Investigating Acupuncture and Manual Therapy for Low Back Pain

Volume 2

Vivienne Claire Dascanio

Doctor of Philosophy

University of York

Health Sciences

July 2018

10. Appendices

Appendix A: Publications

A1 Original Article – Dascanio, VC. Waldock-Goude, A. MacPherson, H. Sheldon, T. (2019) Systematic Review of Manual Therapy Versus Acupuncture for low back pain. To be submitted for publication.

A2 Original Article: Editorial – Dascanio, VC. (2015b) Acupuncture in Physiotherapy: a contemporary UK perspective. Acupuncture in Medicine; 33: 442 – 444. Doi: 10.1136/acupmed-2015-010977

A3 Original Article: Dascanio, V. (2015d) A pragmatic pilot factorial randomized controlled trial of acupuncture versus manual therapy for low back pain nested within an observational cohort study: a trial protocol. Acupuncture in Physiotherapy; 27 (2): 19 – 36

A4 Original Publication: Dascanio, V. van Dongen, C. Ireland, CM. Wilson, AJ. (2015e) Acupuncture in Physiotherapy: The evidence and commissioning resource: Part 1: Acupuncture in Physiotherapy. The Evidence: A summary of evidence for the use of acupuncture in physiotherapy for the benefit of the patient. Publication of The Acupuncture Association of Chartered Physiotherapists (AACP) Limited https://www.aacp.org.uk/assets/ckfinder_library/files/150527%20AACP%20The%20Evidence%20(1).pdf

A5 Original Publication: Dascanio, V. van Dongen, C. Ireland, CM. Wilson, AJ. (2015f) Acupuncture in Physiotherapy: The evidence and commissioning resource: Part 2: Commissioning Guidance: Guidance on commissioning for AACP members. Publication of The Acupuncture Association of Chartered Physiotherapists Limited (AACP) Limited. https://www.aacp.org.uk/assets/ckfinder_library/files/150527%20AACP%20Commissioning%20Guidance%20.pdf

A6 Original Journal Article: - Dascanio, V. Birks, Y. Clark, L. Fairhurst, C. MacPherson, H. Torgerson, D. (2014) Randomized cohort trial was shown

to be feasible for evaluating treatments in low back pain. Journal of Clinical Epidemiology; 67 (8): 940 – 946. Doi: 10.1016/j.jclinepi.2014.04.004

A6b Corrigendum to 'Randomized cohort trial was shown to be feasible for evaluating treatments in low back pain'. Journal of Clinical Epidemiology. Volume 67, Issue 8, August 2014, Pages 940-946. Journal of Clinical Epidemiology (2019) Doi: https://doi.org/10.1016/j.jclinepi.2014.04.004

A7 Original Publication: Conference Abstract - Poster Presentation: Dascanio, V. Birks, Y. Torgerson, D. (2011) A pilot factorial randomised cohort trial of manual therapy or acupuncture for low back pain. Trials; 12 (Suppl 1): A150. Doi: 10.1186/1745-6215-12-S1-A150

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B2 *Conference Presentation* – A Cohort RCT Design for Low Back Pain. The Annual Conference of the British Medical Acupuncture Society (BMAS) – Scientific Meeting, Newcastle, UK. 18th - 19th April 2015

B3 *Conference Presentation* – Integrating Evidence based Acupuncture into Physiotherapy, for the benefit of the patient. Madrid, Spain. 13th December 2014

B4 *Physiotherapy Training symposium* - Cohort Randomised Controlled Trial Design – Acupuncture and Manual Therapy for LBP. VC, Dascanio. Physiotherapy Workshop, Leicestershire, UK. 15th November 2012

B5 *Conference Presentation* – Commissioning – A Way Forward. D, Varsamis & VC, Dascanio. 6th AACP Annual Conference – Piercing the Puzzle of Persistent Pain. Hinckley, Leicestershire, UK. 13th May 2012

B6 *Houses of Parliament Presentation (HoP)* – Musculoskeletal Injury: Cost-Effective Solutions for Industry and the NHS. VC. Dascanio et al. Introduction, LBP and Acupuncture and Discussion sections of presentation. HoP, London. 23rd April 2012

B7 *Conference Presentation* – A Cohort Randomised Controlled Trial Design. VC, Dascanio. The 14th International Acupuncture Research Symposium of ARRC (The Acupuncture Research and Resource Centre). London, UK. 25th February 2012

B8 *Course Lecture* – Cohort Multiple Randomised Controlled Trial Design. VC Dascanio. Maximising Participant Recruitment to Randomised Controlled Trials Course. External Participants. Department of Health Sciences, York Trials Unit, University of York, UK. 28th November 2011

B9 *Conference Presentation* – Commissioning Acupuncture within the NHS. N Pahl & VC Fort. British Acupuncture Council Annual Conference. London. 18th September 2011

B10 *Conference Poster* – Presented at:

- *National Conference of the Acupuncture Association of Chartered Physiotherapists (AACP) Still Pointing the Way after 30 Years. 17th – 18th May 2014.*
- *National Conference of the Acupuncture Association of Chartered Physiotherapists (AACP) Acupuncture at the Sharp End. 18th-19th May 2013.*
- *The 14th International Acupuncture Research Symposium of ARRC (The Acupuncture Research and Resource Centre). 25th February 2012.*
- *The 1st UK Clinical Trials Methodology Conference of The MRC Network of Hubs for Trials Methodology Research. 4th-5th October 2011.*

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Appendix A: Publications

Appendix A1: Original Article

Original Article – Dascanio, VC. Waldock-Goude, A. MacPherson, H. Sheldon, T. (2019) Systematic Review of Manual Therapy Versus Acupuncture for low back pain. To submit for publication.

Editorial

Acupuncture in physiotherapy: a contemporary UK perspective

Vivienne C Dascanio

Correspondence to
Vivienne C Dascanio, C/o David J Torgerson, Department of Health Sciences, University of York, York YO10 5DD;
vcf500@york.ac.uk,
Viviennefort@gmail.com

Accepted 15 October 2015
Published Online First
6 November 2015

Linked

▸ http://dx.doi.org/10.1136/acupmed-2015-010911

CrossMark

To cite: Dascanio VC. *Acupunct Med* 2015;**33**:442–444.

INTRODUCTION

The current debate in the USA over professional 'ownership' of acupuncture, as detailed in the linked paper by Zhou *et al*[1] and reflected by the recent position paper from the American Academy of Medical Acupuncture (http://www.medicalacupuncture.org/ForPhysicians/AbouttheAAMA/AAMAPositionStatement), is in stark contrast to the diverse, multidisciplinary approach that is flourishing in the UK. Dispelling the myths of physiotherapy (physical therapy) led acupuncture is a task that is long overdue. Perhaps the argument "why physiotherapists should not deliver acupuncture" should be reframed "why *not* physiotherapists (or other healthcare professionals who are not physicians)?". Chartered physiotherapists are placed at the forefront of modern healthcare, with >55 000 currently practising in the UK.[2] As professionally regulated and autonomous healthcare professionals, there is huge opportunity for physiotherapists to deliver acupuncture as part of mainstream healthcare for patient benefit.

ACUPUNCTURE IN PHYSIOTHERAPY

Western medical acupuncture (WMA) practice by physiotherapists and other healthcare professionals in the UK and internationally has substantially increased in the last decade. The Acupuncture Association of Chartered Physiotherapists (AACP) was established in 1984 and membership is currently >6500,[3] double that of any other UK acupuncture organisation. Physiotherapists also contribute to the membership of the British Medical Acupuncture Society. Collectively, physiotherapists are the largest professional group of acupuncture providers in the UK and are arguably leading the way in bringing acupuncture into mainstream healthcare.

Physiotherapists have typically completed 3–4-year professional degrees, including extensive training in anatomy, physiology, pathology, and diagnostics. This provides an excellent foundation for learning acupuncture at an advanced level. Physiotherapy uses a holistic approach to patient care, which complements theories underpinning acupuncture. Most UK physiotherapists choose to study/practise WMA. Some complete masters degrees in acupuncture and a small proportion choose to study dry needling (DN) only.

As one example, AACP education/training of physiotherapists in WMA is provided at an advanced (masters degree) level. Courses are mapped against an educational framework of 300 h (in line with WHO recommendations) and include extensive assessment. AACP training includes evidence-based WMA (including a component of DN or trigger point acupuncture) blended with some Traditional Chinese Medicine (TCM) theories and ideologies, providing a comprehensive education and a high standard of training.[4] The rationale behind teaching/practice of WMA is in part due to the statutory requirement for regulated health professionals to use evidence-based practice. Furthermore, the rigorous evidence base from Europe is predominantly based on WMA and not TCM diagnostic theories.

SPECIALISM

Autonomous practice within the UK allows physiotherapists to develop their scope of practice into areas in which they are trained and competent, allowing specialism. Some choose to study DN for use in a limited form within their practice, but are equally aware of their limitations and safety. These practitioners, like all physiotherapists, are regulated by the Health and Care Professionals Council and are required to remain within scope of practice in their delivery of all techniques. Using invasive techniques such as

'needling' requires competence, formal training and safety certification. Short CPD (continuing professional development) courses with no formal assessment component would be questionable for any UK practitioner; however, the principle of professional autonomy means that it is the responsibility of the individual to decide whether their education in DN constitutes sufficient training to achieve competence and extend their scope of practice. The same principle applies when attending CPD courses to maintain competence in a current area of clinical practice (http://www.csp.org.uk/professional-union/professionalism/scope-of-practice/introduction).

Internationally, DN has evolved to provide a solution in countries where traditional acupuncture (TA) is not permitted for scientific reasons or where there is restriction on acupuncture provision; for example, in Italy, only medical doctors are legally permitted to deliver acupuncture.[5] Society and healthcare will always adapt, often for financially driven reasons. As professionals we either adapt, or lose out to others who are willing to do so. Historically, physiotherapists have seen other professions learning/embracing their skills (eg, professional masseurs, sports and exercise therapists) and this is true across many professions. It is important to embrace change and professional collaboration for the benefit of patients.

The National Institute for Health and Care Excellence (NICE) estimated the cost of implementing acupuncture for low back pain in the UK National Health Service (NHS) to be £24 366 000 (~€33 200 000, ~US$37 600 000)—a seemingly impossible spend for a cash-strapped NHS.[6] However, through utilisation of physiotherapists already in NHS posts, acupuncture is currently being provided across the country at a fraction of the cost. Patients benefit from the combination of physiotherapy treatment with evidence-based WMA, effectively receiving two interventions 'for the price of one'.[7] Respecting professional boundaries is important, but patient care needs to remain the priority.

TRADITIONAL ACUPUNCTURE

A protectionist argument by traditional acupuncturists is the allegation that WMA or DN may not represent acupuncture in its 'true form', but in no other area of medicine would it be acceptable/justifiable to use 2000-year-old theories on patients. Historical aspects help us respect the foundation/roots of TA, but whether they should inform current clinical practice is highly debatable. If acupuncture is to become an accepted treatment modality in modern medicine, those delivering it have a responsibility to use evidence-based medicine and current biomedical/scientific knowledge to inform their practice. Physiotherapists are well placed to lead the way in the delivery of evidence-based WMA.

The word acupuncture simply means "the practice of inserting fine needles into specific parts of the body for therapeutic reason",[8] therefore all forms of needling described in the article by Zhou *et al*[1] are technically acupuncture. There is negligible scientific evidence to suggest one method of acupuncture delivery is more effective than another, and research should focus on demonstrating efficacy/effectiveness, not which style to use. Regarding TA (ie, TCM or Japanese, Korean or Five Element acupuncture) there are many schools claiming their traditional theory is most effective, but no evidence to substantiate such claims. UK colleges providing TA training use different acupuncture styles without agreement on which is most effective, which is mirrored internationally. Research has shown it is needling per se that stimulates physiological responses within the body, not the philosophy behind it. Style of acupuncture and practitioner experience have been shown to have no influence on outcome in chronic pain trials.[9]

THE EVIDENCE

Placing an acupuncture needle into the body, regardless of the underlying principle, stimulates the central and peripheral nervous systems, eliciting release of serotonin, melatonin, and endorphins—the body's natural pain-relieving chemicals.[10] Acupuncture also influences connective tissue[11] and induces analgesia by deactivation of the limbic system (demonstrated by functional MRI studies) and releasing endogenous opioids.[12] More recently, electroacupuncture has been shown to modulate systemic inflammation by vagal activation.[13] Such physiological responses are likely to occur regardless of therapist, training or diagnostic principle. Research has also shown that acupuncture is synergistic with conventional therapies,[14] which is highly relevant for physiotherapists as they already combine various interventions. If integration of treatments reduces cost and enhances effects for patients, this should be embraced.

THE FUTURE

Rigorous, evidence-based training is imperative to ensure safe delivery of acupuncture, and all providers should be regulated and follow strict codes of conduct to ensure patient safety. Acupuncture in the hands of chartered physiotherapists and other regulated healthcare practitioners is very safe.[15] Collaboration across professional groups will help normalise acupuncture to make it more acceptable within society, rather than simply complementary/alternative. UK patients often report receiving a limited number of acupuncture sessions from their NHS physiotherapist before seeking further treatment by an independent physiotherapist or traditional acupuncturist. Collaboration aids patient care by allowing referral between practitioners, which is important in the current climate of commissioning so that patients receive the best possible care. Patient choice is also an important and topical consideration. If we are practising healthcare for the benefit of

patients, our priority should be to ensure safe and appropriate treatment in an inclusive healthcare system, not to debate how their treatment is delivered and by whom.

CONCLUSION

In response to the ongoing debate outlined by Zhou *et al*,[1] I would question why traditional acupuncturists are limiting themselves to ancient philosophies, when these principles were developed at a time when there was no possibility to prove or disprove their theory. With advances in modern medicine and technology, we can better demonstrate the effects of acupuncture and are learning more and more about how our amazing bodies work. As caring healthcare professionals we have a responsibility to update our practices constantly for the safety and benefit of our patients. Theories and ideologies are just principles to be explored until fact is demonstrated. Traditional treatments may be effective, but not necessarily for the reasons that underlie their principles. The past is for us to learn from, to lead the way into a new future, but not to restrict our present.

Twitter Follow Vivienne Dascanio at @VCDascanio

Competing interests VCD is a doctoral student, director and past chairman of the Acupuncture Association of Chartered Physiotherapists (AACP). The opinions expressed are those of VCD and not those of the University of York or the AACP.

Disclaimer The opinions expressed are those of VCD and not those of the University of York or the AACP.

Provenance and peer review Commissioned; internally peer reviewed.

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Acupuncture in physiotherapy: a contemporary UK perspective

Vivienne C Dascanio

Acupunct Med 2015 33: 442-444 originally published online November 6, 2015
doi: 10.1136/acupmed-2015-010977

Notes

Acupuncture in Physiotherapy, Volume 27, Number 2, Autumn 2015, 19–36

TRIAL PROTOCOL

A pragmatic pilot factorial randomized controlled trial of acupuncture versus manual therapy for low back pain nested within an observational cohort study

V. C. Dascanio
Department of Health Sciences, University of York, York, UK

Abstract

The objective of this research was to investigate conducting a cohort study with a nested factorial randomized controlled trial (RCT) of acupuncture and manual therapy for the treatment of patients with low back pain (LBP). The study design took the form of a pragmatic pilot factorial RCT embedded within an observational cohort study. The participants in the cohort study were recruited via a general practice database, and consent documentation and baseline questionnaires were completed. On completion of their questionnaires at 3 months, eligible participants (i.e. those with a Roland–Morris Disability Questionnaire score of >4) were randomized to one of the four trial arms. Those assigned to the three treatment groups received their allocated intervention (i.e. acupuncture, manual therapy, or combined acupuncture and manual therapy) weekly for 10 weeks. Those randomized to usual care were not advised of their allocation, and understood that they were continuing in the cohort. Follow-up occurred at 6 months. Now that this trial has been completed, the protocol is being published for educational purposes, and to disseminate the information more widely. Some sections of the protocol have been updated to reflect current research. No attrition occurred after randomization, which demonstrates that this is an excellent method of recruiting participants to an RCT. This design was useful for evaluating multifaceted treatments for LBP, which is a complex condition that can involve episodes of remission and relapse. The study design allowed for ongoing monitoring, and also the recruitment of participants later in the cohort who had initially been ineligible for the trial. Combining and comparing complex interventions in trials is effective. The amalgamation of treatment interventions could result in more cost-effective provision in clinical practice. Regression discontinuity statistical analysis can be used with this design. It is recommended this approach is adopted in larger treatment trials for musculoskeletal conditions.

Keywords: acupuncture, low back pain, manual therapy, physiotherapy, randomized controlled trial.

Introduction

Background

Low back pain (LBP) is a major health and epidemiological problem that imposes a significant economic and social burden on societies (Menezes Costa *et al.* 2009). It is estimated to have a lifetime prevalence of 60–80% in Western industrialized countries (Maniadakis & Gray 2000). The then National Institute for Health and Clinical Excellence (NICE, now the National Institute for Health and Care Excellence) reported that nearly everyone in the UK

Correspondence: Vivienne C. Dascanio, Department of Health Sciences, University of York, York YO10 5DD, UK (e-mail: vcf500@york.ac.uk).

will be affected by LBP at some point in his or her lifetime (NICE 2009).

Current economic data are limited, but the cost of LBP to the UK National Health Service (NHS) alone was estimated at £1.1 billion, with 80% of this total attributed to chronic conditions (Critchley *et al.* 2007). This represents an exponential rise from the estimated cost of £1632 million in 2000 (Maniadakis & Gray 2000). Low back pain has been reported to be the second most common reason for members of the working population consulting a general practitioner (GP) (McCormick *et al.* 1995). However, it has been estimated that only around 20% of LBP sufferers consult with their GP (Papageorgiou & Rigby 1991), which suggests that the problem is vastly underreported, and that its impact could actually be far greater than it is currently understood to be.

Fifteen years ago, the cost of LBP to the UK economy was estimated to be £12.3 million and was predicted to rise (Maniadakis & Gray 2000). There is an apparent lack of current economic costing data regarding the burden of LBP on society. More recently, a report by the Chartered Society of Physiotherapy (CSP 2007a, b) provided some guidance regarding the economic impact of this condition, stating that 5 million working days are lost each year because of LBP, and up to half a million people receive a long-term state incapacity benefit as a result of it.

Although it is considered to be a benign condition, many individuals with LBP experience great personal suffering, and the problem is magnified by the number of those individuals whose problem becomes chronic in nature. Milczarek (2009) reported that approximately 62% of sufferers still live with their LBP after 12 months, and 33% have a recurrence that causes their absence from work. Although many treatments are available for the treatment of LBP, a satisfactory resolution to the problem has yet to be discovered for this very costly problem (Milczarek 2009). Both research into and treatment of this condition require a more comprehensive approach in order to find a more satisfactory and cost-effective solution.

Among other interventions, the most recent UK guidelines for the treatment of LBP (NICE 2009) recommend:

- a course of eight group exercise sessions over a period of up to 12 weeks;
- a course of nine manual therapy sessions over a period of up to 12 weeks; and
- a course of 10 acupuncture sessions over a period of up to 12 weeks.

Further explanations of manual therapy and acupuncture are provided below in the section entitled "What are the planned trial interventions?" (pp. 26–27).

Furthermore, the NICE guidelines also suggest that, if one intervention does not resolve the LBP, the individual should be offered an alternative from the list of recommendations. Therefore, a patient may receive two or more of these interventions independently and at great cost. No guidance is provided as to which form of treatment to offer first or second, and no consideration is given to combining the delivery of the interventions.

The additional cost to the nation of the NHS introducing acupuncture for the treatment of LBP was calculated to be £24 366 000 (NICE 2009). This is the amount required to cover the implementation of new services and staffing across the publically funded healthcare system. Currently, the NICE (2009) guidelines do not recognize the potential benefit of either combining the delivery of manual therapy with acupuncture, or the provision of acupuncture by physiotherapists who are already established and paid for in post within the NHS. Considering these options could potentially lead to huge savings, and allow the delivery of acupuncture at a minimal increase in costs.

There may also be a currently unknown potential mutual additive treatment effect as a result of combining delivery, and if so, this would be in addition to the cost reduction brought about by patients receiving the interventions at the same time. Approximately 6550 physiotherapists working in the NHS and the private sector are registered with the Acupuncture Association of Chartered Physiotherapists (AACP), and are qualified to practise acupuncture alongside other

interventions, such as manual therapy and exercise. A combined approach to the treatment of LBP involving acupuncture and manual therapy could be effortlessly adopted by these physiotherapists. Only the provision of acupuncture needles and a short amount of additional time in a treatment session would be required in order to allow them to provide the dual treatments. This could prove to be a more cost-effective method of delivery than separate treatment sessions.

Literature review

A scoping review of the Cochrane Library, Embase and MEDLINE did not identify any randomized controlled trials (RCTs) investigating the additive or combined effect of providing manual therapy and acupuncture interventions simultaneously for the treatment of LBP.

Leibing *et al.* (2002) used physiotherapy as a control intervention when comparing acupuncture with sham acupuncture. They concluded that acupuncture combined with physiotherapy was significantly superior to physiotherapy alone; however, they did not have a comparative acupuncture-only arm. They also found no significant difference between the acupuncture and the sham acupuncture groups, and concluded that the effects of acupuncture might be non-specific or a placebo effect (Leibing *et al.* 2002).

It has proved difficult for research designs to control for the placebo effect in RCTs of complex interventions (e.g. acupuncture or manual therapy). However, comparing complex interventions to each other using multiple arms or a factorial type design may provide a solution to this problem. A recent evidence report by Furlan *et al.* (2010) recommended making head-to-head comparisons of treatment studies and RCTs comparing new therapies with widely used active treatments, which would allow more comprehensive conclusions to be made about appropriate therapies for LBP.

In a cost-effectiveness analysis of acupuncture treatment for LBP, Ratcliffe *et al.* (2006) concluded that it provided a modest health benefit, and argued that delivering the service would incur only minor additional costs for the NHS (£4241 per quality-adjusted life year gained). However, they assessed this cost as an adjunct to usual GP care, and did not consider the possibility of combining acupuncture with currently delivered NHS active treatments, which could potentially lead to further cost savings.

Murphy & Longbottom (2007) reported that combining physiotherapy and acupuncture interventions was beneficial for LBP; however, since this was a case study, there was no control group, and the conclusions were based on the clinical reasoning skills of the clinician alone. Therefore, the results have very low statistical power, and the study has low internal and external validity. However, it does clearly indicate that there is a need for further investigation in the form of an RCT of whether a combined acupuncture and physiotherapy intervention does, in fact, have any additive or long-term benefits.

The results of previous research into the use of acupuncture in the treatment of LBP have been contradictory, and many trials have been of poor methodological quality. However, a number of RCTs that have been assessed as employing a high-quality methodology (according to the Cochrane Collaboration Back Review Group quality assessment for RCTs) have reported that acupuncture can significantly reduce pain intensity in patients with LBP (Leibing *et al.* 2002; Molsberger *et al.* 2002; Brinkhaus *et al.* 2006; Thomas *et al.* 2006).

Additionally, a Cochrane review by Furlan *et al.* (2005) concluded that acupuncture was more effective for pain relief than no treatment or sham acupuncture for the treatment of chronic LBP at 3-month follow-up. While acupuncture was not found to be more effective than conventional therapies, adding it to these other forms of treatment was shown to reduce pain and improve function more effectively than conventional therapies alone. Further high-quality research into acupuncture and comparative therapies, and a cost-effectiveness analysis of acupuncture interventions were recommended by these authors.

Many trials have been conducted since the development of the present protocol, and as a result of improvements in trial design, recent findings have been more favourable. Three systematic reviews were published in 2013, and all recommended acupuncture for LBP (Kim *et al.* 2013; Lee *et al.* 2013; Xu *et al.* 2013). Addition-

ally, in 2012, a cost–utility and cost–benefit analysis of acupuncture demonstrated that it was cost-effective in the treatment of LBP, headache and osteoarthritis (Kim *et al.* 2012).

Spinal manipulation and mobilization are forms of manual therapy, and it has been suggested that these should be employed in addition to pain relief in order to increase active movement and function in people with LBP. In a comparison of treatments for LBP, Giles & Muller (2003) concluded that spinal manipulation was superior to acupuncture or medication in terms of reducing pain, and improving active movement and activity levels. The UK BEAM trial (UK BEAM Trial Team 2004) reported that manipulation was superior to exercise and standard care for LBP.

In a systematic review of mobilization and manipulation (i.e. manual therapy) for LBP, Bronfort *et al.* (2004) concluded that these forms of treatment could be recommended with confidence. However, they also noted that there had been few high-quality RCTs, and that those that had been conducted were all limited by short-term follow-up periods. The authors highlighted the need for more comprehensive RCTs with longer-term follow-ups and cost-effectiveness analysis of the care (Bronfort *et al.* 2004). A more recent systematic review by Kuczynski *et al.* (2012) fulfilled these requirements, and these authors recommended manipulation for LBP. They reported that it improved clinical outcomes, and also described statistically significant findings with regard to reductions in medication usage, healthcare utilization and absence from work for the manipulation groups (Kuczynski *et al.* 2012).

Nesting a randomized controlled trial within a cohort study

Combining manual therapy and acupuncture interventions in order to assess whether there are any additive effects as a result of performing the two treatments in tandem could provide a more comprehensive solution to the treatment of LBP. It is possible that this may enhance each of the individual treatment effects, and thus, make these modalities more effective in combination than in isolation.

The coupling of the two interventions could also prove to be cost-effective if these can be performed within the same treatment session, regardless of whether this is delivered within the NHS or private sector, and also if these are deemed to enhance each other's effect. Furthermore, this could potentially reduce recovery time and absence from work for those with LBP, thereby reducing the burden of LBP upon society.

There is a real need for an RCT to investigate the combined effects of manual therapy and acupuncture in the treatment of LBP. It is important that the study is of high methodological quality, provides long-term follow-up investigating lasting benefits, and also reviews the effectiveness and cost-effectiveness of the interventions.

Despite its many advantages, the nested RCT is used infrequently, and prior to a study by the present author and her collaborators (Dascanio *et al.* 2014), it had never been employed to investigate LBP. The present trial protocol is reported in order to provide information on designing trials, and also to recommend the use of nested RCTs in future research. Improving the quality of trial design for studies of complex interventions and compound conditions involving physiotherapy, acupuncture and other treatment modalities is essential to the profession. Poor design and the attrition of participants from trials could be detrimentally affecting the trend of results in many studies, leading to false impressions of treatment effects. Potentially, this could result in incorrect conclusions being drawn, and in the current culture of evidence-based medicine informing commissioning and funding, services may be being commissioned or withdrawn on the basis of inaccurate information. The exemplary design of RCTs has never been more critical to the future careers of healthcare professionals.

Attrition in trials is generally poorly reported, but an average of approximately 20% with a range from 7% to 67% has been purported (Dumville *et al.* 2006). If not evenly distributed, a level of attrition of this magnitude can lead to post-randomization selection bias, may alter the direction of the treatment effect and could

lead to misinterpretation of the trial results (Torgerson & Torgerson 2008).

Attrition has been shown to be greatest within the first follow-up period of a trial. In a study of McKenzie physiotherapy for LBP and neck pain, 75% (18%) of the total attrition (24%) occurred within the first follow-up period (Klaber Moffett *et al.* 2006). An attrition rate of 25% was reported in a trial comparing manipulation and exercise for LBP (UK BEAM Trial Team 2004), and a trial of cognitive behavioural therapy for LBP reported 22% attrition (Lamb *et al.* 2010). The use of a cohort study to recruit participants for a nested RCT could eliminate attrition during the first period of a trial. This reduction in attrition has the potential to improve the quality of the trial and accuracy in interpreting the results.

Aims and objectives of the proposed research

The primary objective of this research was to conduct a pilot study to explore undertaking a cohort-design study with a nested factorial RCT to investigate manual therapy and acupuncture alone and in combination versus usual care.

The secondary objectives were to:

(1) investigate recruitment rates in order to plan a full-scale trial;
(2) determine the most effective outcome measure for a full-scale trial;
(3) identify any compliance issues and strategies for reducing these in a full-scale trial; and
(4) assess patient acceptance and clinician delivery of combined therapies for the treatment of LBP.

Participants and methods

Study design

A cohort-design study with a nested pragmatic factorial pilot trial design is proposed. Participants will be recruited to the trial from the cohort. Because of the design methodology, only compliant participants in the cohort are recruited to the trial and then randomized, thus reducing attrition. As previously discussed, attrition is commonplace in the early phases of trials. However, with this design, the RCT is nested within the cohort, and participants will have completed at least one follow-up questionnaire within the cohort before being invited to join the RCT. Therefore, any non-compliant individuals are likely to drop out prior to this stage and the subsequent randomization.

The trial will follow a factorial design and will have four groups:

(1) treatment O – usual care;
(2) treatment A – acupuncture;
(3) treatment B – manual therapy; and
(4) treatment AB – acupuncture and manual therapy.

In a full-scale trial, this factorial design will allow the present author and her colleagues to analyse the effectiveness of the two interventions at the same time, while maintaining a comparative control arm. It will also increase the cost-effectiveness and efficiency of the study (McAlister 2003). In addition, it will allow the investigation of the effects of the two treatments when these are given in isolation and compared head-to-head, and whether their effectiveness is changed when they are provided as a combined treatment. Since this is a pilot study, it will aim to investigate the use and functioning of the factorial methodology. It will also review the practicality of combining two therapeutic approaches within a single treatment session. The effects of treatment will be monitored and appropriate clinical outcomes determined; this will be in order to inform an appropriately powered trial that will aim to investigate the effectiveness of the treatments individually and in combination. In a full-scale trial, the present author and her colleagues would want to explore the combined treatment effect of acupuncture and manual therapy using a factorial approach. This approach means that they are assuming the additivity of the treatments and are able to test for interactions, although the power of this pilot trial is low.

What are the proposed practical arrangements for allocating participants to the study groups?

Recruitment. The recruitment of participants will follow a novel cohort design. The use of this strategy as a recruitment method for nested trials is a relatively new approach, but Grant *et al.*

(2006) suggested that the cohort design can be employed effectively for chronic conditions. A GP database recruitment method will be used to identify potential participants. Those patients aged between 18 and 65 years who have consulted their GP for LBP in the preceding 18 months will be identified using database searches. Patients will be excluded if they: have symptoms of serious spinal or neurological pathology; have a history of spinal surgery; are pregnant; or have given birth within the past 12 months.

All potentially eligible patients will be sent an information pack, which will contain a signed GP invitation letter, a participant information sheet, baseline questionnaires and two consent forms. The letters will invite them to join the study (if they are currently still experiencing their LBP) by returning the completed forms to the University of York, York, UK.

Patients who return a completed consent form and the baseline questionnaires will be assessed for eligibility. The participants will have to have a score of four or more on the Roland–Morris Disability Questionnaire (RMDQ 2015), and be capable of conversing with a physiotherapist in English. Since this is a pilot study in a non-ethnically diverse area, only English-language versions of the questionnaires will be available. There are the financial constraints of a doctoral project attached to this study, and therefore, no provision can be made for the translators or additional physiotherapy time that would be required in order to include non-English-speaking participants. For this reason, one of the inclusion criteria for participants is an adequate grasp of the English language. Any future trial will explore the possibility of ensuring that a more diverse population are sampled. Patients who are ineligible or who are taking part in other research will also be excluded. An explanation letter will be sent to patients who do not meet the inclusion and exclusion criteria.

The identified cohort will be monitored over an 18-month period with quarterly questionnaires. Participants will be asked at baseline which treatments they would consider receiving for their LBP. It will be made clear to them that they may be invited to receive one of the listed treatments for their LBP during the course of the 18-month study, but because of limited funding, not everyone in the cohort will be asked to participate in the pilot treatment trial.

Assignment. Patients who return their consent form and baseline questionnaires to the trial coordinator, score four or more on the RMDQ, and do not fulfil any of the exclusion criteria will be invited to take part the cohort study.

Participants in the cohort will be randomized to one of four groups after they have: consented to being part of the cohort study and treatment trial; consented to receiving the trial treatments; completed the baseline questionnaires; and completed the 3-month questionnaire. The size of the control group will depend on the numbers recruited to the cohort, but it will be at least as large as the intervention groups. However, it is anticipated that the group receiving usual care may be larger than the treatment groups. This will enable the present author and her colleagues to use an unequal allocation ratio of at least 2:1, favouring the control group in comparison to the intervention groups if required.

Prior to randomization, participants will be asked which treatments they would consider for their LBP. If anyone expresses an unwillingness to receive one of the specific treatments (i.e. manual therapy or acupuncture), he or she will still be included in the pilot trial, but only analysed against usual care (i.e. such individuals will not be included in the comparison between the randomized intervention groups). Participants who are unwilling to receive all interventions will not be selected for randomization to the pilot trial, but they will remain in the observational cohort study.

Allocation method. An independent data manager will undertake the random allocation. Once a group of patients have been recruited to the study, they will be randomized to either the intervention or control groups (Fig. 1). Both the participants and their GPs will be advised if they are assigned to one of the treatment groups. If they are assigned to the control group, i.e. "usual care", then the participants will not be advised of this, and they will be unaware of their allocation

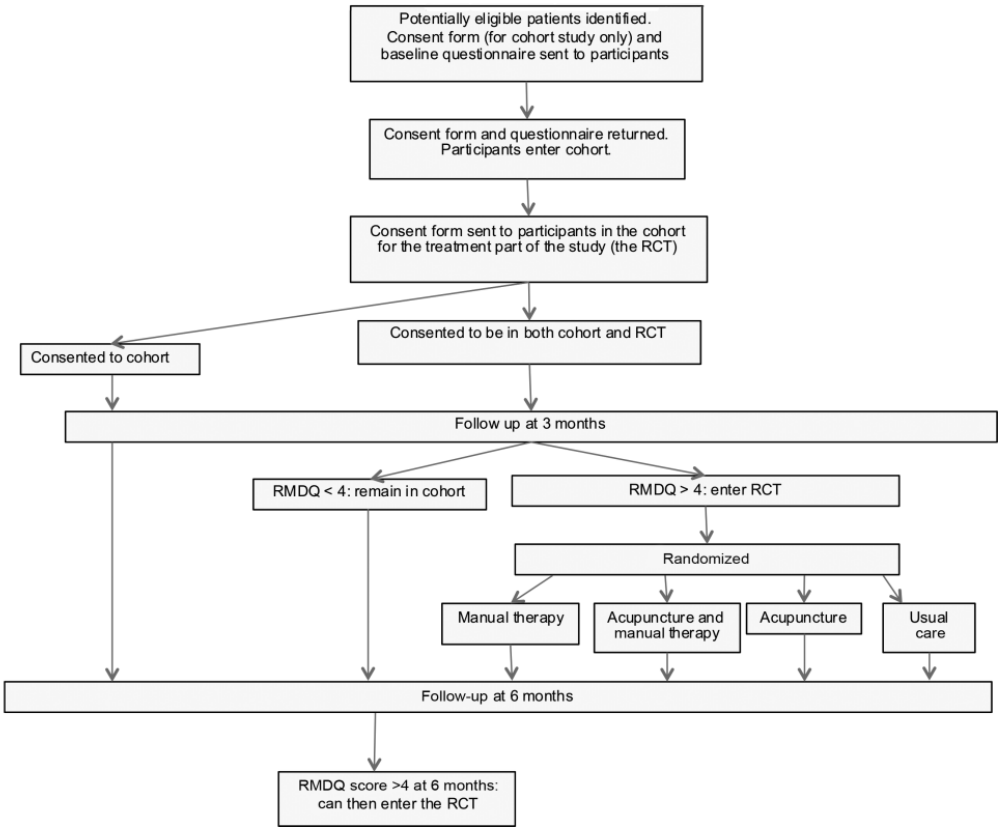

Figure 1. Study design: (RCT) randomized controlled trial; and (RMDQ) Roland–Morris Disability Questionnaire.

and continue only with the knowledge that they are in the cohort study.

What are the planned inclusion and exclusion criteria for all interventions?

Inclusion criteria:

- individuals aged between 18 and 65 years of age;
- individuals registered with a general practice that is participating in the trial;
- individuals who have consulted their GP with mechanical or simple LBP in the preceding 18 months;
- individuals who have been suffering from LBP for between 6 weeks and 18 months;
- individuals with referred pain in the leg will be included in the study (if there was no indication of any serious neurological conditions when they were assessed by their GP);
- individuals with pain that is present on assessment and is persistent in nature (i.e. pain occurring at least once a day for 80% of the days in the history of their recent painful episode);
- individuals who agree to avoid physical treatments other than the study interventions for the 10–12-week period of the pilot study (active treatment participants only); and
- individuals with a score of four or more on the RMDQ at baseline (UK BEAM Trial Team 2004).

Exclusion criteria:

- individuals with clinical indications of serious spinal or neurological pathology, as assessed by their GP;

- individuals with a history of spinal surgery (since this may alter the clinical outcome);
- pregnant women or those who have given birth in the past 12 weeks (since this may alter the clinical outcome);
- individuals who have received manual therapy or acupuncture in the preceding 3 months (since this may alter the clinical outcome);
- individuals with blood disorders who are receiving anticoagulants or antiplatelets (since this is a relative contraindication to acupuncture);
- individuals who are immunocompromised (since this is a relative contraindication to acupuncture);
- individuals with a metal allergy (since this is a relative contraindication to acupuncture);
- individuals who are unable to provide consent;
- individuals who are unable to converse in English (because of the funding limitations of the study);
- individuals with a history of psychosis or alcohol abuse (because of the difficulty in assessing the outcome);
- individuals who have a needle phobia; and
- individuals with valvular heart disease or demand pacemakers (since this is an absolute contraindication to acupuncture).

What are the proposed methods for preventing other sources of bias?

An intention-to-treat (ITT) principle will be used because this is the most robust analytic technique for preventing the introduction of bias (Torgerson & Torgerson 2008). Randomization will eliminate selection bias; however, there are other forms of bias that will need to be avoided.

As a result of the cohort recruitment method, resentful demoralization and patient preference should be limited. This is because the participants entering a cohort will be aware that they may be approached at a future date to take part in a trial, but also that only a small proportion of them may be offered treatment. Informative explanations will be provided to the participants (Torgerson & Russell 1996).

