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RATIONALE AND STUDY PROTOCOL

Does the addition of visceral manipulation improve outcomes for patients with low back pain? Rationale and study protocol

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Summary *Objectives:* There has been no randomised controlled trial conducted to investigate the effectiveness of visceral manipulation (VM) for the treatment of low back pain (LBP). The primary aim of this study would be to investigate whether the addition of VM, to a standard physiotherapy treatment regimen, improves pain 6 weeks post treatment commencement in people with LBP. Secondary aims would be to examine the effect of VM on disability and functional outcomes at 2, 6 and 52 weeks post-treatment commencement and pain at 2 and 52 weeks.
Methods: This paper describes the rationale and design of a randomised controlled trial investigating the addition of VM to a standard physiotherapy treatment algorithm which includes manual therapy, specific exercise and functional exercise prescription. Analysis of data would be carried out by a statistician blinded to group allocation and by intention-to-treat.

Background

Despite the large number of randomised controlled trials investigating interventions for low back pain (LBP), some interventions used by clinicians remain untested for their efficacy. One such intervention is visceral manipulation (VM). VM is a gentle, specific manual therapy aimed at assessing and treating abnormalities in the physiological motion of internal organs (Barral, 2005). The only published

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randomised controlled trial of VM investigated the efficacy of this approach in improving dysfunctional bladder voiding in a paediatric population. When combined with other manual therapies, VM was shown to be more effective than standard medical care in improving dysfunctional bladder voiding (Nemett et al., 2008). There appear to be over 14,000 registered therapists who have completed basic VM training. They are mostly represented in North America and Europe and come from professional fields such as physiotherapy, medicine, nursing and massage (International Association of Healthcare Practitioners, 2012).

There are three main mechanisms by which the altered movement relationship between organs and their supportive connective tissues could potentially manifest as LBP: visceral referred pain, central sensitisation and local fascial changes. It is plausible that, via one of these mechanisms, visceral disorders could be a causative trigger or exacerbation factor for LBP.

LBP is a common reason for patients to present to medical and physiotherapy practices. There is currently no data on the prevalence of patients with LBP presenting to their treating physician or therapist with visceral referred pain. Anecdotally, these patients lack a clear mechanical pattern to their low back symptoms, and may have concurrent gastrointestinal, urinary or gynaecological symptoms. On questioning, they will usually have been cleared of any serious illness by a medical specialist. Visceral referred pain is often diffuse and difficult to localise, making clear diagnosis a clinical challenge. Visceral pain commonly refers to distant and more superficial regions (Foreman, 2004; Giamberardino, 2006; Giamberardino et al., 2005).

The mechanism by which visceral pain causes referral to somatic structures appears to involve neural convergence. Sympathetic nerves, furnishing visceral information, converge with somatic nerves in the dorsal horn. Due to the low proportion of visceral afferents compared to somatic afferents entering the dorsal horn, (Cervero, 2000) conscious sensations of pain can be misunderstood to be arising from somatic structures. This convergence is the most obvious and well understood mechanism by which the altered movement relationship between organs could potentially contribute to conditions such as LBP (Cervero, 1995).

Another mechanism by which visceral disorders may contribute to pain is through central sensitisation (Woolf, 2011). Excessive firing of visceral nociceptors can result in significant central changes (Cervero, 2000). Central sensitisation is a state of hyperexcitability in the viscerosomatic convergent neurons and creates a situation where even normal sensory stimuli, such as mechanical touch, can be experienced as pain.

Altered motion of fascia can also potentially reduce the ability of this connective tissue to attenuate forces and to provide stability and structural support. Mechanical stress, possibly due to prolonged poor posture or inflammation, can potentially alter fascia at a cellular level (Meltzer et al., 2010). This could disrupt normal biomechanics around the spine and cause myofascial pain (Meltzer et al., 2010). In addition, any loss of normal fascial sliding could result in a reduction in blood and lymphatic flow, and hence the removal of inflammatory mediators (Shultz and Feltis, 1996). Moreover, a lowering of the pH of soft tissue can cause nociceptors to become more sensitive to mechanical stimuli (Shah et al., 2005), creating a metabolic milieu for the onset or exacerbation of pain. Alteration of the pH in tissues can be caused by multiple complex pathophysiologies, including disordered breathing patterns (Smith et al., 2006).

