, is important in aiding recovery. It is best to remain active as relaxed movement will help the pain settle quicker. In fact, your back gets stronger with movement.²

In contrast, prolonged bed rest is unhelpful and is associated with higher levels of pain, greater disability, poorer recovery and longer absence from work. In fact, it appears that the longer a person stays in bed because of back pain, the worse the pain becomes.³

Identifying what triggered the back pain episode can be helpful,⁴ for example, were you doing something particularly unusual or were you more tired or stressed than usual as these make the body vulnerable to the onset of pain.

Should I get a scan to better understand my pain?

Both healthcare professionals and members of

the public often consider getting a scan "just in case" there is something serious involved in their pain.

We used to think that if we got a good enough picture of the spine with scans that it would be a big help in solving back pain. However, we now know that this is most often not the case. All the evidence suggests scans only show something truly important in a tiny minority (<5%) of people with back pain.⁵

Unfortunately, when people have scans for back pain, the scans often show up things that are poorly linked with pain. In fact, studies have shown that even people who don't have back pain have things like bulging discs (52% of people), degenerated or black discs (90%), herniated discs (28%) and "arthritic" changes (38%) visible on their scans. Remember, these people do NOT have pain!

Unfortunately, people with back pain are often told that these things indicate their back is damaged and this can lead to further fear, distress and avoidance of activity. The fact is that many of these things reported on scans are more like baldness – an indication of ageing and genetics that do not have to be painful. A brief consultation with a healthcare professional (e.g. GP, chartered physiotherapist) would usually be able to identify if a scan was really needed based on a person's symptoms and medical history.

Will I need surgery?

Only a tiny proportion of people with back pain require surgery. Most people with back pain can manage it by staying active, developing a better understanding about what pain means,

and identifying the various factors that are involved in their pain.

This should help them continue their usual daily tasks, without having to resort to surgery. On average, the results for spinal surgery are no better in the medium and long term than non-surgical treatment.⁶

Should I avoid activities that hurt, like bending and lifting?

It is common, especially during the first few days of back pain, for your movement and activity to be significantly altered. This is similar to limping after spraining your ankle and generally resolves as the pain settles.

While initially hard, getting back to doing valued activities which are painful or feared is important. Many people after an episode of back pain can begin to move differently due to a fear of pain or a belief that the activity is dangerous. Such altered movement can be unhealthy in the long term and can actually increase the strain on your back.

People with back pain often believe that activities such as lifting, bending and twisting are dangerous and

should be avoided. However, contrary to common belief, the research to date has not supported a consistent association between any of these factors and back pain.

Of course, a person can strain their back if they lift something awkwardly or lift something that is much heavier than they would usually lift. Similarly, if a person has back pain, these activities might be more sore than usual. This, however, does not mean that the activity is dangerous or should be avoided.

While a lifting or bending incident could initially give a person back pain, bending and lifting is normal and should actually be practiced to help strengthen the back, similar to returning to running and sport after spraining an ankle.

Should I exercise?

Many people with pain are afraid of exercise and avoid it as they think it may cause them more problems. However, this is not true! We now know that regular exercise helps to keep you and your body fit and healthy and

actually reduces pain and discomfort. It relaxes muscle tension, helps mood and strengthens the immune system once started gradually and progressed over time.

All types of exercise are good, with no major differences in effectiveness between them.⁷ Exercising in a group and exercising on your own can both be of benefit. Therefore, you should pick a form of exercise that you enjoy, that is affordable and convenient.

Walking, using the stairs, cycling, jogging, running and stretching are all good and help relax tension in your body. When you are in pain, starting exercise can be very hard. Under-used muscles feel more pain than healthy muscles. Therefore, if feeling sore after exercise, this does not indicate harm or damage to the body.

What other factors are worth addressing to help my pain?

Poor sleep, stress and low mood negatively influence back pain. In the same way that these factors are linked to other health conditions like cold sores, irritable bowel syndrome and tiredness, they have a very large effect on back pain through increasing the sensitivity of our nervous system, reducing our immunity and

continued on p18

There is strong evidence that keeping active and returning to all usual activities gradually, including work and hobbies, is important in aiding recovery



Physical, psychological or combined interventions: what's best for treating pain?

Non-specific chronic spinal pain (NSCSP), particularly low back pain (LBP) and neck pain (NP), are common and costly musculoskeletal disorders. NSCSP can be associated with physical factors (e.g. stiff postures and movement patterns) and behavioural/psychological factors (e.g. fear, beliefs, stress, depression, sleep problems, physical inactivity). As a result, conservative interventions can be broadly categorised into physical, psychological or combined interventions. Physical interventions usually aim to improve physical capacity (e.g. exercise, manual therapy, ergonomics). Behavioural and/or psychologically informed interventions aim to improve behaviours, cognitions or mood (e.g. relaxation and cognitive behavioural therapy). Combined interventions aim to improve physical and behavioural and/or psychological factors contributing to patients' pain (e.g. multidisciplinary (MDT) programmes).

[This](#) systematic review and meta-analysis included 24 RCTs that compared the effectiveness of physical, behavioural/psychological and combined interventions. Five studies compared physical and behavioural/psychologically informed interventions. 20 studies compared physical and combined interventions. Only one study compared a behavioural/psychologically informed intervention to a combined intervention.

No statistically significant differences were found for pain and disability between

- (i) physical and behavioural/psychologically informed interventions
- (ii) behavioural/psychologically informed and combined interventions

While a small statistically significant difference was found for both pain and disability between the physical and combined interventions, favouring the combined intervention, this difference was small.

This review highlights that current conservative interventions for NSCSP result in similar, small improvements in pain and disability. Choosing the most cost-efficient and feasible may be reasonable, based on the evidence to date. All the interventions in this review were safe, and helpful in the short-term. Combined treatments (e.g. MDT rehabilitation) might not be possible to provide to all patients. Furthermore, combined treatments may not adequately target all the important factors in people with NSCSP (e.g. sleep). Further work is needed to investigate whether tailoring rehabilitation to the needs of individual patients, which has been seen in recent RCTs for LBP (e.g. [here](#) and [here](#)) can enhance outcomes in NSCSP.

About Mary O'Keeffe



Mary is just about to complete the fourth (and final) year of her PhD in the University of Limerick, Ireland. Mary's PhD research is examining whether tailoring multidimensional rehabilitation to the individual chronic LBP patient enhances effectiveness, and is worth the additional time (and costs!) involved.

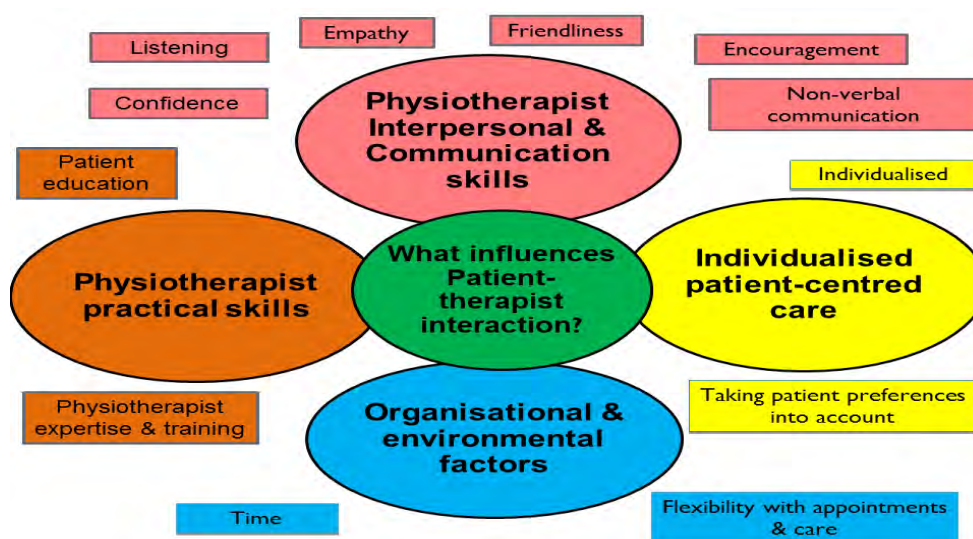
Interaction is Intervention, but how do we foster it?

Musculoskeletal physiotherapy, including sports physiotherapy, involves both “specific” and “non-specific” effects. Specific effects are related to the specific intervention provided (e.g. improvements in strength after an exercise programme). “Non-specific” effects are related to other variables associated with the patient, therapist and setting which may influence clinical outcomes like pain. [Recent quantitative research](#) has shown that “non-specific” factors including a positive patient-therapist interaction can enhance treatment outcomes. This means that patients who reported getting on well with their clinician and receiving kindness and empathy had better outcomes. A recent review by the Pain-Ed team examined what are the characteristics of a good patient-therapist interaction when patients attend for musculoskeletal physiotherapists.