Attrition is one of the major threats to the internal validity of any study. The design of this trial specifically reduces that threat (Relton *et al.* 2010). Using a randomized cohort design will mean that a "run-in period" of 3 months will occur, allowing the present author and her colleagues to collect their baseline data and their first set of outcome data. Only participants who return their 3-month questionnaires will be eligible for randomization. Because the majority of attrition occurs at the first period of follow-up in an RCT, it is expected that subsequent attrition, after randomization, will be minimal. The present author and her colleagues will also attempt to reduce attrition through the provision of comprehensive explanations of the study, and regular contact with the participants in the form of questionnaires throughout the study (Torgerson & Torgerson 2008).

Another potential source of bias may be dilution effects (i.e. some participants randomized to intervention fail to accept the treatment). The present author and her colleagues anticipate that this will be low because of the nature of their design, which offers an element of choice in the early phase of recruitment.

Since this is a pragmatic study, it is not possible to blind the participant or the clinician. The final outcome assessment is provided by the patient, and therefore, the outcome measurement will also not be blinded.

What are the planned trial interventions?

A collaborative group of experienced musculoskeletal physiotherapists will be recruited and inducted into the trial. All physiotherapists will have experience of manual therapy techniques, and some will also have acupuncture training. They will meet prior to the commencement of the trial in order to discuss guidelines for the expected best practice standards for manual therapy in the treatment of LBP, acupuncture for LBP and combining the therapies for LBP. This meeting will include discussion of any other physiotherapy interventions so that this may be standardized to all participants. However, this cannot include any acupuncture or manual therapy techniques for the manual-therapy-only or acupuncture-only groups, respectively. A protocol of exercises will also be agreed to enable

the provision of exercise information sheets for participants in the trial.

Acupuncture. Acupuncture has its origins in traditional Chinese medicine and is one of the oldest forms of therapy available. It involves the insertion of fine needles into the body, and aims to take a holistic, i.e. whole-body, approach to treatment. In Chinese philosophy, illness is considered to be an imbalance of energy sources in the body, and acupuncture strives to recreate this balance in order to achieve harmony within the body (Marcus 2004). In Western medicine, acupuncture is considered to stimulate blood flow, nerve activity and specific areas of the brain that release pain-relieving chemicals (Bradnam 2007).

Manual therapy. Manual therapy is a form of treatment that involves using the hands to deliver mobilization, massage, or manipulation of the joints or soft tissues in the body. It can be undertaken by specially trained professionals like physiotherapists, osteopaths, doctors or chiropractors (NICE 2009).

Combined acupuncture and manual therapy. In the preliminary discussions, an agreed format for providing manual therapy and acupuncture within the same session will be decided. For the combined manual therapy and acupuncture intervention group, it is anticipated that the participants will receive a 50% longer treatment session in order to allow for both interventions to be completed.

What are the planned allocated treatment groups?

Usual GP care intervention group (treatment O). The usual care group will consist of all participants entering the cohort who are not randomized to receive active treatment. They will receive usual GP care, which will involve attention from their GP or other health professionals as appropriate and as would be routine, i.e. it will be the same as if they were not involved in the cohort. It will also involve the provision of the "back book", which is a self-help book for individuals with LBP that is frequently distributed by healthcare professionals. These participants will not be provided with manual therapy or acupuncture through the course of the trial. Data will be collected for all patients on what constitutes "usual care", including receiving any treatment (i.e. acupuncture and manual therapy) independently of the trial, during the cohort period.

Acupuncture intervention group (treatment A). Acupuncture treatment will take place at a local physiotherapy clinic, and will only be delivered by the appropriately AACP-qualified physiotherapists who have been inducted into the trial.

Participants allocated to this intervention will follow a programme of 10 × 30-min acupuncture treatment sessions, which will occur weekly wherever possible.

Acupuncture will be provided as the physiotherapists see appropriate. They will follow the agreed trial guidance and their professional governance, as required by their professional organization. However, the physiotherapists will not be permitted to provide manual therapy to this intervention group.

All usual standards of care, protocols and practices will continue to be observed.

Participants will also be provided with usual GP care, including the provision of the "back book", as would be expected were they not involved in a trial.

Manual therapy intervention group (treatment B). Manual therapy will take place at a local physiotherapy clinic, and will only be delivered by the physiotherapists who have been inducted into the trial.

Participants allocated to this intervention will follow a programme of 10 × 30-min manual therapy treatment sessions, which will occur weekly wherever possible.

The physiotherapists will provide the manual therapy intervention as they see appropriate for their participant. They will follow the guidance of best practice established for the trial and their professional governance, as required by their professional organization. However, the physiotherapists will not be permitted to provide acupuncture to this intervention group.

All usual standards of care, protocols and practices will continue to be observed.

Participants will also be provided with usual GP care, including the provision of the "back book", as would be expected were they not involved in a trial.

Combined acupuncture and manual therapy intervention group (treatment AB). The combined intervention will take place at a local physiotherapy clinic, and will only be delivered by physiotherapists trained in acupuncture and manual therapy who have been inducted into the trial.

Participants allocated to this intervention will follow a programme of 10 × 45-min treatment sessions incorporating both manual therapy and acupuncture. The sessions will occur weekly if possible.

The manual therapy and acupuncture interventions will be delivered in exactly the same ways as for the manual therapy and acupuncture groups, respectively, but within the same treatment session. Treatment will be delivered as the physiotherapists see appropriate. They will follow the trial guidance provided prior to the trial and their professional governance, as required by their professional organization.

All usual standards of care, protocols and practices will continue to be observed.

Participants will also be provided with usual GP care, including the provision of the "back book", as would be expected were they not involved in a trial.

What is the proposed duration of treatment period?

Treatment will aim to be once a week for a 10-week period; however, a 2-week threshold allows treatment to be completed if any delayed or missed treatment sessions occur as a result of sickness or unavailability. This is in line with the NICE (2009) guidelines.

What is the proposed frequency and duration of follow-up?

A baseline assessment will be completed. This will be followed up by a postal questionnaire 3 months later. On completion of these questionnaires, eligible and willing (i.e. consenting) participants will be randomized to one of the four groups. Follow-up will be repeated at 6 months, which will coincide with the completion of therapy for the active treatment intervention groups.

Further follow-ups will occur at 9, 12, 15 and 18 months.

What are the proposed outcome measures?

Primary outcome measures. The primary outcome measures will be to:

(1) investigate recruitment rates and assess any issues with retention in order to inform a full-scale trial; and
(2) determine the main clinical outcome measure, i.e.:
    (a) the RMDQ, a specific LBP measure; or
    (b) the Modified Oswestry Disability Index (MODI), a specific LBP measure.

Both of these clinical outcome measures are frequently used in research, and both have been shown to be valid and reproducible. However, the RMDQ and MODI each have different strengths and limitations (Longo *et al.* 2010). Since this is a pilot study, both will be used in order to investigate which would be a more favourable and informative measure to use in a full-scale study of manual therapy and acupuncture for the treatment of LBP. A comparison of the two questionnaires to assess their reliability with respect to each other as similar measures for LBP will be performed. Additionally, the information gained from the questionnaires will be analysed with regard to usable patient information that could inform a full-scale trial.

Secondary outcome measures. The secondary outcome measures will be:

(1) a visual analogue scale, a pain-specific measure;
(2) the 12-Item Short-Form Health Survey, a quality of life (QoL) questionnaire;
(3) the EuroQol, a generic measure of health for clinical and economic appraisal; and

(4) patient use of a body chart and additional treatment information.

How will the outcome measures be assessed at follow-up?

The outcome measures will be assessed with postal questionnaires. These will be completed at baseline and 3 months later. The main analysis will occur at 6 months, which will also coincide with the end of therapy for the active treatment groups. Further follow-ups will occur every 3 months after this up to 18 months (i.e. at 9, 12, 15 and 18 months). Postal questionnaires will be used to collect outcome data.

What is the proposed sample size?

It is difficult to determine a suitable sample size for a pilot study. However, the present author and her colleagues will aim to recruit at least 16 participants for each intervention group. This will exceed the recommended minimum of 12 (Julious 2005), and give the researchers 80% power to observe a one standard deviation difference between the treatment and control groups.

In order to allow for any attrition, and because this is a pragmatic treatment trial, the present author and her colleagues will attempt to recruit between 16 and 20 participants to each arm of the trial. Therefore, a sample size of 64–80 will be a conservative target within the limitations of the pilot.

What is the proposed recruitment rate?

Initially, although 10 GP surgeries will be identified, only five will be invited by letter to be involved in the study. Interested medical centres will return their expression of interest and practice consent forms to the chief investigator (V.C.). An information pack, containing participant invitation letters, consent forms, a copy of the information sheets and baseline assessment questionnaires, will then be sent out to the participating GP surgeries so that these can be posted to potential participants. If enough individuals are recruited, then no further practices will be contacted. If there is limited or slow recruitment, a further one to five surgeries will be invited by letter to join the trial.

Previous trials have reported good results after using a GP database recruitment method. A study of yoga for LBP had a response rate of 12% (of the 8638 patients invited, 994 responded) (Cox *et al.* 2010), and a trial of acupuncture for irritable bowel syndrome had a response rate of 14% (of the 1651 patients invited, 247 responded) (Reynolds *et al.* 2008).

It is anticipated that the recruitment of participants will take between 10 and 20 weeks.

Are there likely to be any problems with treatment compliance?

A 90% compliance rate is anticipated.

The UK BEAM Trial reported a compliance rate of 92% for the manipulation group (UK BEAM Trial Team 2004). A similar compliance rate of 91% was seen for the acupuncture group in a comparable study (Leibing *et al.* 2002). Because the participants will attend one session a week, and the treatments will occur at the same time in the combined treatment group, a similar compliance rate is anticipated for this study.

What is the likely rate of loss to follow-up?

It is anticipated that attrition will be minimized by the cohort design and active management. Regular contact will be made, and comprehensive explanations will be given to the participants. Systematic follow-up of all participants will occur at 3 months. Further follow-ups are planned at 6, 9, 12, 15 and 18 months. This process will be active, and will include pre-notification letters, contact with GPs and reminders for non-responders. Where possible, data will be collected for all participants; however, if data for an individual is unavailable, it will be coded as missing in the analysis and treated appropriately. In a similar study, Leibing *et al.* (2002) reported that 24% of the participants were lost to follow-up over a 9-month period. Furthermore, in another comparable trial, 20% of the participants in the manipulation group were lost to follow-up over a 12-month period (UK BEAM Trial Team 2004). Therefore, it is

anticipated that the rate of attrition will be around 20%.

Details of planned analyses in the pilot trial

The data analysis and reporting process will follow the Consolidated Standards of Reporting Trials guidelines for RCTs (Moher *et al.* 2001).

Each analysis will follow the ITT principle. All participants will be included and analysed in their original randomized groups, regardless of whether they completed their intended course of treatment (Torgerson & Torgerson 2008):

- An analysis will review the recruitment rates per practice; the rates of consent and attrition will provide information for a full-scale study.
- The main analysis will occur 6 months after the completion of the active treatments. An analysis of mean scores will be performed using a regression analysis, and by adjusting for baseline assessment of the RMDQ and the MODI.
- In addition, the characteristics of these two outcome measures will be compared for reliability. The RMDQ and the MODI will be correlated against the SF-12, and also compared on key indicators, such as the number of days of work lost to sickness, visits to the GP and levels of medication. This information will inform the use of these outcome measures in a full-scale study.
- Regression analysis will be used to compare each of the three treatment groups to the control group. The present author and her colleagues will look for evidence of whether combined treatment is more beneficial than the single treatments. However, there will be relatively low power to demonstrate any difference. Therefore, these results will be treated with caution, and are primarily intended to inform the design of the definitive study.

Are there any planned sub-analyses?

The sub-analyses will include the following:

- A regression analysis will be used to test for interaction. However, the results will have to be interpreted with caution since the study will have a very low power to measure this variable.
- Changes in QoL will be measured by analysing the mean results of the SF-12 over the specified time points. The SF-12 is a valid, reliable and well-accepted QoL questionnaire (Fallowfield 1996). Establishing whether a participant's QoL has improved following a treatment intervention is very important to the study; failure to enhance QoL will render the results meaningless and irrelevant to sufferers of LBP.

What is the proposed frequency of the analyses?

The principal analysis will occur 6 months after the completion of the treatment intervention. Further analyses will occur at 9, 12, 15 and 18 months.

Governance

Prior to the commencement of the study, ethical approval will be sought from the Research Governance Committee of the University of York's Department of Health Sciences. Since this trial will involve NHS patients, the required NHS ethical approval, and NHS Research and Development Forum approval will also be sought.

Monitoring of adverse events and safety

A data and safety monitoring committee will be formed in order to monitor the study and any adverse effects that may occur. Data monitoring will be handled by the trial management committee. The University of York's Standard Operating Procedures (SOPs) will be used to monitor adverse events and safety.

All centres providing acupuncture will be registered and approved by their local health authority. Sharps policies, and health and safety polices will be in place. A needle-stick injury protocol will also be in operation and a formal SOP will be in place.

Although acupuncture and manual therapy are rarely reported to cause adverse effects (MacPherson *et al.* 2001; White *et al.* 2001; White 2006), if any were to occur, the individuals

affected would be assessed and taken to an appropriate location, i.e. an accident and emergency department, a local hospital, or a GP. This course of action would be taken as was judged to be commensurate with the individual reaction at the time. A report would be made to the data and safety monitoring committee in order for recommendations to be made. In the event of minor reactions, such as feeling faint (which is commonly experienced with acupuncture), the University of York SOPs would be followed.

Informed consent

Written informed consent will be required from all participants, and entry into the cohort will not be permitted without it. Participation in the study is entirely voluntary. If any participants would like to withdraw from the cohort or their treatment intervention, then they can do so at any time. However, they will be asked if they are still happy to complete the appropriate questionnaires in order to allow analysis using the ITT principle.

Informing potential participants of the possible benefits and known risks

A clear and easily understandable participant information sheet will be provided to all potential participants prior to their consent to participate in the study. This will clearly state that not entering the study, withdrawal of consent or withdrawal from the study at any time will in no way affect their present or future quality of care, or their legal rights. The information sheet will aim to provide an unbiased explanation of the nature of the cohort study, and will describe the treatment interventions that may be offered and any known risks.

Data protection and confidentiality

All participant documentation will be kept in line with the Data Protection Act 1998, and paper copies will be retained for 7 years after the completion of the study. All electronic data will be password protected on secure computers.

All personal information will remain confidential and be anonymized.

Dissemination of study findings

The dissemination of this pilot study will be extensive so as to help raise awareness of the potential for research. Although a single piece of research may not, by itself, change practice, it can initiate discussion, and therefore, interest in the area. Potentially, this could attract future funding for a full-scale trial that might aim to provide clarity with regard to the NICE guidelines for LBP (NICE 2009).

It is intended that the findings of the study should be presented in a high-impact, peer-reviewed publication. This will make these available to as many health professionals and policymakers as possible.

The results of the study will also be submitted, as appropriate, for presentation as either an abstract or a poster to UK and international conferences relevant to the fields of LBP, acupuncture and manual therapy.

All active contributors will be credited within the main report.

Will the study address any economic issues?

Information about resource use and expense will be collected throughout the pilot study. This will be done in order to compare the cost of implementing the interventions, i.e. manual therapy and acupuncture, in combination or separately. Any treatment benefits will also be compared. As previously discussed, the NICE guidelines calculated that the additional cost to the nation of implementing acupuncture for the treatment of LBP would be £24 366 000 (NICE 2009). However, this estimation was based on the introduction of new staff and services, rather than utilizing services already in place. In addition to the potential additive benefits of combining the two treatments, this study will also aim to inform a full-scale trial in order to allow the investigation of any potential financial benefits of incorporating acupuncture into an already-existing physiotherapy session within the NHS.

Discussion

For the purposes of the present publication, some areas of this protocol have been updated to

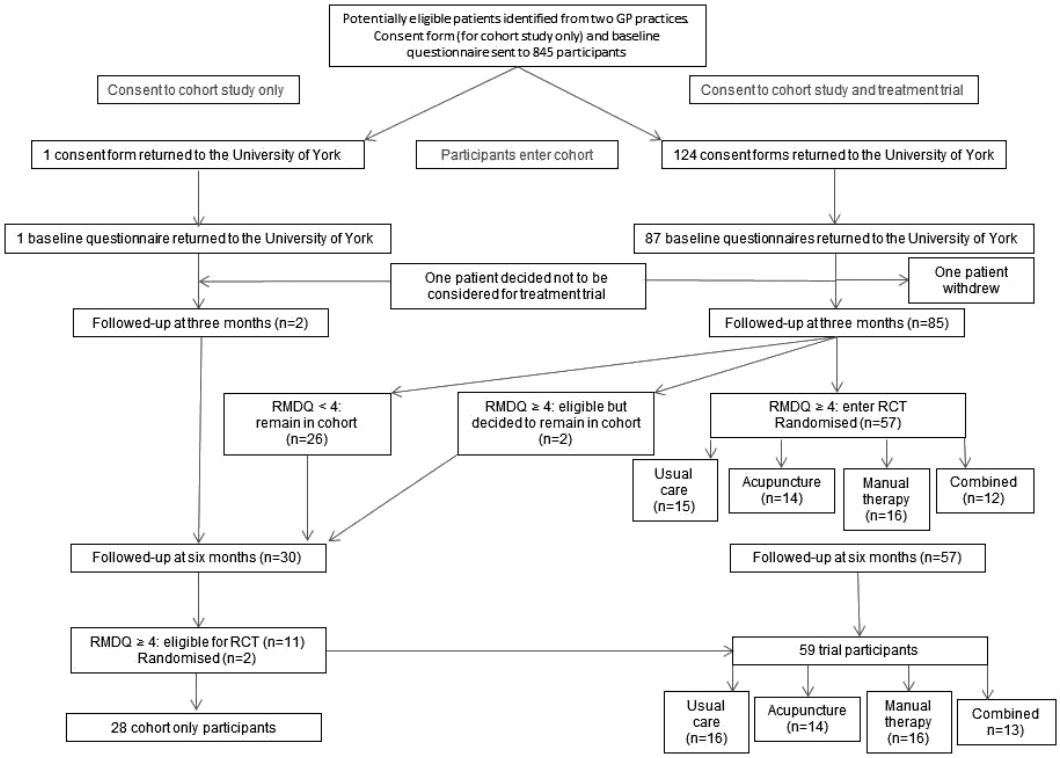

Figure 2. Consolidated Standards of Reporting Trials flow diagram: (GP) general practitioner; (RMDQ) Roland–Morris Disability Questionnaire; and (RCT) randomized controlled trial. [Reprinted with permission from Dascanio *et al.* (2014, Fig. 1, p. 943), © 2014 Elsevier Inc. All rights reserved.]

reflect current research that is now available in the field.

As previously discussed, zero attrition occurred within this trial after randomization. This will eliminate the possibility of post-randomization selection bias, and also provide great confidence in the interpretation of the results. The flow diagram presented in Fig. 2 illustrates the movement of the participants through the study, and highlights those individuals who were lost prior to randomization. If randomization had occurred earlier within this study, significant attrition would potentially have ensued, influencing the results. Of the 125 participants who consented to take part in the study, only 87 (70%) returned their 3-month questionnaires. Thus, a drop-out rate of 30% occurred prior to randomization. Attrition occurring prior to randomization is an important distinction, and a potential consideration for future trials.

At 3 months, eligible participants were then randomized in the RCT or continued in the cohort study, and no further attrition occurred after this time point. This demonstrated that the design was an excellent methodology for recruiting participants to an RCT, i.e. one that ensured that only compliant individuals were involved.

Zero attrition should be a gold standard for trials. It would mean greater confidence in the outcomes of research, and allow more accurate interpretation of the direction of the results. Additionally, no or minimal attrition would provide potential cost savings since fewer participants would be required for trials, and there would be less need to over-recruit in order to account for attrition.

The nested cohort design was useful for evaluating complex treatments for LBP, allowing the comparison of treatments with each other and in combination, and with usual care. Low back pain

is also a complex condition that involves periods of remission and relapses. This design allowed for ongoing monitoring, and also for the recruitment of participants who had initially been ineligible for the trial later in the cohort.

The use of a factorial RCT within this study was also an expedient choice, since it allowed for the comparison and combination of two complex interventions while a control arm was maintained. Effectively, this means of delivery provides results for two trials for the relative cost of one. Additionally, any interaction between treatments that is superior to usual care can be detected with this design, which analyses the additive or synergistic effects of a combination of treatments, and also any counterproductive ones. This makes it an effective methodology for comparing complex interventions, and allows these treatments to be delivered in a pragmatic way.

In a cash-strapped healthcare system, the combined delivery of effective interventions has the potential to allow the NHS to make huge savings. However, NICE have yet to recognize the expertise and extended knowledge base of physiotherapists and other medical staff. Many physiotherapists, doctors, dentists and specialist nurses have the skills to deliver acupuncture. Approximately 6550 AACP-registered physiotherapists working in musculoskeletal medicine in the NHS and private sectors are well placed to incorporate acupuncture into the routine care involving manual therapy and exercise that they provide for the treatment of LBP. Although the recommendations made by NICE (2009) calculated that the cost of introducing acupuncture for the treatment of LBP would be £24 366 000, this could be an overestimation and a potentially unnecessary spend since the staff and expertise are theoretically already in place and costed to deliver this service. Combining the delivery of interventions and minimizing staff costs may be one way the NHS can survive austerity measures while still maintaining patient choice and providing an excellent service.

It is recommended that a full-scale trial investigating acupuncture and manual therapy for LBP should be conducted in order to further explore the combined additive effect and cost-effective delivery of these treatments. It is also recommended that the cohort design with a nested factorial RCT should be adopted in larger treatment trials for musculoskeletal conditions, and used routinely to improve the standard of methodological design within trials.

What are the new findings?

Key findings:

- This observational cohort study with a nested factorial RCT demonstrated zero attrition after randomization. The design followed a novel methodology and is useful for recruiting participants to an RCT.
- The design was appropriate for evaluating treatments for LBP.
- Combining the delivery of acupuncture and manual therapy treatment may provide cost savings to healthcare.

What this adds to what is known:

- The design has not previously been used in the study of LBP, and is an appropriate design for a population suffering from such pain.
- Physiotherapists can combine acupuncture and manual therapy; this is both achievable and effective.

What is the implication and what should change now?

When evaluating interventions for chronic musculoskeletal problems, trials should consider using a cohort design with a nested factorial RCT. Cost-effective integration of acupuncture funding into existing physiotherapy services should be implemented.

Acknowledgments

The author would like to thank her doctoral supervisors at the University of York, Professors David J. Torgerson and Yvonne Birks.

This article presents independent research that was funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research (grant number RP-PG-0707-10186). The research was entitled "Acupuncture for chronic pain and depression in

primary care". A small project grant was awarded by AACP. The views expressed are those of the author, and not necessarily those of the NHS, NIHR, Department of Health or AACP. The funders had no role in the study design, data collection, synthesis and interpretation, or writing the report.

The results of the trial that followed this protocol were published as "Randomized cohort trial was shown to be feasible for evaluating treatments in low back pain" in the *Journal of Clinical Epidemiology* (Dascanio *et al.* 2014).

Conflict of interest

The author was the chairman of AACP; however, she states that she has no financial stake or any other conflict of interest with regard to the publication of this article.

Trial registration

Current controlled trials registry: ISRCTN05293321 (date registered 2 February 2011).

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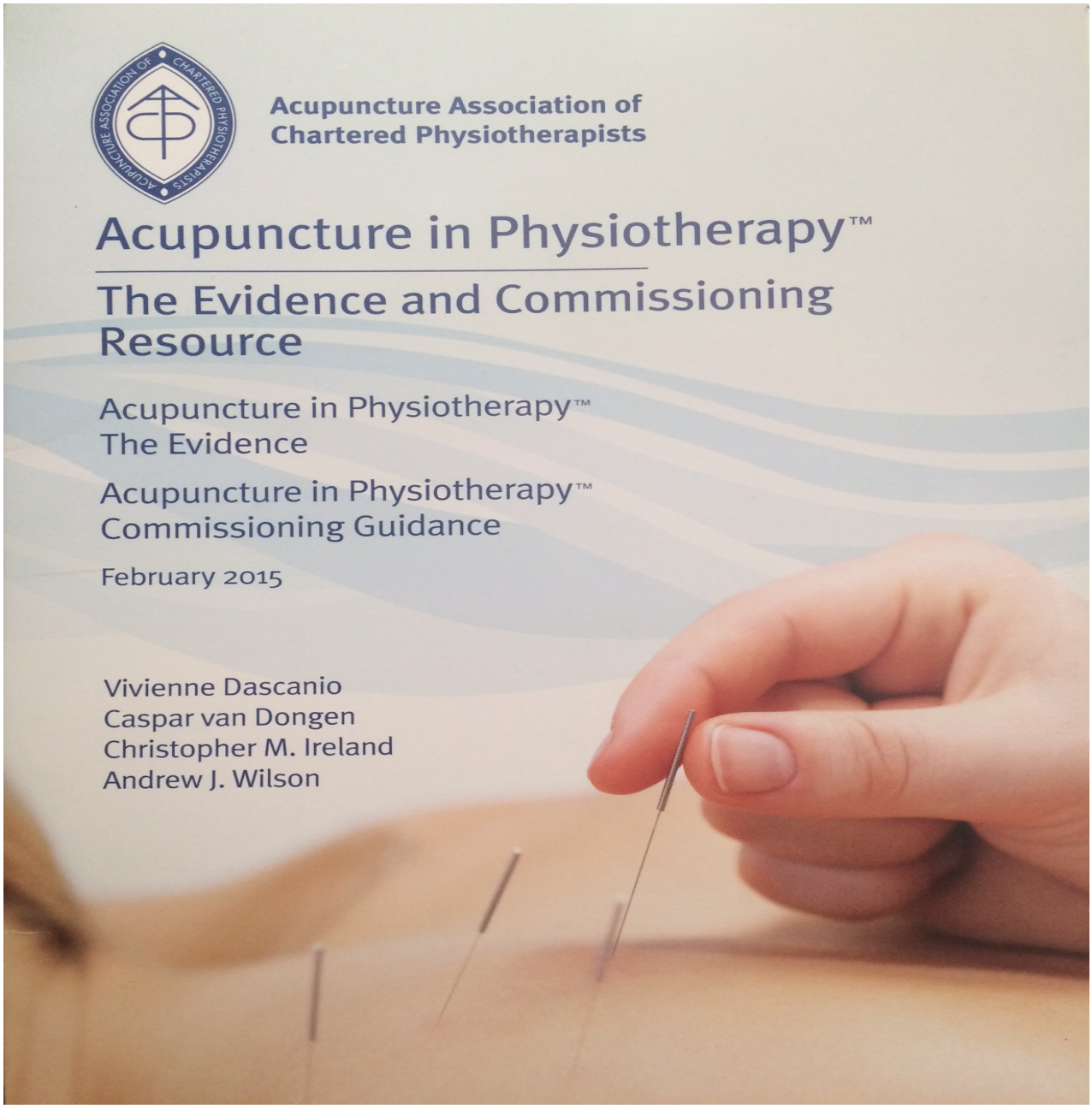
Vivienne Dascanio is currently engaged in doctoral studies at the University of York, where she is investigating acupuncture and manual therapy for LBP. She qualified as a physiotherapist from Coventry University, Coventry, UK, in 1998, and has over 17 years of clinical experience working as a chartered physiotherapist in both the NHS and private practice, specializing in musculoskeletal conditions. She has been a company director of her private physiotherapy practice in Peterborough for over 13 years, and has employed and mentored many physiotherapy practitioners.

Vivienne is a director and the previous chairman of AACP, and also sits on its Education, Training and

Research Committee. She co-authored the recently published AACP Evidence and Commissioning Resource, has represented its members at the Houses of Parliament, and is committed to supporting physiotherapists in the provision of evidence-based acupuncture as part of their practice.

Appendix A4: Original Publication

Dascanio, V. van Dongen, C. Ireland, CM. Wilson, AJ. (2015e) Acupuncture in Physiotherapy. The Evidence and Commissioning Resource: Part 1: The Evidence: A summary of evidence for the use of acupuncture in physiotherapy for the benefit of the patient. Publication of The Acupuncture Association of Chartered Physiotherapists Limited (AACP Ltd) (72 page document).
https://www.aacp.org.uk/assets/ckfinder_library/files/150527%20AACP%20The%20Evidence%20(1).pdf



Appendix A5: Original Publication

Dascanio, V. van Dongen, C. Ireland, CM. Wilson, AJ. (2015f) Acupuncture in Physiotherapy: The Evidence and Commissioning Resource: Part 2: Commissioning Guidance: Guidance on commissioning for AACP members. Publication of The Acupuncture Association of Chartered Physiotherapists limited (AACP Ltd) (28 page document).
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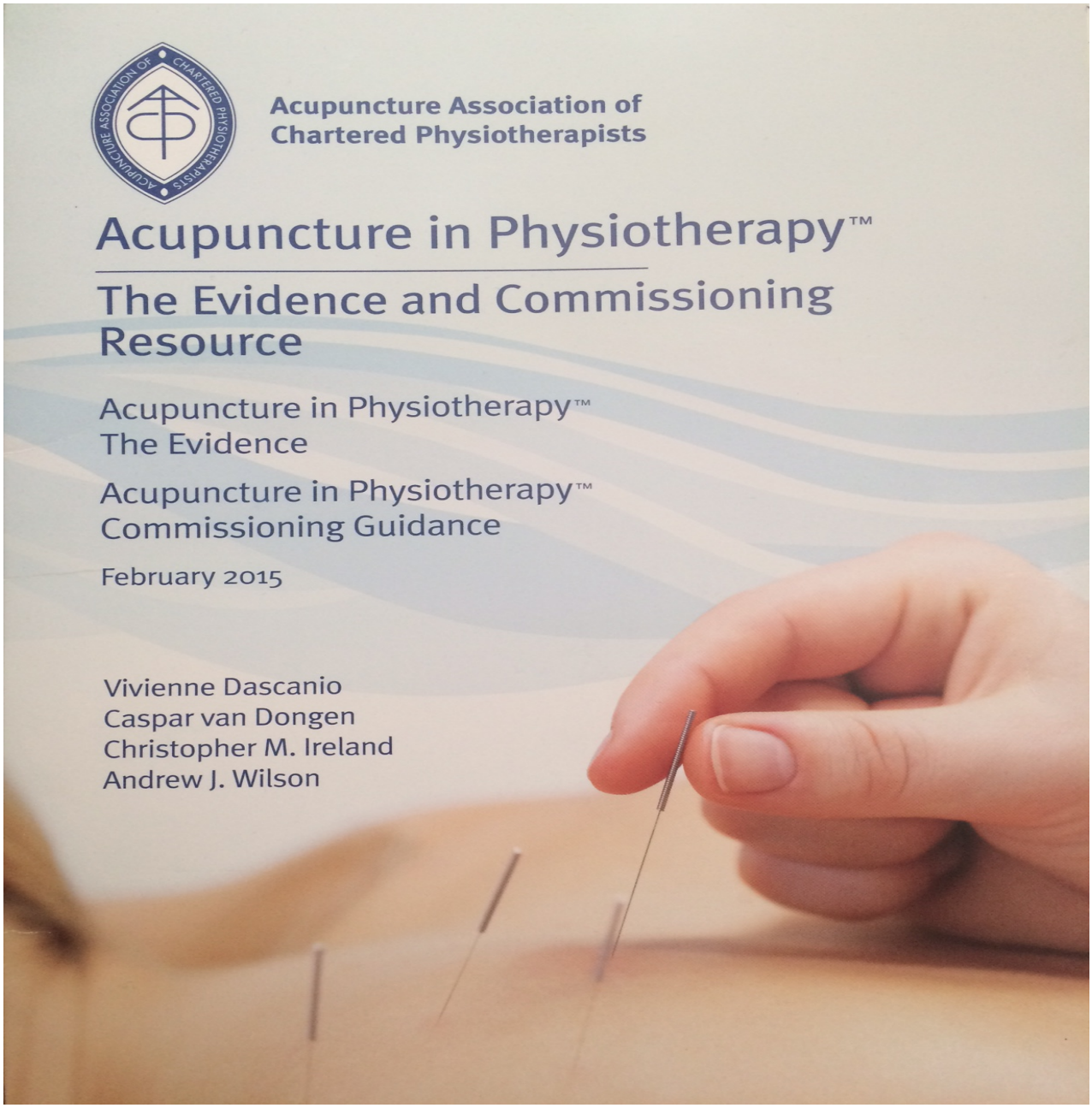

Appendix A6: Original Journal Article

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Journal of Clinical Epidemiology ■ (2014) ■

Journal of Clinical Epidemiology

ORIGINAL ARTICLE

Randomized cohort trial was shown to be feasible for evaluating treatments in low back pain

Vivienne Dascanio[a], Yvonne Birks[b], Laura Clark[c], Caroline Fairhurst[c], Hugh MacPherson[a], David J. Torgerson[c,*]

[a]*Department of Health Sciences, University of York, York, YO10 5DD*
[b]*Social Policy Research Unit, University of York, York, YO10 5DD*
[c]*York Trials Unit, Department of Health Sciences, University of York, York, YO10 5DD*

Accepted 9 April 2014; Published online xxxx

Abstract

Objective: To investigate the feasibility of conducting a cohort, factorial randomized controlled trial (RCT) in the treatment of patients with low back pain (LBP).

Study Design and Setting: Pragmatic feasibility factorial RCT nested within an observational cohort study in two general practices in York, United Kingdom.

Results: Eight hundred forty-five patients aged between 18 and 65 years who had consulted their general practitioner about LBP within the preceding 12 months were mailed an invitation to participate in a cohort trial, with the possibility of later joining a treatment RCT. One hundred twenty-four patients consented to participate in the cohort and treatment trial, and one consented only to the cohort only. Ultimately, 59 patients were randomized into the nested RCT. Outcomes included recruitment, acceptability, and attrition rates as measures of the feasibility of the design and Roland Morris Disability Questionnaire. No statistically significant differences in outcome between treatment groups and usual care were found.

Conclusions: The design was feasible for the evaluation of different back pain treatments. We found zero attrition after randomization and showed that for a remitting relapsing condition, the design allows us to recruit initially ineligible patients from the cohort. Additional statistical analysis using regression discontinuity can also be used with this design.

Keywords: Cohort randomized trial; Feasibility trial; Factorial trial; Low back pain; Acupuncture; Manual therapy

1. Introduction

In effectiveness research, the pragmatic randomized controlled trial (RCT) aims to estimate the kind of treatment differences we would expect to see in clinical practice [1]. Thus, a pragmatic trial tries to mimic "real-life" clinical practice as far as possible and generally eschews design features such as the use of placebos. However, there are potential biases that might occur in pragmatic trials, such as the effect of patient preferences on treatment outcomes [2]. These problems have been recognized, and alternative trial designs such as patient preference or randomized consent designs have been proposed [2,3]. More recently, a trial design—the "cohort randomized controlled trial" (cRCT) approach—has been proposed that may potentially reduce some of the biases associated with unblinded trials [4]. In a cRCT, as described by Relton et al., a group of patients with the condition of interest are recruited and monitored on a regular basis. After a defined period of follow-up, an RCT is nested within the cohort study. Patients eligible for the trial are identified from the whole cohort and randomized to a trial arm. Those allocated to a treatment (as opposed to say, usual care) are then offered the treatment. All cohort patients consent to provide outcome data at enrollment into the cohort study; however, consent to receive a particular intervention is sought only from those offered the intervention.

Funding: This article presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research (grant number RP-PG-0707-10186) titled, "Acupuncture for chronic pain and depression in primary care". The views expressed are those of the author(s) and not necessarily those of the National Health Service, the NIHR, or the Department of Health. The funders had no role in study design, data collection, data synthesis, data interpretation, or writing the report.

Conflict of interest: The authors state that they have no financial or other conflict of interest in the publication of this article.

* Corresponding author. Tel.: 44-1904-321340; fax: 22-1904-321387.
E-mail address: david.torgerson@york.ac.uk (D.J. Torgerson).

0895-4356/$ - see front matter
http://dx.doi.org/10.1016/j.jclinepi.2014.04.004

What is new?

Key findings

- The randomized cohort design is a novel trial method. In this feasibility study, a pilot trial of treatments for low back pain were tested using the randomized cohort trial design. The design resulted in zero attrition during the randomized follow-up; recruitment to the study design was good; patients initially ineligible due to lack of back pain could be recruited later when they relapsed; because participants were selected on a continuous variable, regression discontinuity techniques can supplement standard trial analysis.

What this adds to what was known?

- Few studies have used this design, and none have used it in back pain. This study shows that it is feasible to use the design in a population suffering from chronic musculoskeletal pain.

What is the implication and what should change now?

- When evaluating novel interventions in chronic musculoskeletal problems, trials should consider using a cohort randomized design.

This ''patient-centered'' informed consent replicates pragmatic health care. The risk of resentful demoralization in usual care patients is, in theory, reduced relative to a conventional RCT because the patients are not told in advance about treatments they then do not go on to receive. This in turn may minimize attrition, one of the major threats to the internal validity of any trial. On the other hand, the design can only be used for chronic conditions as it is not possible to assemble a cohort for incident conditions. Maintaining contact with the ineligible patients from the cohort may add information about context of the trial through a description of the outcomes of nontrial participants. Furthermore, continuing to follow-up ineligible cohort members may aid further recruitment if subsequently a change in the clinical symptoms makes some cohort members eligible. Aside from the introduction of this novel trial design by Relton, there is little evidence for the utility of this design. In this article, we report a feasibility trial using a slight variation of this design for the evaluation of multiple treatments for chronic back pain.

Low back pain (LBP) is a major health problem in the United Kingdom and worldwide, estimated to have a lifetime prevalence in western industrialized countries of 60–80% [5]. A survey carried out by the Department of Health in the United Kingdom in 1998 reported a population incidence of LBP of 40% over 12 months [6]. It is estimated to cost the National Health Service £1.1 billion a year, with chronic problems accounting for 80% of this cost [7]. The Chartered Society of Physiotherapy [8] reported that five million working days are lost each year to LBP and up to half a million people receive a long-term state incapacity benefit because of LBP.