Like most manual therapies, the specific mechanism by which VM may have an effect on pain has not been proven but theories exist. Proponents of VM argue that, by specific manual treatment of the supportive fascia of the internal cavities of the thorax, abdomen and pelvis, VM modulates visceral pain signals. One theory is that VM reduces fascial load on spinal structures by improving the fascial sliding mechanism of one organ on another (Barral, 2005). In addition, improved fascial sliding may improve blood and lymphatic flow, aiding the oxygenation of tissue and removing inflammatory mediators (Shultz and Feltis, 1996). By reducing excessive visceral nociceptive input entering the spinal cord, visceral referred pain is less likely to occur and central sensitization changes may begin to revert to more normal states of excitation (Woolf, 2011).

Given the expression of endocannabinoids in myofascial tissue, (McPartland, 2008b) visceral manipulation potentially causes the release of anandamide, an endogenous cannabinoid neurotransmitter (Pamplona and Takahashi, 2012). In patients with LBP treated with joint manipulation, serum anandamide levels were double in patients given an osteopathic manipulation, compared to a sham manipulation (McPartland et al., 2005). It is plausible that stimulation of the endocannabinoid system reduces nociception and circumvents central sensitisation changes (McPartland, 2008a).

It is widely accepted that the causes of LBP are likely to be multifactorial in the majority of cases. VM may effectively deal with a unique contributor to LBP compared to other common treatment techniques which do not aim to directly target or influence the viscera and their surrounding fascia. Without any intervention directly targeted at the potential visceral component of LBP, it is possible that visceral disorders contribute to the development and continuation of chronic LBP in some patients. Therefore, the aim of this proposed study is to investigate whether the addition of VM to standard physiotherapy care improves pain, disability and functional outcomes for patients presenting with LBP.

Methods

Study population/recruitment

64 participants presenting with non-specific LBP presenting to a private physiotherapy clinic in Sydney, Australia will be recruited (Fig. 1). Participants may be referred by another health practitioner such as a General Practitioner or may self-refer. At the time of making the appointment, participants will be informed about the trial and told they may be invited to participate. On the day of their initial appointment, potential participants who are found to meet the study inclusion criteria will be invited to participate in the trial. Any questions will be answered and a signed consent form recorded. At this time, participants will complete baseline data immediately prior to being randomised to a treatment arm of the study. Ethical approval for this study has been received from the University of Sydney Human Research Ethics Committee. This study is registered