[This](#) qualitative meta-synthesis looked at 13 studies in which physiotherapists and/or patients were interviewed through focus groups or semi-structured interviews on their perceptions of factors which influence the patient-therapist interaction.

Four themes were perceived to influence patient-therapist interactions:

- 1) Physiotherapist interpersonal and communication skills:** the presence of skills such as active listening, encouragement, confidence, being empathetic, friendly, humorous and having good non-verbal communication skills facilitated a good interaction. An unfriendly physiotherapist, or one that interrupted the patient frequently, was seen as a barrier to a good interaction.
- 2) Physiotherapist practical skills:** physiotherapist expertise, level of training and ability to provide clear, easy to understand education were seen as facilitators. Lack of education or education given in technical terms was seen as a barrier to a good interaction.
- 3) Individualised patient-centred care:** individualising and modifying the treatment to the patient and taking patient opinions into account facilitated a good interaction.
- 4) Organisational and environmental factors:** giving patients enough time and being flexible with the timing of appointments was seen as a facilitator of good interaction. Feeling rushed or not getting enough time with the physiotherapist was seen as a barrier to interaction.



Physiotherapist awareness of these factors could enhance patient interaction and treatment outcomes. How best to enhance these factors in clinical practice requires further study.

Personal info:



Mary is just about to complete the fourth (and final) year of her PhD at the University of Limerick (UL), Ireland. Mary's PhD research is examining whether tailoring multidimensional rehabilitation to the individual chronic LBP patient enhances effectiveness, and is worth the additional time (and costs!) involved. Her supervisors are Dr Kieran O'Sullivan and Dr Norelee Kennedy from UL and Prof Peter O'Sullivan from Curtin University, Perth.

Brace yourself!

Despite the popularity of exercise programmes that emphasise “core stability” for the prevention and treatment of chronic low back pain (CLBP), numerous high quality randomised controlled trials (RCT) (e.g. [here](#), [here](#) and [here](#)) have not found them to be superior to other therapies such as general exercise. In fact, core stability exercise programs have been found to be only marginally superior to placebo (e.g. [here](#)), and produce only small, short-term improvements in pain and disability.

For this reason, a recent study (Aleksiev 2014) caught our attention. It compared four groups of people with recurrent LBP who were allocated to receive strengthening or flexibility exercises, with and without abdominal bracing. It found that abdominal bracing added significantly to the effect of strengthening and flexibility exercises and concluded that “abdominal bracing could be considered as a preliminary muscle back belt” which “increases the frequency of trunk muscle contractions which increases the chance of successful LBP prevention.” Given that these findings are in marked contrast to the aforementioned RCTs, we wanted to see if there were any reasons for such markedly different results. Several noteworthy aspects to the study were addressed in our letter to the editor (O’Keeffe et al. 2014). These included:

- A tremendously successful follow-up in this study, with not one of 600 participants lost to follow-up after 10 years. This is certainly not common – in fact, it is utterly remarkable!
- The frequency with which exercises were performed was associated with positive results over the follow-up period, and this was much higher among those who were in the bracing groups. Despite this, the author has concluded that it was the abdominal bracing itself which caused the significant difference between groups. The author suggested that “Bracing probably reminded and convinced the patients to exercise more often”. In our opinion it is difficult to extrapolate this conclusion from the data provided.
- Several CONSORT requirements were not fully detailed, such as baseline demographic and clinical characteristics for each group. Similarly, little detail regarding the interventions was provided, such as the length of the intervention, and how compliance was monitored. For example, it is hard to know from the paper how well participants continued to complete their exercises for the duration of follow-up.
- No measure of disability was used.

- No earlier results e.g. at 1, 3 or 5 year follow-up were described
- No detail provided on whether or not a blinded assessor was involved.
- No measure to assess changes in trunk activation and co-contraction, making it difficult to justify conclusions about the mechanism of effect.

Due to the number of studies that contradict these findings, and the concerns we have raised above regarding shortcomings in the study methodology, we believe that the results must be replicated in other settings using more rigorous methodology before they become accepted clinical practice.

It is worth remembering that no relationship has been found between the onset of trunk muscle activity and pain/disability levels, or the degree of change in pain/disability after core stability training as previously discussed on BiM (e.g. [here](#)). Emerging evidence (see [here](#) and [here](#)) also reveals that disabling CLBP may be more closely associated with increased co-contraction and hyperactivity of “core” trunk muscles, guarded spinal movement and an inability of the spinal muscles to relax (including transversus abdominis and lumbar multifidus). Furthermore, increased focus on protecting the spine in a manner which is not seen amongst people without chronic LBP has the potential to increase hypervigilance, and reinforce pain-related protective behaviours that are known to fuel the vicious cycle of pain. There is now considerable evidence that LBP is a multidimensional disorder associated with a complex combination of physical, lifestyle, psychological, cognitive, social and neuro-physiological factors. Therefore, attempts to manage LBP are likely to require consideration of more than just the training of a specific muscle, or set of muscles.

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Biography:

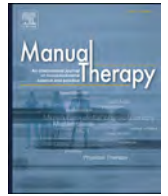


Mary O'Keeffe is a PhD student at the University of Limerick (UL), Ireland. The broad area of her research is the role of multidimensional rehabilitation in chronic low back pain. Her PhD research is examining whether tailoring this rehabilitation to the individual patient presentation enhances effectiveness, and is worth the additional time (and costs!) involved. Her supervisors are Dr. Kieran O'Sullivan and Dr. Norelee Kennedy from UL and Prof. Peter O'Sullivan from Curtin University, Perth. Their research group promotes evidence-based assessment and management of chronic pain through www.pain-ed.com

Appendix 3: Co-authored publications

3a. Hurley, J., **O’Keeffe, M.**, Ryan, C., O’Sullivan, P. and O’Sullivan, K. (2016) ‘Effect of education on non-specific neck and low back pain: A meta-analysis of randomized controlled trials: letter to the editor’, *Manual Therapy*, 23, 1-2.

3b. Synnott, A., **O’Keeffe, M.**, Bunzli, S., Dankaerts, W., O’Sullivan, P. and O’Sullivan, K. (2015) 'Physiotherapists may stigmatise or feel unprepared to treat people with low back pain and psychosocial factors that influence recovery: a systematic review', *Journal of physiotherapy*, 61(2), 68-76.



Letter to the Editor

Effect of education on non-specific neck and low back pain: A meta-analysis of randomized controlled trials

**Keywords:**

Education
Low back pain
Biopsychosocial education
Biomedical education

In the recently published article “Effect of education on non-specific neck and low back pain: A meta-analysis of randomized controlled trials” (Ainpradub et al., 2015), the authors conclude that education programs are not recommended in preventing or treating neck pain and/or low back pain (LBP). We agree there are some important clinical implications in this review, and agree that their results suggest at least some forms of education are ineffective. However, we think that there are alternative conclusions which could be drawn from the presented data.

The authors found thirty-six randomised controlled trials which examined the effect of education programs on non-specific neck and/or LBP, with fifteen of these studies included in a meta-analysis. The meta-analysis indicates that education programs have no consistent positive effects on low back pain. From the data included in the meta-analysis it is logical to suggest that education programs are not effective in preventing/treating neck pain and/or LBP. However, most studies included in the meta-analysis contained biomedical education regarding biomechanics or posture where the focus is often on “protecting” a “damaged” back, which is not in line with contemporary pain physiology. We think the results highlight the importance of considering the type of education provided to patients and that the results are limited by the studies included in the meta-analysis.

Previous systematic reviews have indicated that biomedical education has limited efficacy and may negatively affect outcomes for LBP (Koes et al., 1994; Maier-Riehle and Harter, 2001; Poiraudéau et al., 2006). Shaw et al. (2005) noted that increased biomedical-based communication resulted in an increased incidence of development of chronic pain in a group of acute low back pain sufferers. Biomedical education has also been shown to increase focus and attention on pain and has been shown to have a significant negative impact on pain (Maier-Riehle and Harter, 2001; Main et al., 2010).

For these reasons, we agree with the authors that such education programs should not be used among people with persistent pain (Brox et al., 2008).