National Institute for Clinical Effectiveness recommends the following physical treatments for LBP: exercise, manual therapy, and acupuncture [9]. Acupuncture has its history in Chinese medicine [10] and involves the insertion of fine needles into specified regions of the body [11]. Manual therapy involves a therapist manually delivering mobilization, massage, or manipulation of joints or soft tissues in the body. It is undertaken by specially trained professionals (physiotherapists, osteopaths, doctors, or chiropractors [9]).

The United Kingdom back pain exercise and manipulation factorial randomized trial found that spinal manipulation, a form of manual therapy, was more effective than group exercise for back pain but that a combination of both treatments saw the largest benefit over ''best care'' in general practice [12]. Acupuncture is increasingly used by physiotherapists and has been shown to be more effective than usual care [13]; however, there is relatively little evidence of its use in combination with manual therapy.

2. Design

This was a cohort, factorial, feasibility RCT. Participants were recruited into an 18-month cohort study investigating the quality of life and types of treatment accessed by individuals with LBP. Participants were contacted and recruited in 2011 with participants being allocated to treatment in the autumn of 2011 and the beginning of 2012. Follow-up was every 3 months.

In the study, there was a two-part consent process. Participants were identified from general practitioner (GP) records and approached initially via their GP about entering the cohort. A letter signed by the GP, a participant information sheet, and a consent form were sent to eligible individuals inviting them to participate in the cohort study if they were still experiencing their LBP. All consenting patients were then sent a second information pack containing a baseline questionnaire and a participant information sheet explaining that there would be a future treatment trial within the cohort study and inviting the recipient to express an interest in taking part in the treatment trial by sending a second consent form back to the researchers. A brief description of the potential treatments was included in the information pack.

Participants who consented only to the cohort study continued to receive follow-up outcome postal questionnaires but were not entered into the randomized trial. Participants from the cohort who consented to the treatment trial were assessed for eligibility after completing

the 3-month questionnaire. Eligibility criteria included having a score of ≥4 on the Roland Morris Disability Questionnaire (RMDQ). Eligible patients were randomized into one of four groups: usual care, acupuncture, manual therapy, or both acupuncture and manual therapy. Randomization ensured that the indication for treatment was balanced across groups. Participant preference was taken into consideration, in that if, for example, a participant wanted to take part but not receive acupuncture (eg, because of a needle phobia), they were not randomized into either the acupuncture or combined groups. Participants unwilling or unable to receive any of the treatments continued to be monitored in the observational cohort study and were not included in the comparisons between the randomized groups. Participants with a score <4 were not randomized but continued to be members of the cohort. The hypothesis was that the effects of resentful demoralization by the usual care group would be reduced because although they knew that there was a possibility of being offered an intervention, they never knew at what point the intervention was made available to the intervention groups, unlike in a ''normal'' randomized trial. Consequently, their responses to the outcome measures should not be influenced by the knowledge that they had not been allocated a treatment.

At 6 months, all patients were sent a follow-up questionnaire. For participants who had given consent for the cohort and RCT but had previously had an RMDQ score of <4, if their back pain had worsened such that their RMDQ score had increased to ≥4, they became eligible to enter the treatment trial and were given the option to be randomized.

2.1. Participants

We approached two general practices in the York area with a total registered patient population of 32,000. Individuals aged between 18 and 65 years who had consulted their GP in the preceding 12 months with LBP were identified from the GP databases. An upper age limit of 65 years was used to reduce the possibility of recruiting patients with back pain due to osteoporotic spinal fracture. Patients were excluded if they had symptoms of serious spinal or neurological pathology, had a history of spinal surgery, were pregnant or had given birth in the last 12 months, or were known to have received either of the trial treatments for their LBP in the previous 3 months.

2.2. Randomization

Participants eligible for the study were given an identification number. When a group of participants were found to be eligible for the treatment trial, their identification numbers were sent to D.T., who randomized the participants in a block that was equal to the size of the group. Randomization was conducted using the randomization function in SPSS such that exactly equal numbers were allocated to the arms within the block. The allocation was not stratified, and the characteristics of the individual participants were unknown to the researcher undertaking the allocation.

As this was a pragmatic trial to estimate the effectiveness of acupuncture and manual therapy, blinding of participants and professionals was not possible.

2.3. Interventions

All participants received usual care in addition to the trial treatments.

2.3.1. Acupuncture

A group of experienced musculoskeletal physiotherapists with additional training in western acupuncture incorporating some traditional Chinese medicine principles delivered the acupuncture treatment. Participants followed a program of ten 30-minute acupuncture sessions, which took place weekly where possible.

2.3.2. Manual therapy

Manual therapy was delivered by a group of experienced musculoskeletal physiotherapists who performed spinal mobilization and massage (manipulation techniques were not used as the recruited physiotherapists did not have the required additional training). Participants followed a program of ten 30-minute manual therapy treatment sessions, which took place weekly where possible.

2.3.3. Combined manual therapy and acupuncture

For the combined manual therapy and acupuncture intervention group, participants received ten 45-minute weekly (where possible) treatment sessions incorporating both manual therapy and acupuncture from the same group of experienced musculoskeletal physiotherapists who delivered the individual interventions as described previously.

2.4. Outcome measures

The main outcome measures of this feasibility study were recruitment, acceptability, and attrition rates. The majority of attrition usually occurs at the first period of follow-up in an RCT; therefore, because of the 3-month ''run-in'' period, it was expected that attrition subsequent to randomization in this trial would be minimal. The primary clinical outcome was the RMDQ, selected because of its frequent use in research studies of LBP. The Modified Oswestry Disability Index Questionnaire was used as a secondary measure of back pain. For both scales, a higher score indicates more severe LBP. Outcomes were measured at cohort enrollment and at 3 monthly intervals thereafter for 18 months. This article only discusses clinical outcomes up to 6 months (ie, 3 months postrandomization for those entered into the RCT).

2.5. Sample size

No formal power calculation was conducted for this feasibility trial. It was aimed to achieve at least 16

participants in each trial arm to exceed the minimum recommended number of 12 [14].

2.6. Statistical analysis

Analyses were conducted using two-sided significance at the 5% level on an intention-to-treat basis, including all participants in the groups to which they were randomized. Analysis of this study was largely descriptive; however, a preliminary investigation into the effectiveness of the two interventions was conducted. This involved estimating the effect of (1) manual therapy alone vs. usual care; (2) acupuncture alone vs. usual care; (3) acupuncture and manual therapy vs. usual care; and (4) the combined intervention compared with each of the single treatments, on both the Roland Morris and Oswestry scores at 3 months postrandomization. For each comparison, we used analysis of covariance adjusting for the score reported immediately before randomization (hereafter referred to as "screening score") to obtain treatment estimates with 95% confidence intervals (CIs). This trial was not powered to detect a specific difference however, and so all analyses are exploratory.

Continuous data are summarized as mean and standard deviation (SD) and categorical data as frequency (percentage).

3. Results

3.1. Recruitment and attrition

In the summer of 2011, we mailed out to 845 patients from two GP practices who had visited their doctor for LBP in the preceding 12 months (Fig. 1). We received 125 consent forms back; 124 patients consented to participation in both the cohort and the treatment trials, and one individual consented only to the cohort trial. Seventy percent ($n = 88$) of respondents returned the baseline questionnaire subsequently sent to them. After 3 months, during which time one patient withdrew and one patient withdrew consent for the treatment trial, 59 (68%) cohort participants who had consented to being considered for the treatment trial were eligible for participation in treatment (ie, had

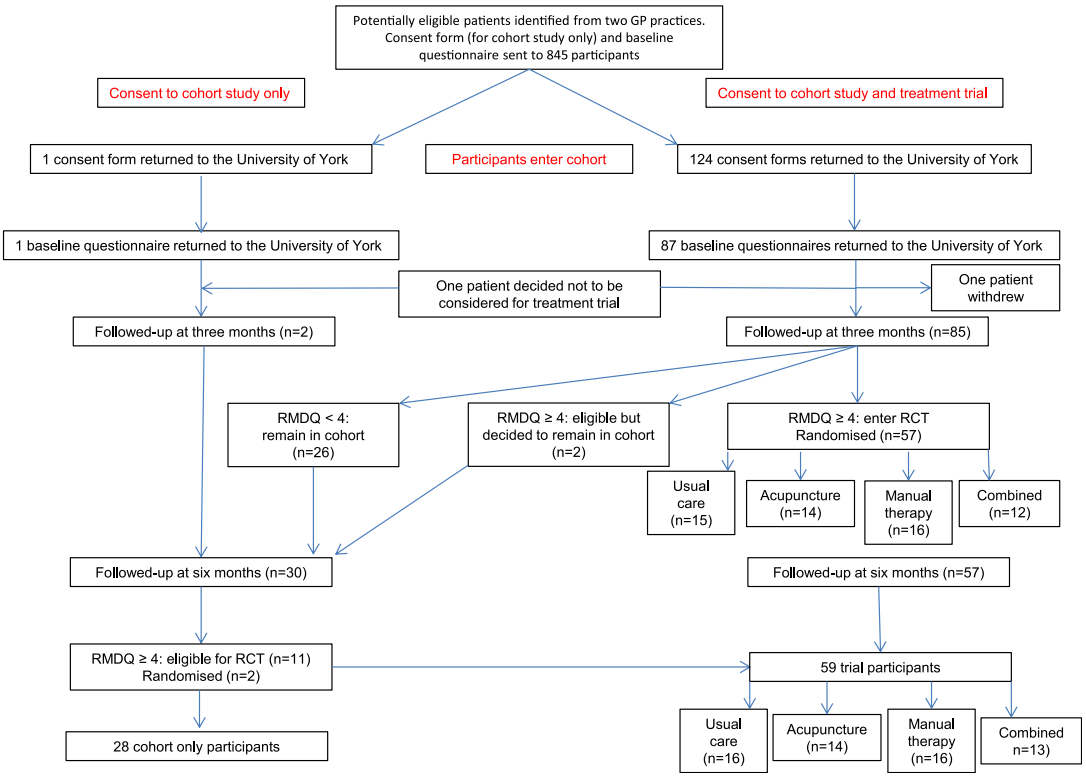

Fig. 1. CONSORT flow diagram. GP, General Practitioner; RCT, randomized controlled trial; RMDQ, Roland Morris Disability Questionnaire.

Table 1. Characteristics of cohort-only and allocated trial treatment groups

Characteristic	Cohort only (n = 28)	Usual care (n = 16)	Acupuncture (n = 14)	Manipulation (n = 16)	Combined (n = 13)
Age (yr), mean (standard deviation)	46.3 (9.6)	46.3 (11.3)	45.6 (11.9)	43.9 (13.7)	50.1 (9.3)
Sex, male	8 (29)	5 (31)	4 (29)	9 (56)	5 (38)
Roland Morris Questionnaire (0–24, 0 = best)	1.8 (2.6)	11.4 (5.3)	8.8 (4.3)	8.0 (4.4)	7.0 (2.6)
Modified Oswestry Score (0–50, 0 = best)	11.6 (9.7)	29.5 (15.4)	29.6 (12.2)	24.0 (13.6)	19.2 (8.0)

an RMDQ score of ≥4). At this stage, two participants chose not to take part in the randomized trial, despite being eligible and so 57 patients were randomized. At 6 months, 11 cohort-only participants scored >4 in the RMDQ, rendering them eligible for participation in the treatment trial. Two chose to join the trial and so were randomized at this point. This was the last time point at which participants could be randomized to a trial treatment. Therefore, there were a total of 28 cohort-only participants and 59 trial participants. No participant who had been randomized withdrew up to the 3-month follow-up point postrandomization (for attrition, 95% CI: 0.0, 6.3).

3.2. Screening

The mean (SD) age of participants at randomization was 46 (12) years (range, 19–64 years) and 61% were female. Patients in the combined intervention group tended to be approximately 5 years older than patients in the other trial arms, and the manipulation group had almost double the proportion of women than the other three groups (Table 1).

3.3. Exploratory analysis—Roland Morris Disability Questionnaire

Two participants were unwilling to receive acupuncture and so were randomized only to either usual care or manual therapy. One participant was unwilling to receive manual therapy and so was randomized only to either usual care or acupuncture. These participants were excluded from any comparisons between acupuncture and manual therapy (alone or in combination). For the two patients who were randomized 6 months into the cohort study, their 6-month score has been classed as their screening score; this means however that because this article only considered data up to the 6-month time point, we do not have 3-month follow-up data for these patients. Exploratory analysis of the efficacy of the trial interventions showed that the Roland Morris Questionnaire scores improved across all groups after 3 months (Table 2). Neither acupuncture nor manual therapy produced a greater improvement in mean Roland Morris score at 3 months than usual care. For the combined group, the additional reduction in RMDQ was 2.1 points (95% CI: −2.0, 6.3) at 3 months. The greatest effect was therefore observed in the combined treatment group, although none of the differences were statistically significant.

Patients in the combined intervention group experienced on average a 1.8-point (95% CI: −1.8, 5.4; P = 0.31) greater improvement in Roland Morris score than the manual therapy group and a 4.3-point (95% CI: 0.8, 7.7; P = 0.02) greater improvement than the acupuncture group adjusting for screening score.

3.4. Exploratory analysis—Modified Oswestry Disability Index

Both the acupuncture and the combined treatment were seen to improve the modified Oswestry score more than usual care, after adjusting for screening score, and as with the Roland Morris Questionnaire, this was seen to the greatest extent in the combined group (additional improvement to usual care of 5.2 points [95% CI: −6.9, 17.3]) although statistical significance was not reached (Table 2). No

Table 2. Results of regression analysis of treatments for low back pain at 3 months postrandomization

Outcome measure	Usual care (UC)	Acupuncture	Additional difference attributed to acupuncture over UC[a] (95% CI)	Manual therapy	Additional difference attributed to manual therapy over UC[a] (95% CI)	Acupuncture and manual therapy	Additional difference attributed to acupuncture and manual therapy combined over UC[a] (95% CI)
Roland Morris Questionnaire (0–24, 0 = best)	7.4 (6.2) n = 14	7.1 (4.6) n = 13	0.6 (−3.8, 5.0) P = 0.78	5.5 (6.3) n = 13	0.4 (−4.2, 4.9) P = 0.87	2.8 (2.7) n = 12	−2.1 (−6.3, 2.0)[b] P = 0.30
Modified Oswestry Score (0–50, 0 = best)	25.4 (22.1) n = 13	22.6 (11.7) n = 13	−2.5 (−13.9, 8.9)[b] P = 0.65	20.6 (11.4) n = 14	0.0 (−10.3, 10.3) P = 1.0	10.8 (7.4) n = 12	−5.2 (−17.3, 6.9)[b] P = 0.38

Abbreviation: CI, confidence interval.

[a] Estimated by analysis of covariance with adjustment for screening score.

[b] Negative differences represent a favorable outcome for the relevant intervention over usual care.

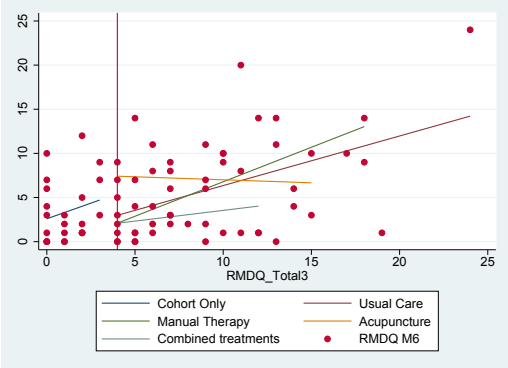

Fig. 2. Pre and post test correlation of RMDQ. RMDQ, Roland Morris Disability Questionnaire.

additional benefit in Oswestry score over usual care was seen in the manual therapy group.

Patients in the combined group experienced on average a 7.1-point (95% CI: 0.7, 13.6; $P = 0.03$) greater improvement in Oswestry score than the manual therapy group and a 7.4-point (95% CI: −1.7, 16.5; $P = 0.10$) greater improvement than the acupuncture group adjusting for screening score.

Fig. 2 plots the screening RMDQ scores against the scores 3 months later, with regression lines for the cohort-only group and then for each of the four trial arms.

4. Discussion

The aim of this study was to investigate the feasibility of conducting a cohort randomized trial in a GP setting amongst LBP sufferers. We were interested in the recruitment and attrition rates and the acceptability of acupuncture and manual therapy as a treatment for people with LBP.

We experienced a response rate to the initial mail out of 15%; 125 patients returned the consent forms, with all but one consenting to participate in both the cohort study and the nested RCT. Of the 124 patients who expressed an interest in being offered one of the trial treatments, only three people expressly stated that they would not consider one of acupuncture or manual therapy for the treatment of their LBP, indicating a high level of acceptability of these treatments. Attrition up to 6 months was extremely low in this study (1%), with only one participant withdrawing before the 3-month screening time point. One other participant contacted the researchers and stated that they did not think they would benefit from treatment because of reduced symptoms and therefore asked not to be considered for the treatment trial. No participant withdrew after randomization. This 0% attrition 3 months postrandomization compares extremely favorably with other back pain trials. For example, the three trials (UK BEAM, a cognitive behavior treatment trial for LBP, and a trial of yoga for LBP) had attrition rates of 25%, 22%, and 13%, respectively [12,15,16], which exceed our upper 95% CI limit of 6% for attrition. We are currently reporting data for up to 6 months and so cannot comment further on loss to follow rates for later on in the study.

Our study design differs slightly from that originally proposed by Relton et al. [4]. In the original Relton design, participants are not specifically told about the possibility of treatment options that could be available. The problem with this is that failure to alert the participants may mean a refusal to take up the treatment under offer, which will lead to treatment dilution. In this study, we flagged up the possibility of future treatments to avoid this problem. This study identified two extra benefits of using a randomized cohort design that was not described in the original article by Relton et al. First, using the design for a chronic remitting/relapsing condition like back pain, is that some participants, who initially were not eligible because of low symptom scores, became eligible at a later date and could be randomized. In a ‘‘normal’’ randomized trial design, these patients would have been lost from being included in the randomization. Second, by including the cohort of low symptom patients, we could, if the trial had been large enough, have supplemented the randomized analysis by including the cohort in a regression discontinuity analysis.

The limitations of this study mainly stem from the limited sample size; however, as a feasibility trial, the study was not powered to detect a difference between the trial groups in terms of Roland Morris score and so results can only be seen as exploratory. Furthermore, we excluded patients over the age of 65 years. Future trials of back pain should include older patients to enhance their external validity.

Although we have shown that the trial design is feasible, if it were scaled up, there would be additional work and cost for the researchers to follow-up the nonrandomized cohort. It is possible that this is not a cost-effective use of research resources. The nonrandomized cohort can improve recruitment in this condition as some patients may become eligible who previously were not. In a larger study, the trial-based analysis can be supplemented with a regression discontinuity analysis, which would improve study inference. However, arguably, the resources spent to obtain these benefits may be better used to increase the overall sample size of the randomizable participants. Consequently, it might be more cost effective to modify the design by not following up the ineligible participants.

5. Conclusion

We would recommend that this research design is used further in larger treatment trials of interventions for musculoskeletal conditions.

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Appendix A6b: Corrigendum to appendix A6

ELSEVIER

Journal of Clinical Epidemiology ■ (2019) ■

Journal of Clinical Epidemiology

CORRIGENDUM

Corrigendum to 'Randomized cohort trial was shown to be feasible for evaluating treatments in low back pain' Journal of Clinical Epidemiology Volume 67, Issue 8, August 2014, Pages 940-946

Vivienne Dascanio[a], Yvonne Birks[b], Laura Clark[c], Caroline Fairhurst[c], Hugh MacPherson[a], David J. Torgerson[c,*]

[a]*Department of Health Sciences, University of York, York YO10 5DD*
[b]*Social Policy Research Unit, University of York, York YO10 5DD*
[c]*York Trials Unit, Department of Health Sciences, University of York, York YO10 5DD*

During a recent re-analysis of the data included in our original manuscript, a database error was uncovered which had resulted in data at the 3 months post-randomisation time point being incorrect for over half the participants. This error was corrected and the analysis rerun. Results of the exploratory analysis for the Roland Morris Disability Questionnaire and the Modified Oswestry Disability Index were impacted. A corrected Table 2 is presented below. This indicates that the manual therapy group, rather than the combined group as previously reported, produced the largest benefit over usual care at 3 months (reduction in RMDQ of 1.4 points, 95% CI: −1.0, 3.8). As before, however, none of the differences were statistically significant. Patients in the combined intervention group experienced on average a 1.4-point (95% CI: −1.5, 4.4; $P = 0.31$) increase in Roland Morris score than the manual therapy group but a 0.9-point (95% CI: −2.9, 4.7; $P = 0.63$) greater improvement than the acupuncture group adjusting for screening score. A revised Fig. 2 is provided here which plots the screening RMDQ scores against the scores 3 months later, with regression lines for the cohort-only group and then for each of the four trial arms.

Similarly with the modified Oswestry score, the largest benefit was observed between manual therapy and usual care, rather than with the combined therapy group as previously reported (reduction in Oswestry score of 5.02 points, 95% CI: −3.3, 13.3) although, as before, statistical significance was not reached in any comparison (Table 2). Patients in the combined group experienced on average a 2.2-point (95% CI: −4.8, 9.3; $P = 0.52$) increase in Oswestry score than the manual therapy group and a 0.5-point (95% CI: −7.7, 8.7; $P = 0.90$) increase than the acupuncture group adjusting for screening score (both differences favour the individual intervention rather than the combined group).

Table 2
CORRECTED results of regression analysis of treatments for low back pain at 3 months postrandomization

Outcome measure	Usual care (UC)	Acupuncture	Additional difference attributed to acupuncture over UC[a] (95% CI)	Manual therapy	Additional difference attributed to manual therapy over UC (95% CI)	Acupuncture and manual therapy	Additional difference attributed to acupuncture and manual therapy combined over UC (95% CI)
Roland Morris Questionnaire (0-24, 0 = best)	9.5 (6.3) $n = 14$	6.8 (4.5) $n = 13$	0.3 (−2.9, 3.5) $P = 0.85$	4.6 (4.0) $n = 15$	−1.4 (−3.8, 1.0) $P = 0.24$	5.4 (4.8) $n = 11$	−0.01 (−4.3, 4.3) $P = 1.00$
Modified Oswestry Score (0-50, 0 = best)	29.2 (21.0) $n = 13$	25.4 (12.0) $n = 13$	−1.9 (−9.9, 6.1)[b] $P = 0.63$	18.3 (11.1) $n = 15$	−5.0 (−13.3, 3.3) $P = 0.23$	16.7 (10.9) $n = 11$	2.1 (−6.5, 10.6) $P = 0.62$

Abbreviation: CI, confidence interval.
[a] Estimated by analysis of covariance with adjustment for screening score.
[b] Negative differences represent a favorable outcome for the relevant intervention over usual care.

DOI of original article: 10.1016/j.jclinepi.2014.04.004.

https://doi.org/10.1016/j.jclinepi.2019.06.006

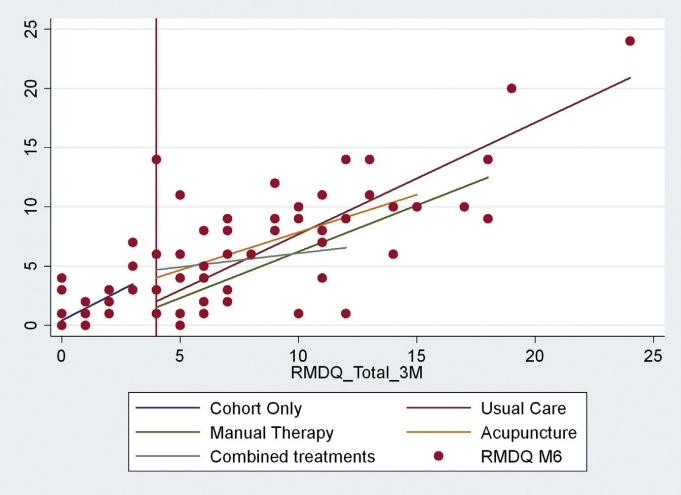

Fig. 2. CORRECTED pre and post test correlation of RMDQ.

These amendments do not impact on the conclusions drawn from the study.

The authors would like to apologise for any inconvenience caused.

Dascanio *et al. Trials* 2011, **12**(Suppl 1):A150
http://www.trialsjournal.com/content/12/S1/A150

TRIALS

POSTER PRESENTATION Open Access

A pilot factorial randomised cohort trial of manual therapy or acupuncture for low back pain

Vivienne C Dascanio*, Yvonne Birks, David Torgerson

From Clinical Trials Methodology Conference 2011
Bristol, UK. 4-5 October 2011

Background

Randomised control clinical trials of acupuncture have been hampered by the challenges of assessing it as a complex intervention. Controlling for and separating placebo effects whilst identifying its efficacy as a treatment can be difficult [1]. The comparison of acupuncture to other complex interventions has been recommended to assess the effectiveness of acupuncture against other interventions [2].

The objective of this pilot trial is to investigate the feasibility of undertaking a novel randomised cohort design study with a nested factorial RCT, investigating acupuncture alone versus manual therapy alone versus a combination of acupuncture and manual therapy versus usual care.

The pilot will investigate recruitment rates to allow for planning a full-scale trial, identify any compliance issues and strategies for reducing these in a full-scale trial and assess patient's acceptance and therapist delivery of combined therapies for the treatment of their LBP.

Methods

The study will follow a randomised cohort trial design and participants from the cohort will be selected to participate in the pilot trial. The use of this design as a recruitment method for nested trials is relatively new methodology but the cohort design has been suggested as an effective method for the use with chronic conditions [3] and its potential for minimising attrition. Attrition is one of the major threats to the internal validity of any trial. The design of this trial specifically reduces that threat [4]. Using a randomised cohort design will provide a 'run-in period' of three months, from collecting baseline data to the first set of outcome data. Only participants who return their three monthly questionnaires will be eligible for randomisation to the pilot trial. As the majority of attrition occurs at the first period of follow-up in an RCT, it is expected subsequent attrition, after randomisation, to be minimal [4].

The factorial pilot RCT will investigate the treatment of low back pain with Acupuncture vs Manual Therapy vs Acupuncture and manual therapy vs Usual GP care. All interventions will be delivered by a chartered physiotherapist.

Results and conclusions

Recruitment and retention rates will be presented. The acceptability and feasibility of the design for use with complex interventions and in a common musculoskeletal condition will be discussed.

Acknowledgements

NIHR Programme grant project. Funding applicant Dr Hugh MacPherson, Professor David Torgerson.
Small project grant award from Acupuncture Association of Chartered Physiotherapists (AACP).

Published: 13 December 2011

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* Correspondence: Vcf500@york.ac.uk
York Trials Unit, Department of Health Sciences, ARRC Building, University of York, Heslington, York, YO10 5DD, UK

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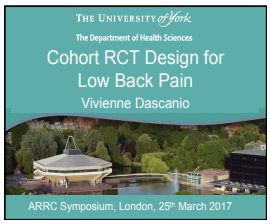
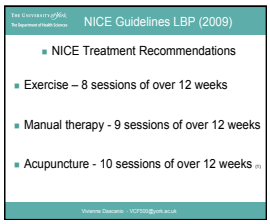
doi:10.1186/1745-6215-12-S1-A150
Cite this article as: Dascanio *et al.*: A pilot factorial randomised cohort trial of manual therapy or acupuncture for low back pain. *Trials* 2011 **12**(Suppl 1):A150.

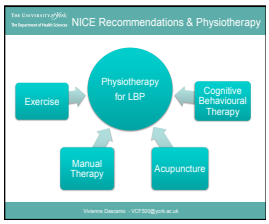
Appendix B: Dissemination of Research

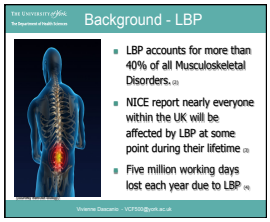
Appendix B1: Conference Presentation

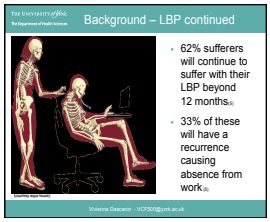
Acupuncture or Manual Therapy for LBP? – Considering the Design of RCTs for Studies of Acupuncture. The 19th International Acupuncture Research Symposium of ARRC, London. 25th March 2017

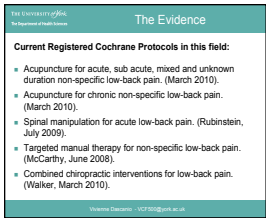


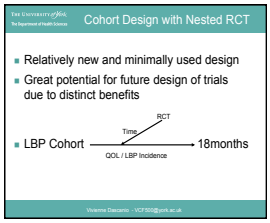


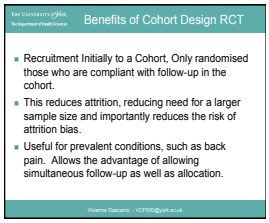












1

Disadvantages of Cohort Design RCT

- Can't be used for an incident condition, such as a treatment trial of fracture of humerus.
- Still need to recruit a cohort, which could be problematic.
- Take up of treatment may potentially be lower than a normal RCT.

Aims and Objectives of the Research

- **Primary Aim**
  - Conducting a pilot study to explore the methodological process of undertaking a cohort design study for the recruitment of participants to a nested factorial RCT, investigating acupuncture and manual therapy alone and in combination versus usual care for LBP.
- **Primary Objectives**
  - To ascertain recruitment rates of participants to the cohort from GP practices
  - To ascertain recruitment rates of participants from the cohort to the nested RCT
  - To inform consent rates and acceptance of the interventions by participants
  - To assess attrition rates of participants pre and post randomisation
  - To assess the use of this design for evaluating a population with low back pain
- **Secondary Objectives**
  - To review of the usage and completion rates of Roland Morris disability questionnaire (RMDQ) and Modified Oswestry Disability Index (MODI).
  - To compare of the objective measure tools (RMQD and MODI) to assess which would be most appropriate for a full-scale trial.

Outcome Measures of the Research

- **Primary Outcome Measures**
  - To determine the main clinical outcome measure, for a full scale trial:
    - Roland-Morris disability questionnaire, (Specific Low back pain measure).
    - Modified Oswestry Disability Index, (Specific Low back pain measure).
- **Secondary Outcome Measures**
  - Visual Analogue Scale (VAS) pain scales, (Pain specific measure).
  - SF 12, (Quality of life questionnaire).
  - Euro-Qol (EQ-5D), (Generic measure of health for clinical and economic appraisal).
  - Patient use of body chart and additional treatment information.

Cohort Recruitment

- Used a GP database recruitment whereby we mail out to all individuals who presented with LBP in the preceding 18months.
- They were advised about the cohort and the *possibility* of being offered a treatment intervention and asked that if they were offered an intervention would they take up the offer.
- Those who consented to the treatment intervention were sent further information regarding the nested trial.

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Table: Factorial design of the pilot RCT

	B	O	Margin
A	Acupuncture and manual therapy (cell AB)	Acupuncture (cell AO)	A5.1 (verb: A8 & A9)
O	Manual therapy (cell BO)	Usual GP Care (cell OO)	O1 to 4 (verb: B3 & O5)
Margin	B1.8 (verb: A8 & B3)	A3 to 6 & B (verb: A7 & O5)	

Figure 2: CONSORT flow diagram:

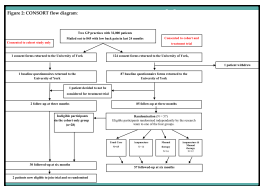

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Table 1: Characteristics of cohort only and allocated trial treatment groups

Characteristic	Cohort only (n=28)	Usual care (n=14)	Acupuncture (n=14)	Manipulation (n=16)	Combined (n=13)
Age, years	46.3 (9.6)	46.3 (11.3)	45.6 (11.9)	43.9 (13.7)	50.1 (9.3)
Male	8 (29)	5 (31)	4 (29)	9 (56)	5 (38)
Roland Morris questionnaire (0-24, 0=best)	3.8 (2.6)	11.4 (5.3)	8.8 (4.3)	8.0 (4.4)	7.0 (2.6)
Modified Oswestry score (0-54, 0=best)	11.6 (9.7)	29.5 (13.4)	25.6 (12.2)	24.0 (13.6)	19.2 (8.0)

The University of York

Table 2: Results of regression analysis of treatments for low back pain at three months post randomisation

Outcome measure	Usual care	Acupuncture	Additional difference attributed to acupuncture (95% CI)	Manual therapy	Additional difference attributed to manual therapy (95% CI)	Acupuncture and manual therapy	Additional difference attributed to acupuncture and manual therapy (95% CI)
Roland Morris questionnaire (0-24, 0=best)	7.4 (6.2) n=42	7.1 (6.6) n=35	0.6 (-3.0, 3.8) p=0.79	5.3 (6.2) n=37	3.6 (-0.2, 6.9) p=0.05	2.8 (2.7) n=32	-3.3 (-6.5, -0.0) p=0.05
Modified Oswestry score (0-54, 0=best)	26.4 (20.1) n=43	22.4 (21.7) n=35	-2.5 (-12.5, 6.9) p=0.65	20.4 (11.6) n=34	-9.0 (-18.2, 0.2) p=0.05	18.8 (7.4) n=32	-12.2 (-17.2, -6.9) p<0.01

Results by analysis of covariance with adjustment for screening score

Negative differences represent a favourable outcome for the relevant intervention over usual

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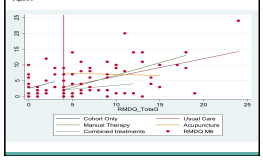
Figure 3



2

Conclusions from the Pilot

- Support to run a full scale-trial of this study
- The cohort RCT offers some advantages over the standard RCT, not least that it exploits database recruitment
- Pool of cohort participants to recruit from
- Provides a worthwhile reduction in attrition
- Useful design for MSK conditions

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David Torgerson & Yvonne Birks

Hugh MacPherson and NIHR Programme Grant

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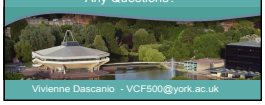
Thank You

Any Questions?



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- Self referral physio info. Updated costs table (2010) URL: www.selfreferralphysio.co.uk/costs.html

Additional Useful Resources

- **Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design –** Relton et al *(2010) BMJ; 340:bmj.c1066*
- **Randomized cohort trial was shown to be feasible for evaluating treatments in low back pain –** Dascanio et al (2014) Journal of Clinical Epidemiology
- **Designing randomised trials in health, education and the social sciences – An introduction.** Torgerson and Torgerson – Palgrave Macmillan - 2008

NICE Guidelines

Disclaimer –

Healthcare professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and, where appropriate, their guardian or carer.

(NICE, 2016)

NICE Debate Videos

- https://www.youtube.com/watch?v=0ICMQNdKvmg
- https://www.youtube.com/watch?v=XHU6AI1xWNI

3

Appendix B2: Conference Presentation

The Annual Conference of the British Medical Acupuncture Society (BMAS) – Scientific Meeting, Newcastle. 18th April 2015

THE UNIVERSITY of York
The Department of Health Sciences

Cohort RCT Design for Low Back Pain

Vivienne Dascanio

BMAS Spring Meeting, 18th April 2015

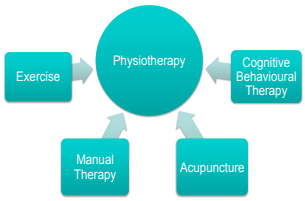
NICE Guidelines LBP (2009)

- Treatment Recommendations
- Exercise eight sessions of over twelve weeks,
- Manual therapy, nine sessions of over twelve weeks

or

- Acupuncture, ten sessions of over twelve weeks[1]

NICE Recommendations & Physiotherapy



Background - LBP

- LBP accounts for more than 40% of all Musculoskeletal Disorders.[2]
- NICE report nearly everyone within the UK will be affected by LBP at some point during their lifetime [3]
- Five million working days lost each year due to LBP [4]

Background – LBP continued

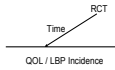
- 62% sufferers will continue to suffer with their LBP beyond 12 months[5]
- 33% of these will have a recurrence causing absence from work[5]

Cost Indications for Commissioners

- 2 Government departments in Northern Ireland, provided early access to physiotherapy for staff with MSD's [6]
  - 80% reported physiotherapy prevented them from having sick leave
  - 80% of those off sick reported the physiotherapy enabled them to return to work more quickly.
  - Thus saving money and reducing sickness at work.
- In Cambridge Self-referral to physiotherapy reduced GP costs in prescription and diagnostic tests.
  - Saving £12,000 per GP practice [7]
- In Scotland self-referral to physiotherapy saved approximately £2.5million per year [7]

Cohort Design RCT

- Relatively new and minimally used design
- Great potential for future design of trials due to distinct benefits
- LBP Cohort → 18months



Benefits of Cohort Design RCT

- Recruitment Initially to a Cohort, Only randomised those who are compliant with follow-up in the cohort.
- This reduces attrition, reducing need for a larger sample size and importantly reduces the risk of attrition bias.
- Useful for prevalent conditions, such as back pain. Allows the advantage of allowing simultaneous follow-up as well as allocation.

Disadvantages of Cohort Design RCT

- Can't be used for an incident condition, such as a treatment trial of fracture of humerus.
- Still need to recruit a cohort, which could be problematic.
- Take up of treatment may potentially be lower than a normal RCT.

Aims and Objectives of the Research

Primary Objectives

- To investigate the feasibility of undertaking a cohort design study with a nested factorial RCT, investigating manual therapy and acupuncture alone and in combination versus usual care.
- To determine the most effective outcome measure for a full-scale trial.
- To investigate recruitment rates to allow for planning a full-scale trial.
- To identify any compliance issues and strategies for reducing these in a full-scale trial.
- To assess patient's acceptance and therapist delivery of combined therapies for the treatment of their LBP.

Secondary Objectives

- To perform a simple value of information (VOI) study to assess if the additional cost of combining the interventions would be worthwhile on the assumption the additional therapy would be effective.
- To investigate perceived quality of life in a population of patients with LBP.
- To determine the types of treatment accessed by those with low back pain.

Outcome Measures of the Research

Primary Outcome Measures

- To determine the main clinical outcome measure, for a full scale trial:
  - Roland-Morris disability questionnaire, (Specific Low back pain measure).
  - Modified Oswestry Disability Index, (Specific Low back pain measure).