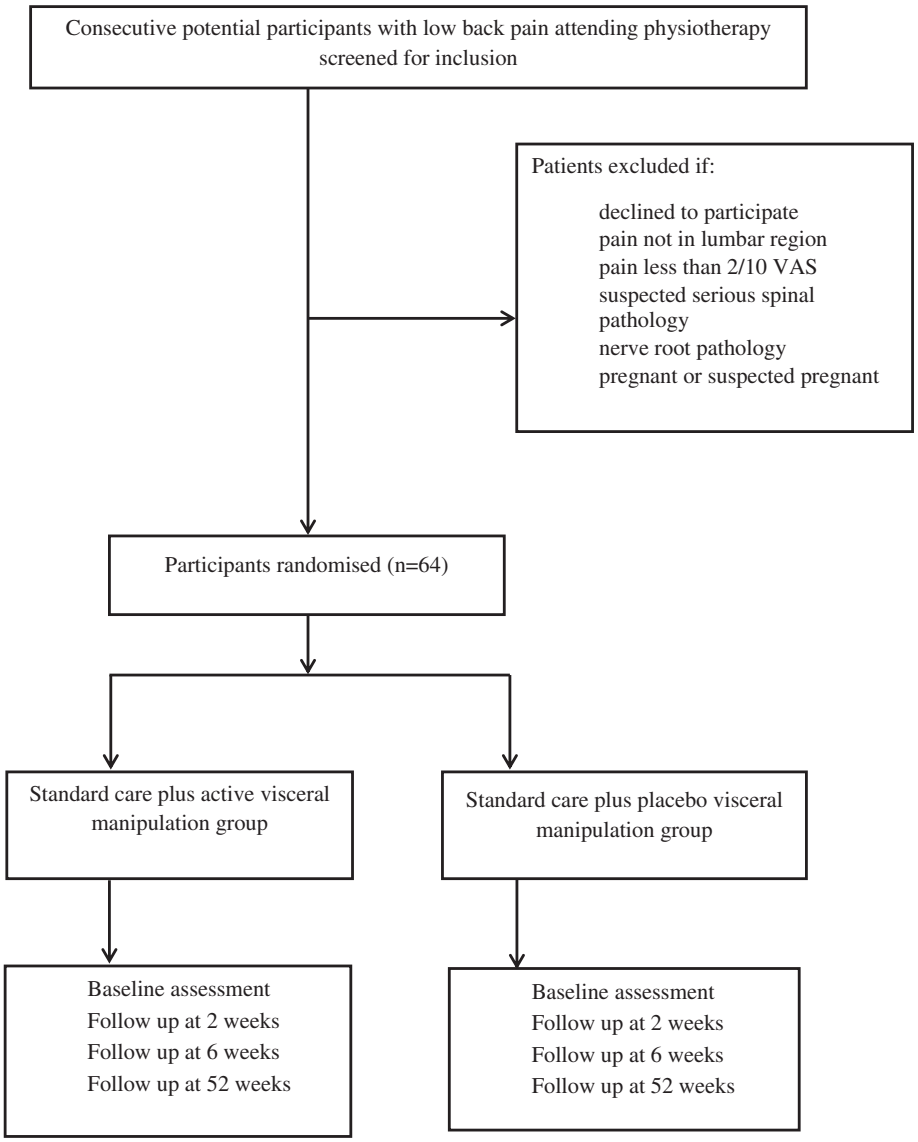

Figure 1 Flow diagram showing participants through each stage of the study.

with the Australia and New Zealand Clinical Trials Registry under ACTRN12611000757910.

Inclusion criteria

To take part in the trial, participants must meet all of the following criteria as assessed by the treating physiotherapist:

- Primary complaint of pain in the area extending from the 12th rib to the buttock crease. This may or may not be accompanied by pain in the leg or other spinal areas.
- LBP symptoms which have a score of $\geq$2/10 on numerical pain rating scale (Pengel et al., 2004).
- Aged 18—80.
- No known or suspected serious spinal pathology (e.g. metastatic, inflammatory or infective diseases of the spine, cauda equina syndrome, canal stenosis, spinal fracture).
- No nerve root compromise evidenced by at least two of the following (i) myotomal weakness, (ii) dermatomal or widespread sensory loss, (iii) hypo or hyper-reflexia of the lower limb reflexes.
- No spinal surgery within the preceding six months.
- No visceral surgery within the preceding six months.
- No other vascular abnormality such as abdominal aortic aneuryms.
- Not currently be receiving chiropractic, osteopathic or other physical therapy.
- Not pregnant or suspect being pregnant.
- Not currently taking medications that significantly alter gut motility.
- Not currently in an acute inflammatory phase of known gastro-intestinal or urinary diseases such as cholecystitis, renal calculi, peritonitis, appendicitis.
- Not currently taking medications such as oral corticosteroids which are known to increase the risk of intestinal perforation.

- No known gastro-intestinal disease that associates with a risk of intestinal perforation e.g. Crohn's disease, diverticular disease, peptic ulcer disease.
- Not taking anti-platelet medications such as Warfarin and Clopidogrel.

Enrolment and baseline measures

At the initial assessment and treatment session, baselines measures and demographic data will be collected.

The following baseline measures of outcome will be recorded:

- Numerical pain rating scale on a 0—10 scale (NPR) (Pengel et al., 2004).
- A back specific disability scale (Roland Morris Disability Scale — RMDQ) (Roland and Morris, 1983).
- A patient specific measure of disability (Patient Specific Functional Scale — PSFS) (Stratford et al., 1995).
- Presence of gastro-intestinal/urinary/reproductive symptoms. This will be assessed by asking participants simple yes/no questions about whether they suffer from each of the following — bloating, diarrhoea, constipation, period pain, cramping, food sensitivity or reflux.

As there are currently no specific outcome measures for VM, general outcomes measures for treatment effectiveness will focus on self-reporting LBP symptoms. Although the exact mechanism by which VM occurs will not be demonstrated by this proposed trial, the effects on participants' LBP symptoms will indicate whether VM is a worthwhile addition to a standard physiotherapy regimen.

Treatment allocation

A researcher not involved in data collection or analysis will develop a randomisation schedule using Excel to generate 64 sealed opaque randomisation envelopes. These envelopes will contain a paper with words "VM" or "placebo". After baseline data has been collected the treating physiotherapist will open the next randomisation envelope and allocate the participant according to the randomisation schedule.

Evaluation

Participants will be assessed by one of two senior musculoskeletal physiotherapists working in the clinic. All participants will have a standardised assessment involving active movement testing, passive intervertebral motion testing, palpation, neural tension testing and functional stability testing. Participants will also have palpation testing of their visceral system to assess which visceral structures may be involved in the participant's clinical presentation. This palpation testing will involve the gastro-intestinal, urinary, respiratory, reproductive and cardiovascular systems. For participants allocated to placebo VM, these findings will be noted but not used in treatment.