However, the authors acknowledge that some education may be effective in the treatment and prevention of neck pain and/or LBP. There has been a shift in recent years towards biopsychosocial education which includes education on the robustness and function of the spine, information on keeping active and information on coping with pain. Two reviews (Louw et al., 2011; Clarke et al., 2011) indicated that neuroscience education, which is based on biopsychosocial education, may be effective in treating chronic musculoskeletal pain and LBP. Pincus et al. (2013) and Traeger et al. (2015) also completed reviews indicating that biopsychosocial reassurance significantly reduces healthcare utilisation. Previous studies (Moseley, 2004; Moseley et al., 2004) and reviews (Henrotin et al., 2006) suggest that biopsychosocial education produces superior outcomes to biomedical education, though the effect sizes are modest. Therefore we believe it is important to distinguish between the effects of different types of education, rather than assuming their effectiveness is similar.

In conclusion, we think this review effectively highlights that poor education, which is not in line with a contemporary understanding of pain mechanisms, results in poor outcomes. However, not all education is the same and to treat them as such within a meta-analysis runs the risk of throwing the baby out with the bathwater. Therefore we disagree with the blanket conclusion that education programs are not recommended in preventing or treating neck pain and/or LBP.

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Research

Physiotherapists may stigmatise or feel unprepared to treat people with low back pain and psychosocial factors that influence recovery: a systematic review

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KEY WORDS

Physiotherapy
Qualitative
Systematic review
Metasynthesis
Low back pain



ABSTRACT

Question: What are physiotherapists' perceptions about identifying and managing the cognitive, psychological and social factors that may act as barriers to recovery for people with low back pain (LBP)? **Design:** Systematic review and qualitative metasynthesis of qualitative studies in which physiotherapists were questioned, using focus groups or semi-structured interviews, about identifying and managing cognitive, psychological and social factors in people with LBP. **Participants:** Qualified physiotherapists with experience in treating patients with LBP. **Outcome measures:** Studies were synthesised in narrative format and thematic analysis was used to provide a collective insight into the physiotherapists' perceptions. **Results:** Three main themes emerged: physiotherapists only partially recognised cognitive, psychological and social factors in LBP, with most discussion around factors such as family, work and unhelpful patient expectations; some physiotherapists stigmatised patients with LBP as demanding, attention-seeking and poorly motivated when they presented with behaviours suggestive of these factors; and physiotherapists questioned the relevance of screening for these factors because they were perceived to extend beyond their scope of practice, with many feeling under-skilled in addressing them. **Conclusion:** Physiotherapists partially recognised cognitive, psychological and social factors in people with LBP. Physiotherapists expressed a preference for dealing with the more mechanical aspects of LBP, and some stigmatised the behaviours suggestive of cognitive, psychological and social contributions to LBP. Physiotherapists perceived that neither their initial training, nor currently available professional development training, instilled them with the requisite skills and confidence to successfully address and treat the multidimensional pain presentations seen in LBP. **Registration:** CRD 42014009964. [Synnott A, O'Keeffe M, Bunzli S, Dankkaerts W, O'Sullivan P, O'Sullivan K (2015) Physiotherapists may stigmatise or feel unprepared to treat people with low back pain and psychosocial factors that influence recovery: a systematic review. *Journal of Physiotherapy* 61: 68–76].

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Introduction

Low back pain (LBP) is no longer accurately viewed as a purely structural, anatomical or biomechanical disorder of the lumbar spine. Research in recent decades has highlighted that LBP is a complex disorder, which can be influenced by a wide range of other factors.^{1,2} These include cognitive (eg, catastrophic thoughts and beliefs, unhelpful expectations, poor motivation), psychological (eg, depression, anxiety), social (eg, low job satisfaction, interpersonal relationship stress, cultural factors), physical (eg, guarded and restricted movement patterns), and lifestyle (eg, physical inactivity) factors.² These factors are seen to act as catalysts for chronicity, contributing to poorer recovery and prolonged disability in at least some people with LBP.^{3,4}

Guidelines for LBP treatment generally acknowledge a shift towards a biopsychosocial management approach.^{3,5} However, physiotherapists have mostly received training of a more biomedical nature, at least in their initial education, similar to

many other healthcare professionals (eg, chiropractors, osteopaths, medical doctors).⁶ Management of physical factors, such as guarded movement patterns and muscle tension, and lifestyle factors, such as sedentary behaviour and deconditioning, have been a focus of physiotherapy training for many decades. However, the need to incorporate consideration of cognitive, psychological and social factors in LBP management may pose a greater challenge for physiotherapists.^{7–9}

Physiotherapy students have been found to have relatively evidence-based attitudes and beliefs about pain compared to other healthcare students.^{10–12} However, even recently graduated physiotherapists demonstrate some attitudes and beliefs about pain that are not fully in line with LBP guidelines and contemporary research findings.^{10,12,13} Physiotherapists increasingly receive training in treatment packages that take into account cognitive, psychological and social factors in LBP;^{14–18} however, it is unclear as to whether such training adequately equips them with the requisite skills to change patient management and outcomes.¹⁹ A recent review of

several different study designs concluded that whilst physiotherapists theoretically support a biopsychosocial approach to LBP, in practice, very few are doing so adequately, despite training in cognitive behavioural principles.²⁰ However, that review²⁰ focused primarily on return to work rather than the wider population of people with LBP. Furthermore, that review included only a limited number of qualitative studies that offered useful methodology to investigate physiotherapists' perceptions and identify potential barriers, and facilitators to incorporate such factors into clinical practice. Gaining a detailed insight of physiotherapists' perceptions about these factors could be very useful in order to evaluate whether such factors are considered in LBP assessment and management. Qualitative metasynthesis is 'an interpretive integration of qualitative findings that are themselves interpretive syntheses of data'²¹ that may contribute to clinically oriented theory.²²

Therefore, the research question for this systematic review and metasynthesis was:

What are physiotherapists' perceptions about identifying and managing cognitive, psychological and social factors that may act as barriers to recovery in people with LBP?

Method

Identification and selection of studies

This review has been reported in accordance with the enhancing transparency in reporting the synthesis of qualitative research (ENTREQ) guidelines;²³ the checklist for the synthesis of qualitative data is detailed in Appendix 1 on the eAddenda. The databases EbscoHost (Academic Search Complete, AMED, Biomedical Reference Collection, CINAHL, Medline, PsychArticles, PsychInfo, SportDiscus), Embase, Scopus and Web of Science were searched between March 2014 and May 2014 by two independent reviewers.

The search strategy was developed by the authors and key words were compiled based on systematic searches of key words utilised in systematic reviews^{20,24} performed in this area. The strategy used four groups of key words, to ensure that the selected studies included: qualitative research methodologies; physiotherapists as the treating healthcare professional; cognitive, psychological and social factors; and LBP as the condition of interest. The specific key words had to be included in the abstract to be shortlisted for this review. The full search strategy is detailed in Appendix 2 on the eAddenda.

The search was limited to English-language papers involving humans; no year limits were applied. Titles and abstracts were screened by two independent reviewers. Full-text versions of potentially eligible articles were retrieved. Manual searches of reference lists of the shortlisted articles were also performed by two independent reviewers. Recent systematic reviews of qualitative literature on LBP^{20,24} were also shortlisted and

Box 1. Eligibility criteria.

Design

- Qualitative studies
- Published in English

Participants

- Physiotherapists with experience in treating LBP

Outcomes

- Physiotherapists' perceptions regarding identifying and managing the cognitive, psychological and social factors that may act as barriers to recovery in people with non-specific LBP

searched for references. The primary authors of the studies that were initially shortlisted were contacted to identify any additional studies of potential relevance. The eligibility criteria are detailed in Box 1. Mixed-method studies were included if the qualitative analysis could be isolated. Studies investigating the perceptions of physiotherapists and other healthcare professionals or patients were only included if the physiotherapists' data could be isolated. The physiotherapists' perceptions had to relate to non-specific LBP or chronic LBP but not specific diagnoses such as cauda equina syndrome, radicular syndrome, infection, inflammatory disorders, tumour, fractures, osteoporosis or pregnancy.

Assessment of characteristics of studies

The Critical Appraisal Skills Programme (CASP) qualitative assessment tool was applied by two authors working independently to evaluate the trustworthiness of the eligible articles. Articles were not excluded on the basis of the CASP criteria. The trustworthiness criteria evaluated within CASP are listed in Table 1, with more detailed explanation in Appendix 3 on the eAddenda. For each article, the reasoning for the unfulfilled CASP criteria is detailed in Appendix 4 on the eAddenda.

Data extraction and synthesis

The data extracted using a purpose-designed format were: a description of the participants, the sample sizes, the methods of data collection, the aims of the studies, and the main findings related to the metasynthesis.