Secondary Outcome Measures

- Visual Analogue Scale (VAS) pain scales, (Pain specific measure).
- SF 12, (Quality of life questionnaire).
- Euro-Qol (EQ-5D), (Generic measure of health for clinical and economic appraisal).
- Patient use of body chart and additional treatment information.

Cohort Recruitment

- Used a GP database recruitment whereby we mail out to all individuals who presented with LBP in the preceding 18months.
- They were advised about the cohort and the *possibility* of being offered a treatment intervention and asked that if they were offered an intervention would they take up the offer.
- Those who consented to the treatment intervention were enrolled into the trial.

Figure 1: Study design

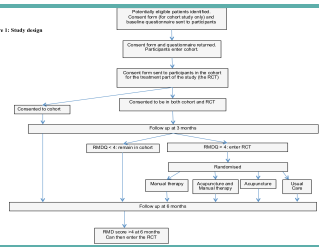


Figure 2: CONSORT flow diagram:

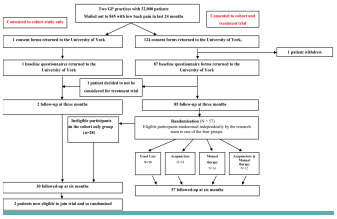


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Table 1: Characteristics of cohort only and allocated trial treatment groups

Characteristic	Cohort only (n=28)	Usual care (n=16)	Acupuncture (n=14)	Manipulation (n=16)	Combined (n=13)
Age, years	46.3 (9.6)	46.3 (11.3)	45.6 (11.9)	43.9 (13.7)	50.1 (9.3)
Male	8 (29)	5 (31)	4 (29)	9 (56)	5 (38)
Roland Morris questionnaire (0-24, 0=best)	1.8 (2.6)	11.4 (5.3)	8.8 (4.3)	8.0 (4.4)	7.0 (2.6)
Modified Oswestry score (0-50, 0=best)	11.6 (9.7)	29.5 (15.4)	29.6 (12.2)	24.0 (13.6)	19.2 (8.0)

Vivienne Dascanio - VCF500@york.ac.uk

THE UNIVERSITY of York

Table 2: Results of regression analysis of treatments for low back pain at three months post randomisation

Outcome measure	Usual care	Acupuncture	Additional difference attributed to acupuncture over UC (95% CI)	Manual therapy	Additional difference attributed to manual therapy over UC (95% CI)	Acupuncture and manual therapy	Additional difference attributed to acupuncture and manual therapy combined over UC (95% CI)
Roland Morris questionnaire (0-24, 0=best)	7.4 (6.2) n=34	7.1 (4.6) n=31	0.6 (-3.0, 5.0) p=0.78	5.5 (6.3) n=33	0.4 (-4.2, 4.9) p=0.87	2.6 (2.7) n=32	-2.1 (-6.3, 2.0) p=0.30
Modified Oswestry score (0-50, 0=best)	25.4 (22.1) n=33	22.6 (11.7) n=31	-2.5 (-13.9, 8.9) p=0.65	20.6 (11.4) n=34	0.0 (-10.3, 10.3) p=1.0	10.8 (7.4) n=32	-5.2 (-17.3, 6.9) p=0.38

timated by analysis of covariance with adjustment for screening score
egative differences represent a favourable outcome for the relevant intervention over usual
re

Vivienne Dascanio - VCF500@york.ac.uk

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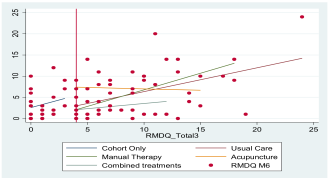
Figure 3



Conclusions

- The Cohort RCT offers some advantages over the standard RCT, not least that it exploits database recruitment
- May provide a worthwhile reduction in attrition.

THE UNIVERSITY of York
The Department of Health Sciences
David Torgerson & Yvonne Birks

Hugh MacPherson and NIHR programme Grant
The Acupuncture Association of Chartered Physiotherapists

Vivienne Dascanio - VCF500@york.ac.uk

THE UNIVERSITY of York
The Department of Health Sciences

Thank You

Any Questions?

Vivienne Dascanio - VCF500@york.ac.uk

Additional Useful Resources

- **Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design -** *BMJ 2010;340:bmj.c1066*
- **Designing Randomised Trials in Health, Education and the Social Sciences – An Introduction.** David J Torgerson and Carole J Torgerson – Palgrave Macmillan - 2008

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1. National Institute for Health and Clinical Excellence (2009) Low Back Pain: Early Management of Persistent Non-Specific Low Back Pain. NICE, London.
2. Department of Health (2006) The Musculoskeletal Services framework.
3. National Institute for Health and Clinical Excellence (2009) Low Back Pain: Early Management of Persistent Non-Specific Low Back Pain. NICE, London.
4. The Chartered Society of Physiotherapy. (2007). Guidelines for the management of persistent low back pain, parts 1&2. London: The Chartered Society of Physiotherapy.
5. Milczarek, M. (2009) Literature Review: Acupuncture and the Treatment of Low Back Pain: An Evidence-Based Literature Review. *Journal of the Acupuncture Association of Chartered Physiotherapists*. Autumn, 38-44.
6. Northern Ireland Audit Office. Management of sickness absence in the Northern Ireland civil service. Re ort by the Comptroller and Auditor General NIA 132/07-08. 22 May 2008. Norwich: TSO (The stationary office); 2008. URL: www.nerve8physio.co.uk/Updated%20Low%20Back%20Pain.html
7. Self referral physio info. Updated costs table (2010) URL: www.wetherbyphysiocity.com/sp.html

Appendix B3: Conference Presentation

Integrating Evidence Based Acupuncture into Physiotherapy, for the benefit of the patient, Madrid. 13th December 2014

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

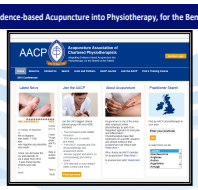
Celebrating 30 years of the Acupuncture Association of Chartered Physiotherapists

Integrating Evidence-based Acupuncture into Physiotherapy, for the Benefit of the Patient

Vivienne Dascanio
AACP Chairman
13th December 2014

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

Integrating Evidence-based Acupuncture into Physiotherapy, for the Benefit of the Patient



Vivienne Dascanio
AACP Chairman

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

The AACP, still pointing the way after 30 years!

A snapshot of examples of how the AACP actively promote the integration of Evidence-based acupuncture into physiotherapy for the benefit of the patient?

- The Evidence and Commissioning Resource
- The AACP Conference
- Parliament
- Social Media
- Promoting Acupuncture in Physiotherapy
- Acupuncture in Physiotherapy (*JAACP*)
- Clinical Advisor
- NICE

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

The AACP are in the final stages of updating their "Acupuncture in Physiotherapy: The Evidence and Commissioning Resource".

Includes two documents:

- Acupuncture in Physiotherapy: Commissioning Guidance.
- Acupuncture in Physiotherapy: The Evidence.

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

Research into Practice

- The Researched Effects of Acupuncture and it's application to patient treatments:
  - Analgesic
  - Inflammatory
  - Soft Tissue
- Incorporating the Condition Specific Research and its place with patient care:
  - Headaches & Migraines
  - Low Back Pain (LBP)
  - Pelvic and LBP Pain in Pregnancy

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

Pain Relieving effects of Acupuncture

- Acupuncture points are chosen with the intention of inducing a strong segmental inhibitory effect. Chemicals produced by mechanisms at spinal and supraspinal level as well as locally assist in healing and offer pain relief, which is helpful when used in conjunction with other physiotherapy modalities such as manual therapy, exercise and education.
- Natural pain-relieving chemicals such as endorphins, melatonin and serotonin are produced when acupuncture needles stimulate different physiological mechanisms within the central nervous system and in the local peripheral tissues being needled (Stein *et al.* 2001).

Stein C., Machelska H., Binder W., Schafer M. (2001) Peripheral Opioid Analgesia. *Current Opinion in Pharmacology* **1** (1), 62-65

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

Pain Relieving effects of Acupuncture

- Physiological and imaging studies are providing insight into the neurophysiological mechanisms of acupuncture analgesia. Data suggests that acupuncture triggers a sequence of events involving the release of endogenous opioid like substances including encephalin, beta endorphin and endomorphin. These modulate pain signals processed along the pathway. Imaging studies demonstrate that the limbic system plays an important role in acupuncture induced analgesia (Wang *et al.* 2008).

Wang S. M., Kain Z. N. K., White P. (2008) Acupuncture Analgesia: 1. The Scientific Basis. *Pain Medicine* **106** (2), 602-10.

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

Inflammatory effects of Acupuncture

- Wang *et al.* (2014) shows that acupuncture regulates opioid containing macrophages and anti-nociceptive mediators in inflammatory pain, supporting further the interaction between acupuncture, pain and inflammation thus speeding up healing and the recovery processes.

Wang Y., Gehringer R., Mousa S. A., *et al.* (2014) CSCL10 Controls Inflammatory Pain via Opioid Peptide-Containing Macrophages in Electroacupuncture. *PLOS one*.

- Acupuncture has been shown to induce a phenotypic switch of muscle macrophages causing a reduction in pro-inflammatory cells (M1 macrophages) and an increase in anti-inflammatory cells (M2 macrophages and IL-10) to reduce pain, swelling and inflammation at local tissue (Da Silva *et al.* 2014).

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AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

Acupuncture Research Published in 'Nature Medicine'

Inflammatory effects of Acupuncture continued:

- Torress-Rosas *et al.* (2014) states sciatic nerve activation with electroacupuncture controls systemic inflammation by inducing vagal activation of aromatic L-amino acid decarboxylase, leading to the production of dopamine in the adrenal medulla. This can provide therapeutic advantages to control inflammation in infectious and inflammatory disorders.

Torres-Rosas R., Yehia G., Pena G., *et al.* (2014) Dopamine mediates vagal modulation of the immune system by electroacupuncture. *Nature Medicine* **20**, 291-295.

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Research into Practice

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AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

Take Home Messages

- Staying current reduces the burden of EBM - Ask your professional organisations to help you?
- Access to the AACP's "Evidence and Commissioning Resource"
- Access Research Journal Contents 'Alerts' for a quick review of relevant research
- Use the review of Journal articles for your CPD activity and form journal groups
- Technology allows you to be aware of current research:
  Follow Social media for updates – e.g. 'theAACP' on facebook, @AACP_Physio on twitter
- Keep it simple - Don't reinvent the wheel

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

Questions?

? ? ?

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

International Membership of the AACP is Available to Physiotherapists

BENEFITS OF AACP MEMBERSHIP

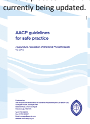
Membership of the Acupuncture Association of Chartered Physiotherapists (AACP) entitles physiotherapists to:

» consultative advice from experienced physiotherapists on the use of acupuncture
» consultative advice and support from AACP on regulatory and licensing issues
» discounts from publishers
» access to online research databases
» apply for funding for acupuncture research
» apply for funding for travel and conference fees for events associated with the promotion of acupuncture
» receive the AACP journal and newsletters
» treat patients registered with Bupa and Prudential with acupuncture
» treat patients in many National Health Service (NHS) trusts with acupuncture
» treat patients in the Her Majesty's Armed Forces with acupuncture
» avoid the need to pay for a licence to practise acupuncture in the Inner London Boroughs
» reduced fees for the AACP Annual Conference
» stand for the AACP Board
» access reduced fees at AACP-organised training and continuing professional development (CPD) days
» remain on the AACP register on completion of 10 hours of recognised CPD every 2 years.
» vote at the AACP Annual General Meeting

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

Benefits of AACP membership

The AACP publish guidelines for safe practice which are currently being updated.



The AACP produce acupuncture in physiotherapy information leaflets for members.
These help to promote acupuncture in physiotherapy to patients.

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

AACP posters to promote acupuncture as part of physiotherapy to patients.

AACP ACUPUNCTURE ASSOCIATION of CHARTERED PHYSIOTHERAPISTS

Useful websites

- www.aacp.org.uk & www.aacp.uk.com
- http://clinicalevidence.bmj.com
- http://zetoc.mimas.ac.uk
- http://www.evidence.nhs.uk
- http://acupunctureresearch.org.uk

Appendix B4: Presentation

Physiotherapy Training Symposium, Leicestershire, UK. 15th November 2012

THE UNIVERSITY of York
The Department of Health Sciences

Cohort Randomised Controlled Trial Design
Acupuncture & Manual therapy for LBP

Vivienne Dascanio

15th November 2012

- Vivienne Dascanio
- Private Practice Owner
- Chair - Acupuncture Association of Chartered Physiotherapists (AACP)
- PhD final year student at the University of York – Studying Acupuncture and Manual therapy for LBP, using a novel trial design

---

Acupuncture

- Supporting the evidence base
- Intention to find an appropriate Placebo for RCTs
- Placebo – shallow needling, non point needling, non penetrating needles, alternative treatments as standard care
- Separating the placebo effect from the treatment effect – do we know the physiology of the treatment effect?

- MRI studies showing Brain activity on use of placebo interventions – not inert
- Thomas Lundeberg et al 2011
  - Is Placebo Acupuncture What It Is Intended to Be?
  - Open access - Evidence-Based Complementary and Alternative Medicine Volume 2011, Article ID 932407, 5 pages doi:10.1093/ecam/nep049 – Commentary
- Complementary and alternative therapies for Back Pain II – Evidence report no 194 AHRQ Publication No.10 (11)-E007, October 2011

NICE Guidelines - LBP

- NICE Guidelines for LBP 2009
- Recommend:
- Structured exercise programme 8 sessions over 12 weeks
- Manual therapy 9 sessions over 12 weeks
- Acupuncture 10 sessions over 12 weeks
- But; No advice with what to offer first or in what order? If one didn't work offer another!

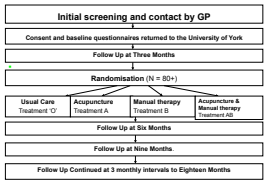
NICE EVIDENCE BRIEF REVIEW

For Manual therapy
- 7 RCTs –
- 1x High quality with low risk of bias
- 1x Well conducted with low risk of bias
- 5x Low quality studies with high risk of bias (due to lack of power to the studies, lack of available detail of the methodology and randomisation processes and high risk of dropouts and loss to follow-up)
- 3 out of these 5, found no difference between the manual therapy intervention and the control
- The guideline also included an RCT on massage.
- Though systematic reviews have been published on manips and mobs, they were excluded from NICE guidelines due to heterogeneity

For Acupuncture
- 1x systematic review with high quality and low risk of bias. Positive effects, but small.
- 3x RCTs well conducted RCT with low risk of bias
- 1x RCT with high risk of bias,
- (1x RCT on neuroreflex therapy, 1x RCT Percutaneous Electrical Nerve Stimulation (PENS)

- Cohort Design RCTs
- Relatively new and minimally used design
- Great potential for future design of trials due to distinct benefits
- LBP Cohort → 18months

Flow Diagram



- Advantages of Cohort Design RCT
- Recruitment from a Cohort
- Only randomised those compliant with follow-up
- Reduces attrition, the risk of selection bias
- Reducing need for a larger sample size
- Reduces resentful demoralisation of control group
- Useful for prevalent conditions, i.e. back pain
- Allows simultaneous follow-up as well as allocation

- Disadvantages
- Can't be used for an incident condition, i.e. treatment trial of fracture of humerus
- The need to recruit participants remains, which can be problematic
- Up take of treatment could be lower than a normal RCT

- Conclusions
- The Cohort RCT offers advantages over the standard RCT
- Exploits database recruitment
- May provide a worthwhile reduction in attrition
- Minimises bias within trials

- References

- **Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design** - *BMJ 2010;340:bmj.c1066*
- **Designing Randomised Trials in Health, Education and the Social Sciences – An Introduction.** David J Torgerson and Carole J Torgerson – Palgrave Macmillan - 2008

- Recognition & Thank you
- My supervisors David Torgeson and Yvonne Birks
- Hugh MacPherson and the NIHR programme grant
- The Acupuncture Association of Chartered Physiotherapists (AACP)

- Thank you

- Vivienne Dascanio
- chair@aacp.uk.com

15th November 2012

Appendix B5: Conference Presentation

Commissioning – A Way Forward. 6th AACP Annual Conference Piercing the Puzzle of Persistent Pain. Hinckley, Leicestershire UK. 13th May 2012

Commissioning – A way forward

Dimitri Varsamis & Vivienne Dascanio

www.aacp.uk.com

What is Commissioning

Role of commissioners:
To commission a comprehensive and equitable range of high quality, responsive and efficient services within allocated resources and across all service sectors and the performance management of these services.

The public body decides what it wants to achieve (its strategy), what services it wants (analysis), how much money it has for them and how it is going to get the services (planning), and then goes about putting them in place (sourcing) and making sure they are delivered properly (monitoring and review).

Procurement is one part of the commissioning process.
It is about purchasing the service the public body has decided to buy and giving a contract to the organisation that provides the service.

Commissioning should be understood by health and care as a cycle of activity

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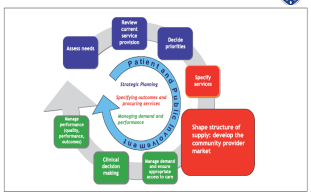
What is Commissioning



From: Transforming Community Services: Ambition, Action, Achievement

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What is Commissioning

Mark Britnell, the then DH Director General of Commissioning, said in 2007: 'The history of commissioning in the NHS has been turbulent since its introduction as "purchasing" in 1991: since then it has undergone seven reorganisations and has had no chance to mature as a discipline'.
2 more since 2007!

These definitions, of course, are set in the context of the healthcare systems in England and Northern Ireland, as a market-based context has been increasingly eroded or extremely limited in Scotland and Wales.

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GPs as commissioners

Clinical Commissioning Groups (previously also known as GP Consortia)
•GPs currently play a very important role in determining the care that their patients receive, not only in the surgery but also through referrals for more specialist treatment.
•Also, GPs are arguably better placed than PCTs to determine what services should be available for their patients.

•The plan is for GPs to be responsible for commissioning the majority of services.
•The NHSCB will commission services including: primary medical, dental, ophthalmic care, community pharmacy, specialised services and prison health services.

Of course making GPs the equivalent of senior PCT staff is not going to be any easy ride, for anyone!

www.aacp.uk.com

Contracting

•90% of community services in 2009 was funded through block contracts.

Block contracts, however, do not reward people for providing high quality services or improving value for money, or encourage innovation.

•You will need to think and be prepared to think on how to "cut" the service you provide.
•Most of this thinking (and definitely the decision) will be done by the commissioner, but you should not shy away from recommending a re-think.

Spectrum of different "currencies" – next slide

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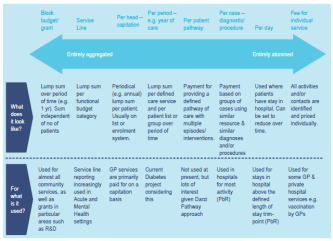

From: Transforming Community Services, Currency and Pricing Options for Community Services

www.aacp.uk.com

Contracting: standard contracts

Several of the contracts used to commission NHS-funded services are standard documents produced by the DH.
GP commissioners, as they take on commissioning responsibility, will have to use these, for all NHS funded services they commission.

These are lengthy and complex contracts, which contain many mandatory terms. They also contain very specific provisions about contract management, including an escalation system for dealing with any issues. This includes serving notices, having meetings and putting in place remedial plans. It will be important for someone to be familiar with these processes.

In the longer term, the **NHS Commissioning Board** will be responsible for producing any applicable contractual models.

There are currently standard contracts for acute, mental health, community, care home and ambulance services.

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Decommissioning and Disinvestment

•Half way through NHS efficiency savings £20bn+ to 2014;
•the decommissioning challenge has been considerable

It is the process of planning and managing a reduction in service activity or terminating a contract in line with commissioning objectives

• Resources released can be reinvested in more productive services, better products and more efficient assets
• Must be planned and proactive, not reactive

Alternative to direct decommissioning is to improve / change contracting:
•Open competition (e.g. AQP)
More efficient, higher quality providers thrive; others withdraw service

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Any Qualified Provider – the theory

•The governmental and EU procurement rules do not impose a blanket obligation to run tender processes for all clinical services.
•The Department of Health's procurement guide also emphasises that there is no general requirement to do so.

•Under the AQP model, any provider who is able to provide a specific service and meets the required minimum standards, is able to be listed as a possible provider.
•No provider has any guarantee of any volume of business. Instead, patients are able to choose which provider on the AQP list they wish to see.
•There is no need to run a tender to put together an AQP list.
•In the future, a provider will need to be jointly licensed by the CQC and Monitor, in order to be on an AQP list.
•There is an intention to significantly increase the use of the AQP model, across most sectors of care. As well as opening up patient choice, one of its stated aims is to simplify the procurement process.

Any Qualified Provider – the theory

AQP works best where:
– Demand is manageable
– There are no economies of scale
– Applied to Routine Elective Services
– There are low barriers to market entry
– A service will not create a monopoly
– there needs to be many providers willing to compete

AQP does not work where:
– High value, low volume or specialised services
– There is no control over demand
– There is a very limited market – few providers / high barriers to market entry
– A service is new and has not been commissioned before
– There is a need for high levels of control to mitigate financial & reputational risk
– There is Unplanned Care/Complex Medical Conditions

Any Qualified Provider – recently…

•In 2010, Government reaffirmed commitment to increase choice and personalisation in NHS-funded services
•Choice can be in terms of way care is provided or budgetary control to self manage
•In July 2011, DH published guidance on how to make this happen, at PCT Cluster level, for community or mental health services

•AQP is being implemented based on introducing competition based on Quality and not Price
•Patients referred to specific services under AQP will be able to choose from a list of qualified providers

•Note: Any **Willing** Provider to Any **Qualified** Provider

Any Qualified Provider – Where are we now?

•Across all England PCT Clusters, based on the priorities of the shadow CCGs, three service lines were agreed and selected (different in each Cluster)
•For PCT clusters, this has been very challenging, as different contracts exist on same service for each PCT, so aggregating and harmonising these at Cluster level has not always been possible.

•Implementing AQP is starting NOW, with patients being offered choice of provider by Sept 2012

•E.g. the South-East London PCT Cluster is AQPing: continence, wheelchairs and hearing services

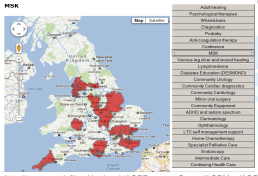
Current AQP examples

North East Essex
• In 2008 existing providers were invited to bid
• 20 providers – 11 Physiotherapists, 4 Chiropractors, 5 osteopaths
• 2009/2010 - 2810 patients seen
• Patients to be seen within 2 weeks (97% achieved)
• 4 treatments provided per patient (including assessment)

12 month review
• Referral to spinal surgeons reduced by more than 25%
• Reduced primary care consultations, imaging and medication costs
• Reduced inappropriate referral to secondary care
• 99.6% patient satisfaction rate
• 92% GP satisfaction rate

• AQP in other areas:

MSK



http://www.supply2health.nhs.uk/AQPResourceCentre/AQPMap/AQPMap.aspx

What the AACP are doing to support members with commissioning?

The Commissioning and research pack – developed and distributed
Presentations and representation at the Houses of Parliament
Facilitating member representation at NICE scoping events and providing evidence for guideline development groups
Representing and campaigning for members at local & national levels
Promoting AACP members as cost effective employable practitioners
Advising members how to present themselves as cost effective practitioners
Providing training and professional support
Disseminating acupuncture research & providing clinically reviewed summaries

What can AACP members can do?

Be prepared!! Know your service and costs
Use the commissioning & research pack - present it to managers, GPs, commissioners
Write to GP's and commissioners, advise them of your excellent service and follow up with face to face presentations
Collect audit data on success and cost effectiveness of your service – PROMS & PREMS
Build relationships with local GP's and commissioners
Apply or encourage managers to apply for public health funding for services
Attend NICE scoping meetings and be a voice for your profession
Keep up to date with the latest research and evidence base
Be PR savvy, we all love our profession – we need to get better at shouting about how good we are and promoting our success

Public Health Opportunities

New Funding Source – Public Health England - under the new commissioning structure
Opportunity for funding service provision
Investigate Public Health priorities locally – consider if able to provide services for these
- obesity, fitness, return to work

NICE Guidelines – Where do they fit?

Commissioning bodies will seek guidance from guidelines:
• Require evidence base and cost effective analysis
• Future services will be informed by guidelines
• Very important physiotherapy and acupuncture are included in the guidelines

Any Qualified Provider – What do GPs as Commissioners AND / OR Providers think?

•Many GPs, who in essence are providers of services to the NHS (Primary Care), have always been involved to an extent with providing additional services

•They see AQP as an opportunity to extend the services they provide and also important to enter the market, in order to keep large private organisations out

•Many GPs are therefore looking at suitable models that suit them: from providing a service themselves from the practice by employing directly the relevant staff, to sub-contracting out the delivery completely.

One last thing..

Be prepared to start thinking in terms of a patient's journey (ie patient pathway) rather than the current segmentation of services.

Work underway to fund (and therefore pay) for "year of care" services, ie for the whole package of care that say a person with diabetes will use, irrespective of how many appointments, and who provides the care etc..

The old way of thinking:

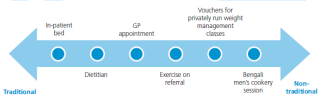
Staying Healthy	Maternity & Newborn Care	Children & Young People	Long-Term Conditions	Acute Care	Planned Care	Mental Health	End of Life Care
· Obesity · Alcohol misuse · Smoking prevention cessation services · Screening · Sexual health · Drug misuse · Falls · Prison Health	· Maternity Services · Neonatal care	· Depression / anxiety in children / ADHD · Children with complex needs · Looked after children · Safeguarding children · Asthma · Teenage conception	· COPD · Diabetes · Coronary heart disease · Chronic kidney disease · Epilepsy · Neurological conditions	· Stroke · Critical care · Intensive care · Acute major trauma	· Continuing care · Orthotics · General dentistry · Low volume specialties · Cancer · Pain management · Orthopaedics	· Dementia · Adult mental illness · Adult psychological · Services · Specialist mental health · Learning disabilities	· End of Life

From: Commissioning Support for London training material, 2011

One last thing..

The different way of thinking: "what will make my patient better?"

Where do you see acupuncture in physiotherapy?



Thank you

Any Questions?

References and Useful links:

The Chartered Society of Physiotherapy (CSP)
http://www.csp.org.uk/professional-union/practice/your-business/commissioning-planning/any-qualified-provider-nhs-england

The Department of Health (DoH)
http://healthandcare.dh.gov.uk/any-qualified-provider-2/

NHS supply2health – Resource centre for Any Qualified provider
http://www.supply2health.nhs.uk/AQPResourceCentre/Pages/AQPhome.aspx

"Equity and Excellence: Liberating the NHS", White Paper consultation, July 2010
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance / DH_117353

"Liberating the NHS – managing the transition", letter from Sir David Nicholson, NHS Chief Executive, 17th February 2011
http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_124440

NHS Evidence – QIPP: Musculoskeletal physiotherapy: patient self-referral
http://www.library.nhs.uk/qipp/ViewResource.aspx?resID=406806

References and Useful links:

Transforming Community Services (DH)
http://www.dh.gov.uk/en/Healthcare/TCS/index.htm

A beginner's guide to commissioning (NAVCA)
http://www.navca.org.uk/publications/beginnersguide

A guide to developing and commissioning non-traditional providers to support the self management of people with long term conditions 2011 (DH)
www.diabetes.nhs.uk/year_of_care

Implementation Pack for AQP: MSK services for back and neck pain (Supply2Health)
http://www.supply2health.nhs.uk/AQPResourceCentre/AQPServices/PTP/NeckBackPain/Pages/Home.aspx

Introduction to the standard NHS contract (Mills and Reeve)
http://www.commissioningportal.co.uk/contract2012

CSP survival guide workshops
www.csp.org.uk

Appendix B6: Houses of Parliament (HoP) Presentation

Musculoskeletal Injury: Cost-Effective Solutions for the NHS: Welcome, Introduction, LBP and Acupuncture, and Discussion Section Presented by VCD. HoP London. 23rd April 2012

Musculoskeletal Injury: Cost-effective solutions for Industry and the NHS

The Acupuncture Association of Chartered Physiotherapists

Vivienne Dascanio, Lesley Pattenden, Merian Denning, Paul Battersby

www.aacp.uk.com

The Acupuncture Association of Chartered Physiotherapists

Integrating Evidence-Based Acupuncture into Physiotherapy for the Benefit of the Patient

- 6500 members - largest member organisation providing acupuncture
- Physiotherapists are trained in acupuncture at a post graduate level

www.aacp.uk.com

Patient safety:

- Patient and clinician safety is rightly of paramount importance.
- Acupuncture when administered by suitably qualified and competent practitioners has been shown to be a safe intervention.
- A prospective survey of 66,229 patients treated with acupuncture by members of AACP and BMAS showed no serious adverse events that required hospital intervention (1)

Current trends in Acupuncture treatment:

- It is estimated that about 4 million sessions of acupuncture are provided per annum and of these, approximately one third are given within the NHS mainly for musculoskeletal complaints such as osteoarthritis and low back pain (2).

www.aacp.uk.com

Over 200 types of Musculoskeletal Disorders (MSD) (3)

- Low Back Pain
- Neck Pain and Migraines
- Upper Limb
- Osteoarthritis

www.aacp.uk.com

The Scale of the Problem

- 7.6 million working days lost due to MSD's 2010/11 (4)
- 60% of those on long term sick cite MSD's as the reason for absence (3)
- 22% of people on incapacity benefit suffer from MSD's (5) (equating to approximately 500,000 people)
- MSD's are the most common reason for repeat consultations with GP's, accounting for 30% in primary care (3)
- Estimated MSD's cost society £7.4 billion per year (5)

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LOW BACK PAIN

(courtesy Wellness Biology)

Vivienne Dascanio

www.aacp.uk.com

Low Back Pain

- LBP accounts for more than 40% of all MSD's (3)
- NICE report nearly everyone within the UK will be affected by LBP at some point during their lifetime (6)
- Five million working days lost each year due to LBP (7)
- 62% sufferers will continue to suffer with their LBP beyond 12 months, 33% of these will have a recurrence causing absence from work (8)

www.aacp.uk.com

Musculoskeletal Physiotherapists are experts in the assessment and treatment of MSD's

- Treatments include:
  - Manual therapy
  - Acupuncture
  - Exercise prescription
  - Electrotherapy
  - Self education
  - Postural and workplace advice

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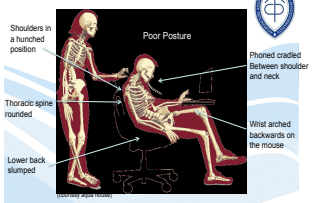

(courtesy Alpha House)

A physiotherapist would address these issues as part of their holistic treatment approach

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2 Government departments in Northern Ireland, provided early access to physiotherapy for staff with MSD's (9)

- 80% reported physiotherapy prevented them from having sick leave
- 80% of those off sick reported the physiotherapy enabled them to return to work more quickly.

Thus saving money and reducing sickness at work.

In Cambridge Self-referral to physiotherapy reduced GP costs in prescription and diagnostic tests.
Saving £12,000 per GP practice (10)

In Scotland self-referral to physiotherapy saved approximately £2.5million per year (10)

NECK PAIN & MIGRAINE

(Courtesy physio-solutions)

Lesley Pattenden M.C.S.P

Neck Pain/Migraine
The scale of the problem.....

Neck Pain...
Between 26% and 71% of the adult population can recall an episode of Neck Pain or stiffness
10% males and 17% of women have experienced pain lasting longer than 6 months (1)
Migraine...
Lifetime prevalence of 15%-20% of people who experience one sided symptoms often with photophobia / nausea
Cost of 20 Billion pounds per year (3)
Tension Type Headaches...
Episodes last between 1 and 15 days per year (and classed as "frequent")
These are suffered by 30% and 78% of the population (4)

Cochrane review for Neck Pain (1)

OUTCOME.....

Moderate Evidence that Acupuncture is:
- Better than some sham treatments
- Better than Waiting List Control
- More effective than inactive treatments at short term follow up

Cochrane Review for Migraine Prophylaxis (3)

"the studies suggest that migraine patients benefit from acupuncture, although the correct placement of needles seems to be less relevant than is usually thought by acupuncturists"

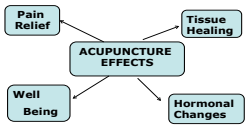
Acupuncture Choices.....

WESTERN	EASTERN
SEGMENTAL	MERIDIANS
MYOFASCIAL TRIGGER POINTS	ROOTS and BRANCHES
SENSORY STIMULATION	EMPIRICAL POINTS
TISSUE CHANGES	

Cochrane review for Tension Type Headaches

"the available evidence suggests that acupuncture could be a valuable option for patients suffering from frequent tension-type headache"

Acupuncture Effects.....

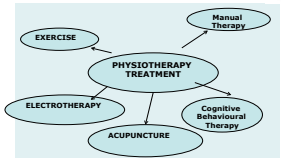


Whiplash Associated Disorders (WAD).. Chartered Society of Physiotherapy

Best Evidence for Best Practice:
In the sub acute stage (between 2 and 5 weeks)

" Acupuncture may be effective in reducing neck pain (*majority view 52%)*

Treatment Choices



What the critics say.....

"Research" requires careful interpretation

"Acupuncture: a rather theatrical placebo, with no real therapeutic benefit in most, if not all, cases (5)

"The specific effects on non-pharmaceutical treatments are not always divisible from placebo effects and may be missed in randomised trials". (6)

UPPER LIMB PAIN

(Courtesy Merian Denning)

Merian Denning

Arm pain

A major cause of incapacity to work in the UK.

4.1 Million working days lost annually due to arm pain (17)

1 in 7 primary care consultations in working age population (18)

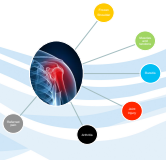
Shoulder pain.

Many causes of shoulder pain leading to substantial disability

Sick leave can account for up to 80% of total cost of health care (19)

Early intervention can reduce impact of problem and £££'s

Pilot study N.Ireland – 80% participants avoided sick leave (21)

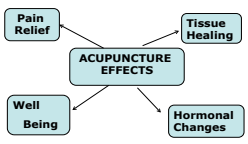


Evidence based treatments

CSP guidelines for treatment of sub-acromial impingement (22)
CSP guidelines for treatment of frozen shoulder (23)

Cochrane Collaboration - supervised exercises, joint mobilisation, +/- corticosteroid injection (24)
Acupuncture-short term benefit in pain relief and improved function.
Need for more data (25)

Why use acupuncture?



Exercise
Acupuncture
Advice
Bracing
Topical NSAID
Injection-various
Surgery

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OSTEOARTHRITIS

(BMJ blogs)

Paul Battersby

www.aacp.uk.com

Osteoarthritis is the most common form of joint disease. It causes pain and stiffness in joints and affects at least 8 million people in the UK today (Arthritis Research UK, 2011). The knee is one of the most commonly affected joints. Prevalence increases with age and the first manifestations of primary osteoarthritis of the knee can be present by the age of forty (Backer et al., 2010). The management of knee pain from osteoarthritis (OA) is limited to several therapeutic interventions, one being non steroidal anti-inflammatory drugs and analgesic medications.

www.aacp.uk.com

Osteoarthritis is a disease of the joints characterised by cartilage destruction and new bone formation. Although not fully understood, genetic and biochemical factors play a major part in the development of osteoarthritis. There are however, a number of other predisposing factors which may also contribute to the development of osteoarthritis.

(Courtesy of sportsinjuryclinic.net)

www.aacp.uk.com

Like many disabling conditions osteoarthritis imposes a sizable economic burden on society, with cost of illness estimates accounting for 2.5% of gross national product in developed countries (Whitehurst et al 2011). In the UK this amounts to £18 billion.

(Courtesy of sportsinjuryclinic.net)

www.aacp.uk.com

There is also the societal perspective which increases the cost indirectly to society, these factors are due to;

- The reduced productivity in the work place
- Knee pain absenteeism (206 million working days per year)

This cost would be almost impossible to calculate however some recent studies have ascertained that; work absenteeism is unlikely to be more frequent in people receiving acupuncture treatments.

www.aacp.uk.com

According to Whitehurst's (2011) study there would be a threshold of £20,000 per additional QALY, and that there is a 77% chance that true acupuncture provided by NHS physical therapist would be a cost effective adjunct to a course of advice and exercise.

This would be a magnitude of difference in health care resource use.

Utilising an AACP practitioner not only do patients receive exercise and advice they also receive acupuncture.

www.aacp.uk.com

By utilising this type of therapy within the National Health Service means that the wider population can benefit as it is a truly portable therapeutic intervention.

www.aacp.uk.com

Thank you

The Acupuncture Association of Chartered Physiotherapists

Integrating Evidence-Based Acupuncture into Physiotherapy for the Benefit of the Patient

www.aacp.uk.com

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www.aacp.uk.com

NICE GUIDELINE 2009 / 031

"The National Institute for Health and Clinical Excellence (NICE) and the National Clinical Guideline Centre today (Wednesday 27 May 2009) publish a guideline to improve the early management of persistent non-specific low back pain. This covers people who have been in pain longer than six weeks but less than one year, where the pain may be linked to structures in the back such as the joints, muscles and ligaments. Setting out a range of effective mainstream and complementary treatments, the guideline recommends what care and advice the NHS should offer to people affected by low back pain."