Treatments

The treatments for each group will be as follows:

Active (VM) group — participants will be treated for the same minimum/maximum number of sessions over 6 weeks. Participants will receive the same standardised physical examination and standard care as the control group. In the active group, any fascial restrictions or lack of organ motility will be treated using specific VM techniques (Barral, 2005; Tozzi et al., 2012). This may be in the gastro-intestinal, urinary, respiratory, reproductive and cardiovascular systems. This will take approximately 5—10 min and may involve light or deep manual fascial releases and specific organ mobilisations in the thoracic, sub-diaphragmatic, abdominal and pelvic areas (Barral, 2005).

Standard care plus Placebo VM group — participants will be treated 1—2 times per week for a minimum of one week and a maximum of 12 treatments over 6 weeks. The minimum/maximum number of treatment sessions will be decided based on participants' symptom progression.

All participants will receive current evidence based advice focussing on remaining active (Koes et al., 2010). Participants will receive manual therapy, soft tissue massage, specific muscle re-training and functional exercise prescription as felt necessary by the treating practitioner. Real-time ultrasound imaging may be used to facilitate motor control re-training when appropriate. This algorithm of manual therapy, soft tissue techniques, specific -and functional exercise prescription is commonly used in clinical practice and thus increases the generalizability of the study (Lee et al., 2008). Participants will have a placebo visceral "treatment" which will involve approximately 5 min of sham treatment aimed around the abdomen area. This will involve light touch and no intention on the part of the physiotherapist to impart a therapeutic effect to the patient. This placebo will be done on areas of the abdomen not involved in a mechanical, functional or neural sense to any visceral issues present. This placebo technique was pilot tested on experienced physiotherapists (who had no prior experience of VM) prior to the trial start. These physiotherapists were unable to distinguish between the placebo and real VM.

Therapists will keep a record of the number of times the patient attended physiotherapy and record details of the treatment including the techniques used. These will be used to ensure compliance with the protocol and to help describe the treatment given in this study.

For both groups, initial treatment sessions will last for about 40 min and follow up sessions will last approximately 25—30 min.

Co-interventions — patients will be asked not to seek other treatments for their LBP during the treatment period. In cases where this is unavoidable, a record of additional treatments will be kept.

Outcome measures

Measures of outcome will be recorded by an assessor blinded to group assignment. Outcomes will be recorded at baseline, 2 weeks, 6 weeks and 52 weeks after treatment commencing. If the participant has ceased treatment, the outcome measures will be collected by a blinded assessor

over the phone. At 6 weeks, participants will be asked a treatment credibility question regarding which additional treatment they thought they received (real or sham treatment). This will assess if blinding was successful.

Primary Outcome: The primary outcome will be pain intensity (NPR) at 6 weeks. This was chosen as pain is the most common reason patients present to a private physiotherapy clinics for treatment of LBP. From a patient's perspective, it is also the outcome that most determines whether treatment has been successful (Verbeek et al., 2004).

Secondary Outcomes: The secondary outcomes will be pain at 2 and 52 weeks, function and disability at 2, 6 and 52 weeks.

Data analysis

Data will be analysed by a statistician who is blinded to group status. The analyses will be by intention-to treat. We will limit the number of analyses to reduce the possibility of Type I errors. For primary outcomes a p value of <0.05 will be considered statistically significant. For the secondary outcomes a p value of <0.01 will be considered significant. For our primary outcome of NPR at 6 weeks we will consider a 1.5 point difference between groups to represent the smallest worthwhile effect.

Treatment effects on pain, function, disability at 2, 6 and 52 weeks will be evaluated using linear mixed models, which incorporate terms for treatment, time, and treatment time interactions. We will investigate models for the effect of time on pain intensity, and adjust our model accordingly.

We will perform an exploratory secondary analysis to investigate a possible subgroup who responds best to the addition of VM. We will limit this to a single potential effect modifier, the presence or absence of baseline gastrointestinal/gynaecological symptoms, to reduce the chance of spurious findings. This analysis will likely be underpowered but is based on logical rationale and the limits of the confidence intervals will be explored to determine the value of the findings.

Sample size

A sample size of 64 (32 participants in each group) was determined to provide 80% power to detect a 1.5 point difference on the Numerical Pain Rating Scale (NPRS) allowing for an estimated standard deviation of 2 and loss to follow up of 10%.

Conclusion

We have presented the rationale and design for a randomised controlled trial investigating the effect of adding VM to the standard treatment regimen for patients presenting to a private physiotherapy clinic with LBP. The primary outcome will be assessment of pain at 6 weeks, as measured by the NPRS. Secondary outcomes will be assessment of pain, function, disability and presence or absence of gastrointestinal symptoms at 6 weeks.

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