Data synthesis was conducted by the first author (AS), an undergraduate physiotherapy student. The analytic process described by Sandelowski and Barroso²¹ was adapted for the review. The first stage of the process was the extraction of findings and coding of findings for each article. The second stage was grouping of findings according to their topical similarity to determine if findings confirm, extend or refute each other. The third stage was abstraction of findings – analysing the grouped findings to identify additional patterns, overlaps, comparisons and

Table 1
Achievement of the Critical Appraisal Skills Programme criteria by the included studies.

Study	Clear statement of aim	Qualitative methodology appropriate	Appropriate research design	Sampling	Data collection	Researcher reflexivity	Ethical consideration	Appropriate data analysis	Clear statement of findings	Research value
Billis et al 2005 ²⁵	Y	Y	N	N	N	Y	Y	Y	N	Y
Bond et al 2012 ²⁹	Y	Y	N	Y	Y	N	Y	N	N	Y
Côté et al 2009 ³¹	Y	Y	Y	Y	N	N	Y	Y	N	Y
Daykin et al 2004 ¹³	Y	Y	Y	Y	Y	N	Y	Y	N	Y
Dean et al 2005 ²⁶	Y	Y	Y	N	N	Y	N	Y	Y	Y
Jeffrey and Foster 2012 ³²	Y	Y	Y	N	N	Y	Y	Y	N	Y
Josephson et al 2011 ³⁴	Y	Y	N	N	N	Y	N	Y	N	Y
Josephson et al 2013 ³⁶	Y	Y	N	N	N	Y	N	Y	N	Y
Sanders et al 2013 ³⁰	Y	Y	N	Y	Y	N	Y	Y	N	Y
Sanders et al 2014 ³⁷	Y	Y	N	Y	Y	N	Y	Y	N	Y
Slade et al 2012 ³⁵	Y	Y	Y	Y	Y	N	Y	Y	N	Y
Wynne-Jones et al 2014 ³³	Y	Y	N	Y	Y	N	Y	Y	Y	Y

Y = yes, N = no.

redundancies to form a set of concise statements (themes), which capture the content of all findings. The three stages were completed simultaneously rather than sequentially. The emerging groupings of early codings were cross-checked with on-going codes and were used to inform future codes. Final groupings were reviewed by all authors to ensure homogeneity of the codes between groups, and to ensure no potential groupings were overlooked during the analysis. To ensure that the findings were grounded in primary data and to guide the interpretive process, the coding and thematic analysis was presented to, discussed with, and critiqued by two co-authors (KOS, MOK both clinical and research physiotherapists). The suitability of the fit of the final themes to early codes/grouping was further reviewed by another author (SB) with experience in qualitative analysis.

Results

Identification and selection of studies

The identification and selection of studies for analysis is summarised in Figure 1. In total, 6338 articles were found in the databases. After 1133 duplicates were removed, 5205 titles and abstracts were scanned. Thirteen articles were retrieved, with four articles being excluded because they did not fulfil the inclusion criteria. One study was deemed suitable from hand searching of relevant systematic reviews. Two articles recommended by relevant authors in the LBP area fulfilled the inclusion criteria. Twelve articles in total were included in the metasynthesis. A summary of the included articles is presented in Table 2. Nine studies were located in Europe, two in Australia and one in Canada, with the majority taking place between 2004 and 2013 in physiotherapy settings. A total of 182 participants were interviewed in the 12 studies.

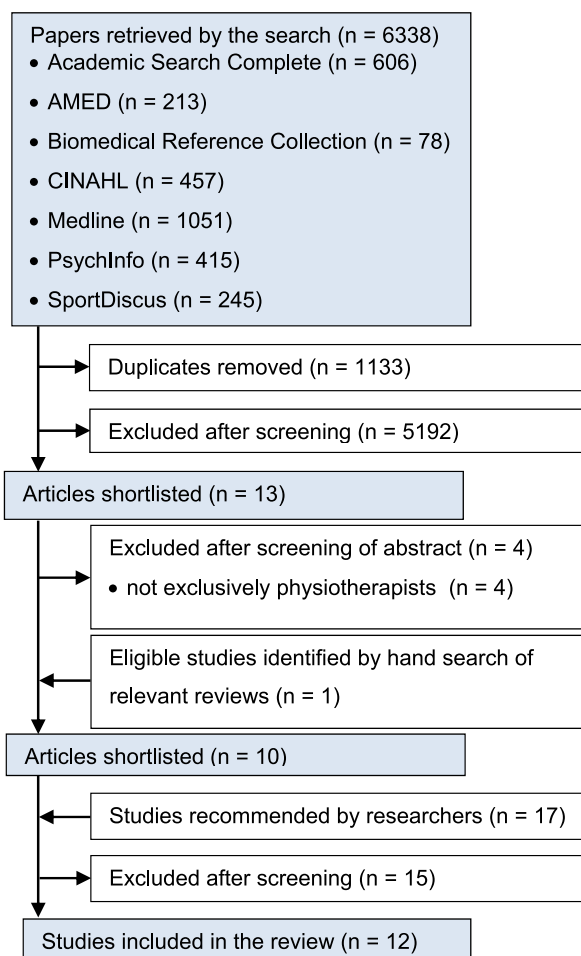


Figure 1. Flow of studies through the review.

Description of studies

Confounding factors

Two studies in this review interviewed physiotherapists who primarily had experience in treating an acute LBP population.^{25,26} Physiotherapists rarely use validated outcome measures to screen for psychosocial issues in acute LBP patients,²⁷ due to the traditional thinking that acute episodes of LBP resolve rapidly,²⁸ with outcome measures often reserved solely for those who present with poor clinical improvement. As a result, physiotherapists in the two studies that primarily had experience with an acute LBP caseload may not have had a comparable awareness of the cognitive, psychological and social factors that physiotherapists treating chronic or non-specific LBP may have had in the remaining studies.

One study²⁹ recruited physiotherapists who were employed within a military setting and were involved in treating a non-specific LBP population. It is not clear how this military setting and experience influenced these physiotherapists and if their experiences were comparable to those of the physiotherapists treating LBP recruited by the remaining studies. Participants in the remaining studies were all based within either public or private health settings.

Trustworthiness of results

The CASP criteria of trustworthiness met by each study are presented in Table 1. Further details about the specific reasons that individual studies failed to meet the criteria are presented in Appendix 4. For example, ten studies failed to fulfil criterion 9 due to an absence of member checking, where the original data and study findings are cross-checked with the participants. Because some studies did not meet some of the criteria, the completeness, interpretation and generalisability of the results may each have been affected. However, the studies all had clear aims research value, with consistent use of appropriate qualitative methodology and data analysis.

Themes identified in the metasynthesis

Table 3 provides an overview of the themes and subthemes identified. Table 4 presents the number of times each subtheme was identified by a study, and the total number of times it was supported by a statement in any of the included studies.

Theme 1. Limited recognition by physiotherapists of the role that cognitive, psychological and social factors play in LBP

Subtheme 1.1. Patients' biomedical expectations

Physiotherapists in several studies described how patients' biomedical treatment expectations influenced their management approach. Some physiotherapists seemed to struggle when communicating with patients in these situations, with a view that treatment should involve either education or passive treatment, but not both.

You certainly get a gut feel of the ones that you're wasting your time on... they perhaps think they're coming to me for a massage or something to be done to make them feel better... so they are difficult and I have to say... well, look if you don't want to follow what I'm saying I'm afraid I can't help you.³⁰

Let's say you give them a nice little speech... it would surprise me if they were satisfied and if they would come back. You know they're just going to think... there's not much point in going for treatment.³¹

They don't want to hear what you're saying. They want you to make them better.³²

Consequently, the default position of many physiotherapists seemed to involve yielding to these patient expectations and administering passive treatments.

Table 2
Characteristics of the included studies.