"Recommendations from the guideline for health professionals include: Offer one of the following treatment options, taking into account the patient's preference: an exercise programme, a course of manual therapy including manipulation, or a course of acupuncture (more details on each below)":
"Consider offering a course of acupuncture needling, up to a maximum of 10 sessions over a period of up to 12 weeks"

www.aacp.uk.com

Elaine Buchanan, Guideline Developer and Consultant Physiotherapist said:

"This guideline provides an essential opportunity for physiotherapists and other health professionals to ensure that people with low back pain benefit from evidence-based treatment. In addition to advice and medication, people who have back pain persisting beyond six weeks now have the choice of three effective treatments: acupuncture, exercise and manual therapy. The small number of people who continue to have problematic back pain following these therapies will have access to an intensive treatment programme, run by a team of specialists. These programmes combine physical and cognitive behavioural approaches to help people maximise their quality of life, by teaching them skills and techniques which reduce the disability and distress caused by their condition."

www.aacp.uk.com

Appendix B7: Conference Presentation

The 14th International Acupuncture Research Symposium of ARRC. London, UK. 25th February 2012

THE UNIVERSITY of York

The Department of Health Sciences

Cohort Randomised Controlled Trial Design

Vivienne Dascanio

25th February 2012

THE UNIVERSITY of York

The Department of Health Sciences

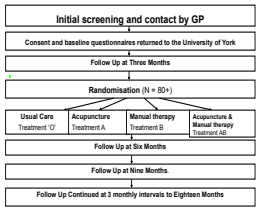
Cohort Design RCTs

- Relatively new and minimally used design
- Great potential for future design of trials due to distinct benefits
- LBP Cohort → 18months
  - Time
  - RCT
  - QOL / LBP Incidence

THE UNIVERSITY of York

The Department of Health Sciences

Flow Diagram



THE UNIVERSITY of York

The Department of Health Sciences

Advantages of Cohort Design RCT

- Recruitment from a Cohort
- Only randomised those compliant with follow-up
- Reduces attrition, the risk of selection bias
- Reducing need for a larger sample size
- Reduces resentful demoralisation of control group
- Useful for prevalent conditions, i.e. back pain
- Allows simultaneous follow-up as well as allocation

THE UNIVERSITY of York

The Department of Health Sciences

Disadvantages

- Can't be used for an incident condition, i.e. treatment trial of fracture of humerus
- The need to recruit participants remains, which can be problematic
- Up take of treatment could be lower than a normal RCT

THE UNIVERSITY of York

The Department of Health Sciences

Conclusions

- The Cohort RCT offers advantages over the standard RCT
- Exploits database recruitment
- May provide a worthwhile reduction in attrition
- Minimises bias within trials

THE UNIVERSITY of York

The Department of Health Sciences

References

- **Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design** - *BMJ 2010;340:bmj.c1066*
- **Designing Randomised Trials in Health, Education and the Social Sciences – An Introduction.** David J Torgerson and Carole J Torgerson – Palgrave Macmillan - 2008

THE UNIVERSITY of York

The Department of Health Sciences

Recognition & Thank you

- My supervisors David Torgeson and Yvonne Birks
- Hugh MacPherson and the NIHR programme grant
- The Acupuncture Association of Chartered Physiotherapists (AACP)

THE UNIVERSITY of York

The Department of Health Sciences

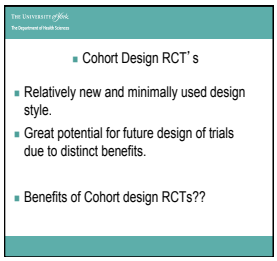
Thank you

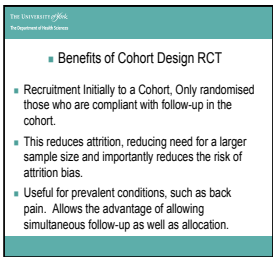
- Vivienne Dascanio
- chair@aacp.uk.com

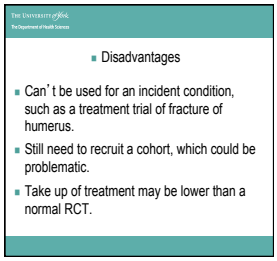
25th February 2012

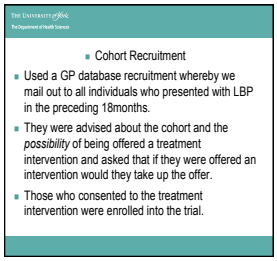
Appendix B8: Course Lecture – *University of York*

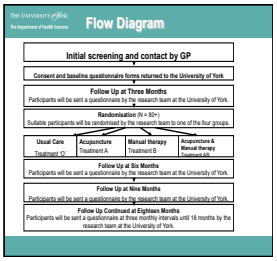
Maximising participant recruitment to randomised controlled trials course. External participants – Department of Health Sciences. York Trials Unit – University of York. 28th November 2011

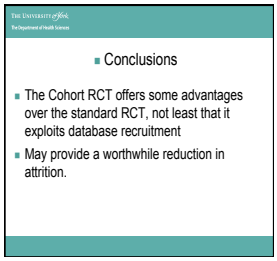


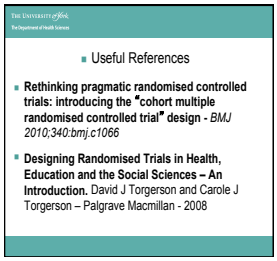


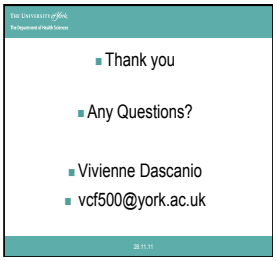












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Appendix B9: Conference Presentation

Commissioning Acupuncture in the NHS. British Acupuncture Council Annual (BAcC) London UK. 18th September 2011

British Acupuncture Council

Commissioning Acupuncture within the NHS

Nick Pahl and Vivienne Fort

18th September 2011

British Acupuncture Council

About us

Nick Pahl – CEO, British Acupuncture Council; and held senior public health and NHS commissioning roles
nick@acupuncture.org.uk

Vivienne Fort – Chair, AACP
chair@aacp.uk.com
Private Physiotherapy Practice Owner and Director; Worked in and alongside the NHS

British Acupuncture Council

Agenda

1. What is commissioning?
2. Who commissions?
3. Policy context
4. Preparation
5. Ask
6. Make the case
7. Convince

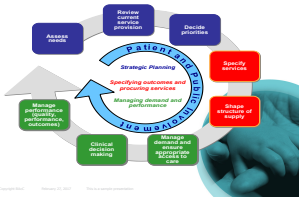
Questions

British Acupuncture Council

1 What is commissioning?

1. Commissioning involves assessing the health needs of the (local) population and reviewing how well services meet those needs
2. Commissioning is a way of identifying priorities for investment
3. Commissioners design services with providers to meet patient needs/demands
4. Commissioners then contract with providers, after various vetting processes are be met
5. Commissioners ensure services are provided effectively, and monitor quality and outcomes

British Acupuncture Council



British Acupuncture Council

2 Who Commissions?

-England - new Consortia (PCTs will hold responsibility until 2013). The NHS Commissioning Board will commission GP services and specialised services

-Scotland – 14 Health Boards

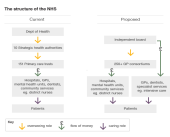
-Wales – 7 Health Boards

-Northern Ireland – Health and social care Board

- new Individual service users or patients groups – through personal budgets and treatment choice

British Acupuncture Council

Overview of who commissions in England



British Acupuncture Council

3 Policy context

- Commissioning Consortia are new local NHS commissioners for health services in England
- NHS now open for any "qualified willing provider" to provide services. An application process is required if these services are to be "re-commissioned".
- Acupuncturists will need to "keep their nose to the ground" to know when re-commissioning occurs
- Commissioning priorities will be outcome focused – so acupuncturists will have to justify what outcomes they achieve. "Patients are at the heart of everything NHS does" so audits of local patients may be good evidence
- The NHS across the UK has an urgent need to save money and be cost effective. When acupuncturists links with the NHS, they need to have this in mind

British Acupuncture Council

Any Qualified Provider

- Definition – the impact of this scheme
- Time frame
- Key points
- Quality is the objective – Budget cuts of £40million
- Future plans to role out this scheme to other services
- Future outlook on NHS services

British Acupuncture Council

4 Preparation

- Read your local Commissioning plan to understand priorities. Ask for this or look on the website
- Ensure you understand the evidence base for acupuncture and collect any local data you have. If you are not doing so, start to monitor your own patient outcomes using MYMOP
- Build relationships with your local providers, both at local authority level and NHS commissioners.

British Acupuncture Council

5 Ask

Are there opportunities to provide acupuncture:

- within GP practices?
- within any new pathways you are commissioning e.g. for musculoskeletal?
- in "intermediate care" – this is care by acupuncturists for those coming out of hospital but not ready to go home – clinics/hospices
- in hospitals e.g. within pain clinics or in hospital wards?

British Acupuncture Council

NHS Services

- Find out what services exist – Speak with them
- Feedback on NHS Acupuncture Services from BAcC & AACP members
- Current services – the situation
- Pro's and Con's to life in the NHS
- Working inside or alongside – Which is preferable for you?
- Benefit to Private Practitioners of availability of NHS Acupuncture services

British Acupuncture Council

6 Make the case

Acupuncture can:

- Improve outcomes for people with variety of issues such as pain, mental ill-health
- Reduce long-term demands on health and social care services e.g. reducing repeat visits, prescriptions and onward referrals to other "pathways"
- Support "personalisation" – for those on individual budgets
- Support healthy lifestyles

British Acupuncture Council

7 Convince

Member of the BAcC – a Professional body which has:

- Regulatory and Clinical Governance function - codes of practice, complaints, conduct and ethics.
- Comprehensive accreditation process for training (BAAB)
- Continuing Professional Development to ensure the highest patient standards are maintained
- Comprehensive insurance cover

British Acupuncture Council

As a BAcC member you can:

- Provide patient-centred, highly effective services
- Meet requirements to provide effective, quality care to NHS patients
- monitor relevant patient performance and research data
- offer acupuncture for a variety of issues

British Acupuncture Council

Other things you can do

- Ask for contacts of planned new "health and well being boards" – which will comprise of GPs and councillors and are being set up. Contact those members
- Ask local authorities to what extent people use acupuncture as part of their personal budgets?
- Ask to join local health watch groups where possible
- Read the BAcC NHS toolkit!
- Make links with AACP members

British Acupuncture Council

You can do it! – examples of NHS funding

- Mendip PCT - acupuncture integrated into its musculoskeletal service
- Gateway clinic in London – acupuncture treating immune deficiency, mental health problems and addictions
- Nottingham MSK service
- Manchester Hospital Mental Health service
- Derriford Hospital, Plymouth maternity service
- AACP services

British Acupuncture Council

Thankyou.....Questions?

Appendix B10: Conference Poster - presentations at:

- *National Conference of the Acupuncture Association of Chartered Physiotherapists (AACP) Still Pointing the Way after 30 Years. May 2014*
- *National Conference of the Acupuncture Association of Chartered Physiotherapists (AACP) Acupuncture at the Sharp End. May 2013*
- *The 14th International Acupuncture Research Symposium of ARRC (The Acupuncture Research and Resource Centre). February 2012*
- *The 1st UK Clinical Trials Methodology Conference of The MRC Network of Hubs for Trials Methodology Research. October 2011*

THE UNIVERSITY of York
The Department of Health Sciences

A pilot factorial randomised cohort trial of manual therapy or acupuncture for low back pain.

Background

- Low Back Pain (LBP) is a major health and epidemiological problem which imposes significant economic and social burden on societies [1]
- Randomised control clinical trials of acupuncture have been hampered by the challenges of assessing it as a complex intervention.
- Controlling for and separating placebo effects whilst identifying its efficacy as a treatment can be difficult [2].
- The comparison of acupuncture to other complex interventions has been recommended to assess the effectiveness of acupuncture against other interventions [3].

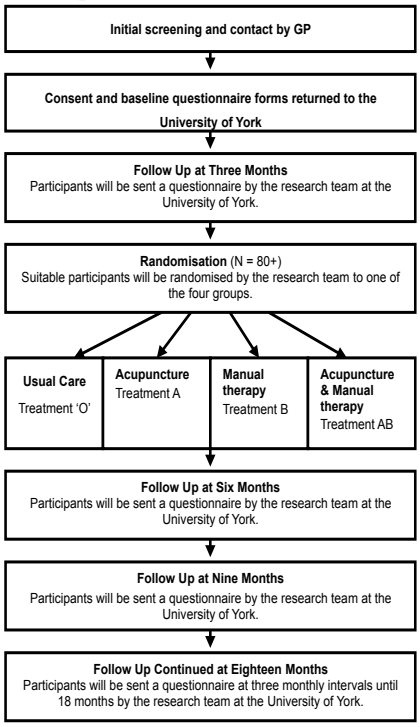
Objective

- To investigate the feasibility of undertaking a novel randomised cohort design study with a nested factorial RCT,
- Investigating acupuncture alone versus manual therapy alone versus a combination of acupuncture and manual therapy versus usual care.

Methods

- The study will follow a randomised cohort trial design and participants from the cohort will be selected to participate in the pilot trial.
- The use of this design as a recruitment method for nested trials is relatively new methodology but the cohort design has been suggested as an effective method for the use with chronic conditions [3]
- Attrition is one of the major threats to the internal validity of any trial. The design of this trial specifically reduces that threat [4].
- Using a randomised cohort design will provide a 'run-in period' of three months, from collecting baseline data to the first set of outcome data. Only participants who return their three monthly questionnaires will be eligible for randomisation to the pilot trial. As the majority of attrition occurs at the first period of follow-up in an RCT, it is expected subsequent attrition, after randomisation, to be minimal [4].

Flow Diagram



Results & Conclusions

- Recruitment for this trial is currently under way.
- The acceptability and feasibility of the design for use with complex interventions and in a common musculoskeletal condition will be discussed & analysed.

Discussion

- Retention; A two stage consent process was implemented following advice from the Ethics committee – this appears to be creating a 40% drop out rate.
- Participant acceptability and choice – 20% participants are rejecting the opportunity of Acupuncture treatment. All participants appear accepting of manual therapy.

References

- 1. Costa, L. d. C. M., C. G. Maher, et al. (2009). "Prognosis for patients with chronic low back pain: inception cohort study." BMJ **339**(oct06_2): b3829-.
- 2. Lundeberg, T.L., I. Sing, A. Naslund, J., *Is Placebo Acupuncture What It is Intended to Be?* Evidence-Based Complementary and Alternative Medicine, (2011). **Volume 2011** (Article ID 932407, 5 pagesdoi:10.1093/ecam/nep049): p. 1-5.
- 3. Furlan, A., et al., *Complementary and Alternative Therapies for Back Pain II.* 2010, University of Ottawa Evidence-based Practice Center under Contract No. 290-2007-10059-I (EPCIII). Agency for Healthcare Research and Quality. : Rockville, MD. .
- 4. Grant, J., et al., *The North West Adelaide Health Study: detailed methods and baseline segmentation of a cohort for selected chronic diseases.* Epidemiologic Perspectives & Innovations, 2006. **3**(1): p. 4.
- 5. Relton, C., et al., *Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design.* . BMJ, 2010. **340**: p. 1066.

Acknowledgements

- NIHR Programme grant project. Funding applicant Dr Hugh MacPherson, Professor David Torgerson.
- Small project grant award from Acupuncture Association of Chartered Physiotherapists (AACP)

Correspondence

- Email: Vcf500@york.ac.uk

Vivienne C Dascanio (nee Fort), Yvonne Birks, David Torgerson

Appendix C1: Ethics Approval Letter

Appendix C – Pilot Study Documentation

NHS
National Research Ethics Service

Leeds (Central) Research Ethics Committee
Yorkshire and Humber REC Office
First Floor, Millside
Mill Pond Lane
Meanwood
Leeds
LS6 4RA

Telephone: 0113 3050127

01 April 2011

Ms Vivienne Claire Fort
ARRC Building (2nd Floor)
The University of York
Heslington, York
YO10 5DD

Dear Ms Fort

Study title:	**A Cohort Design Study; Investigating Quality of Life and Treatment Selection for Individuals with Low Back Pain;Incorporating A Nested;Pilot Factorial Randomised Controlled Trial of Manual Therapy and / or Acupuncture for Individuals with Low Back Pain.**
REC reference:	**11/YH/0028**
Protocol number:	**N/A**

The Research Ethics Committee reviewed the above application at the meeting held on 18 March 2011. Thank you for attending to discuss the study.

Ethical opinion

The Committee asked you how often you intended to send out text reminders for participants to complete their questionnaires. You stated that you would only send a maximum of two text reminders as a prompt to participants.

Members suggested that you create a separate PIS and consent form for the second, randomised part of the study. Members explained that having two separate sheets will make the information clearer. You agreed that it had been difficult to condense all the information in to one information sheet.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as

one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

- The consent form should include the following standard clause '**I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [*company name*], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.**' You may remove 'medical notes' if this is not relevant to your study.

- A separate PIS and consent form should be created to make the questionnaire stage and treatment stage clearer.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Letter of invitation to participant	1.1	25 January 2011
Letter of invitation to participant	1.1	25 January 2011
GP/Consultant Information Sheets	1.1	25 January 2011
GP/Consultant Information Sheets	1.0	25 January 2011
Covering Letter		21 February 2011

Summary/Synopsis	1.1	17 February 2011
Letter from Sponsor		22 February 2011
Investigator CV		17 February 2011
Evidence of insurance or indemnity		22 February 2011
CV - Supervisor V Birks		15 February 2011
Questionnaire: Modified Oswestry Questionnaire (Validated)		
Questionnaire: SF 12 Questionnaire (Validated)		
Questionnaire: EQ5D Questionnaire (Validated)		
Questionnaire: Body Chart (Non-Validated)	1.1	14 February 2011
Protocol	1.0	17 February 2011
Participant Information Sheet: Information Sheet	1.2	14 February 2011
REC application	1.0	21 February 2011
Participant Consent Form: Consent Form	1.2	14 February 2011
Questionnaire: Roland Morris Questionnaire (Validated)		
Questionnaire: Costs Questionnaire (Non-Validated)	1.0	17 February 2011
CV - Supervisor D Togerson		15 February 2011
The Back Book		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/YH/0028	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Dr Margaret L Faull
Chair

Email: nicola.mallender-ward@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Ms Sue Final, University of York*

Leeds (Central) Research Ethics Committee

Attendance at Committee meeting on 18 March 2011

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Chris Bennett	Consultant Clinical Geneticist	Yes	
Mr Mick Burns	Senior Commissioning Manager	Yes	
Dr Margaret L Faull	Chair	Yes	
Mr Mark Godley	IT Consultant	Yes	
Dr Janet Holt	Senior Lecturer	Yes	
Ms Sarah Kirkland	Learning Disability Services Directorate	Yes	
Mr Vernon Long	Consultant Ophthalmologist	Yes	
Mrs Claire M Ramsden	Health visitor	Yes	
Dr Jinous Tahmassebi	Senior Lecturer and Specialist in Paediatric Dentistry	No	
Ms Bren Torry	Lecturer/Programme Leader	No	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Nicola Mallender-Ward	REC Co-ordinator
Mr Marc Neal	Assistant Co-ordinator

***Appendix* C2: GP Invitation letter**

THE UNIVERSITY of York

Version 1.1 (25.01.11)

DEPARTMENT OF HEALTH SCIENCES

ARRC Building, 2nd Floor
University of York
Heslington
York YO10 5DD

Telephone: 01904 32….

Email: vcf500@york.ac.uk

Dear Doctor,

The York Trials Unit, Department of Health Sciences at the University of York, has recently been awarded funding from the NHS National Institute for Health Research to undertake a cohort design investigation incorporating a nested randomised controlled trial of manual therapy and acupuncture for the treatment of low back pain. We are writing to ask if your practice would be willing to participate in this study. We enclose details of the study which has been designed to make little demand on the workload of a busy GP practice. Your time spent on the study however would be compensated by a fixed payment.

If after reading the information you and/or your partners are interested in taking part could you please complete the attached slip and return it to vcf500@york.ac.uk
If you have any questions or require any further information please do not hesitate to contact me, Vivienne Fort, Chief Investigator, on 01904 321877 /321726 or vcf500@york.ac.uk . I would be happy to provide more detailed information and will liaise with you or your practice manager regarding the study.

We look forward to hearing from you and thank you in advance for reading the information provided.

Yours sincerely

Vivienne Fort
Bsc (Hons), MCSP
Chief Investigator
York Trials Unit

Our practice/practices would like to take part in the Cohort investigation of low back pain with a nested randomised control trial of manual therapy and acupuncture

Please complete ALL sections

PCT:_____

Your name:_____

Practice name:_____

Practice address:_____
_____
_____
_____
_____

Practice telephone number:_____

Approximate practice size:_____
(number registered patients)

Please return this slip in the envelope provided

Thank You

Appendix **C3: GP Confirmation letter**

THE UNIVERSITY of York

Version1.1 (25.01.11)

DEPARTMENT OF HEALTH SCIENCES

ARRC Building (2nd Floor)
University of York
Heslington
York YO10 5DD

Telephone: 01904 32….

Email: vcf500@york.ac.uk

COHORT INVESTIGATION FOR LOW BACK PAIN

Dear Doctor,

Thank you for indicating your practice would like to take part in our cohort investigation for low back pain. We are extremely grateful for your support and are looking forward to working with you, your practice, and your patients. I am writing to you to give you some information regarding time frames and the identification of patients.

We envisage the following time frames:

- As soon as possible we ask that you search your database using your codes to identify patients who have presented over the previous 18 months with Low back pain (advice on codes etc is overleaf).
- We ask that you then report back to me the number of patients you have identified and which codes you have used for my records.
- Once you have done your database search, you should then label each patient pack with each identified patients name and address. The patient packs will contain consent forms and screening questionnaires which we will have provided and stamped for you by us. We will bring the boxes of these packs out to you.
- The patient packs then need to be sent out as soon as they are identified.

This is where the work for you stops, and the following process occurs:

- Those patients who are interested in taking part in the study return the documentation over the next three weeks to us at the University of York where we assess their eligibility using the screening questionnaire they will have completed and returned.
- Those patients who are eligible will from part of the cohort investigation. Some participants will be selected to take part in the nested randomised control trial of manual therapy Vs acupuncture Vs combined manual therapy and acupuncture Vs usual GP care. Participants will be selected for this part of the study following the return of their three monthly questionnaires. At this point we will send you a list of all your patients who have been randomised to active treatment as part of the study for your records.
- Active treatment will commence shortly after recruitment and will run for 10-12 weeks.

Identification of Patients

As you are probably aware different practices may well code back pain in different ways. We conducted a pilot trial in York with **one GP practice** and they used the following codes:

N142-1 low back pain

N145-2 back pain unspecified

16C9 chronic low back pain

N142-3 acute back pain lumbar

N145-1 acute back pain unspecified

N142 pain in lumbar spine

They excluded:

- *those under 18 years of age and those over 65 years of age,*
- *pregnant women,*
- *those suffering from serious spinal or neurological pathology or previous spinal surgery,*
- *those with blood disorders, valvular heart disease or who are immuno-comprised,*
- *those with a history of psychosis or alcohol abuse,*
- *those who have received acupuncture or manual therapy in the last 3months (if known).*

The practice size was approximately 7,000 and using the codes above they identified and mailed out to 282 patients. Out of these 282 patients, 52 returned their consent form and screening questionnaire to us at the University. Of these 52 patients who indicated an interest in being in the trial, 20 were eligible and were randomised to treatment. So as you can see a practice of 7,000 yielded 20 patients for the study.

Do not worry if your practice doesn't identify the same number as we estimate some geographical variation and of course practices are different sizes so the above figures are just a guide. The codes you use may also differ from the ones above.

In summary your practice should:

- Identify patients using any code that would pick up back pain patients at your practice who had presented between the date you conduct your search and the previous 18 months from that date.
- When doing your search only include those between 18 and 65 years of age and please exclude pregnant women and those of serious pathology as above.

I will contact you by telephone later this week or early next week to finalise the process and discuss any queries you might have. In the meantime if you require any further information please do not hesitate to contact me on the contact details overleaf.

Yours sincerely

Vivienne Fort, Bsc (Hons), MCSP

Chief Investigator, York Trials Unit

Appendix **C4: Participant information sheet one**

Patient information sheet 1 Version 1.3 31.03.11

THE UNIVERSITY of York

NHS National Institute for Health Research

Cohort Investigation of Individuals who Suffer *with Low Back Pain*

Participant Information Sheet

We would like to invite you to take part in a research study exploring patient experiences of Low Back Pain (LBP). Before you decide, it is important for you to understand why this research is being carried out and what it will involve for you.

We hope you find this information useful in making a decision whether or not to take part. Please do read the information carefully and do not hesitate to contact us if you have any further questions. Some people find it useful to discuss this information with their family and friends before making a decision.

Why have you been chosen?
You have been invited to take part in this research because you have previously been to see your GP with symptoms of Low Back Pain.

Do I have to take part?
No. It is your decision to take part or not. If you decide not to take part this will **not** affect your usual medical care or legal rights in any way.

What is the purpose of this study?
Low back pain (LBP) is a very common problem for many people in the UK and can affect the quality of life of people's lives. Many people who suffer from LBP continue to have pain for more than one year and it can become a chronic problem. Treatment for LBP has not always been shown to be effective for some people and we would like to investigate this.

We would like to look at the quality of life and the types of treatment people with LBP use. We will ask you this information using a questionnaire sent to you every three months for an 18 month period. There may be the opportunity for some individuals to receive some treatment through the study, if you have selected on your consent form to be contacted about part two; the active treatment part of the study, you MAY be contacted at a later date regarding this; however it will not be possible to offer everyone treatment and only it is only possible to be in part two (active treatments) if you are involved in the cohort study.

The active treatments that may be offered through this study are manual therapy, acupuncture, or a combination of both. All treatments will be carried out by an appropriately qualified Chartered Physiotherapist in the York area. Treatments will last between 30-45minutes and be completed over a 10-12 week period. You will not be required to pay for treatments and travel expenses will be reimbursed. After treatments you will still receive a questionnaire every three months for an 18 month period. Further information about the treatments will be provided to those who wish to be involved in part two of the study.

The University of York and the Department of Health are supporting this study. It is funded by a programme grant for applied research awarded by the NHS National Institute for Health Research. It will form part of a study which will be submitted for a PhD by Vivienne Fort.

What will happen if I decide to take part?
After you have completed and signed the consent forms and questionnaire and returned them to the University of York, they will look at your information and contact you by letter.

What will happen if I don't want to carry on with the study?
You are free to withdraw from the study at any time. You do not have to give any reason for this. Withdrawing from the study at any time will not affect you future care in any way.

Cohort study:
This will involve you receiving a questionnaire every three months for an 18 month period. This questionnaire will ask you questions about your LBP, how it affects your life and if you have used any treatments for it. It should take approximately 20 minutes to complete and pre-paid addressed envelopes are provided for you to return your questionnaires.

If you have selected on the consent form to be contacted about the active treatments, part two of the study, you may be contacted at a later date to receive some active treatment provided through the study.

What is required of me?
In addition to completing the consent forms and questionnaire included with this letter, you will be asked to complete and return a questionnaire sent to you at 3, 6, 9, 12, 15 and 18 months. These should only take about 20 minutes to complete. We will enclose a pre-paid addressed envelope each time for this purpose. The questionnaires are designed to enable us to determine how useful the treatment was for you. Questions will cover your general health, your low back pain, how the treatments worked for you, any medication you are taking, and your use of health care services. Should you experience any difficulty in completing these questionnaires then you can be offered telephone advice.

What happens to the data collected about me?
All information collected about you during the course of the study will be kept in strict confidence. The information, including your questionnaires, is subject to legal requirements and the Data Protection Act of 1998. The data will be held in a secure place in the co-ordinating centre in the University of York, all data will be kept for a minimum of 20years.

Only your GP and the principal researchers at The University of York will know which patients have agreed to be included in the study. Your personal information will not be disclosed to anyone. Any information about you which is used in reports of the study will be made completely anonymous and used in such a way that you cannot be identified.

When the study ends?
After the study has ended, additional treatments will not be funded by the research group. Your GP will be able to advise you on any other treatments that might be available to you.

Results of the research study
The results of this research study should be available in 2012. We will publish the results in a healthcare journal to provide GPs and other healthcare practitioner's with information. You will be able to access the results of this study via the following university webpage: www.york.ac.uk/healthsciences/research/trials.htm

Who reviewed the study?
Before research goes ahead it has to be checked by a research Ethics Committee. They make sure the research is fair. The study has been reviewed by the University of York Ethics Committee, NHS research approval and the Local Research Ethics Committee for the York area.

Further independent information about taking part in research - PALS
For independent information about taking part in research within the NHS, contact your local Patient Advisory Liaison Service (PALS). For NHS North Yorkshire and York telephone 0800 068800 or email nyy-pct.pals@nhs.net.

Dissatisfaction with the study
If you are dissatisfied with any aspect of this study, you can file a complaint in one of the following ways:

1. NHS complaints procedure (Tel: 01214 495725 or free phone: 0800 389 8391). Taking part in this study in no way affects your right to complain about any aspect of the way in which you have been treated during the course of this study.

Who can I contact for further information?

If you would like any further information about study, about manual therapy, acupuncture or the questionnaires please do not hesitate to contact the study's chief investigator Vivienne Fort at The University of York, she would be very happy to speak to you:

Trial Telephone Number: 0800 *****
Telephone number 01904 32**
Email vcf500@york.ac.uk

If you would like to write to the research team for any reason, please address your letter to: Vivienne Fort, Trials Unit, ARRC Building, The University of York, Heslington, York, YO10 5DD.

You can also contact the research team by sending an email to Vivienne Fort; vcf500@york.ac.uk

On behalf of the research team, thank you very much for taking the time to read this information sheet and considering whether to take part in this study.

Appendix **C5: Participant consent form – part one**

Consent Form 1 Office Use only Patient ID Number……. Version 1.3 31.03.11

THE UNIVERSITY of York

DEPARTMENT OF HEALTH SCIENCES
York Trials Unit
ARRC Building
Heslington
York YO10 5DD
Direct line: (01904) 321914
Email: vcf500@york.ac.uk

PARTICIPANT CONSENT FORM

A Cohort Investigation of Individuals with Low Back Pain

Please **initial** each box

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to consider the information, ask questions and to have them answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason or without my medical care and legal rights being affected. I understand that if I withdraw, I can ask for all record of my contact details to be deleted. ☐
3. I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports of this study. I give permission for responsible appropriate individuals working at the University of York to have access to my data. ☐
4. I agree to my General Practitioner being informed of my participation in this study. I agree if there are any problems contacting me, my GP should be contacted and asked where appropriate to contact me and for my address. ☐
5. I agree to this consent form and other data collected on me as part of this research study to be kept at York Trials Unit, at The University of York. I understand that records relating to me will be kept confidential. No information will be released or printed that would identify me without my permission, unless required by law. ☐
6. I understand that the relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the York Trials Unit, from regulatory authorities or from the NHS trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
7. I understand that this is a study collecting information by questionnaire every three months and that there may be the opportunity to be involved in some form of active treatment as part of the study; I have selected overleaf the treatments I would consider. ☐
8. I am happy to receive text and email reminders for my questionnaires ☐
9. I agree to take part in the above study. ☐

If you agree to the above nine points, please complete the personal details and the options on the reverse side of this form to select your preference.

Please return this form with the questionnaire in the pre-paid envelope provided.

Your personal information will be kept confidential and will only be used to contact you regarding the study.

If you have any questions, please contact the chief investigator Vivienne Fort on 01904 32…….

Thank you for your interest in participating in this study.

Please Turn Page Over

DEPARTMENT OF HEALTH SCIENCES
York Trials Unit
ARRC Building
Heslington
York YO10 5DD
Direct line: (01904) 321914
Email: vcf500@york.ac.uk

Additional Information:

We would like to look at the quality of life of those who suffer with Low Ba number and types of services people use.

To do this we would like to send you a questionnaire every three months for an 18 month period to ask you about you pain and if you have seen your GP or used any other treatments.

In addition to our cohort study, we would also like to evaluate some treatments for low back pain, in part two of this study. Please review the list below and select which parts of this study, if any, you would be interested in being involved in by **initialling** the box. Please select as many or as few as you like;

PLEASE NOTE: WE NEED YOU TO **INITIAL** THE BOX YOU SELECT, NOT TICK.

	Yes	No
1. I am happy to receive a regular questionnaire (e.g. every three months) about my low back pain as part of the cohort study.	☐	☐
2. I am happy to be contacted about the second part of this study, which I understand may include the provision of treatment (i.e. acupuncture and manual therapy delivered by a physiotherapist).	☐	☐
3. I understand I will only receive information about potential future treatments if I have initialled 'Yes' to option two above.	☐	☐
4. I do not want to receive any further information or be part of this study.	☐	☐

If you would like to give a reason for initialling 'No' for the options above, please feel free to do so, though there is no requirement to give any reason or to return these forms if you do not want to be part of this study: _____
_____
_____

Please sign below to confirm you are happy with the above information above and the selections you have initialled:

Signature: _____ Date: _____

Title: _____ Date of Birth: ☐☐☐☐☐☐☐☐

Forename(s): _____

Surname: _____

Address: _____

_____

_____

POSTCODE: ☐☐☐☐☐☐☐

Signature: _____

Date: _____

Email: _____

Telephone number: _____
(Including dialling code)

Mobile Number: _____

Appendix **C6: Participant information sheet two**

Version 1.1 04.04.11

THE UNIVERSITY of York

NHS National Institute for Health Research

Cohort Investigation and Trial of Acupuncture and Manual Therapy of Individuals who Suffer with Low Back Pain

Participant Information Sheet – Part Two

We would like to thank you for agreeing to take part in our cohort study and also for expressing an interest in part two of this study which is a trial looking at different treatments for low back pain (LBP). Before you decide to be involved in part two, it is important for you to understand why this research is being carried out.

We hope you find this information useful in making a decision whether or not to take part. Please do read the information carefully and do not hesitate to contact us if you have any further questions. Some people find it useful to discuss this information with their family and friends before making a decision.

Why have you been chosen?
You have agreed to take part and been accepted in the cohort part of the study and you selected to be contacted about the treatment part of the study.

Do I have to take part in part two?
No. It is your decision to take part or not. If you do not choose to take part in part two of the study, it will not affect your involvement in the cohort part of the study. If you decide not to take part this will **not** affect your usual medical care or legal rights in any way.

What is the purpose of this study?
Low back pain (LBP) is a very common problem for many people in the UK and can affect the quality of life of people's lives. Many people who suffer from LBP continue to have pain for more than one year and it can become a chronic problem. Treatment for LBP has not always been shown to be effective for some people and we would like to investigate this.

As previously explained, we would like to look at the quality of life and the types of treatment people with LBP use through the cohort study. This information will be collected using a questionnaire sent to you every three months for an 18 month period. Only individuals in the cohort study will be eligible to take part in the treatment part of the study. It is not possible to be part of the treatment part of the study only, as we will be using the same questionnaires to collect our data and information.

There is some evidence that acupuncture alone or manual therapy alone can be useful for LBP, we do not know if combining both treatments has any additional benefit or not for LBP.

The University of York and the Department of Health are supporting this study. It is funded by a programme grant for applied research awarded by the NHS National Institute for Health Research. It will form part of a study which will be submitted for a PhD by Vivienne Fort.

What will happen if I decide to take part?
After you have completed and signed the consent form for part two of the study and returned it to the University of York, you will be randomly allocated (like picking your name out of a hat) into one of the four groups in the treatment part of the study.

What will happen if I don't want to carry on with the study?
You are free to withdraw from the study at any time. You do not have to give any reason for this. Withdrawing from the study at any time will not affect you future care in any way.

Cohort study:
You are already part of and will remain in the cohort study and this involves you receiving a questionnaire every three months for an 18 month period. This questionnaire will ask you questions about your LBP, how it affects your life and if you have used any treatments for it. It should take approximately 20 minutes to complete and pre-paid addressed envelopes are provided for you to return your questionnaires. You will not receive any additional questionnaires for part two of the study, we will collect all the information we require from the questionnaires you are already completing as part of the cohort study.

The active treatments that may be offered through this study are manual therapy, acupuncture, or a combination of both. All treatments will be carried out by an appropriately qualified Chartered Physiotherapist in the York area. Treatments will last between 30-45minutes and be completed over a 10-12 week period. You will **not** be required to pay for treatments and any travel expenses can be reimbursed. After completion of the treatments in part two of the study, you will still receive a questionnaire every three months for an 18 month period.

What is Manual Therapy?
Manual therapy is a form of therapy that involves the physiotherapist using their hands to give the treatment to your back. It is a technique regularly used by physiotherapists and other health professionals to treat LBP. You will receive the above treatments while lying on a treatment couch and will take approximately 30minutes.

What is Acupuncture?
Acupuncture is a form of therapy that originated in China many years ago. It involves the insertion of very fine disposable needles into specific areas of the skin, while you lie on a treatment couch. The physiotherapist will ask you if you feel a sensation, this should not be painful, but may feel like a dull ache or tingling. Needles are typically left in for 20-30minutes.

What happens if I have both treatments?
If you are allocated to receive both treatments, you will receive them in the same session. This means each treatment session will last slightly longer and take approximately 45 minutes. The treatments will be the same as described above.

What happens at the first appointment?
The physiotherapist treating you will take a full and detailed history. Questions are likely to focus on your current pain, treatments you have received, your medical history, activities you can and cannot do, your work status, sleep patterns, and what you would like to be able to do. The physiotherapist will examine your low back and check your nerves and pulses. Using this information, the physiotherapist will make a diagnosis and design a treatment specific to

your needs. You may ask questions as many questions as you like in this or any subsequent session. Your first appointment will be slightly longer and approximately one hour.

How will it be decided if I get treatment?
We can only offer a course of treatment to a small number of people, if you complete and return the consent form for part two of the study, we will randomly select whether to offer you one of the above treatments (e.g. like picking your name out of a hat) those individuals who are not selected to receive treatment will continue to be part of the cohort study.

What is required of me?
You have already completed and returned your first set of questionnaires, to be involved in part two the only additional paper work will be completing the consent form included with this letter. You will then only receive and be asked to complete and return the questionnaires for the cohort study sent to you at 3, 6, 9, 12, 15 and 18 months. These should only take about 20 minutes to complete. We will enclose a pre-paid addressed envelope each time for this purpose. Questions will cover your general health, your low back pain, how the treatments worked for you, any medication you are taking, and your use of health care services. The questionnaires are designed to enable us to determine how useful the treatment was for you. Should you experience any difficulty in completing these questionnaires then you can be offered telephone advice.

The possible disadvantages and risks
Both manual therapy and acupuncture are commonly used treatments and routinely offered in practice. The risks of side effects from either manual therapy or acupuncture are low.

Manual therapy; occasionally leaves people feeling a little sore, but this usually settles within 24 hours.

Acupuncture very rarely can cause unwanted effects. Sometimes people feel a pricking sensation when the needle is inserted. When the needle is withdrawn, it may cause minor bleeding (few drops) or a slight bruise. Very occasionally some people report feeling sick or fainting during treatment, others can feel tired following treatments.