Study	Participants	Data collection	Aim	Main findings
Billis et al 2005 ²⁵	PTs dealing with a LBP population N = 18 (22% female) Qualified (yr) = 3 to 28 Workplace = 83% private	Three focus groups, each containing 6 to 8 participants	To evaluate the clinical and social factors that practising PTs and post-graduate PTs recognise as important in the assessment and management of LBP patients.	PTs readily recognised social factors such as marriage and family life as contributors to the patient's pain. However, PTs were less cognisant of the role that cognitive and psychological factors may play in the patient's pain presentation. Only a small group of PTs who had received post-graduate training paid attention to these factors in their initial examination of the patient. PTs were comfortable in utilising a biomedical approach in treating this patient caseload and often negatively stereotyped those presenting with non-specific LBP as attention seeking.
Bond et al 2012 ²⁹	PTs dealing with LBP in a military population N = 14 (60% female) Qualified (yr) = 5 to 30 Workplace = military	Semi-structured interviews	To understand civilian PTs' attitudes and beliefs towards assessing and managing LBP in a military population.	PTs recognised the influence of social factors on pain; however, they often administered contradictory biomedically-oriented treatment with weak evidence. Patients that were seen to have poor compliance and motivation for treatment were often referred onto other healthcare providers.
Côté et al 2009 ³¹	PTs dealing with a LBP population (> 25% of caseload) N = 16 (gender n/s) Qualified (yr) = half < 10, half > 10 Workplace = 50% private	Semi-structured interviews	To identify perceived barriers and facilitators to PTs' use of clinical practice guidelines in management of LBP.	PTs recognised that cognitive factors such as patient expectations were barriers to recovery in LBP, as many patients expected hands-on treatment and were intolerant of a hands-off approach. PTs lacked confidence in their training to implement the recommended biopsychosocial approach clinically.
Daykin et al 2004 ¹³	PTs dealing with a chronic LBP population N = 6 (100% female) Qualified (yr) = 15 to 27 Workplace = 0% private	Semi-structured interviews	To explore PTs' pain beliefs and their influence on the management of patients with chronic LBP.	PTs labelled those presenting with behaviours suggestive of cognitive, social and psychological factors as difficult. The self-perceived inexperience, and lack of training of PTs, may have contributed to this labelling.
Dean et al 2005 ²⁶	PTs dealing with a LBP population N = 8 (100% female) Qualified (yr) = 5 to 13 Workplace = 75% private	Semi-structured interviews	To explore PTs' perceptions of LBP patient's adherence to treatment.	PTs recognised cognitive factors such as unhelpful patient expectations as barriers to both patient adherence and treatment.
Jeffrey and Foster 2012 ³²	PTs dealing with a LBP population N = 11 Gender = 45% female Qualified (yr) = 10 to 39 Workplace = 36% private	Semi-structured interviews	To understand the personal experiences and beliefs of PTs that influence relevant decision making and management of a LBP patient population.	Even in the absence of a definitive mechanical diagnosis, PTs still classified patients purely on a mechanical basis. Cognitive factors such as patient expectations were barriers to successfully managing LBP patients. PTs questioned the value of intervention in patients that were perceived as passive or unmotivated, with some stigmatising such patients.
Josephson et al 2011 ³⁴	PTs dealing with LBP N = 21 Gender = 17% female Qualified (yr) = 6 to 40 Workplace = 19% private	Four focus groups, each containing 4 to 6 participants	To explore PTs' opinions about gaining the essential knowledge or information to successfully manage LBP.	PTs deemed those LBP patients that did not present with cognitive, psychological and social factors as 'easy'. In contrast, those that did present with these factors were described as 'complex' and posed a challenge to clinical practice.
Josephson et al 2013 ³⁶	PTs dealing with a LBP population N = 21 Gender = 71% female Qualified (yr) = 6 to 40 Workplace = 19% private	Four focus groups, each containing 4 to 6 participants	To learn how PTs describe reasoning behind their management interventions in LBP patients, and how they manage challenging patient presentations.	PTs believed that they had a responsibility to treat the easy cases. However, they were unsure of their role in the management of more complex cases when patients presented with cognitive, psychological and social factors, describing limitations in their expertise and scope of practice when managing such cases.
Sanders et al 2013 ³⁰	PTs dealing with a LBP population N = 12 (50% female) Qualified (yr) = 4 to 33 Workplace = 80% private	Semi-structured interviews	To learn how PTs incorporate a biopsychosocial approach into LBP management, and how they manage to balance the mechanical and psychosocial aspects of LBP patient care.	Combining both a biomedical and biopsychosocial approach in the management of this patient population posed a significant challenge amongst the PTs. While many recognise the importance of cognitive, psychological and social factors, they believe that addressing these factors extends beyond their scope of practice.
Sanders et al 2014 ³⁷	PTs dealing with a LBP population N = 26 (gender n/s) Qualified = n/s Workplace = 0% private	Semi-structured interviews	To evaluate perceived barriers among PTs to the implementation of a new biopsychosocial intervention in clinical practice.	PTs recognised LBP as a complex problem which involves social and psychological contributions. However, PTs felt inadequately prepared by their biomedically-oriented training to successfully address these factors in practice and advocated the need for further training.
Slade et al 2012 ³⁵	PTs dealing with a chronic LBP population N = 23 (56% female) Qualified (yr) = 1 to 37 Workplace = 43% private	Four focus groups, each containing 4 to 6 participants	To learn how PTs manage a LBP population in the absence of a definitive mechanical diagnosis.	PTs often lacked confidence or felt inadequately prepared to treat patients with non-specific LBP who did not have a clear biomedical diagnosis, due to their own biomedically-oriented training.

Table 2 (Continued)

Study	Participants	Data collection	Aim	Main findings
Wynne-Jones et al 2014 ³³	PTs dealing with a LBP population N=6 (100% female) Qualified = n/s Workplace = 0% private	Semi-structured interviews	To explore both GPs' and PTs' views of managing LBP in the context of work.	While PTs routinely discussed work in the context of an assessment of a patient with LBP, their advice and treatment was often functional and mechanical in nature, perceiving that their profession is limited in instilling any change in the work environment.

GP=general practitioner, LBP=low back pain, n/s = not stated, PT=physiotherapist.

Table 3

Overview of themes and subthemes.

Themes	Subthemes
Limited recognition by physiotherapists of the roles that cognitive, psychological and social factors play in LBP.	1. Biomedical expectations of patients 2. Biomedical preferences of physiotherapists
Some physiotherapists stigmatise patients whose behaviour indicates that cognitive, psychological or social factors are influencing their LBP.	No subthemes identified
Limited role in managing cognitive, psychological and social factors.	1. Limited willingness to discuss with patients that these factors may influence their LBP 2. Concerns about training, expertise and exceeding professional scope of practice

Table 4

Number of contributing statements and articles that identified subthemes.

Subthemes	Contributing statements (n)	Contributing articles (n)
Biomedical expectations of patient	13	6
Biomedical preferences of the physiotherapist	18	7
Stigmatising of behaviours suggestive of cognitive, psychological and social factors	15	5
Limited willingness to identify factors as contributors to LBP	17	7
Concerns about training, expertise and exceeding their scope of practice	16	8

*Most people come in and they're looking for a diagnosis and therefore a click, crunch, and off they go they'll be fine.*²⁶

Subtheme 1.2. Physiotherapists' biomedical preferences

Many physiotherapists believed that their role was mainly to address the mechanical aspects of LBP. Whilst there are no details on the training received by the physiotherapists, their own comments suggest that their preference for dealing with the 'mechanical' aspects of LBP reflects their own previous training and their professional confidence.

*Everyone (of my patients) gets stability exercises cause that's in fashion at the moment, so it's almost a case they get it whether they need it or not... so you are basing a lot of input on very little evidence base and yet it seems to be in fashion.*²⁹

Even among patients who had been told that their LBP was non-specific in nature, physiotherapists preferred to explore the mechanical nature of LBP, either oblivious to the other dimensions of LBP, or choosing not to address it.

*I would probably explain to her that it was most likely postural strain... There could be an underlying facet joint degenerative problem evident.*³²

Testament to this, amongst physiotherapists, there was an overwhelming preference for the biomedical pain presentation.

*I like clear pictures! It's easier isn't it, more straightforward.*¹³

*An uncomplicated back that feels well and allows someone to lead a rewarding life while still experiencing back pain is easy to treat.*³⁰

Whilst physiotherapists recognised the implications of social issues, such as the influence of work-related factors on a patient's pain disorder, their advice was often linked to the functional and mechanical adaptations that patients can make in the context of work.

*If it (work) comes up in the questioning, in terms of either why they're off work, or the problems they're having at work, then yes, we'll look at, you know, the postures and the function, and any sort of ways round it or who they need to speak about it.*³³

In fact, some physiotherapists attributed a progression to chronicity solely to a lack of understanding or awareness of the biomedical and mechanical drivers of pain, with no acknowledgement of the cognitive, psychological and social drivers of chronicity in back pain.

*Especially since our role as physiotherapists is to make sure that movement is restored, but we need to know what is preventing movement. Giving exercises to promote activity is fine but not enough. If you don't resolve the physical or biomechanical components, I think you will be heading towards chronicity.*³¹

Given the biomedically oriented preferences of patients and physiotherapists, it appeared that the cognitive, psychological and social factors were not widely recognised. Some physiotherapists seemed to recognise the significant influence on LBP of certain life events, as well as social factors such as the patient's family life and occupational environment. Very little mention of psychological factors was observed, apart from some mention of the role of fear in LBP. Overall, there was little discussion of if, or how, these factors were considered in the treatment program.

*It could be a lot of life problems behind (LBP) as the most important factor.*³⁴

*... yea she may even need to switch jobs.*³⁴

*Fear. Fear they might reproduce their symptoms, especially if they're not completely pain free, erm, and I think also they're worried about taking sick time again, erm, from the employers' perspective, losing their job if they keep taking sick leave.*³³

Theme 2. Some physiotherapists stigmatise patients whose behaviour indicates that cognitive, psychological or social factors are influencing their LBP

Several physiotherapists described some LBP patients as poorly motivated, demanding, attention-seeking and, in some cases, self-centred and not interested in helping themselves to recover.

*Whether they're (patients) motivated to actually do something for themselves or they want you to, sort of... click your fingers; wave your magic wand and the pain'll be gone.*³²

*This group of people (chronic LBP patients) are very self-centred self-focused group of people who are very interested in themselves. They're a self internal, internalizing group.*³⁰

*Those extravagant pain people.*³⁰

*Some do not get better with treatment due to their attention seeking need usually the neglected by their husbands women.*²⁵

*Neglected women tend to moan I'm in pain... for attention.*²⁵

This suggests some recognition by physiotherapists of the cognitive, psychological and social factors that might influence the pain experience. This includes depression or low mood contributing to low motivation, anxiety contributing to hypervigilance, low self-efficacy and an external locus of control contributing to a desire for passive treatment, and catastrophising contributing to extravagant behaviours.^{1,2} However, physiotherapists neither seemed to identify cognitive, psychological or social factors as underlying causes for these observed behaviours, nor considered them as potentially modifiable factors for targeted intervention. From the language used in the above examples ('those' people, 'that' group), it appears that at least some physiotherapists in the included studies had little empathy for the cognitive, psychological or social aspects of the pain experience.

Some physiotherapists alluded to the possibility that some LBP patients may be in receipt of financial aid or disability and, as a result, are driven by a financial incentive and consequently lack a motivation for recovery.

*I suppose, I mean, if you really went down to it, you could talk about those people who are, or you know, poverty in patients, little money, sometimes, is quite, you know, they're quite willing to be ill, if you understand me?*³⁰

*Maybe their own benefits, they will be earning more through that way than going back to work... but although I'm saying that, it's very hard to prove anything. You always have your own suspicions.*³⁰

Theme 3. Limited role in dealing with the cognitive, psychological and social factors

Subtheme 3.1. Limited willingness to discuss with patients that these factors may influence their LBP

Physiotherapists recognised the need to provide a clear and simple explanation for the patient's pain and felt that a biomedical diagnosis offered the best framework for this, even amongst those diagnosed as having non-specific LBP and where evidence for the explanation was lacking.

*The explanation is tailored entirely... on how much you feel they can understand without scaring them.*³⁵

*Simplistic (mechanical) explanations (for their back pain), so the patients have something to hang their hat on... without saying that's the absolute truth.*³⁵

*It's very easy to say, you've got a disc that's bulging out this way, if you do this McKenzie technique that pushes it back in... and we know that that's probably not true, but it's a simplistic way for patients to understand and you can give them a model.*³⁵

*You have to give them some sort of diagnosis... even if I'm not a hundred per cent sure that it's facet I'll just tell them it's facet, tell them it's a disc strain so they know it's going to get better.*³⁵

Physiotherapists expressed concerns about discussing with patients the influences that cognitive, psychological and social factors have on the presentation of pain, for fear of it 'going wrong'. Consequently, physiotherapists preferred it when patients brought up the certain cognitive, psychological or social factors related to their pain themselves, relieving the physiotherapists from this responsibility and the fear of it 'going wrong'.

*It was if I placed all the emphasis on the fact that she didn't like her job. She didn't like that; she really reacted then because I managed to identify too clearly the fact that she didn't like her job.*³¹

*I prefer a person (LBP patient) who can vent for herself and tell me things herself without me asking questions... cause it can go wrong.*³⁶

Other physiotherapists described how experience from treating similar LBP patient presentations facilitated them being willing, or able, to identify these factors.

*Just through experience, you know, is that there are some joints that physios would call emotional joints.*³⁰

*You're going to get a lot more of the psychological side coming in and that's why you need far more experienced physiotherapists, I think, to cope with that.*¹³

Subtheme 3.2. Concerns about training, expertise and exceeding professional scope of practice

Physiotherapists recognised the limitations of their professional training in dealing with influencing cognitive, psychological and social factors. Physiotherapists described a lack of adequate skill acquisition and were often unable to implement skills learned during training when working in clinical practice, which posed a barrier to addressing these issues in practice. In many cases, where cognitive, psychological and social factors were implicated, there was considerable pessimism about the potential for therapy to result in clinical improvement.

*I think that we are really not well equipped to give the right message across to these patients... I don't think we have enough training and background to maybe to know exactly what to say to these people, to be positive but to be realistic. I think we need more input with that kind of thing, the right things to say and the wrong things to say, would help.*³⁷

*There is a limitation to what I can achieve with regard to, say, my counselling skills and my skills of helping them modify their pain behaviour and helping them with their cognitive, you know, construct if you like, regarding LBP.*³⁰

*We can guide them as to ways of avoiding sitting all day, trying to encourage them to get up and move around regularly, as to make sure that they're sitting in a correct position as possible, but as far as changing what they're actually doing at work, I don't think I have much influence at all really.*³³

Some physiotherapists described how their lack of expertise in these domains was so profound, there was no point even asking about them, since they could not treat them. Furthermore, even among those physiotherapists who recognised that these factors were important in LBP, many considered that the management of them was beyond their professional role and scope of practice, as they were not equipped with the knowledge or skills to have any successful input.

*Why would I give a questionnaire to my patient to identify whether he is afraid to move, if I don't know what to do about it?*³¹

*If there's a relationship issue and things like that, that's stuff that I won't necessarily address, because I don't think it's my area. I mean, I'm not going to start saying to patients, you know, how is your relationship with your husband at the minute, because... what am I going to do about it, if you know what I mean? If they start bringing up those sort of issues?*³⁰

*That is where I feel I don't have much to offer, only to lend a listening ear and a bit of advice if I can, but I have no way of knowing whether that advice is appropriate.*³⁷

This was often described in such a way as to absolve the profession from having any professional involvement. Consequently, the responsibility for treating patients presenting with cognitive, psychological and social factors is often shifted on to other healthcare professionals.

*I mean, it can't be our, we who fail (physiotherapy profession), and take the blame for it. I don't think we're barking up the wrong tree either. You can't dump it (patients' psychosocial issues) over on somebody else like that.*³⁶

*Is that really what we think is better (physiotherapy) than just letting things take their natural course?*³⁶

In the event that such 'difficult' patients were offered treatment, physiotherapists reported feeling pessimistic about these interactions and expected patient outcomes, which in turn reduced their own job satisfaction and their self-confidence about being capable of helping people.

*You can treat again until you're blue in the face, but you'll take two steps forwards and the patient will go away, do whatever they want, and take two steps back... and this is when you get frustrating... unresolved cases.*¹³

*A physiotherapist who is treating a difficult patient may switch off a little bit... I think you become less sympathetic.*¹³

*Difficult patients were not expected to have good treatment outcomes so the physiotherapist would write them off quickly.*¹³

*The sort of patient who you've been seeing for twice a week for 10 weeks, 12 weeks, 14 weeks, and yeah, when you say Mrs So-and-So's coming in and you see Mrs So-and-So's name on the books, your heart sinks down into your boots. You think 'Oh no!' That's a 'heart sink' patient.*¹³

Discussion

The first theme that was identified in this review was that physiotherapists displayed limited recognition of the roles that cognitive, psychological and social factors play in LBP. Physiotherapists appeared to be more comfortable with the concept of LBP as a mechanical disorder of the spinal tissues. This is consistent with patients requesting passive 'hands-on' therapy for the spine, and physiotherapists being quite happy to provide advice on local structural diagnoses, and exercise or manual therapies directed at a local mechanical spinal disorder.