Manual therapy and acupuncture rarely pose a health risk, but if you have any concerns with regard to this do speak with your physiotherapist, GP or you can discontinue your treatment.

It is essential that you tell us and the physiotherapist if you think you are pregnant.
Your physiotherapist will provide further advice for your comfort and safety as necessary.

The possible benefits
Some participants may feel they have improved with treatment. However, it is not known which of these treatments may be most beneficial; the intention of this small study is to inform a potential future large study, so that we may investigate the benefits of each treatment.

What happens to the data collected about me?
All information collected about you during the course of the study will be kept in strict confidence. The information, including your questionnaires, is subject to legal requirements and the Data Protection Act of 1998. The data will be held in a locked secure place in the co-ordinating centre in the University of York, all data will be kept for a minimum of 7years.

Only your GP and the principal researchers at The University of York will know which patients have agreed to be included in the study. Your personal information will not be disclosed to anyone. Any information about you which is used in reports of the study will be made completely anonymous and used in such a way that you cannot be identified.

When the study ends?
After the study has ended, additional treatments will not be funded by the research group. Your GP will be able to advise you on any other treatments that might be available to you.

Results of the research study
The results of this research study should be available in 2012. We will publish the results in a healthcare journal to provide GPs and other healthcare practitioner's with information. You will be able to access the results of this study via the following university webpage: www.york.ac.uk/healthsciences/trials-unit/painfreelowback

Who reviewed the study?
Before research goes ahead it is checked by a research Ethics Committee. They make sure the research is fair. The study has been reviewed by the University of York Ethics Committee, NHS research approval and the Local Research Ethics Committee for the York area.

Further independent information about taking part in research - PALS
For independent information about taking part in research within the NHS, contact your local Patient Advisory Liaison Service (PALS). For NHS North Yorkshire and York telephone 0800 068800 or email nyy-pct.pals@nhs.net.

Dissatisfaction with the study
If you are dissatisfied with any aspect of this study, you can file a complaint in one of the following ways:

1. NHS complaints procedure (Tel: 01214 495725 or free phone: 0800 389 8391). Taking part in this study in no way affects your right to complain about any aspect of the way in which you have been treated during the course of this study.
2. The Health Professionals Council (HPC) Telephone 0800 328 4218
   Email: ftp@hpc-uk.org
3. The Acupuncture Association of Chartered Physiotherapists (AACP) Telephone 01733 390007 email: sec@aacp.uk.com

Who can I contact for further information?

If you would like any further information about study, about manual therapy, acupuncture or the questionnaires please do not hesitate to contact the study's chief investigator Vivienne Fort at The University of York;

Trial Telephone Number: 0800 ***** Telephone number 01904 32******
Email vcf500@york.ac.uk

If you would like to write to the research team for any reason, please address your letter to: Vivienne Fort, Trials Unit, ARRC Building, The University of York, Heslington, York, YO10 5DD. You can also contact the research team by sending an email to Vivienne Fort; vcf500@york.ac.uk
Thank you for reading this information sheet and taking the time to consider whether to take part in this study.

Appendix **C7: Participant consent form – part two**

Office Use only Patient ID Number……. Version 1.1 04.04.11

THE UNIVERSITY of York

DEPARTMENT OF HEALTH SCIENCES
York Trials Unit
ARRC Building
Heslington
York YO10 5DD
Direct line: (01904) 321914
Email: vcf500@york.ac.uk

PARTICIPANT CONSENT FORM – PART TWO

A Cohort Investigation and Acupuncture and Manual Therapy Treatment Trial of Individuals with Low Back Pain.

Please **initial** each box

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to consider the information, ask questions and to have them answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason or without my medical care and legal rights being affected. I understand that if I withdraw, I can ask for all record of my contact details to be deleted. ☐
3. I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports of this study. I give permission for responsible appropriate individuals working at the University of York to have access to my data. ☐
4. I agree to my General Practitioner being informed of my participation in this study. I agree if there are any problems contacting me, my GP should be contacted and asked where appropriate to contact me and for my address. ☐
5. I agree to this consent form and other data collected on me as part of this research study to be kept at York Trials Unit, at The University of York. I understand that records relating to me will be kept confidential. No information will be released or printed that would identify me without my permission, unless required by law. ☐
6. I understand that the relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the York Trials Unit, from regulatory authorities or from the NHS trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
7. I understand that this is a study collecting information by questionnaire every three months and that there may be the opportunity to be involved in some form of active treatment as part of the study; I have selected overleaf the treatments I would consider. ☐
8. I am happy to receive text and email reminders for my questionnaires ☐
9. I agree to take part in the above study. ☐

If you agree to the above nine points, please complete the personal details and the options on the reverse side of this form to select your preference.

Please return this form with the questionnaire in the pre-paid envelope provided.

Your personal information will be kept confidential and will only be used to contact you regarding the study.

If you have any questions, please contact the chief investigator Vivienne Fort on 01904 32…….

Thank you for your interest in participating in this study.

Please Turn Page Over

Additional Information:

You have consented and been accepted to be involved in the Cohort part of this study, additionally you consented to being contacted about the treatment part of this study and have been provided with additional participant information to explain part two of the study.

You will continue to receive a questionnaire every three months for an 18 month period to ask you about you pain and if you have seen your GP or used any other treatments or received treatment through the study.

We would also like to evaluate some treatments for low back pain, in part two of this study. Please review the list below and select which parts of this study, if any, you would be interested in being involved in by **initialling** the box. Please select as many or as few as you like;

PLEASE NOTE: WE NEED YOU TO **INITIAL** THE BOX YOU SELECT, NOT TICK.

	Yes	No
1. I am happy to continue to receive a regular questionnaire (e.g. every three months) about my low back pain as part of the cohort study.	☐	☐
2. I am happy to consider receiving;		
a) Manual therapy by a physiotherapist	☐	☐
b) Acupuncture by a physiotherapist	☐	☐
c) Acupuncture and Manual therapy by a physiotherapist.	☐	☐
3. I do not want to receive any further information or be part of this study.	☐	☐

If you would like to give a reason for initialling 'No' for the options above, please feel free to do so, though there is no requirement to give any reason or to return these forms if you do not want to be part of this study: _____
_____

Please sign below to confirm you are happy with the above information above and the selections you have initialled:

Signature: _____ Date: _____

Title: _____ Date of Birth: ☐☐☐☐☐☐☐☐

Forename(s): _____

Surname: _____

Address: _____

_____

_____

POSTCODE: ☐☐☐☐☐☐☐

Signature: _____

Date: _____

Email: _____

Telephone number: _____
(Including dialling code)

Mobile Number: _____

Confidential

THE UNIVERSITY of York
The Department of Health Sciences

Low Back Pain Study

Pre Screen Questionnaire

To be completed by the participant prior to entering the research study

For office use only

Participant ID Number: ☐☐ - ☐☐☐☐

Date Sent: ☐☐ / ☐☐ / 20☐☐
day *month* *year*

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. This is the pre-screening questionnaire, which tells us about you at the time you enter the study.

Please answer ALL the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one.

If you find it difficult to answer a question, do the best you can.

Please follow the instructions carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick, as if you were filling out a ballot paper.

For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car? Yes ☒

No ☐

If you are asked to circle a number, please use a circle rather than underlining a number.

For example, in the following question if you are asked 'how happy are you today?' where '1' is 'very unhappy' and '5' is 'very happy', if you feel neither happy nor unhappy you may wish to answer 3. You do this by clearly circling the number 3.

1	2	(3)	4	5
Very Unhappy				**Very Happy**

PLEASE USE A BLACK OR BLUE PEN. Please do not use a pencil or any other coloured pen.

Thank you for your help. Please complete all sections in this questionnaire and return it to us in the pre-paid envelope enclosed

Please enter the date you are completing this questionnaire: ☐☐ / ☐☐ / 2 0 ☐☐

day *month* *year*

In this section we would like to know about your back pain. When your back hurts you may find it difficult to do some of the things you normally do. This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you **TODAY**.
When you read a sentence that describes you **today**, place a cross in the box under the **'YES'** heading. If the sentence does not describe you, then place a cross under the **'NO'** heading, and then go on to the next sentence.

Remember only put a cross under the 'YES' heading if you are sure that the sentence describes you TODAY.

		YES	NO
1.	I stay at home most of the time because of my back.....	☐	☐
2.	I change position frequently to try and get my back comfortable.....	☐	☐
3.	I walk more slowly than usual because of my back.....	☐	☐
4.	Because of my back, I am not doing any of the jobs that I usually do around the house..	☐	☐
5.	Because of my back, I use a handrail to get upstairs.....	☐	☐
6.	Because of my back, I lie down to rest more often.....	☐	☐
7.	Because of my back, I have to hold onto something to get out of an easy chair.....	☐	☐
8.	Because of my back, I try to get other people to do things for me.....	☐	☐
9.	I get dressed more slowly than usual because of my back.....	☐	☐
10.	I only stand up for short periods of time because of my back.....	☐	☐
11.	Because of my back, I try not to bend or kneel down.....	☐	☐
12.	I find it difficult to get out of a chair because of my back.....	☐	☐
13.	My back is painful almost all the time.....	☐	☐
14.	I find it difficult to turn over in bed because of my back.....	☐	☐
15.	My appetite is not very good because of my back pain.....	☐	☐
16.	I have trouble putting on my socks (or stockings) because of the pain in my back.....	☐	☐
17.	I only walk short distances because of my back pain.....	☐	☐
18.	I sleep less well because of my back.....	☐	☐
19.	Because of my back pain, I get dressed with help from someone else.....	☐	☐
20.	I sit down for most of the day because of my back.....	☐	☐
21.	I avoid heavy jobs around the house because of my back.....	☐	☐
22.	Because of my back pain, I am more irritable and bad tempered with people than usual..	☐	☐
23.	Because of my back, I go upstairs more slowly than usual.....	☐	☐
24.	I stay in bed most of the time because of my back.....	☐	☐
	Official use only	☐☐	

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For each activity below, please place a cross in the appropriate box that best describes you and your ability.
(*please cross one sentence for each section*)

1. Pain Intensity

- ☐ I can tolerate the pain I have without having to use pain medication.
- ☐ The pain is bad, but I can manage without having to take pain medication.
- ☐ Pain medication provides me with complete relief from pain.
- ☐ Pain medication provides me with moderate relief from pain.
- ☐ Pain medication provides me with little relief from pain.
- ☐ Pain medication has no effect on my pain.

2. Personal Care (e.g. Washing Dressing)

- ☐ I can take care of myself normally without causing increased pain.
- ☐ I can take care of myself normally, but it increases my pain.
- ☐ It is painful to take care of myself, and I am slow and careful.
- ☐ I need help, but I am able to manage most of my personal care.
- ☐ I need help every day in most aspects of my care.
- ☐ I do not get dressed, I wash with difficulty, and stay in bed.

3. Lifting

- ☐ I can lift heavy weights without increased pain.
- ☐ I can lift heavy weights, but it causes increased pain.
- ☐ Pain prevents me from lifting heaving weights off the floor, but I can manage if the weights are conveniently positioned (e.g. on a table).
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can lift only very light weights.
- ☐ I cannot lift or carry anything at all.

4. Walking

- ☐ Pain does not prevent me from walking any distance.
- ☐ Pain prevents me from walking more than 1 mile. (1 mile = 1.6 km)
- ☐ Pain prevents me from walking more than 1/2 mile.
- ☐ Pain prevents me from walking more than 1/4 mile.
- ☐ I can walk only with crutches or a cane.
- ☐ I am in bed most of the time and have to crawl to the toilet.

5. Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can sit in my favourite chair for as long as I like.
- ☐ Pain prevents me from sitting for more than 1 hour.
- ☐ Pain prevents me from sitting for more than 1/2 an hour.
- ☐ Pain prevents me from sitting for more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

6. Standing

- ☐ I can stand as long as I want without increased pain.
- ☐ I can stand as long as I want but my pain increases with time.
- ☐ Pain prevents me from standing more than 1 hour.
- ☐ Pain prevents me from standing more than 1/2 hour.
- ☐ Pain prevents me from standing more than 10 minutes.
- ☐ I avoid standing because it increases my pain right away.

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7. Sleeping

- ☐ I get no pain when I am in bed.
- ☐ I get pain in bed, but it does not prevent me from falling asleep.
- ☐ Because of my pain, my sleep is only 3/4 of my normal amount.
- ☐ Because of my pain, my sleep is only 1/2 of my normal amount.
- ☐ Because of my pain, my sleep is only 1/4 of my normal amount.
- ☐ Pain prevents me from sleeping at all.

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8. Social Life

- ☐ My social life is normal and does not increase my pain.
- ☐ My social life is normal, but it increases my level of pain.
- ☐ Pain prevents me from participating in more energetic activities (ex. sports, dancing, etc.)
- ☐ Pain prevents me from going out very often
- ☐ Pain has restricted my social life to my home.
- ☐ I have hardly any social life because of my pain.

---

9. Traveling

- ☐ I get no increased pain when traveling
- ☐ I get some pain while traveling, but none of my usual forms of travel make it any worse.
- ☐ I get increased pain while traveling, but it does not cause me to seek alternative forms of travel.
- ☐ I get increased pain while traveling which causes me to seek alternative forms of travel.
- ☐ My pain restricts all forms of travel except that which is done while I am lying down.
- ☐ My pain restricts all forms of travel.

---

10. Employment/Homemaking

- ☐ My normal job/homemaking activities do not cause pain.
- ☐ My normal job/homemaking activities increase my pain, but I can still perform all that is required of me.
- ☐ I can perform most of my job/homemaking duties, but pain prevents me from performing more physically stressful activities (ex. lifting, vacuuming).
- ☐ Pain prevents me from doing anything but light duties.
- ☐ Pain prevents me from doing even light duties.
- ☐ Pain prevents me from performing any job or homemaking chores.

These questions ask for your views about your health. This section will help us keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking a cross in the appropriate box. If you are unsure on how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
(please cross one box only)

Excellent	Very Good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. During a typical day does **your health** limit you in **moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf? If so, how much?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3. During a typical day does **your health** limit you in climbing **several** flights of stairs? If so, how much?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

4. During the **past 4 weeks**, how much of the time have you accomplished less than you would like in regular daily activities **as a result of your physical health**?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

5. During the **past 4 weeks**, how much of the time have you been limited in performing any kind of work or other regular daily activities **as a result of your physical health**?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

6. During the **past 4 weeks**, how much of the time have you accomplished less than you would have liked in your work or any other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

7. During the **past 4 weeks**, how much of the time have you done work or other activities less carefully than usual **as a result of any emotional problems** (such as feeling depressed or anxious)?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (both outside the home and housework)?
(please cross one box only)

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

9. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** have you felt calm and peaceful ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

10. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** did you have a lot of energy ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

11. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** have you felt downhearted and depressed?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

12. During the **past 4 weeks** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives etc.)?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

YOUR HEALTH IN SUMMARY

By placing a cross in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

Self-Care

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

Anxiety/Depression

I am not anxious or depressed ☐

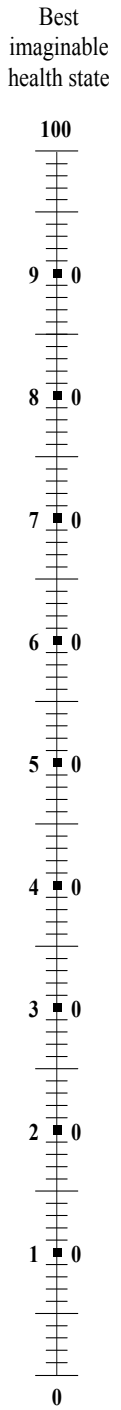
I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Office use only

This section is about health care you have had in the **last three months**.
Please read each question carefully. For each question, if you have had no treatments or visits, please enter '0' as indicated. We would like to know about visits to health professionals for any reason, not just back pain.

Care from your GP's surgery

1. In the **last three months**, how often have you consulted any of the following at your GP's surgery?

Your own GP or another GP	☐☐ *If none enter '0'*
Practice nurse	☐☐ *If none enter '0'*
Physiotherapist	☐☐ *If none enter '0'*
Other (please specify) _____	☐☐ *If none enter '0'*
Other (please specify) _____	☐☐ *If none enter '0'*

Care from NHS hospitals

2. In the **last three months**, have you been admitted to an NHS hospital **as an emergency**? ☐ Yes ☐ No

   If you have placed a cross in 'Yes' please indicate the number of times you have been admitted to an NHS hospital as an emergency. ☐☐ *If none enter '0'*

3. In the **last three months**, have you been admitted to an NHS hospital **NOT as an emergency**? ☐ Yes ☐ No

   If you have placed a cross in 'Yes' please indicate the number of times you have been admitted to an NHS hospital not as an emergency. ☐☐ *If none enter '0'*

4. In the **last three months**, how often have you been seen by a doctor at an NHS hospital **outpatient clinic**? ☐☐ *If none enter '0'*

Care from NHS hospitals

5. In the **last three months**, how often have you been seen by any other health professionals in an NHS hospital?

Physiotherapist ☐☐ *If none enter '0'*

Other (please specify) _____ ☐☐ *If none enter '0'*

Other (please specify) _____ ☐☐ *If none enter '0'*

Private Treatments

6. In the **last three months**, have you been admitted to a **private hospital**? ☐ Yes ☐ No

If you have placed a cross in 'Yes' please indicate the number of times you have been admitted to a private hospital. ☐☐ *If none enter '0'*

7. In the **last three months**, how often have you consulted other **private** health care professionals?

Doctor ☐☐ *If none enter '0'*

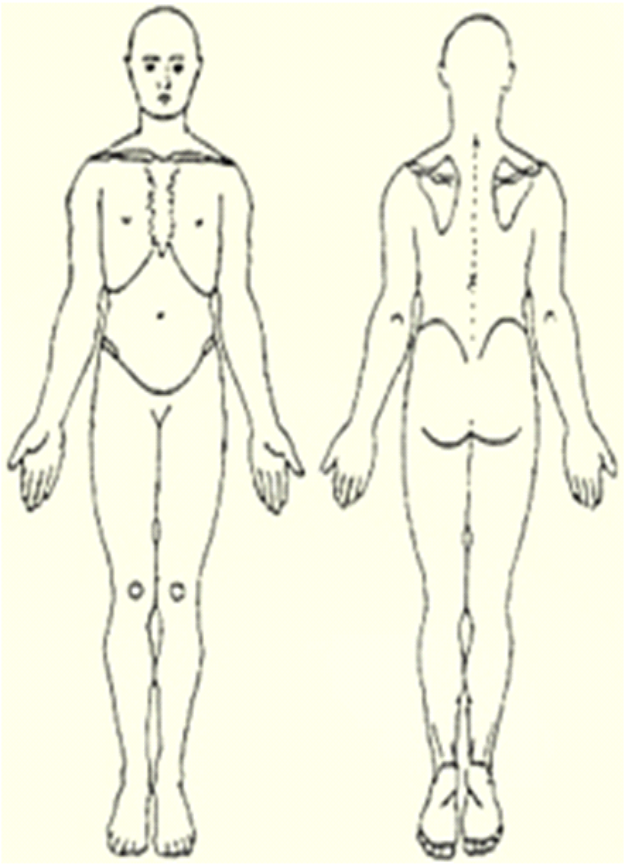
Physiotherapist, Chiropractor or Osteopath ☐☐ *If none enter '0'*

Other (please specify) _____ ☐☐ *If none enter '0'*

Other (please specify) _____ ☐☐ *If none enter '0'*

Your Pain, Symptoms and Information

1. Please colour / shade the body chart below to provide a visual presentation of where you feel your pain:



2. Pain Scale

   Using the scale below please place a **single cross** to mark how your pain level is most of the time.

No Pain — **Worst pain imaginable**

0 10 20 30 40 50 60 70 80 90 100

(For office use only)

3. Describe in words how your pain feels to you?

4. For my low back pain:

	I have tried.... **Yes**	**/ No**	I would consider.... **Yes**	**/ No**
a) Manual therapy by a physiotherapist	☐	☐	☐	☐
b) Acupuncture by a physiotherapist	☐	☐	☐	☐
c) Acupuncture and Manual therapy by a physiotherapist	☐	☐	☐	☐
d) Group exercise	☐	☐	☐	☐
e) Pilates	☐	☐	☐	☐
f) Yoga	☐	☐	☐	☐
g) Alexander technique	☐	☐	☐	☐

Other treatments (please specify):

5. Is there any other information you would like to provide about any treatment you have had, activity your have done or things you have tried specifically for your low back pain and how these have helped or not helped you:

Thank you for completing this questionnaire

Appendix **C9 – Six month Questionnaire booklet**

Confidential

THE UNIVERSITY of York
The Department of Health Sciences

Low Back Pain Study

Six Month Questionnaire

For office use only

Participant ID Number: ☐☐ - ☐☐☐☐

Date Sent: ☐☐ / ☐☐ / 20☐☐
day *month* *year*

Version 1

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PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. This is the eighteen month and final questionnaire, which tells us about how you are now.

Thank you so much for all your time and participation in our study.

Please answer ALL the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one.

If you find it difficult to answer a question, do the best you can.

Please follow the instructions carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick, as if you were filling out a ballot paper.

For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car? Yes ☒

No ☐

If you are asked to circle a number, please use a circle rather than underlining a number.

For example, in the following question if you are asked 'how happy are you today?' where '1' is 'very unhappy' and '5' is 'very happy', if you feel neither happy nor unhappy you may wish to answer 3. You do this by clearly circling the number 3.

1	2	③	4	5
Very Unhappy				**Very Happy**

PLEASE USE A BLACK OR BLUE PEN. Please do not use a pencil or any other coloured pen.

Thank you for your help. Please complete all sections in this questionnaire and return it to us in the pre-paid envelope enclosed

Please enter the date you are completing this questionnaire: ☐☐ / ☐☐ / 2 0 ☐☐

day *month* *year*

0336332561

In this section we would like to know about your back pain. When your back hurts you may find it difficult to do some of the things you normally do. This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you **TODAY**.
When you read a sentence that describes you **today**, place a cross in the box under the **'YES'** heading. If the sentence does not describe you, then place a cross under the **'NO'** heading, and then go on to the next sentence.

Remember only put a cross under the 'YES' heading if you are sure that the sentence describes you TODAY.

		YES	NO
1.	I stay at home most of the time because of my back	☐	☐
2.	I change position frequently to try and get my back comfortable	☐	☐
3.	I walk more slowly than usual because of my back	☐	☐
4.	Because of my back, I am not doing any of the jobs that I usually do around the house	☐	☐
5.	Because of my back, I use a handrail to get upstairs	☐	☐
6.	Because of my back, I lie down to rest more often	☐	☐
7.	Because of my back, I have to hold onto something to get out of an easy chair	☐	☐
8.	Because of my back, I try to get other people to do things for me	☐	☐
9.	I get dressed more slowly than usual because of my back	☐	☐
10.	I only stand up for short periods of time because of my back	☐	☐
11.	Because of my back, I try not to bend or kneel down	☐	☐
12.	I find it difficult to get out of a chair because of my back	☐	☐
13.	My back is painful almost all the time	☐	☐
14.	I find it difficult to turn over in bed because of my back	☐	☐
15.	My appetite is not very good because of my back pain	☐	☐
16.	I have trouble putting on my socks (or stockings) because of the pain in my back	☐	☐
17.	I only walk short distances because of my back pain	☐	☐
18.	I sleep less well because of my back	☐	☐
19.	Because of my back pain, I get dressed with help from someone else	☐	☐
20.	I sit down for most of the day because of my back	☐	☐
21.	I avoid heavy jobs around the house because of my back	☐	☐
22.	Because of my back pain, I am more irritable and bad tempered with people than usual	☐	☐
23.	Because of my back, I go upstairs more slowly than usual	☐	☐
24.	I stay in bed most of the time because of my back	☐	☐
	Official use only	☐☐	

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For each activity below, please place a cross in the appropriate box that best describes you and your ability.
(*please cross one sentence for each section*)

1. Pain Intensity

- ☐ I can tolerate the pain I have without having to use pain medication.
- ☐ The pain is bad, but I can manage without having to take pain medication.
- ☐ Pain medication provides me with complete relief from pain.
- ☐ Pain medication provides me with moderate relief from pain.
- ☐ Pain medication provides me with little relief from pain.
- ☐ Pain medication has no effect on my pain.

2. Personal Care (e.g. Washing Dressing)

- ☐ I can take care of myself normally without causing increased pain.
- ☐ I can take care of myself normally, but it increases my pain.
- ☐ It is painful to take care of myself, and I am slow and careful.
- ☐ I need help, but I am able to manage most of my personal care.
- ☐ I need help every day in most aspects of my care.
- ☐ I do not get dressed, I wash with difficulty, and stay in bed.

3. Lifting

- ☐ I can lift heavy weights without increased pain.
- ☐ I can lift heavy weights, but it causes increased pain.
- ☐ Pain prevents me from lifting heaving weights off the floor, but I can manage if the weights are conveniently positioned (e.g. on a table).
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can lift only very light weights.
- ☐ I cannot lift or carry anything at all.

4. Walking

- ☐ Pain does not prevent me from walking any distance.
- ☐ Pain prevents me from walking more than 1 mile. (1 mile = 1.6 km)
- ☐ Pain prevents me from walking more than 1/2 mile.
- ☐ Pain prevents me from walking more than 1/4 mile.
- ☐ I can walk only with crutches or a cane.
- ☐ I am in bed most of the time and have to crawl to the toilet.

5. Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can sit in my favourite chair for as long as I like.
- ☐ Pain prevents me from sitting for more than 1 hour.
- ☐ Pain prevents me from sitting for more than 1/2 an hour.
- ☐ Pain prevents me from sitting for more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

6. Standing

- [ ] I can stand as long as I want without increased pain.
- [ ] I can stand as long as I want but my pain increases with time.
- [ ] Pain prevents me from standing more than 1 hour.
- [ ] Pain prevents me from standing more than 1/2 hour.
- [ ] Pain prevents me from standing more than 10 minutes.
- [ ] I avoid standing because it increases my pain right away.

7. Sleeping

- [ ] I get no pain when I am in bed.
- [ ] I get pain in bed, but it does not prevent me from falling asleep.
- [ ] Because of my pain, my sleep is only 3/4 of my normal amount.
- [ ] Because of my pain, my sleep is only 1/2 of my normal amount.
- [ ] Because of my pain, my sleep is only 1/4 of my normal amount.
- [ ] Pain prevents me from sleeping at all.

8. Social Life

- [ ] My social life is normal and does not increase my pain.
- [ ] My social life is normal, but it increases my level of pain.
- [ ] Pain prevents me from participating in more energetic activities (ex. sports, dancing, etc.)
- [ ] Pain prevents me from going out very often.
- [ ] Pain has restricted my social life to my home.
- [ ] I have hardly any social life because of my pain.

9. Traveling

- [ ] I get no increased pain when traveling.
- [ ] I get some pain while traveling, but none of my usual forms of travel make it any worse.
- [ ] I get increased pain while traveling, but it does not cause me to seek alternative forms of travel.
- [ ] I get increased pain while traveling which causes me to seek alternative forms of travel.
- [ ] My pain restricts all forms of travel except that which is done while I am lying down.
- [ ] My pain restricts all forms of travel.

10. Employment/Homemaking

- [ ] My normal job/homemaking activities do not cause pain.
- [ ] My normal job/homemaking activities increase my pain, but I can still perform all that is required of me.
- [ ] I can perform most of my job/homemaking duties, but pain prevents me from performing more physically stressful activities (ex. lifting, vacuuming).
- [ ] Pain prevents me from doing anything but light duties.
- [ ] Pain prevents me from doing even light duties.
- [ ] Pain prevents me from performing any job or homemaking chores.

These questions ask for your views about your health. This section will help us keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking a cross in the appropriate box. If you are unsure on how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
(please cross one box only)

Excellent	Very Good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. During a typical day does **your health** limit you in **moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf? If so, how much?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3. During a typical day does **your health** limit you in climbing **several** flights of stairs? If so, how much?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

4. During the **past 4 weeks**, how much of the time have you accomplished less than you would like in regular daily activities **as a result of your physical health**?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

5. During the **past 4 weeks**, how much of the time have you been limited in performing any kind of work or other regular daily activities **as a result of your physical health**?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

6. During the **past 4 weeks**, how much of the time have you accomplished less than you would have liked in your work or any other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

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7. During the **past 4 weeks**, how much of the time have you done work or other activities less carefully than usual **as a result of any emotional problems** (such as feeling depressed or anxious)?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (both outside the home and housework)?
(please cross one box only)

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

9. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** have you felt calm and peaceful ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

10. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** did you have a lot of energy ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

11. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** have you felt downhearted and depressed?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

12. During the **past 4 weeks** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives etc.)?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

YOUR HEALTH IN SUMMARY

By placing a cross in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

Self-Care

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

Anxiety/Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

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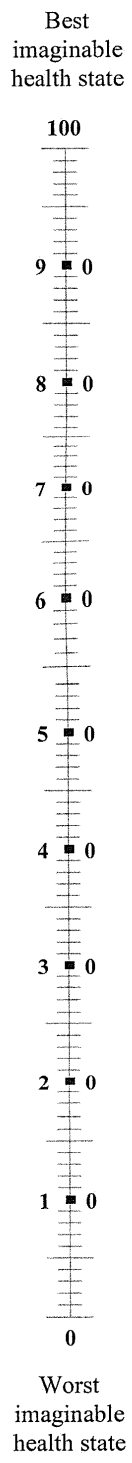
To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Office use only

This section is about health care you have had in the **last three months**.
Please read each question carefully. For each question, if you have had no treatments or visits, please enter '0' as indicated. We would like to know about visits to health professionals for any reason, not just back pain.

Care from your GP's surgery

1. In the **last three months**, how often have you consulted any of the following **at your GP's surgery**?

Your own GP or another GP	☐☐ *If none enter '0'*
Practice nurse	☐☐ *If none enter '0'*
Physiotherapist	☐☐ *If none enter '0'*
Other (please specify) _____	☐☐ *If none enter '0'*
Other (please specify) _____	☐☐ *If none enter '0'*

Care from NHS hospitals

2. In the **last three months**, have you been admitted to an NHS hospital **as an emergency**? ☐ Yes ☐ No

   If you have placed a cross in 'Yes' please indicate the number of times you have been admitted to an NHS hospital as an emergency. ☐☐ *If none enter '0'*

3. In the **last three months**, have you been admitted to an NHS hospital **NOT as an emergency**? ☐ Yes ☐ No

   If you have placed a cross in 'Yes' please indicate the number of times you have been admitted to an NHS hospital not as an emergency. ☐☐ *If none enter '0'*

4. In the **last three months**, how often have you been seen by a doctor at an NHS hospital **outpatient clinic**? ☐☐ *If none enter '0'*

Care from NHS hospitals

5. In the **last three months**, how often have you been seen by **any other health professionals** in an NHS hospital?

Physiotherapist ☐☐ *If none enter '0'*

Other (please specify) _____ ☐☐ *If none enter '0'*

Other (please specify) _____ ☐☐ *If none enter '0'*

Private Treatments

6. In the **last three months**, have you been admitted to a **private hospital**? ☐ Yes ☐ No

If you have placed a cross in 'Yes' please indicate the number of times you have been admitted to a private hospital. ☐☐ *If none enter '0'*

7. In the **last three months**, how often have you consulted other **private** health care professionals?

Doctor ☐☐ *If none enter '0'*

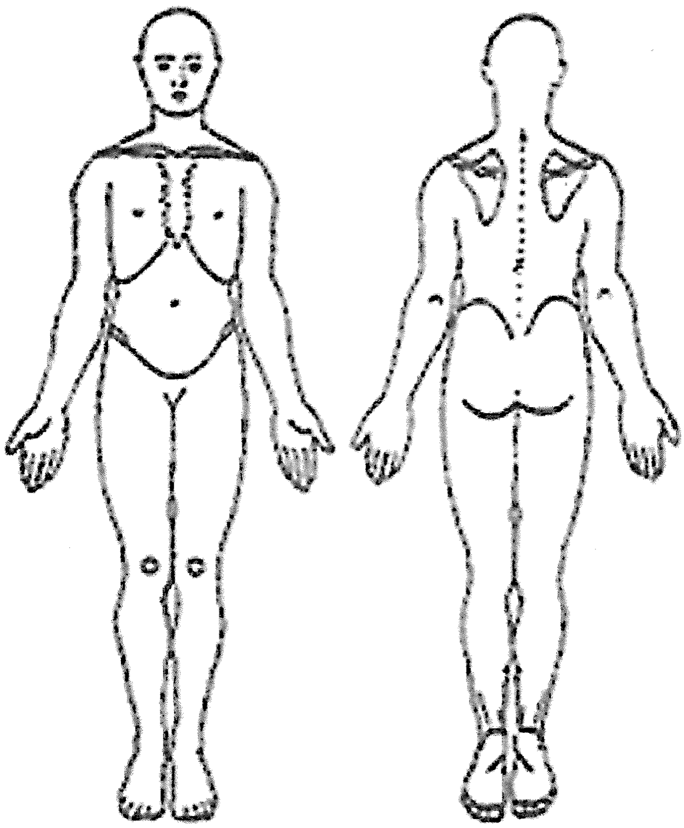
Physiotherapist, Chiropractor or Osteopath ☐☐ *If none enter '0'*

Other (please specify) _____ ☐☐ *If none enter '0'*

Other (please specify) _____ ☐☐ *If none enter '0'*

Your Pain, Symptoms and Information

1. Please colour / shade the body chart below to provide a visual presentation of where you feel your pain:



2. Pain Scale

   Using the scale below please place a **single cross** to mark how your pain level is most of the time.

No Pain 0 10 20 30 40 50 60 70 80 90 100 **Worst pain imaginable**

☐☐☐ (For office use only)

3. Describe in words how your pain feels to you?

4. For my low back pain:

	I have tried.... **Yes**	**No**	I would consider.... **Yes**	**No**
a) Manual therapy by a physiotherapist	☐	☐	☐	☐
b) Acupuncture by a physiotherapist	☐	☐	☐	☐
c) Acupuncture and Manual therapy by a physiotherapist	☐	☐	☐	☐
d) Group exercise	☐	☐	☐	☐
e) Pilates	☐	☐	☐	☐
f) Yoga	☐	☐	☐	☐
g) Alexander technique	☐	☐	☐	☐

Other treatments (please specify):

5. Is there any other information you would like to provide about any treatment you have had, activity your have done or things you have tried specifically for your low back pain and how these have helped or not helped you:

Thank you for completing this questionnaire

***Appendix* C10 – Physiotherapy Health Screening Questionnaire and assessment**

HEALTH SCREENING QUESTIONNAIRE

Patient Name: Date of Birth:

Address:

Home telephone number:

Postcode:

Email Address: Mobile telephone number:

(Please tick)

	YOUR GENERAL HEALTH	YES	NO
1	Are you diabetic?		
2	Are you epileptic?		
3	Do you suffer from heart problems e.g. angina, heart valve problems or have a pacemaker?		
4	Does anyone in your family have a history of heart problems?		
5	Do you have any circulatory problems, such as high or low blood pressure or a history of DVT, blood clots or pulmonary embolism?		
6	Does anyone in your family have a history of DVT, blood clots or pulmonary embolism?		
7	Do you take any medication to thin your blood e.g. aspirin, heparin. warfarin?		
8	Have you ever been on long term steroids, performance enhancing medication or supplements to thicken your blood?		
9	Do you have any chest or breathing problems such as asthma, COPD or emphysema?		
10	Have you ever been diagnosed as having TB or an infectious disease?		
11	Have you ever been diagnosed or treated for cancer?		
12	Have you ever undergone treatment such as chemotherapy or radiotherapy?		
13	Have you experienced any sudden weight loss?		
14	Have you ever been diagnosed with osteoporosis?		
15	Have you had any fractures within the last 5 years or related to the condition you have a problem with now?		
16	Have you had any recent x-rays, scans or blood tests		
17	Do you have any allergies?		
18	Have you ever been diagnosed with osteoarthritis or rheumatoid arthritis?		
19	Does anyone in your family suffer from arthritis or are you aware of any history of family illness?		
20	Have you had any operations (If yes please specify):		
21	Please list any medication you are currently taking (including contraceptives and painkillers).		
22	Please list any other problems that you may have or are being treated for that have not been mentioned:		
23	Please list below your GP's name, address and postcode:		

DECLARATION

The information provided above is to the best of my knowledge true and accurate. I have read the above and confirm that I do not suffer from any medical condition that will prevent me from having physiotherapy treatment.

I hereby give my consent for physiotherapy treatment. I also give my consent for you to contact my GP after discharge with details of my physiotherapy treatment.

Print Name: Signed: Date:

***Appendix* C11 – Physiotherapy LBP assessment form**

PHYSIOTHERAPY LUMBAR ASSESSMENT

Date:

Name: Patient D.O.B: Insurance Details:

Social Occupation:

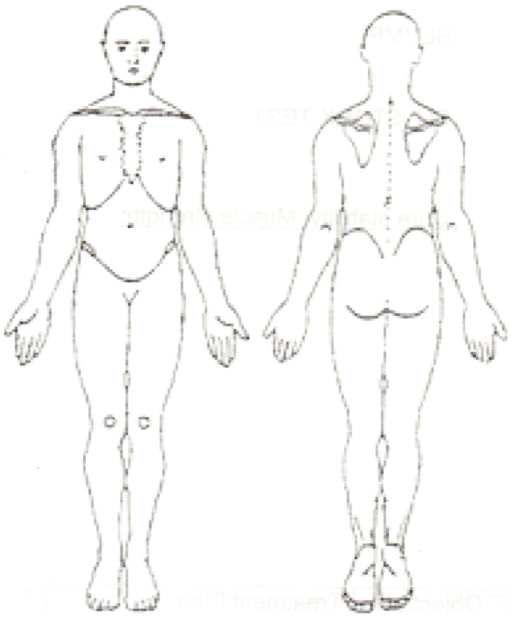
Telephone Number:

Mobile Number:

Hobbies/ Activities:

PM Hx/ SQ:

	YES	NO
Health Questionnaire		
Sleep Affected		
In good General Health		
Nausea		
Pins and Needles		
Numbness		
Ataxia		
Cough/ Sneeze		
Saddle Anaesthesia		
Bladder or Bowel Changes		
COMMENTS		



Aggravating factors:

Easing Factors

24 Hour Behaviour:

Present Condition:

Previous Relevant Injuries/ Pain:

PHYSIOTHERAPY
LUMBAR OBJECTIVE ASSESSMENT

Continuation sheet no: Date: Patient Name: Date of Birth:

Observation:

AROM:

Flex

Extension

Right SF

Left SF

Neurological Tests:

Myotomes

Dermatomes

Reflexes

Pulses

Neural Tension Tests:

SLR

SLUMP

SIJ: STORK TEST

Core stability/ Muscle strength:

Palpation:

Mark Area:

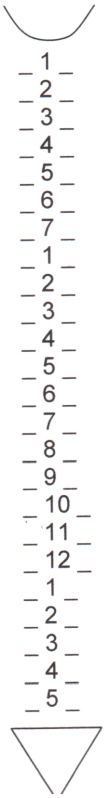
Pain

Tender ○

Stiff X ●

Muscle Spasm Z

Analysis:



Problems/ Plan:

Problem List	Goals/ SMART Objectives	Treatment Plan
1)		
2)		
3)		

Outcome Measures:

Rx:

Rx Outcomes:

Appendix C12 – Safety reporting flowchart (NIHR, 2017)

Safety reporting flowchart

Adverse Event Reporting: UK Open Label Trial

SYMONS ASSOCIATES LTD
Clinical Research Consultancy

PI assesses causality[1]

Related | **Not related**

Adverse Reaction (AR) | **Adverse Event (AE)**

PI assesses seriousness

Not serious[2] → **Adverse Event/Reaction (AE/R)**
PI records and notifies sponsor as per protocol

Serious SAE/R

PI checks protocol to confirm whether SAE/R requires expedited reporting

NO → **'Non-Expeditable' (SAE/R)**
PI records and notifies sponsor as per protocol

YES

PI notifies sponsor of SAE/R within 24 hours

Sponsor's assessment of causality[3]

Unrelated to IMP → **Serious Adverse Event (SAE)**
Sponsor keeps records and follows up until resolution

Related to IMP

Serious Adverse Reaction (SAR)

Sponsor's assessment of expectedness using the RSI[4]

Unexpected → **Suspected Unexpected Serious Adverse Reaction (SUSAR)**
Sponsor to report to MHRA and Ethics Committee:

- Fatal or life threatening SUSARs within 7 days
- All other SUSARs within 15 days

SUSARs reported to PIs as per protocol

Expected

Expected Serious Adverse Reaction (SAR)
Sponsor keeps records and follows up until resolution

Adverse Event (AE):
Any untoward medical occurrence in a clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.

Adverse Reaction (AR):
Any untoward and unintended response to an IMP which is related (a reasonable causal relationship) to any dose administered.

Serious Adverse Event/Reaction (SAE/R):

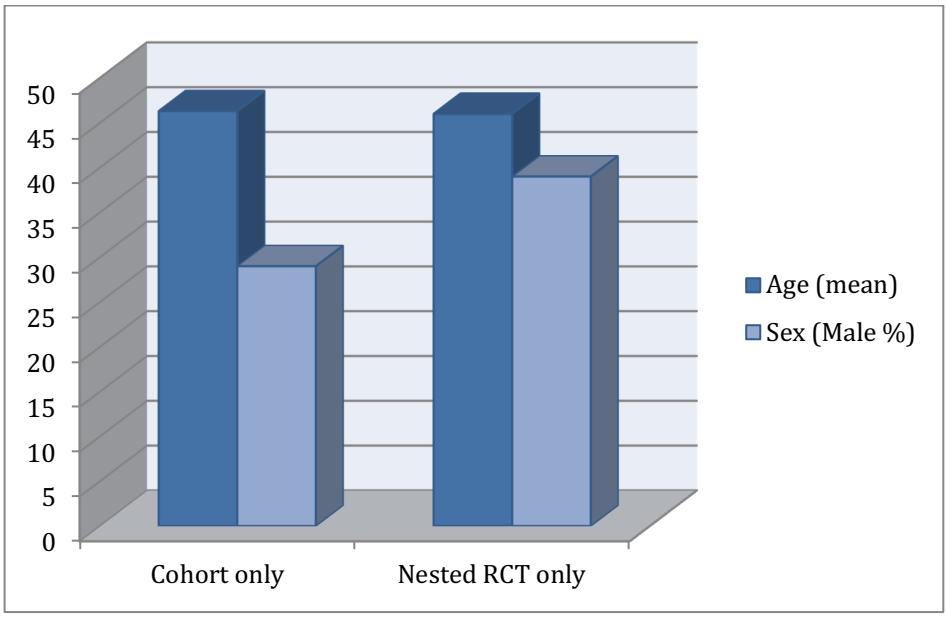
- Results in death,
- is life-threatening,
- requires hospitalisation or prolongation of existing hospitalisation,
- results in persistent or significant disability or incapacity,
- is a congenital anomaly or birth defect,
- any other safety issues considered medically important.

PI should **actively seek** follow-up information on reported SAE/Rs.

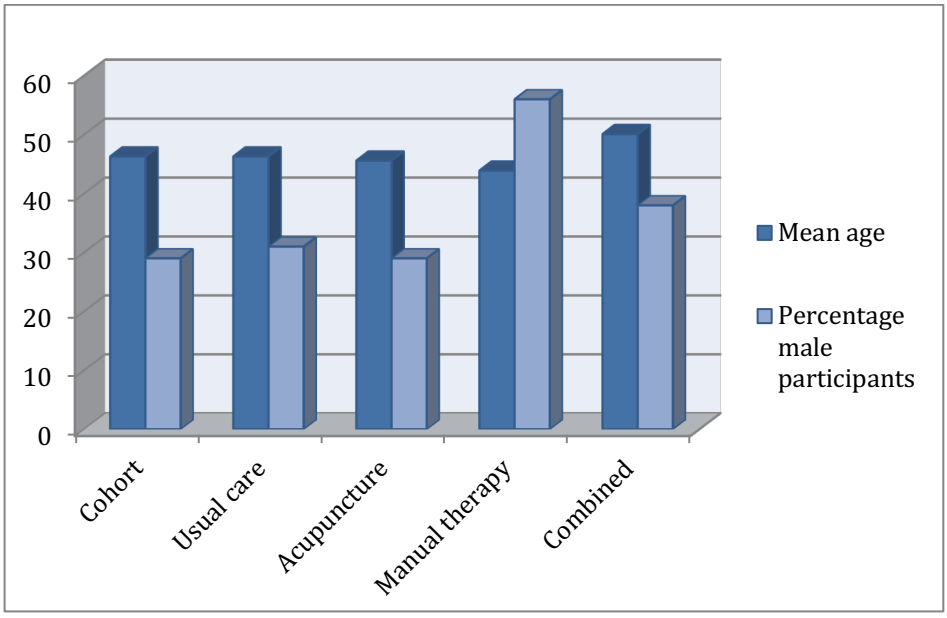
Footnotes

[1] PI or delegate.
[2] Notable or safety critical events must be reported as per protocol.
[3] Sponsor cannot downgrade the PI's causality assessment, but can upgrade it.
[4] Reference Safety Information (RSI) in IB or SmPC.

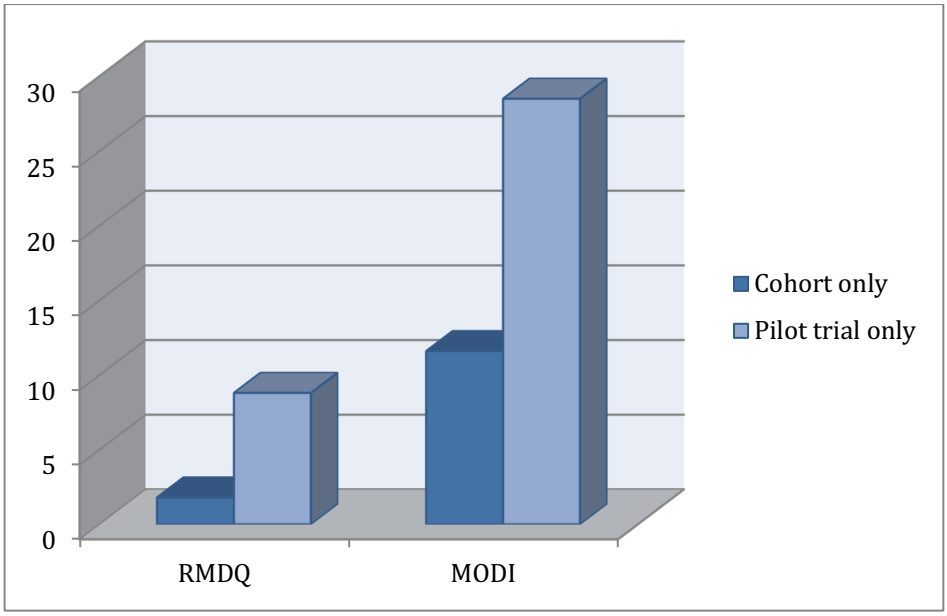
Appendix D: Results Charts & Sample size raw data:



Bar chart showing age and sex demographics of cohort and nested RCT study



Bar chart showing baseline mean age distribution across groups



Bar chart showing baseline results of the objective measures

Sample size raw data:

PS1 input data info: Sample size calculation.

- *Selected – t-test*
- *Inputted - Sample size*
- *Design – Independent*
- *Input (alpha) - 0.05*
- *Delta - 1.5*
- *Within S.D – 5*
- *Power - 0.9*
- *M – 1*

Appendix E – Systematic Review Documentation

Appendix E0: Systematic Review Protocol

Acupuncture Versus Manual Therapy for the Treatment of Low Back Pain. A Systematic Review

Review Question:

1. To determine the effectiveness of acupuncture versus manual therapy for LBP

2. To determine the available literature on acupuncture and manual therapy for LBP

Methodology:

The review will be conducted following the PRISMA statement (Liberati, 2009) to ensure transparency and completeness of the review.

Searches:

A comprehensive computerised search of databases will be conducted (EBSCOhost, ProQuest, SIGLE, HSRProj, CENTRAL, ACULARS, Acubriefs, Clinical trials and ISRCTN register).

The search terms will be adjusted according to the indexing of each database to ensure all available appropriate studies are identified, following the Cochrane Back Review Group (CBRG). Tables of database search results will be produced so searches can be replicated.

Types of studies included:

The inclusion of studies will follow the PICOS criteria:

- *Population:* *Persons suffering low back pain*
- *Interventions:* *Acupuncture versus manual therapy*
- *Control:* *Each intervention acting as a control for the other with or without an additional control group*
- *Outcome:* *Reduction of pain, improvement in function*
- *Study design:* *Randomised controlled trials*

(Stone, 2002)

Population:

Studies of adult participants of all genders aged between 18 - 65 years with a diagnosis of 'non-specific' LBP will be included.

Studies where a diagnosis of 'non-specific' LBP of the population was determined by a General Practitioner (GP) or other healthcare practitioner (Physiotherapist, Osteopath, Chiropractor, Nurse practitioner) only were included to ensure appropriate screening had been conducted and an accurate diagnosis determined.

> *'Non-specific' Low Back Pain; = a musculoskeletal problem, not attributable to a specific pathology (Milczarek, 2009).*

Trials investigating any one or more of acute (one to six weeks), sub-acute (six to twelve weeks) and chronic LBP (more than twelve weeks) (Milczarek, 2009) will be included, to be inclusive of the population of LBP sufferers.

Intervention and Control:

RCTs comparing the use of acupuncture with manual therapy for the treatment of LBP will be selected for this review.

Both the acupuncture and manual therapy interventions in any selected studies will be required to be conducted by a suitably qualified health care professional, trained in their respective field. Each intervention will act as a control to the other, with or without an additional control group.

Acupuncture will be restricted to 'real acupuncture' defined as the insertion of an acupuncture needle into specific acupuncture points (WHO, 2002). The style of acupuncture will not be limited for this review to ensure completeness of trial information. If more than one type of acupuncture or two acupuncture arms are studied they will be included if an appropriate comparator arm is also apparent.

Studies of acupuncture with non-penetrating needles, acupressure and laser acupuncture will be excluded.

Some acupuncture trials may have considered manual therapy / physiotherapy as 'usual care' or as a control arm; RCTs using this design will be considered for the review if the intervention included the use of manual therapy.

Manual therapy; incorporates mobilisation, therapeutic massage and manipulation treatments, all these interventions will be included under the classification of manual therapy:

- *Mobilisation; Joint and soft tissue movement within normal range*
- *Massage; Manual manipulation or mobilisation of soft tissues*
- *Manipulation; Low amplitude, high velocity movement taking joints beyond normal range*

(NICE guidelines, 2009)

Studies of all these types of manual therapy will be included. Studies using mechanical devices to deliver manual therapy or light touch / sham manual therapy techniques will be excluded.

Outcomes:

Studies will be included if a primary outcome measure focused on 'Pain Intensity', 'Quality of Life', 'Functional Status' or 'Occupational Status'. These are considered to be key areas of focus in the discipline of LBP and are important areas of attention for patients with LBP (Maughan and Lewis, 2010; Furlan et al. 2008).

Primary outcomes:

- *Quality of Life: e.g. EQ5D, SF-36, SF-12, Patient self-efficacy questionnaire (PSEQ)*
- *Functional status; e.g. Roland Morris disability scale, Oswestry disability index, Quebec back pain disability scale, SF-36, Sickness impact profile, Patient Specific Functional Scale (PSFS)*
- *Occupational status; e.g. Return to work status, number of sick*

days off work

- *Pain intensity; would be included if used in combination with one of the above measures e.g. Visual analogue scale (VAS), Numerical pain rating scale, Numerical Rating Scale (NRS), McGill pain inventory*

(Chiarotto et al. 2018; Maughan and Lewis, 2010; Resnik and Dobrzykoski, 2003; Furlan et al. 2008)

Other outcomes will not be considered for this review; e.g. economic outcomes, patient satisfaction, adverse reactions, negative consequences of the interventions, side effects, recurrence, fear avoidance behaviours, medication, depression e.g. Hamilton depression rating scale (HAMD). If a primary outcome does not measure quality of life, functional status, pain intensity, or occupational status, they were excluded. Other measures not listed above will only considered if they are appropriate to LBP and evidenced to be reliable, accurate and valid.

Study design:

All randomised controlled trials only comparing acupuncture with manual therapy for low back pain, published in English will be eligible for inclusion.

Data extraction:

The first reviewer will generate the electronic search strategies for EBSCOhost, ProQuest Dialog Healthcare and the other databases.

The database searches and searches of other sources will then be conducted by the first reviewer. Once the search results are complete, the identification of potential studies will be conducted independently by both reviewers. The titles and abstracts of all studies initially will be carefully screened by the two reviewers using the piloted study eligibility form and either excluded or selected to be reviewed as full text. Reasons for exclusion will be documented

Selected full texts studies will be independently reviewed, observing the inclusion and exclusion criteria. Study eligibility forms will be independently completed, with reasons for any exclusion provided.

Reasons for excluding studies will be provided to ensure transparency of the selection process and to limit any bias within the review process. Consensus will be used for any discrepancies; and arbitration by a third independent reviewer utilised to resolve any disagreement.

The data extraction form will be piloted to ensure consistency, the extraction is appropriate, no errors occur and biases excluded.

The two reviewers will independently extract data from the studies selected for inclusion. The data extraction will incorporated authors, year of publication, language, setting, country, study information, methodology, study population, study interventions, study comparisons, study outcomes, randomisation, blinding, data analysis, data to assess risk of bias, results, attrition and funding sources.

The objective of two independent reviewers is to reduce the risk of mistakes, data input errors and any relevant information being missed, reducing the introduction of bias (Edwards et al. 2002).

Data extraction will be recorded on data extraction forms to ensure transparency of information, consistency, and reproducibility, consequently reducing any risk of bias in this review. Any discrepancy not resolved through discussion, will be arbitrated by a third independent reviewer, whom also will have the concluding decision.

An attempt to retrieve any missing data will be planned, by contacting the authors.

If multiple publications of the same study exist, all appropriate information will be extracted, but the data will be treated as one study and analysed once.

Measurement bias can arise due to differences in outcome measurements. High quality trials provide full descriptions of the criteria for measuring outcomes and reduce the risk of bias. All selected studies will be reviewed for their reporting of the measurement outcomes, to assess the quality of the studies.

Quality assessment:

The assessment of methodological quality including the risk of bias will be assessed for this review using the 12 criteria recommended by the Cochrane Back Review Group (CBRG) (Furlan et al; 2009; Bombardier, Esmail and Nachemson, 1997) and considered design, quality of methodology, consistency of results, sufficient data, generalizability and risk of bias. This is considered a comprehensive tool in the field of LBP and relates to the Cochrane risk of bias tool.

Prior to assessing the selected studies, a pilot process of assessing the criteria will be performed by both reviewers independently to identify and address any opportunity for misinterpretation or disagreement.

The 12 criteria will be scored as 'yes', 'no' or 'don't know' and reported with reasons for each decision to demonstrate transparency of the decisions. For this review an RCT will be considered at 'low risk of bias' of high quality if it meets criteria 'A' (randomisation), 'B' (allocation concealment), 'C5' (outcome assessor blinding) and a minimum of three other criteria.

Due to the nature of many acupuncture and manual therapy RCTs being pragmatic and blinding of clinicians and patients to treatment intervention being unrealistic in many studies, criteria 'C3' (patient blinding) and criteria 'C4' (clinician blinding) will be interpreted as the clinician and patient not being informed of the outcome of their intervention in relation to the study objectives until after analysis of the whole study.

The two reviewers will assess the methodological quality and risk of bias of the selected studies independently to ensure accuracy, consistency and transparency of the review, reducing any risk of bias. This assessment will

be conducted to ensure any studies with serious flaws were excluded from any meta-analysis, (e.g. exceptionally high attrition rates, or trial conclusions not supported by the reported statistical results), and also to grade the quality of the trials from low too high to guide the strengthen of the evidence presented (Low quality studies with a high risk of bias fulfilled six or less of the criteria, high quality studies with a low risk of bias fulfilled seven or more criteria) attrition rate will be also considered for the risk of bias assessment.

Studies with low risk of bias will be included in any pooling or meta-analysis of the results, any studies of low quality and a high risk of bias will be considered further before any inclusion or rejection from pooling or meta-analysis, a sensitive analysis may be considered if appropriate (Bland, 2000).

Adequacy of interventions:

The adequacy of interventions within the selected studies is a subjective analysis therefore both reviewers will agree on the adequacy in delivery of the intervention for each included study. The reviewers will hold extensive knowledge and experience in acupuncture and manual therapy and will be well informed to assess the adequacy of an intervention.

Each intervention was judged as adequate, moderate or inadequate for the studies; if any interventions are deemed to be inadequate in their delivery of the intervention the studies will be excluded from pooling of the results in a meta-analysis. Adequacy will include the consideration to the type of treatment, the length of session, the number of treatment sessions, the period of time they were delivered over and the therapist delivering the intervention.

Detailed explanations will be provided of the reviewer's views of any studies excluded for inadequate interventions. If studies were considered of moderate adequacy they would be given further consideration in relation to quality and the other parameters of the systematic review to

decide if they would be appropriate or not for pooling in a meta-analysis, with explanations provided.

Clinical Relevance:

An assessment of clinical relevance of the studies will be performed and discussed. The assessment will be made using an adapted version of the assessment guide for clinical relevance developed by the Cochrane Back Review Group (Furlan et al. 2008).

GRADE:

The GRADE framework will be used for the SR to assess the quality and strength of evidence, and to make recommendations based on the assessment (GRADE, 2013; Schünermann et al. 2013).

Data analysis:

Descriptive data will be used to summarise the main characteristics and conclusions of the studies and these will be presented.

A meta-analysis is regarded as useful tool for a systematic review as it provides a clear picture of the evidence, provides a common effect of the study data by pooling the data, and summarises the results of several studies into one single estimate of treatment effect. The meta-analysis would consider the interventions comparative to each other to consider any differences within the study results. Sub-group analyses are not anticipated as a requirement for this review.

To perform a meta-analysis of the studies for continuous data, the mean, standard deviation and sample size will be required for each trial for analysis to occur. If data from a study were inadequate for analysis, the authors were contacted to request further information (Singh et al. 2017; Bland, 2000).

For continuous data outcomes, mean difference and standard deviations will be presented. Any data presented with alternative measurements will be converted into standard deviations for the pooling of the data for meta-analysis. Any dichotomous data present was reported as risk ratios or odds

ratios and their 95% confidence intervals. Inverse variance methods (Mantel-Haenszel method) will be used for pooling of data where appropriate (Bland, 2000).

The software package RevMan 5.3 will be used for the meta-analysis. A common estimate of the mean and standard deviation will be used, and data presented in other forms was converted to mean values and standard deviations for each study to provide a common study denominator.

Chi-squared will be calculated as:

$$Q = \text{sum of (study estimate} - \text{common estimate / standard error)}^2$$

Heterogeneity between the studies will be assessed using I^2. The I^2 is the percentage of variation across the RCTs that is due to heterogeneity rather than chance (Higgins and Thompson, 2002). I^2 was calculated as:

$$I^2 = (Q - df) / Q$$

If heterogeneity / I^2 were below 50% a meta-analysis will be performed to pool the data using the fixed effects model. If heterogeneity fell between 50 - 75% then a meta-analysis will be performed using a random effects model. If heterogeneity rose above 75%, pooling of the results would not be recommended as it would be invalid to pool the results into a single summary and a narrative analysis will be provided (Singh, 2017; Gagnier et al. 2012; Bland, 2000).

If any data is inadequate for analysis, the trial will be excluded from any pooling of the results and presented descriptively. The extent of attrition bias and the use of the intention to treat (ITT) analysis to reduce the risk of attrition bias will be considered for each trial (Torgerson and Torgerson, 2008). Trials utilising ITT will be included, trials not using ITT may indicate bias and low quality, these trials will be considered for quality, and attrition levels assessed prior to pooling of any data for a meta-analysis.

A sensitivity analysis may be performed if weaker (low quality or very small) studies looked to be influencing the results; this will be assessed considering outlying results or substantial differences to other studies. A sensitivity analysis without these studies will be an efficient way to consider the influence of quality. An analysis of the stronger evidence may be useful, to see if the results differ, giving an indication of the influence of strength of research. If questionable studies exist in the review, an analysis will be performed without them to assess their influence on the results. If any treatments were assessed as inadequate, a sensitivity analysis to investigate the impact of their exclusion will be conducted to ensure the reviewer's views had not biased the results.

Outcome measurements will be analysed together at their primary outcome measurement time point. If the continuous outcome measures were not measured on the same outcome scale the standardised mean difference (SMD) will be used. The weighted mean difference (WMD) would be used to provide a standard unit of measurement for the meta-analysis for pooling data. They will be weighted by how informative each study is. Studies would be weighted to reflect their importance, the greater the sample size the greater the weighting of the trial for the meta-analysis (Bland, 2000). Forest plots will be presented for the results of any meta-analysis conducted.

The GRADE assessment will be detailed for the SR and the recommendations presented.

Dissemination strategy:

It is intended for this review to be published in a high impact journal, which will access as many doctors, therapists and policy makers as possible e.g. Lancet, BMJ or JAMA. It would be anticipated that the review would also be available on the internet. The Centre for Reviews and Dissemination (CRD) would be contacted for support in dissemination of the review and aid targeting DARE, NHS EED and the HTA for inclusion.

Appendix E1: Search strategy for EBSCOhost

Databases for EBSCOhost included:

- *AMED (1985 – July 2017)*
- *CINAHL (1981 – July 2017)*
- *CINAHL Plus (1937 - July 2017)*
- *CSP Online Library Catalogue (1937 – July 2017)*
- *Medline (July 2017)*
- *SPORTDiscus (July 2017)*

Search specification to include / limit to for all:

- *Boolean /phrase*
- *Apply equivalent subjects*
- *Apply related words*
- *Also search within full text of articles*

Special limiters for AMED

- *Journal article*
- *Abstract available*
- *English Language*

Special limiters for CINAHL

- *Abstract available*
- *English Language*
- *Human*
- *Exclude MEDLINE records*
- *Journal subset – All*
- *Gender – All*
- *Special Interest – All*
- *Language – English*
- *Clinical queries – All*
- *Publication type – Clinical Trial*
- *Age groups – All Adult*
- *Geographic subset – All*

Special limiters for CINAHL plus with Full Text

- *Abstract available*
- *English Language*
- *Exclude MEDLINE records*
- *Human*
- *Journal subset – Peer reviewed*
- *Publication type – clinical trial*
- *Research Article*
- *Special Interest – All*
- *Clinical queries – All*
- *Randomised controlled trials*

- *Geographic subset – All*
- *Sex – All*
- *Age groups – All Adult*
- *Language – English*

Special limiters for CSP Online Library Catalogue

- *Publication type – All*
- *Language – English*
- *Catalog Only*

Special limiters for MEDLINE

- *Human*
- *Sex – All*
- *Clinical queries – All*
- *Journal & Citation Subset – All*
- *Language – English*
- *Abstract available*
- *English Language*
- *Review Articles*
- *Age Related – All Adult*
- *Subject Subset – All*
- *Publication type – Journal article*

Special limiters for SPORTDiscus

- *English abstract available*
- *Country – All*
- *Document type – Article*
- *Language – English*
- *Publication type – Academic Journal*
- *Database Subset – All*

Search strategy: (In abstract or title)

1. *randomised control trial 'or'*
2. *randomized controlled trial 'or'*
3. *controlled clinical trial 'or'*
4. *randomised 'or'*
5. *randomly in abstract 'or'*
6. *rct*
7. *and*
8. *lbp 'or'*
9. *Back Pain 'or'*
10. *Low Back Pain 'or'*
11. *Lower back pain 'or'*
12. *spinal disease 'or'*
13. *disc degeneration 'or'*
14. *disc prolapse 'or'*
15. *disc herniation 'or'*

16. *facet joints 'or'*
17. *intervertebral disc 'or'*
18. *back strain 'or'*
19. *dorsalgia 'or'*
20. *backache 'or'*
21. *lumbar pain 'or'*
22. *coccyx 'or'*
23. *coccydynia 'or'*
24. *sciatica 'or'*
25. *sciatic neuropathy 'or'*
26. *spondylosis 'or'*
27. *lumbago 'or'*
28. *radiculopathy 'or'*
29. *radicular pain 'or'*
30. *non-specific back pain 'or'*
31. *nonspecific back pain 'or'*
32. *simple back pain 'or'*
33. *low back syndrome 'or'*
34. *back 'or'*
35. *spine 'or'*
36. *and*
37. *acupuncture 'or'*
38. *acupuncture therapy 'or'*
39. *acupuncture points 'or'*
40. *acupuncture analgesia 'or'*
41. *dry needling 'or'*
42. *dry needle 'or'*
43. *acupressure 'or'*
44. *indwelling needles 'or'*
45. *auricular acupuncture 'or'*
46. *needling*
47. *and*
48. *manual therapy 'or'*
49. *musculoskeletal manipulation 'or'*
50. *manipulation 'or'*
51. *mobilisation 'or'*
52. *mobilization 'or'*
53. *physiotherapy 'or'*
54. *physical therapy 'or'*
55. *osteopathy 'or'*
56. *chiropractic 'or'*
57. *massage 'or'*
58. *soft tissue manipulation 'or'*
59. *soft tissue therapy 'or'*
60. *trigger point release 'or'*
61. *trigger point therapy*
62. *myofacial release 'or'*
63. *soft tissue release 'or'*
64. *mobilisation with movement 'or'*
65. *mwm 'or'*
66. *nag 'or'*
67. *snag*

Results from search 04/07/2017

EBSCOhost = 48 results

AMED = 13

MEDLINE = 28

SPORTDiscus = 7

CINAHL = 0

All studies reviewed independently by both reviewers.

Duplicates removed.

Appendix E2: Table showing excluded publications by title and abstract

Title, author, date	Participants /conditions	Interventions	Reason for exclusion	Study No:
Schinan, M. Neubauer, B. Pieber, K. Gruber, M. Kainberger, F. Castellucci, C. Olischar, B. Maruna, A Windhager, R. Sabeti-Aschraf, M. **Clinical Journal of Sport Medicine 2016. 26 (3): 199** **Climbing has a positive effect on low back pain: A prospective randomized controlled trial.**	Low back pain	Climbing	Inappropriate intervention	1/48 SPORT Discus (reviewer one only)
Bervoets DC. Luijsterburg PA. J. Alessie JJN. Buijs, MJ. Verhagen, AP. **Journal of physiotherapy 2015. 61 (3): 106** **Massage therapy has short-term benefits for people with common musculoskeletal disorders compared to no treatment: a systematic review.**	Musculoskeletal disorders	Massage	Not RCT	2/48 SPORT Discus
Furlan, AD. Giraldo, M. Baskwill, A. Irvin, E. Imamura, M. **Cochrane Database of Systematic Reviews 2015.** **Massage for low back pain.**	Low back pain	Massage	Not RCT	3/48 MEDLINE
Southerst, D. Marchand, AA. Cote, P. Shearer, HM. Wong, JJ. Varatharajan, S. Randhawa, K. Sutton, D. Yu, H. Gross, DP. Jacobs, C. Goldrub, R. Stupar, M. Mior, S. Carroll, LJ. Taylor-Vaisey, A. **Journal of Manipulative and Physiological Therapeutics 2015. 38 (7): 521** **The effectiveness of noninvasive interventions for musculoskeletal thoracic spine and chest wall pain: a systematic review.**	Thoracic spine pain	Non-invasive interventions	Not RCT	4/48 MEDLINE (reviewer one only)
Lee, J. Shin, JS. Lee, YJ. Kim, M. Byung Park, A. Kropf, MA. Shin, BA. Lee, MS. Ha, I. Jinho, L. Shin, J. Lee, Y. Kim, M. Ahn, Y. **Trials 2015. 10/12/2015** **Effects of Shinbaro pharmacopuncture in sciatic pain patients with lumbar disc herniation: study protocol for a randomized controlled trial.**	Lumbar disc herniation	Shinbaro pharmacupunture	Inappropriate intervention	5/48 MEDLINE

Olson, E. Bodziony, M. Ward, J. Coats, J. Koby, B. Goehry, D. **Journal of Chiropractic Medicine 2014. 13 (4): 230** **Effect of lumbar spine manipulation on asymptomatic cyclist sprint performance and hip flexibility.**	Asymptomatic cyclist	Manipulation	Inappropriate condition	6/48 SPORT Discus
Llamas-Ramos, R. Pecos-Martin, D. Gallego-Izquierdo, T. Llamus-Ramos, I. Plaza-Manzano, G. Ortega-Santiago, R. Cleland, J. FerÁNdez-De-Las-PeŃas, C. **Journal of Orthopaedic & Sports Physical Therapy 2014. 44 (11): 852** **Comparison of the short-term outcomes between trigger point dry needling and trigger point manual therapy for the management of chronic mechanical neck pain: a randomised clinical trial.**	Neck pain	Acupuncture and manual therapy	Inappropriate condition	7/48 SPORT Discus
Shin, YS. Shin, JS. Lee, YJ. Kim, MR. Ahn, YJ. Park, KB. Shin, BC. Lee, MS. Kim, JH. Cho, JH. Ha, IH. **Complementary and Alternative Medicine 2015. 15 (1): 432** **A survey among Korea doctors (KMDs) in Korea on patterns of integrative Korean medicine practice for lumbar intervertebral disc displacement: Preliminary research for clinical practice guidelines.**	Disc	Medicine	Not RCT	8/48 MEDLINE
Chen, HM. Wang, HH. Chiu MH. Hu HM. **Journal of American Society of Pain Management Nurses 2015. 16 (3): 188** **Effects of acupressure on menstrual distress and low back pain in dysmenorrheic young adult women: an experimental study.**	Low back pain	Acupressure	Inappropriate comparator	9/48 MEDLINE
Sokunbi, OG. **South African journal of Physiotherapy 2014. 70 (2): 4** **A pilot study on using acupuncture and core stability exercises to treat non-specific acute low back pain among industrial workers.**	Low back pain	Acupuncture	Inappropriate comparator	10/48 AMED
Tellez-Garcia, M. de-liave-Rincon, A. Salom-Moreno, J. Palacios-cena, M. Ortega-Santiago, R. Fernandez-de-las-penas, C. **Journal of bodywork & movement Therapies 2015. 19 (3): 464** **Neuroscience education in addition to trigger point dry needling for the management of patients with mechanical chronic low back pain: A preliminary clinical trial.**	Low back pain	Education & dry needling	Inappropriate comparator	11/48 SPORT Discus
Buselli, P.Bosoni, R. Buse, G. Fasoli, P. La Scala, E. Mazzolari, R. Zanetti, F. Messina, S. **Trials 2011. 04/10/11** **Effectiveness evaluation of an integrated automatic thermo mechanic massage system in non-specific sub-acute and chronic low back pain – a randomized double-blinded controlled trial, comparing SMATH therapy versus sham therapy: study protocol for a randomized controlled trial.**	Low back pain	Massage	Inappropriate comparator	12/48 MEDLINE

Fiore, P. Panza, F. Castella, G. Russo, A. Frisardi, V. Solfrizzi, V. Ranieri, M. Di Teo, L. Santamato, A. **European Journal of Physical and Rehabilitation Medicine 2011. 47 (3): 367** **Short-term effects of high-intensity laser therapy versus ultrasound therapy in the treatment of low back pain.**	Low back pain	Laser therapy	Inappropriate intervention	13/48 MEDLINE
McMorland, G. Suter, E. Casha, S. du Plessis, SJ. Hurlbert, RJ. **Journal of Manipulative & Physiological Therapeutics 2010. 33 (8): 576-84** **Manipulation of microdiskectomy for sciatica? A prospective randomised clinical study.**	Sciatica	Manipulation of microdiskectomy	Inappropriate intervention	14/58 MEDLINE
Li, Y. **International Journal of Clinical Acupuncture 2013. 22 (2): 61** **Therapeutic effect and blood rheology of patients with cervical spondylosis treated with acupuncture combined with massage**	Cervical spondylosis	Acupuncture and massage	Inappropriate condition	15/48 AMED (Reviewer one only)
Shankar, N. Thakur, M. Tandon, OP. Saxena, AK. Arora, S. Bhattacharya, N. **Indian Journal of Physiology and Pharmacology 2011. 55 (1): 25** **Autonomic status and pain profile in patients with low back pain and following electro acupuncture therapy: a randomized control trial.**	Low back pain	Electro acupuncture	Inappropriate comparator	16/48 MEDLINE
Koog, H. Jin, SS. Yoon, K. Min, B. **Disability & Rehabilitation 2010. 32 (4): 282** **Interventions for hemiplegic shoulder pain: systematic review of randomised controlled trials.**	Hemiplegic shoulder pain	Interventions	Inappropriate condition	17/48 SPORT Discus
Ding, Q. Yan, M. Zhou, J. Yang, L Guo, J Wang, J. Shi, Z. Wang, Y. Zhao, H. **Journal of Traditional Chinese Medicine 2012. 32 (3): 388** **Clinical effects of innovative tuina manipulations on treating cervical spondylosis of vertebral artery type and changes in cerebral blood flow.**	Cervical spine	Tuin a (massage)	Inappropriate condition	18/48 MEDLINE
Furlan, AD. Imamura, M. Dryden, T. Irvin, E. **Cochrane Database of Systematic Reviews, 2008.** **Massage for low back pain.**	Low back pain	Massage	Not RCT	19/48 MEDLINE
Kennedy, S. Baxter, GD. Kerr, DP. Bradbury, I. Park, J. McDonough, SM. **Complementary Therapies in Medicine 2008. 16 (3): 139** **Acupuncture for acute non-specific low back pain: a pilot randomised non-penetrating sham controlled trial.**	Low back pain	Acupuncture only	Inappropriate comparator	20/48 MEDLINE
Carneiro, KA. Rittenberg, JD. **Physical Medicine & Rehabilitation Clinics of North America 2010. 21 (4): 777** **The role of exercise and alternative treatments for low back pain**	Low back pain	Exercise and alternative treatments	Inappropriate intervention	21/48 AMED

Thomas, KL. MacPherson, H. Thorpe, L. Brazier, J. Campbell, M. Fitter, M. Roman, M. Walters, S. Nicholl, JP. **Health Technology Assessment 2005. 9 (32): 1** **Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain.**	Low back pain	Acupuncture	Inappropriate comparator	22/48 MEDLINE
Myers, SS. Phillips, RS. Davis, RB. Cherkin, DC. Legedza, A. Kaptchuk, TJ. Hrbek, A. Buring, JE. Post, D. Connelly, MT. Eisenberg, DM. **Journal of General Internal Medicine 2008. 23 (2): 148** **Patient expectations as predictors of outcome in patients with low back pain.**	Low back pain	Expectations	Inappropriate intervention	23/48 MEDLINE
Herman, PM. Szczurko, O. Cooley, K. Mills, EJ. Herman, P. Szczurko, O.Cooley, K. Mills, EJ. **Alternative Therapies in Health & Medicine 2008. 14 (2): 32** **Cost-effectiveness of naturopathic care for chronic low back pain.**	Low back pain	Naturopathic care	Not RCT	24/48 AMED
Furlan, AD. Brosseau, L. Imamura, M. Irvin, E. **A systematic review within the framework of the Cochrane collaboration back review group, 2002.** **Massage for low-back pain**	Low back pain	Massage	Not RCT	28/48 MEDLINE
Chenot, JF. Becker, A. Leonhardt, C. Keller, S. Donner-Banzhoff, N. Baum, E. Pfingsten, M. Hildebrandt, J. Basler, HD. Kochen, MM. **BMC Complementary and Alternative Medicine 2007. 7: 42** **Use of complementary and alternative medicine for low back pain consulting in general practice: a cohort study.**	Low back pain	CAM	Not RCT	30/48 MEDLINE
Leibing, E. Leonhart, U. Koster, G. Rosenfeldt, JA. Hilgers, R. Ramadori, G. **PAIN 2002. 96 (1-2) 189** **Acupuncture treatment of Chronic Low-back pain – a randomized, blinded, placebo-controlled trial with 9-month follow-up.**	Low back pain	Acupuncture	Inappropriate comparator	33/48 MEDLINE
Hsieh, LL. Kuo, CH. Lee, LH. Yen, AM. Chien, KL. Chen, TH. **BMJ (Clinical research Ed.) 2006. 332 (7542): 696** **Treatment of low back pain by acupressure and physical therapy: randomised controlled trial.**	Low back pain	Acupressure	Inappropriate intervention	34/48 MEDLINE
Muller, R. Giles, LGF. **Journal of Manipulative & Physiological Therapeutics 2005. 28 (1): 3-11** **Long-term follow-up of a randomized clinical trial assessing the efficacy of medication, acupuncture, and spinal manipulation for chronic mechanical spinal pain syndromes.**	Spinal pain syndromes	Medication, acupuncture, and spinal manipulation	Long term follow up of included study - Duplicate results	35/48 MEDLINE
Langevin, HM. Bouffard, NA. Churchill DL. Badger, GL.	Fibroblast	Acupuncture	Not RCT	37/48 AMED