Some physiotherapists appeared to readily recognise and discuss social factors, such as family life and work, as being relevant to LBP. The main cognitive barrier to recovery that was identified was patients' biomedical treatment expectations. The issue of how to handle patients' expectations, that are deemed by physiotherapists to be unhelpful, is an interesting one. On the one hand, it has been suggested that patients' expectations and preferences should be elicited and used in the clinical decision-making process to help select treatments that have the best chance

of promoting recovery.³⁸ On the other hand, by ceding to patients' expectations and providing biomedical explanations of pain and treatments, physiotherapists may be perpetuating patients' biomedical beliefs and fears that pain indicates significant tissue damage.³⁹ It is possible that the perceived expectations of patients are heavily influenced by the beliefs and attitudes of their physiotherapists, and that patients may be more open to 'non-physical' treatment, if high-quality two-way communication is used. In addition, it may be more relevant to challenge patient beliefs around the overall range of factors involved in their LBP rather than worrying unduly about which specific treatment or exercise is used as part of treatment.

Despite expressing frustration with patients expecting biomedically oriented treatment, many physiotherapists themselves were more comfortable with LBP presentations that were deemed straightforward and did not involve complicating factors, allowing treatment to focus on 'mechanical' factors such as mobility and movement patterns. However, there is no evidence to suggest that even in 'routine' LBP presentations that an approach which only addresses mechanical factors is optimal. Such conflicting management principles have been previously documented, with physiotherapists recognising the influence of psychosocial factors on outcome in LBP, yet advising patients to remain off work.⁷ Such an approach has previously been rationalised as indicative of pessimistic beliefs about pain, and an attempt to legitimise the experience of pain for the patient and enhance patient satisfaction.⁴⁰

Apart from one study mentioning the importance of fear in LBP,³³ there was little mention of specific psychological factors that are known barriers to recovery, including depression, anxiety and post-traumatic stress disorder. The lack of focus on some of these factors may explain why previous research has suggested that clinicians are not as capable of identifying risk or complexity among LBP patients using questionnaires that examine these factors in a standardised manner.^{41,42} Several such questionnaires, including the Orebro and Startback questionnaires, are now available and, based on these results, may be worth using in clinical practice.^{41,42} However, even the use of such questionnaires would not address the reported lack of competence and confidence among physiotherapists in influencing these factors.

The second theme that was identified was that physiotherapists stigmatised some behaviours that were suggestive of cognitive, psychological and social factors being involved in patients' LBP experience. Many LBP patients had negative personal characteristics attributed to them. This included accusations of patients looking for attention, lacking motivation, being dependent of others, helping them rather than self-managing, and being motivated by the prospect of financial gain. Similar findings have been reported elsewhere, where LBP is attributed to personal weakness and a desire for secondary gain with manipulative, excessively demanding patients seen to be placing huge strain on healthcare services.⁴³ As discussed, this may reflect a lack of awareness that these behaviours may be indicative of underlying cognitive, psychological and social factors.

Another consideration is that physiotherapists often rely heavily on a structural diagnosis to inform their treatment.⁴⁴ When a non-specific diagnosis is used, this diagnostic ambiguity poses a challenge to the physiotherapist. Consequently, this 'non-fitting' scenario threatens their professional competence, with physiotherapists attributing responsibility for poor patient outcomes to the patient.⁴⁵ Quinter and Cohen⁴⁶ have recently discussed the stigmatisation of people with chronic pain by healthcare professionals, proposing that it can be explained by a lack of empathy towards pain patients who don't 'fit' neatly into the healthcare professional's biomedical perspective of pain. Attempts to enhance empathy may first need to come from educating physiotherapists about the underlying mechanisms of chronic LBP, as empathy is at least predicated on being able to understand what is going on with patients. Perceptions of stigmatisation by health professionals are common amongst

people with LBP and may jeopardise the patient-therapist relationship, which is closely linked to patient compliance⁴⁷ and successful management.^{44,48}

It is possible that the factors perceived by physiotherapists to reflect the negative personality characteristics of a patient are in fact potentially modifiable barriers to recovery that require targeted intervention. For example, rather than being a sign of laziness or being unmotivated to help themselves, the search for a 'magic-bullet' cure may reflect deeply held biomedical beliefs that, if left unchallenged, present a barrier to recovery. Equally, repeatedly seeking passive care may indicate low self-efficacy and poor coping strategies. Thus, in order to reduce perceptions of stigmatisation amongst people presenting with LBP, it may be important to educate physiotherapists about identifying what is a potentially modifiable factor.

The third, and final, theme that was identified was the limited perceived role for physiotherapists in managing cognitive, psychological and social factors among people with LBP. Patients commonly report fear and anger, and mentioning the presence of these factors in their lives may de-legitimise their LBP in the eyes of their clinician.^{49,50} This appears to have been experienced by some of the physiotherapists, so that they often avoided even discussing a factor unless the patient brought it up. However, in contrast to this reluctance of physiotherapists to discuss these factors with patients, previous research has identified that acknowledgement by a clinician of the impact of pain on a person's psychological health is considered to be very valuable by patients.⁵¹ In other words, patients may be quite happy to have the impact of pain on their lives discussed and acknowledged, as long as there is no suggestion that these factors mean that their pain is 'psychosomatic' or imagined.

Many physiotherapists reported that they lacked the requisite skills and confidence to successfully discuss and address these factors among patients with LBP. In many ways, this probably reflects their biomedically oriented nature of their training, and the absence of explicit training in communication, such as the use of role playing during training to enhance communication skills.¹³ In some cases, this lack of skills and confidence seems to have been used to absolve physiotherapists of their responsibility to help patients with these issues. Linton et al⁵² previously described the physiotherapy profession as 'fear-avoidant' when confronted with these issues in practice. This fear-avoidance may be employed as a defence mechanism, in order to protect their professional confidence and self-esteem, which can be threatened by repeated encounters with patients whose 'non-specific' diagnosis is outside their clinical comfort zone.

Among the physiotherapists who reported a willingness to engage with these factors, any currently available training courses were deemed to be insufficient for developing their skills and enhancing their patient management. Instead, it was considered that substantial clinical experience was needed in order to develop sufficient expertise to enable successful management of these patients. However, there is no evidence that healthcare professionals with greater clinical experience or even a special interest in LBP display better beliefs about LBP.^{15,53,54} These limitations might be alleviated by attending biopsychosocially-oriented workshops on LBP. However, while such training may succeed in changing beliefs regarding pain, the skills and knowledge learned during these courses do not always translate into changes in physiotherapists' management and patient outcomes and satisfaction.^{15,19,55} One possible explanation is that physiotherapists who attend such courses know what they are expected to say after training, in terms of identifying on a case vignette some important cognitive, psychological or social factors; however, this may not reflect their actual practice. Other possibilities are that they are simply overwhelmed in trying to translate this into practice, and local resource issues (eg, staffing, space, training) do not facilitate integrating the training into their clinical practice. Some other methods of helping physiotherapists to use additional training to manage these factors in their everyday clinical practice may be needed.⁵⁶

This review has several important clinical implications. The fact that cognitive, psychological and social factors were only partially identified by physiotherapists as barriers to recovery factors in LBP supports the role for using short screening tools (eg, STarTBack⁴¹ and Orebro⁴²) to specifically highlight when such factors are present. The presence of these factors, the limited understanding of how they affect patient engagement with therapy, and a lack of confidence in exploring these factors may partly explain some of the stigmatising of patients with LBP that occurs among some physiotherapists. Physiotherapists should consider whether some characteristics such as poor motivation, or dependence on passive therapies, may indicate the presence of other factors such as depression, anxiety or poor self-efficacy, which require greater consideration. Furthermore, there may be a need for greater appreciation by physiotherapists of how important it is to manage factors like patient expectations, because they are related to clinical outcomes.^{57,58} This may require expansion of the core range of clinical tools used by physiotherapists, which can be done without reinforcing passive dependence on the physiotherapist. Because some physiotherapists feel underprepared by their traditional biomedically oriented education to adequately identify and address these factors, there is a need for additional training to ensure any additional knowledge and skills gained are transferrable to clinical practice. Consequently, it may be of benefit for physiotherapists involved in treating LBP to undergo training that specifically involves the assessment and treatment of 'live' patients, to enable physiotherapists to translate the skills they have learned into practice, with ease and confidence. This may lead to improved confidence and competence of physiotherapists, and improved patient outcomes. It may also be necessary to carry out research to establish the correct language to use when explaining pain in order to legitimise patients' pain and avoid stigmatisation.^{40,59} Guidance from professional organisations and/or statutory healthcare providers on how these issues can be dealt with by a physiotherapist, including when onward referral to another professional or service is indicated, is currently lacking and may be very useful.

What is already known on this topic: Recovery from LBP can be limited by cognitive factors (eg, catastrophic beliefs, poor motivation), psychological factors (eg, depression, anxiety), and social factors (eg, low job satisfaction, relationship stress).