Journal of Alternative & Complimentary Medicine 2007. 13 (3): 355 **Connective tissue fibroblast response to acupuncture: dose dependant effect of bidirectional needle rotation.**				
Drivdahl, CE. Miser, WF. **The Journal of American Board of Family Practice 1998. 11 (3): 193** **The use of alternative health care by a family practice population**	Family practice	Alternative health care	Not RCT	42/48 MEDLINE
Ernst, E. Pittler, MH. **Journal of Manipulative & Physiological Therapeutics 1999. 22 (2): 87** **Experts' opinions on complementary/ alternative therapies for low back pain.**	Low back pain	CAM	Not RCT	43/48 AMED
Vickers, AJ. **Clinical Journal of Pain 2004. 20 (5): 319** **Statistical reanalysis of four recent randomized trials of acupuncture for pain using analysis of covariance**	Pain	Acupuncture	Not RCT	44/48 AMED
Ernst, E. **European Journal of Physical Medicine & Rehabilitation, 1998. 8 (2): 53** **The use, efficacy, safety and costs of complementary/alternative therapies for low back pain.**	Low back pain	CAM	Not RCT	45/48 AMED
Richardson, J. **Complementary Therapies in Medicine 1995. 3 (3): 153-7** **Complementary therapies on the NHS: the experience of a new service.**	N/A	Complementary therapies	Not RCT	47/48 AMED
Garvey, TA. Marks, MR. Wiesel, SW. **Spine 1989. 14 (9): 962** **A prospective, randomized, double-blind evaluation of trigger-point injection therapy for low back pain**	Low back pain	Injection therapy	Inappropriate intervention	48/48 MEDLINE

Appendix E3: Table showing excluded publications by full text

Study	**Participants / conditions**	**Interventions**	**Reason for exclusion**	**Study No:**
Eisenberg, DM. Post, DE. Davis, RB. Connelly, MT. Legedza, AT. Hrbek, AL. Prosser, LA. Buring, JE. Inui, TS. Cherkin, DC. **Spine 2007. 15 (2): 151-8** **Addition of choice of complementary therapies to usual care for acute low back pain: a randomized controlled trial.**	Low back pain	Complimentary therapies	Inappropriate comparator	25/48 MEDLINE

Haake, M. Muller, HH. Schade-Brittinger, C. Basler, HD. Schafer, H. Maier, C. Endres, HG. Trampisch, HJ. Molsberger, A. **Archives of Internal Medicine 2007. 167 (17): 1892** **German acupuncture trials (GERAC) for low back pain: randomized, multicentre, blinded, parallel-group trial with 3 groups.**	Low back pain	Acupuncture	Inappropriate comparator	26/48 MEDLINE
Prady, SL. Thomas, K. Esmonde, L. Crouch, S. Macpherson, H. **Acupuncture in Medicine 2007. 25 (4): 121-9** **The natural history of back pain after a randomised controlled trial of acupuncture vs usual care – long term outcomes.**	Back pain	Acupuncture vs usual care	Inappropriate comparator	27/48 MEDLINE
Sherman, KJ. Cherkin, DC. Deyo, RA. Erro, JH. Hrbek, A. Davis, RB. Eisenberg, DM. **Clinical Journal of Pain 2006. 22 (3): 227** **The diagnosis and treatment of chronic pain by acupuncturists, chiropractors and massage therapists**	Low back pain	Assessment	Not RCT	31/48 MEDLINE
Hsieh, LL. Kuo, C. Yen, M. Chen, TH. **Preventative Medicine 2004. 39 (1): 168-76** **A randomised controlled clinical trial for low back pain treated by acupressure and physical therapy.**	Low back pain	Acupressure and physical therapy	Inappropriate intervention	32/48 MEDLINE
Bruce, B. Lorig, K. Laurent, D. Ritter, P. **Patient Education and Counselling 2005. 58 (3): 305** **The impact of a moderate e-mail discussion group on use of complementary and alternative therapies in subjects with recurrent back pain.**	Low back pain	CAM	Not RCT	38/48 MEDLINE
Cherkin, DC. Sherman, KJ. Deyo, RA. Shekelle, PG. **Annals of Internal Medicine 2003. 138 (11): 898** **A review of the evidence for the effectiveness, safety, and cost of acupuncture, massage therapy, and spinal manipulation for back pain.**	Back pain	Acupuncture, massage therapy, and spinal manipulation	Not RCT	39/48 AMED
Kalauokalani, D. Cherkin, DC. Sherman, KJ. Koepsell, TD. Deyo, RA. **Spine 2001. 26 (13): 1418-24** **Lessons from a trial of acupuncture and massage for low back pain: patient expectations and treatment effects…including commentary by Lurie JD.**	Low back pain	Acupuncture and massage	Not RCT	40/48 AMED
Murray, K. **Journal of Chiropractic 2004. 41 (1): 50** **A randomized trial comparing Medication, Acupuncture and spinal manipulation.**	Low back pain	Medication, Acupuncture and manipulation	Not RCT	46/48 SPORT Discus

Appendix E4: Table showing publications selected for inclusion

Title, authors and date	Participants / Conditions	Intervention	Outcome	Study No
Kumnerddee, W. **Journal of the Medical Association of Thailand 2009. 92 (1): 117** **Effectiveness comparison between Thai traditional massage and Chinese acupuncture for myofascial back pain in Thai military personnel: a preliminary report.**	Back pain	Massage Acupuncture	Included	29/48 MEDLINE
Giles, GFL. Muller, R. **Journal of Manipulative & Physiological Therapeutics 1999. 22 (6): 376-81** **Chronic spinal pain syndromes: a clinical pilot trial comparing acupuncture, a nonsteroidal anti-inflammatory drug, and spinal manipulation.**	Chronic spinal pain syndromes	Acupuncture, a non-steroidal anti-inflammatory drug, and spinal manipulation	Included	36/48 AMED
Cherkin, DC. Eisenberg, D. Sherman, KJ. Barlow, W. Kaptchuk, TJ. Street, J. Deyo, RA. **Arch Internal Medicine 2001. 161: 1081** **Randomized trial comparing traditional Chinese medical acupuncture, therapeutic massage and self-care education for chronic low back pain.**	Chronic low back pain	Acupuncture, Therapeutic massage and self-care	Included	41/48 AMED

Appendix E5: Search strategy for ProQuest Dialog Healthcare

Databases ProQuest Dialog Healthcare included:

- *British Nursing Index – 1994 - July 2017*
- *Allied & Complementary Medicine 1985 – July 2017*
- *DH-DATA: Health Administration, Medical Toxicology & Environment 1983 –July 2017*
- *Medline 1946 –July 2017*
- *Embase 1947 – July 2017*
- *Embase Alert – July 2017*

Search specification to include / limit to:

- *Abstract included*
- *Humans*
- *Males*
- *Females*
- *Clinical trials*
- *Not anima trials*

Publication dates:

- *All dates*

Document type:

- *Article*
- *Conference*
- *Conference paper*
- *Conference preceding*
- *Government and official documents*
- *Instructional material/ guideline*
- *Reference document*

Language selection:

- *English*

Duplicate documents not included.

Search strategy: (In abstract or title)

1. *randomised control trial 'or'*
2. *randomized controlled trial 'or'*
3. *controlled clinical trial 'or'*
4. *randomised 'or'*
5. *randomly in abstract 'or'*
6. *rct*
7. *and*
8. *lbp 'or'*
9. *Back Pain 'or'*
10. *Low Back Pain 'or'*
11. *Lower back pain 'or'*
12. *spinal disease 'or'*
13. *disc degeneration 'or'*
14. *disc prolapse 'or'*
15. *disc herniation 'or'*
16. *facet joints 'or'*
17. *intervertebral disc 'or'*
18. *back strain 'or'*
19. *dorsalgia 'or'*
20. *backache 'or'*
21. *lumbar pain 'or'*
22. *coccyx 'or'*
23. *coccydynia 'or'*
24. *sciatica 'or'*
25. *sciatic neuropathy 'or'*
26. *spondylosis 'or'*
27. *lumbago 'or'*
28. *radiculopathy 'or'*
29. *radicular pain 'or'*
30. *non-specific back pain 'or'*
31. *nonspecific back pain 'or'*
32. *simple back pain 'or'*

33. *low back syndrome 'or'*
34. *back 'or'*
35. *spine 'or'*
36. *and*
37. *acupuncture 'or'*
38. *acupuncture therapy 'or'*
39. *acupuncture points 'or'*
40. *acupuncture analgesia 'or'*
41. *dry needling 'or'*
42. *dry needle 'or'*
43. *acupressure 'or'*
44. *indwelling needles 'or'*
45. *auricular acupuncture 'or'*
46. *needling*
47. *and*
48. *manual therapy 'or'*
49. *musculoskeletal manipulation 'or'*
50. *manipulation 'or'*
51. *mobilisation 'or'*
52. *mobilization 'or'*
53. *physiotherapy 'or'*
54. *physical therapy 'or'*
55. *osteopathy 'or'*
56. *chiropractic 'or'*
57. *massage 'or'*
58. *soft tissue manipulation 'or'*
59. *soft tissue therapy 'or'*
60. *trigger point release 'or'*
61. *trigger point therapy*
62. *myofacial release 'or'*
63. *soft tissue release 'or'*
64. *mobilisation with movement 'or'*
65. *mwm 'or'*
66. *nag 'or'*
67. *snag*

Results from ProQuest search 04/07/2017:

32 results
All studies reviewed independently by both reviewers.
All duplicates were removed.

British Nursing Index: 4

Allied & Complementary Medicine: 5

DH DATA: 1

MEDLINE: 20

Embase: 0

Embase Alert: 2

Appendix E6: Table showing excluded publications by title and abstract

Study	Participants / conditions	Interventions	Reason for exclusion	Study No:
Haas, M. Abreu Lourenco, R. **PharmacoEconomics 2015. 33 (6): 561** **Pharmacological Management of Chronic Lower Back Pain: A Review of Cost Effectiveness.**	Low back pain	Pharmacological management	Not RCT	1/32 Embase Alert
Xu, M. Yan, S. Yin, X. Li, X. Gao, S. Han, R. Wei, L. Luo, W. Lei, G. **American Journal of Chinese Medicine 2013. 41 (1): 1** **Acupuncture for chronic low back pain in long-term follow-up: A meta-analysis of 13 randomised controlled trials.**	Low back pain	Acupuncture	Not RCT	2/32 Allied & Complementary Medicine
Chen, HM. Wang, HH. Chiu, MH. Hu, HM. **Pain Management Nursing 2015. 16 (3): 188 W.B. Saunders Co.** **Effects of acupressure on menstrual distress and low back pain in dysmenorrheic young adult women: an experimental study.**	Low back pain	Acupressure	Inappropriate comparator	4/32 British Nursing Index
Close, C. Sinclair, M. Liddle, S. D. Madden, E. McCullough, J. **Journal of Advanced Nursing 2014. 70 (8): 1702 Wiley-Blackwell Publishing Ltd.** **A systematic review investigating the effectiveness of Complementary and Alternative Medicine (CAM) for the management of low back and/or pelvic pain (LBPP) in pregnancy.**	Low back pain	CAM	Not RCT	5/32 British Nursing Index
Lewis, RA. Williams, NH. Sutton, AJ. Burton, K. Din, NUD. Matar, HE. Hendry, M. Phillips, CJ. Nafees, S. Fitzsimmons, D. Rickard, I. Wilkinson, C. **Spine Journal 2015. 15 (6): 1461** **Comparative clinical effectiveness of management strategies for sciatica: systematic review and network meta-analyses.**	Sciatica	Management strategies	Not RCT	6/32 MEDLINE
Mejuto-Vazquez, MJ. Salom-Moreno, J. Ortega-Santiago, R. Truyols-Dominguez, S. Fernandez-de-las-Penas, C. **Journal of Orthopaedic & Sports Medicine 2014. 44 (4): 252** **Short term changes in neck pain, widespread pressure pain sensitivity and cervical range of motion after the application of trigger point dry needling in patients with acute mechanical neck pain: A randomized clinical trial.**	Neck pain	Dry needling	Inappropriate condition	7/32 MEDLINE
Santaguida, PL. Gross, A. Busse, J. Gagnier, J. Walker, K. Bhandari, M. Raina, P. **Evidence Report/ Technology Assessment. 2009 (177)** **Complementary and alternative medicine in back pain utilization report**	Back pain	Complementary medicine	Not RCT	8/32 DH DATA
Xu, S. **Acupuncture and Electrotherapeutics Research 2011. 36 (3-4): 259**	Depression	Electro-acupuncture	Inappropriate condition	9/32 Allied & Compleme

Effects of electro acupuncture on depression in a rat model				ntary Medicine
Zhang, W. **International Journal of clinical Acupuncture 2005. 14 (4): 261** **Treatment of arterial-type cervical spondylosis with acupoint-injection, combined with massage manipulation**	Cervical spondylosis	Injection and massage	Inappropriate condition	10/32 Allied & Complementary Medicine
Johnston, BC. da Costa, BR. Devereaux PJ. Akl, EA. Busse, JW. **Spine 2008. 33 (8): 914** **The use of expertise-based randomized controlled trials to assess spinal manipulation and acupuncture for low back pain: a systematic review.**	Low back pain	manipulation and acupuncture	Not RCT	11/32 MEDLINE
Furlan, AD. Imamura, M. Dryden, T. Irvin, E. **Cochrane Database of Systematic reviews. 2008.** **Massage for low-back pain.**	Low back pain	Massage	Not RCT	12/32 MEDLINE
Itoh, K. Katsumi, Y. Katakoji, H. **Acupuncture in Medicine 2004. 22 (4): 170** **Trigger point acupuncture treatment of chronic low back pain in elderly patients – a blinded RCT.**	Low back pain	Acupuncture	Inappropriate comparator	13/32 MEDLINE
Chen, L. Su, Y. Su, C. Lin, H. Kuo, H. **Journal of Clinical Nursing 2008. 17 (9): 1174** **Acupressure and meridian massage: combined effects on increasing body weight in premature infants.**	Body weight in premature infants	Acupressure and meridian massage	Inappropriate condition	14/32 British Nursling Index
Pincus, T. Anwar, S. McCracken, L. McGregor, A. Graham, L. Collinson, M. Farrin, AJ. OBI Trial Management Team. **Trials 2013. 14 (1): 172** **Testing the credibility, feasibility and acceptability of an optimised behavioural intervention (OBI) for avoidant chronic low back pain patients: protocol for a randomised feasibility study.**	Low back pain	OBI	Inappropriate intervention	16/32 MEDLINE
Pennick, V. Liddle, SD. **Cochrane Database of Systematic Reviews 8 2013.** **Interventions for preventing and treating pelvis and back pain in pregnancy.**	Pelvis and low back pain in pregnancy	Interventions	Not RCT	17/32 MEDLINE
Chou, R. Huffman, LH. **Annals of Internal Medicine 2007. 147 (7): 492** **Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/ American College of Physicians clinical practice guideline.**	Low back pain	Non-pharmacologic therapies	Not RCT	18/32 MEDLINE
Maiers, MJ. Westrom, KK. Legendre, CG. Bronfort, G.	Low back pain	Integrative care	Not RCT	19/32 EMBASE Alert

BMC Health Services Research 2010. 10: 298 **Integrative care for the management of low back pain: use of a clinical care pathway.**				
Deyo, RA. **Spine 1996. 21 (24): 2840** **Drug therapy for back pain: which drugs help which patients?**	Back pain	Drug therapy	Inappropriate intervention	20/32 MEDLINE
Jones, L. Othman, M. Dowswell, T. Alfirevic, Z. Gates, S. Newburn M; Jordan, S. Lavender, T. Neilson, JP. **Cochrane Database of Systematic Reviews 2012. (3)** **Pain management for women in labour: an overview of systematic reviews.**	Labour	Pain management	Not RCT	21/32 MEDLINE
Ke Ma. Mi Yiqun. Tao Wu. Wenhao Wang. Xiaoming, L. Xiahohui, H Yingwei, W. **Pain Medicine 2011. 12 (1): 27** **Efficacy of diclofenac sodium in pain relief after conventional radiofrequency denervation for chronic facet joint pain: A double-blind randomized controlled trial.**	Facet joint pain	Medication	Inappropriate intervention	23/32 MEDLINE
Karppinen, J. Shen, FH. Luk, KD. Andersson, GB. Cheung, KM. Samartiz, D. **The Orthopaedic Clinics of North America 2011. 42 (4): 513** **Management of degenerative disk disease and chronic low back pain.**	Low back pain	Management	Inappropriate intervention	24/32 MEDLINE
Cagnie, B. Castelein, B. Pollie, F. Steeelant, L. Verhoeyen, H. Cools, A. **American journal of Physical Medicine & Rehabilitation 2015. 94 (7): 573** **Evidence for the use of ischemic compression and dry needling in the management of trigger points of the upper trapezius in patients with neck pain: A systematic review.**	Neck pain	Trigger points & Dry needling	Not RCT	25/32 MEDLINE
Abou-Setta, AM. Beaupre, LA. Rashiq, S. Dryden, DM. Hamm, MP. Sadowski, CA. Menon, MR. Majumdar, SR. Wilson, DM. Karkhaneh, M. Mousavi, SS. Wong, K. Tjosvold, L. Jones, CA. **Annals of Internal Medicine 2011. 155 (4): 234-245** **Comparative effectiveness of pain management interventions for hip fracture: a systematic review.**	Hip pain	Pain management	Inappropriate condition	26/32 MEDLINE
Close C., Sinclair M., Liddle SD. Madden, E. McCullough, JEM. Hughes, C. **Journal of Advanced Nursing 2014. 40 (8): 1702-16** **A systematic review investigating the effectiveness of complementary and alternative medicine (CAM) for the management of low back and/ or pelvic pain (LBPP) in pregnancy.**	Low back pain	CAM	Not RCT	28/32 British Nursing Index
Strauss, AJ. **Chiropractic Journal of Australia 1999. 29 (3): 112**	Low back pain	Acupuncture	Not RCT	29/32 Allied & Compleme

Acupuncture and the treatment of low-back pain: a review of the literature				ntary Medicine
Norton G., McDonough C. M., Cabral H. Shwartz, M. Burgess, JF. () **Spine 2015. 40 (10): 725-33** **Cost-utility of cognitive behavioural therapy for low back pain from the commercial payer perspective.**	Low back pain	Cognitive behavioural therapy	Not RCT	30/32 MEDLINE
Hughes, CM. Quinn, F. Baxter, GD. **Complimentary therapies in Medicine 2011. 19 (3): 149-54** **Complementary and alternative medicine: perception and use by physiotherapists in the management of low back pain.**	Low back pain	CAM	Inappropriate intervention	31/32 Allied & Complementary Medicine
Louw, Q. Morris, l. Sklaar, J. **South African Journal of Physiotherapy 2007. 63 (3): 7-14** **Evidence of physiotherapeutic interventions for acute LBP patients.**	Low back pain	Physiotherapeutic treatments	Not RCT	32/32 MEDLINE

Appendix E7: Table showing excluded publications by full text

Study	Participants / conditions	Interventions	Reason for exclusion	Study No:
Norrbrink, C. Lundeberg, T. **Acupuncture in Medicine 2011. 29 (2): 108** **Acupuncture and massage therapy for neuropathic pain following spinal cord injury: an exploratory study.**	Spinal cord injury	Acupuncture and massage therapy	Inappropriate condition	3/32 MEDLINE
Muller, R. Giles, LGF. **Journal of manipulative and physiological therapeutics 2005. 28.1: 3-11** **Long-term follow-up of a randomized clinical trial assessing the efficacy of medication, acupuncture, and spinal manipulation for chronic mechanical spinal pain syndromes**	Spinal pain	Acupuncture Spinal manipulation Medication	Long term follow up results of included study - Duplicate results	15/32 MEDLINE
Dascanio, VC. Birks, Y. Torgerson, D. **Trials; 1 (12) Bio Med Central Ltd. Dec 13, 2011** **A pilot factorial randomised cohort trial of manual therapy or acupuncture for low back pain**	Low back pain	Acupuncture Manual therapy Combined acupuncture and manual therapy Usual care	Conference paper. Full study accessed and Included	22/32 MEDLINE

Appendix E8: Table showing publications included in review

Study	Participants / conditions	Interventions	Reason for exclusion	Study No:
Giles, GFL. Muller, R. **(also reported as Giles et al, 2003)** **Spine 2003. 28 (14): 1490-502; discussion 1502-3** **Chronic spinal pain: a randomized clinical trial comparing medication, acupuncture, and spinal manipulation.**	Chronic spinal pain	Medication, acupuncture, and spinal manipulation	Included	27/32 MEDLINE

Appendix E9: Other searches:

Appendix E9a: Grey literature search 1: 04/07/2017

Repeated search strategy for grey literature.
SIGLE (System for information on Grey Literature in Europe).

5 additional results - all excluded from review of title and abstract.

Appendix E10a: Table showing excluded publications by title and abstract

Author, Date, Title	Participants / conditions	Interventions	Reason for exclusion	Reviewer
Sheldon, TA. et al. 1995. Back pain its management and cost to society.	Back pain	N/A	Not RCT	1 and 2
Ramadori, G. et al. 2000. Investigations of effectiveness of back pain treatment with acupuncture, final report.	Back pain	Acupuncture	Inappropriate comparator	1 and 2
National congress. 2003 Acupuncture, chronic pain and acute low back pain.	Chronic pain and acute low back pain	Acupuncture	Not RCT	1 and 2
Purepong, N. 2008 Acupuncture in the management of low back pain.	Low back pain	Acupuncture	Not RCT	1 and 2
Hurst, H. 2011. Outcomes of back and neck pain patients undergoing chiropractic treatment and can these be predicted?	Back and neck pain	Chiropractic treatment	Not RCT	1 and 2

Appendix E9b: Grey Literature search 2: 04/07/2017

HSRProj (Health Services Research Projects in progress)

Repeated search strategy – 6 additional results – all excluded from review of title and abstract.

Appendix E10b: Table showing Excluded publications by title and abstract

Author, Date, Title	Participants / conditions	Interventions	Reason for exclusion	Reviewer
Cherkin, DC. 2001. Evaluating the efficacy of acupuncture for back pain.	Low back pain	Acupuncture	Inappropriate comparator	1 and 2
Cherkin, DC. 1998. Alternative therapies back pain. A randomised trial.	Back pain	Alternative therapies	No data provided	1 and 2
McKee, MD. 2011. Acupuncture to decrease disparities in outcomes of pain treatment (ADDOPT).	Pain	Acupuncture	Not RCT	1 and 2
Graham, E. et al 2015. Non-invasive treatments for low back pain.	Low back pain	Medication	Not RCT	1 and 2
Smith, M. 2011. Complementary and alternative (CAM) use, costs and outcomes in recurrent back pain episodes.	Low back pain	Chiropractic and acupuncture	Not RCT	1 and 2
Cherkin, D. 2014. Implementing evidence-based treatments for persistent back pain into primary care.	Back pain	Acupuncture manipulation massage +	Not RCT	1 and 2

Appendix E9c: Reference lists and source evidence of selected studies reviewed

Appendix E10c: Table showing results from reference list and source evidence search

Two studies found:

Author, Date, Title	Participants / conditions	Interventions	Reason for inclusion / exclusion	Reviewer
Giles, LG. Müller, R. Journal of Manipulative Physiology Therapy. 1999 Jul-Aug; 22 (6): 376-81. Chronic spinal pain syndromes: a clinical pilot trial comparing acupuncture, a nonsteroidal anti-inflammatory drug, and spinal manipulation.	Low back pain	Acupuncture	Excluded Duplicate study; already included	1 and 2
Dascanio, VC. Birks, Y. Torgerson, D. Journal of Clinical Epidemiology 2014. 67 (8): 960. Randomised cohort trial was shown to be feasible for evaluating treatments in low back pain.	Back pain	Acupuncture	Included	1 and 2

Appendix E9d: Hand Searching

Acupuncture in Physiotherapy – (Previously: Journal of the Acupuncture Association of Chartered Physiotherapists, March 2015. Previously unavailable electronically):

Appendix E10d: Results Table from hand searching

Author, Date, Title	Participants / conditions	Interventions	Reason for inclusion / exclusion	Reviewer
Murphy, G. Longbottom, J. 2007. Case report: Physiotherapy management of low back pain using manual therapy and acupuncture. Journal of the Acupuncture Association of Chartered Physiotherapists. Autumn: 39-44.	Low back pain	Acupuncture	Excluded Not RCT	1 and 2

Appendix E9e: Other databases

- *CENTRAL, the Cochrane Library*
- *ACULARS (Acupuncture Literature Analysis and Retrieval System)*
- *Acubriefs.com to September 2015*
- *The Clinical Trials Register and the ISRCTN Registry*

No additional studies were located from the above databases.

***Appendix* E11: Descriptive search summaries**

EBSCOhost

The search of EBSCOhost yielded 48 studies (appendix E2, E3, E4). The titles and abstract were reviewed against the inclusion and exclusion criteria, resulting in 39 studies being excluded by title and abstract. Full texts of the remaining 9 studies were requested, a further 6 studies were excluded through full text review and duplicate studies were excluded. Three studies met the eligibility requirement for this systematic review and all three were included from this search. The results from EBSCOhost are combined with the other search results in the PRISMA diagram (figure 7.1).

The studies were sourced from the following databases via EBSCOhost:

- AMED = 13
- MEDLINE = 28
- SPORTDiscus = 7
- CINAHL = 0

ProQuest Dialog Healthcare

The search of ProQuest yielded 32 studies. The titles were reviewed against the inclusion and exclusion criteria resulting in 27 studies being excluded by title and abstract review. Full texts of the remaining 5 studies were requested, a further 4 studies were excluded through full text review, duplicates were excluded, and one study met the eligibility requirement for this systematic review and were included from the search.

Two studies required further consideration and discussion by the two reviewers. Following discussion of Muller et al. (2005) (15/35) the study was rejected due to it being a long-term follow up of an already included study, the study utilised the same patient data set of an original study: the data had therefore already been included once within the review. Another study reviewed (Dascanio et al. 2011. 22/32) was excluded but led to an additional study (Dascanio et al. 2014) being uncovered and included in the systematic review. One original study was included from this search and one study was uncovered from a conference paper within this search.

The results from ProQuest are combined with the other search results in the PRISMA diagram (figure 7.1).

The studies were sourced from the following databases via ProQuest:

- *British Nursing Index: 4*
- *Allied & Complementary Medicine: 5*
- *DH DATA: 1*
- *MEDLINE: 20*
- *Embase: 0*
- *Embase Alert: 2*

Grey Literature

Grey literature was searched in two locations; via Opengrey.eu for the System for Information on Grey Literature in Europe (SIGLE), which uncovered five studies, all studies were excluded by title and abstract due to not meeting the inclusion criteria.

The National Information Centre on Health Research and Health Care Technology (NICHSR) database was accessed to review Health Service Research Projects in Progress (HSRProj). Six studies were found, and all six studies were excluded by review of the title and abstract due to not meeting the inclusion criteria.

The results from the grey literature searches are combined and presented in the PRISMA flow diagram (figure 7.1).

Reference list check and hand searching

One additional study was uncovered from a review of an excluded conference paper, which lead to the source published RCT paper being uncovered and included.

The reference lists were checked of the five included studies, one additional article was found; but was a duplicate study of a previously included study.

Hand searching uncovered one additional study though this was excluded, as it was not an RCT.

Appendix E12:

Study Eligibility Form:

1) Was the study adequately randomised?

   Yes ___Unclear____Exclude____

2) Were the participants clinically assessed as having Low Back Pain?

   Yes ____Unclear____Exclude____

3) Did the study contain at least two groups, one group with acupuncture and one group receiving manual therapy?

   Yes ____Unclear____Exclude____

4) Did the study report pain, function or occupation?

   Yes ____Unclear____Exclude____

Final decision:

Include____Unclear____Exclude

*Further information required:

Appendix E13:

Data Extraction Form:

Article ID: Reviewer: Date:

General Information	**Instructions**	**Data extracted**
Title	Copy the title of the article	
First author	Not necessary if you have a blinded copy	
Author affiliation		
Author degree		
Institution		
Source of this article	Ask librarian	
Verification of study eligibility	Correct population? Correct intervention? Correct outcome? Correct study design?	yes no yes no yes no yes no
Methods		
Study design	RCT, quasi-RCT, non-randomised CCT	
Unit of allocation	Patient, hospital, school	
Method of randomization		
Allocation concealment		
Blindedness		
Population		

Recruitment of patients		
Place	Hospital / City / Country	
Enrolment dates:		
Inclusion criteria		
Exclusion criteria:		
Age	Describe the age of the included population	
Sex	Describe the sex distribution of he included population	
Ethnicity		
Work status		
Diagnosis of LBP	How did the authors define low-back pain?	
Duration of pain		
Previous treatments		
Cause of pain		
Total number of patients recruited		
Number of patients who met inclusion criteria		
Total number of patients randomized		
Total number of patients followed		
Interventions:		
Intervention group: technique, number of sessions, therapist experience	You may copy the description of the therapy here or simply indicate on which page and paragraph it can be found.	
Control group (1):	Idem	
Control group (2):	Idem	
Control group (3):	Idem	
Outcomes		
Who carried out the measurement?		
What was measured at baseline? How it was measured? Is the tool validated (as stated in the article)?	For example: • *Pain: VAS (valid)* • *Function: Oswestry*	

	(validation not mentioned) • *Physical examination (not validated)*	
What was measured immediately after the intervention? ? How it was measured? Is the tool validated (as stated in the article)?		
When was the first follow-up? **What was measured at the first follow-up? How it was measured? Is the tool validated (as stated in the article)?**		
Analysis:		
Statistical technique used:	Which tests? Alpha? Power? Sample size calculation? Software used	
Intention-to-treat analysis?	Patients were analysed according to the group they were randomized	yes no don't know
Does technique adjust for confounding?		
Number (or %) of followed-up from each group:		
Results:		
Quantitative results (e.g. estimates of effect size, between group p values)	**If between group comparisons are given, please use the next page.** **If no between-group comparisons are given, then report here the general results**	
Qualitative results		
Cost of intervention:		
Cost-effectiveness		
Adverse effects or complications		

Adapted from Furlan et al. 2015; Furlan et al. 2008; Bombardier et al. 1997

Appendix E14:

Quality and Risk of Bias Assessment Form

Item	Judgement	Description
Was the method of randomization adequate?	Yes / No / Unsure	
Was the treatment allocation concealed?	Yes / No / Unsure	
Was knowledge of the allocated interventions adequately prevented during the study? **Was the patient blinded to the intervention?** **Was the care provider blinded to the intervention?** **Was the outcome assessor blinded to the intervention?**	Yes / No / Unsure Yes / No / Unsure Yes / No / Unsure Yes / No / Unsure	
Were incomplete outcome data adequately addressed? **Was the drop-out rate described and acceptable?** **Were intention to treat analysis methods used? (all randomized participants analysed in the group to which they were allocated?)**	Yes / No / Unsure Yes / No / Unsure Yes / No / Unsure	
Are reports of the study free of suggestion of selective outcome reporting?	Yes / No / Unsure	
Other sources of potential bias: **Were the groups similar at baseline regarding the most important prognostic indicators?** **Were co-interventions avoided or similar?** **Was the compliance acceptable in all groups?** **Was the timing of the outcome assessment similar in all groups?**	Yes / No / Unsure Yes / No / Unsure Yes / No / Unsure Yes / No / Unsure	
		Risk of bias: Low Medium High

Adapted from CBRG (Furlan et al. 2015; Furlan et al. 2008; Bombardier et al. 1997)

Risk of Bias Criteria:

Criteria for a judgment of 'yes' for the sources of risk of bias:

1. Was the method of randomization adequate?

A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with two groups), rolling a dice (for studies with two or more groups), drawing of balls of different colours, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments

Examples of inadequate methods are: alternation, birth date, social insurance/security number, date in which they are invited to participate in the study, and hospital registration number

2. Was the treatment allocation concealed?

Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.

Was knowledge of the allocated interventions adequately prevented during the study?

3. Was the patient blinded to the intervention?

This item should be scored "yes" if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.

4. Was the care provider blinded to the intervention?

This item should be scored "yes" if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful

5. Was the outcome assessor blinded to the intervention?

Adequacy of blinding should be assessed for the primary outcomes. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or:

- **for patient-reported outcomes** in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes"
- **for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors** (e.g., clinical examination): the blinding procedure is adequate if

patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination

- **for outcome criteria that do not suppose a contact with participants** (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome
- **for outcome criteria that are clinical or therapeutic events** that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item "4" is scored "yes"
- **for outcome criteria that are assessed from data of the medical forms**: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data

Were incomplete outcome data adequately addressed?

6. Was the drop-out rate described and acceptable?

The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a 'yes' is scored. (N.B. these percentages are arbitrary, not supported by literature).

7. Were all randomized participants analysed in the group to which they were allocated?

All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.

8. Are reports of the study free of suggestion of selective outcome reporting?

In order to receive a 'yes', the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.

Other sources of potential bias:

9. Were the groups similar at baseline regarding the most important prognostic indicators?

In order to receive a “yes”, groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).

10. Were co-interventions avoided or similar?

This item should be scored “yes” if there were no co-interventions or they were similar between the index and control groups.

11. Was the compliance acceptable in all groups?

The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore, it is necessary to assess how many sessions each patient attended. For single-session interventions (for ex: surgery), this item is irrelevant.

12. Was the timing of the outcome assessment similar in all groups?

Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.

Adapted from CBRG (Furlan et al. 2015; Furlan et al. 2008; Bombardier, 1997)

Appendix E15:

Clinical Relevance Form

Item	Judgement	Description
Based on the data provided, can you determine if the results will be clinically relevant?	Yes / No / Unsure	
Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?	Yes / No / Unsure	
Are the interventions and treatment settings described well enough so that you can provide the same for your patients?	Yes / No / Unsure	
Were all clinically relevant outcomes measured and reported?	Yes / No / Unsure	
Is the size of the effect clinically important?	Yes / No / Unsure	
Are the likely treatment benefits worth the potential harms?	Yes / No / Unsure	

For low-back pain, consider 30% on VAS/NRS for pain as clinically significant, and two to three points on the Roland-Morris Disability Questionnaire or 8% to 12% for function.

For effect size, Cohen's three levels

Small

- WMD less than 10% of the scale (e.g., <10mm on a 100 mm VAS).
- SMD or “d” scores <0.5.
- Relative risk, <1.25 or >0.8 (depending on whether it reports risk of benefit or risk of harm)

Medium

- WMD 10 to 20% of the scale.
- SMD or “d” scores from 0.5 to < 0.8.

- Relative risk between 1.25 to 2.0, or 0.5 to 0.8.

Large

- WMD >20% of the scale.
- SMD or "d" scores ≥ 0.8.
- Relative risks >2.0 or <0.5.

Adapted from CBRG (Furlan et al. 2015; Furlan et al. 2008; Bombardier et al. 1997)

Information from the clinical relevance assessment will inform users if the results apply to their population. This analysis will be performed by two reviewers independently and follow the guidance from the CBRG (Bombardier et al. 1997).

E16: Calculations and conversions for meta-analysis:

Dascanio et al. (2014)

Analysis of covariance – Mean and SD provided

RMDQ Acupuncture mean 6.8 (4.5 SD). Manual therapy mean 4.6 (4.0 SD)

MODI Acupuncture mean 25.4 (12.0 SD). Manual therapy mean 18.3 (11.1 SD)

Outcome measure	Intervention	Mean (SD)
RMDQ	Acupuncture	6.8 (4.5)
	Manual therapy	4.6 (4.0)
MODI	Acupuncture	25.4 (12.0)
	Manual therapy	18.3 (11.1)

Cherkin et al. (2001)

Mean and confidence intervals provided, need to calculate SD.

Standard error = SE. Standard deviation = SD. N = No of participants. SE = V(square root) over N / SD

Acupuncture; 7.9 – 6.5 (confidence interval) = 1.4 (SE)

square root of 94 (N) = 9.6 / 1.4 = **6.86 SD**

Massage; 6.3 – 5.1 (confidence interval) = 1.2

Square root 78 = 8.83 / 1.2 = ***7.36 SD***

Outcome measure	Intervention	Mean (SD)

RMDQ	Acupuncture	7.9 (6.86)
RMDQ	Massage	6.3 (7.36)

Giles et al. (2003)

Interquartile range provided – need to convert into standard deviation, using the normal distribution model (Bland, 2000)

Manipulation = 12 mean (0-29 interquartile range)

0.67 is the proportion of SD from where the mean falls to the IQR

12 – 0 = 12 / 0.67 = 17.91 SD

Acupuncture = 24 mean (11-36 interquartile range)

24 – 11 = 13 / 0.67 = 19.40 SD

Outcome measure	Intervention	Mean (SD)
MODI	Acupuncture	24 (19.40)
MODI	Manipulation	12 (17.91)

Giles et al. (1999)

Interquartile range provided – needed to convert into standard deviation, using the normal distribution model (Bland, 2000)

Manipulation = 28 (14.5 - 41.5 interquartile ranges)

28 – 14.5 = 13.5 / 0.67 = 20.77 SD

0.67 is the proportion of SD from where the mean falls to the IQR

Acupuncture = 24 (18.5 -35.5 interquartile ranges)

24 – 18.5 = 5.5 / 0.67 = 8.21

Outcome measure	Intervention	Mean (SD)
MODI	Acupuncture	24 (8.21)
MODI	Manual therapy	28 (20.77)