What this study adds: While some physiotherapists recognise the importance of these factors as important barriers to recovery, most prefer to treat the mechanical aspects of LBP and some stigmatise patients who demonstrate such factors. Many physiotherapists feel underprepared to treat these aspects of LBP. Physiotherapists may benefit from using screening tools with which to identify these factors and from training to help discuss and manage these factors with patients.

eAddenda: Appendices 1, 2, 3 and 4 can be found online at doi:10.1016/j.jphys.2015.02.016.

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Appendix 4: Letters to the editor

4a. O’Keeffe, M., O’Sullivan, P. and O’Sullivan, K. (2016) ‘Cell-based Therapies for lumbar discogenic low back pain: A letter to the editor’, *Spine*. Accepted for Publication.

4b. O’Keeffe, M., Dankaerts, W., O’Sullivan, P. and O’Sullivan, K. (2015). ‘Swiss ball enhances lumbar multifidus activity in chronic low back pain: A letter to the editor’, *Physical Therapy in Sport*, 16(2), 202-203.

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Cell-based Therapies for lumbar discogenic low back pain: A letter to the editor.

Dear Editor,

We have concerns about the recent review¹ on cell-based therapies for low back pain (LBP):

1. The review was not prospectively registered.
2. The search strategy appears uncomprehensive, possibly explaining why studies inconsistent with their findings are not reported.²
3. Using exclusively the Oswestry Disability Index rather than the parameter disability to exclude studies is unusual. Furthermore, this criterion is not applied consistently, with one study³ lacking a pain and disability measure being included in the review.
4. The heterogeneity in the meta-analysis is extremely high.
5. Single-arm reviews do not consider natural history or “placebo” effects related to study participation. Consequently, a more sceptical tone is warranted in discussing these results.
6. Finally, the paper does not appear to appreciate the contemporary understanding of “pathology” in LBP. A weak correlation between disc degeneration and LBP development has been found in most studies.⁴ The idea that disc degeneration is a cause of LBP, which is then targeted with cell-based therapy, is a presumption not backed up with strong evidence. Therefore this should be acknowledged.

We believe that recommendations for the use of cell-based therapies must be only made when high quality RCTs demonstrate effectiveness compared to current management.

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Letter to the Editor

Swiss ball enhances lumbar multifidus activity in chronic low back pain: A letter to the editor



A recent paper in your journal (Scott, Vaughan, & Hall, 2015) reports the findings of a cross-sectional study which examined the effects of stable and unstable sitting surfaces on people with and without chronic low back pain (CLBP). The authors conclude that sitting on an unstable surface (Swiss ball) results in greater lumbar multifidus (LM) activity than sitting on a stable surface. Based on this, it is stated that unstable sitting should be used in spinal rehabilitation where the “main objective is to restore spinal segmental stability” or for the prevention of spinal pain. While we applaud their efforts to examine the relevant functional task of sitting in a clinically relevant population, we have some concerns about this conclusion, based on the data presented, methodology described, and how the findings contrast with other research evidence;

- While there was higher muscle activation sitting on an unstable surface (Swiss ball), the methods reveal that it was not relaxed or usual sitting. In fact, participants were instructed to sit up straight in anterior pelvic tilt on both surfaces. This makes it hard to conclude that just sitting on a ball can result in increased activation. Interestingly, a systematic review of seven studies (O'Sullivan, O'Sullivan, O'Keefe, O'Sullivan, & Dankaerts, 2013) conducted by our research group found that usual sitting on an unstable surface (including a Swiss ball) resulted in no differences in muscle activation when compared to usual sitting on a stable surface. The fact that participants in this study (Scott et al., 2015) were shown how to sit is a notable difference to most studies using unstable surfaces. The fact that the specific spinal angle participants were positioned in while sitting on each surface does not seem to have been standardised is another reason for caution in interpreting the reported differences in muscle activation, as subtle differences in spinal curvature could explain the observed differences.
- The authors conclude that the increases in muscle activation from sitting on a Swiss ball could be advantageous in the prevention and treatment of CLBP. Caution is warranted in making this suggestion since the study did not measure pain (except for baseline). Furthermore, increased muscle activation may not necessarily result in reduced pain. In fact, the opposite appears to often be true, with evidence showing that chairs which require more muscle activation are less comfortable (Gregory, Dunk, & Callaghan, 2006). The fact that the duration of sitting on each surface was not reported, and that neither pain nor discomfort were not reported, means that the author's conclusion that increasing muscle activation would help CLBP is not justified. Overall, a systematic review (O'Sullivan, O'Keefe, O'Sullivan, O'Sullivan, & Dankaerts, 2012) conducted by our

group revealed that unstable sitting has no significant effect on LBP or discomfort when compared to stable sitting, once the presence or absence of a backrest is considered.

- Other reasons why we have concerns about the conclusions made include existing data demonstrating that people with LBP commonly present with increased co-contraction and hyper-activity of trunk muscles (including LM), and difficulty reducing the activation of these muscles (Dankaerts, O'Sullivan, Burnett, Straker, Davey, & Gupta, 2009; Geisser, Haig, Wallbom, & Wiggert, 2004; Lewis, Holmes, Woby, Hindle, & Fowler, 2014; Moreside, Quirk, & Hubley-Kozey, 2014). Therefore deliberately attempting to increase the activity of these muscles may not necessarily be advantageous. The use of terms like ‘instability’ and the need for greater ‘core’ muscle activation in relatively low level tasks such as sitting may even serve to increase patient fears about LBP (Barker, Reid, & Lowe, 2009).
- In addition, given the fact that no relationship has been found between trunk muscle activation (including LM) and either baseline pain and disability scores, or the degree of change in pain and disability after rehabilitation (Hebert, Kjaer, Fritz, & Walker, 2014; Wong, Parent, Funabashi, Stanton, & Kawchuk, 2013), the likelihood that simply changing seated muscle activation will always make a clinically meaningful difference to LBP is questionable.
- The fact that the response of people with and without LBP was similar on both surfaces suggests that the increased activation on an unstable surface was not a response that is uniquely applicable to, or useful for, people with LBP. Instead, it would appear that this change simply reflects a slightly different way of loading the spine, and in the absence of clinical data such as pain or discomfort, it is not possible to say if this change is beneficial or not.

The lack of evidence to support sitting on an unstable surface as an effective stand-alone intervention in the prevention or treatment of CLBP is consistent with the emerging international consensus that CLBP is best considered as a multidimensional problem. Substantial evidence reveals that CLBP is not as closely associated with spinal loading (Roffey, Wai, Bishop, Kwon, & Dagenais, 2010; Wai, Roffey, Bishop, Kwon, & Dagenais, 2010a, b; Wai et al., 2010) and spinal pathology (Jarvik, Hollingworth, Heagerty, Haynor, & Deyo, 2001; Steffens, Hancock, Maher, Williams, Jensen, & Latimer, 2014) as previously thought. Rather CLBP is associated with a complex combination of physical (Dankaerts, O'Sullivan, Burnett, & Straker, 2006), psychological (Bener et al. 2013), lifestyle (Griffin, Harmon, & Kennedy, 2012; Kelly, Blake,

Power, O'Keefe, & Fullen, 2011), cognitive (Main, Foster, & Buchbinder, 2010; Wertli, Eugster, Held, Steurer, Kofmehl, & Weiser, 2014), social (Battié, Videman, Levalahti, Gill, & Kaprio, 2007; Lallukka et al. 2014) and neuro-physiological (peripheral and central nervous system changes) (Wand et al. 2011) factors. Therefore, we believe that any purely 'biomechanical' approach to the management of CLBP such as varying the mode of seating is unlikely to be clinically effective as a stand-alone approach for large proportions of people with CLBP. The lack of evidence for sitting on an unstable surface is consistent with the poor effectiveness of other stand-alone physical and ergonomic approaches for managing CLBP (Driessen, Proper, van Tulder, Anema, Bongers, & van der Beek, 2010; Martimo et al. 2008; Verbeek, Martimo, Karppinen, Kuijer, Viikari-Juntura, & Takala, 2011).

It is our contention that randomised controlled trials analysing the effectiveness of dynamic sitting in CLBP, ideally involving a long-term follow-up period with pain and/or discomfort measures, need to show positive results before making any strong conclusions about efficacy. Given the multidimensional nature of CLBP, it is our opinion that future research in this area should consider the contribution of dynamic sitting surfaces, and similar ergonomic devices, as one part of a more comprehensive LBP management plan.

Competing interests

None declared.

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TO THE EDITOR:

Re: Aleksiev AR. Ten-year follow-up of strengthening versus flexibility exercises with or without abdominal bracing in recurrent low back pain.

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