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Individualised manual therapy plus guideline-based advice vs advice alone for people with clinical features of lumbar zygapophyseal joint pain: a randomised controlled trial

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Abstract

Objectives To determine whether individualised manual therapy plus guideline-based advice results in superior outcomes to advice alone in participants with clinical features potentially indicative of lumbar zygapophyseal joint pain.
Design Multi centre parallel group randomised controlled trial.
Setting 14 physiotherapy clinics in Melbourne, Australia.
Participants Sixty-four participants with clinical features potentially indicative of lumbar zygapophyseal joint pain.
Interventions 10-weeks of physiotherapy comprising individualised manual therapy based on pathoanatomical, psychosocial and neurophysiological barriers to recovery plus guideline-based advice (10 sessions) or advice alone (two sessions).
Main outcome measures Primary outcomes were activity limitation (Oswestry Disability Index), and separate 0 to 10 numerical rating scales for leg pain and back pain. Measures were taken at baseline and 5, 10, 26 and 52-week.
Results Between-group differences for back pain favoured individualised manual therapy over advice for back pain at 5 (1.0; 95% CI 0.6 to 2.0), 10 (1.5; 95% CI 0.5 to 2.4) and 26-weeks (1.4; 95% CI 0.4 to 2.3) as well as for activity limitation at 26 (8.3; 95% CI 2.6 to 14.2) and 52-weeks (8.2; 95% CI 2.3 to 14.2). There were no significant between-group differences for leg pain. Secondary outcomes and responder analyses also favoured individualised manual therapy at almost all time-points.
Conclusions In participants with clinical features potentially indicative of lumbar zygapophyseal joint pain, individualised manual therapy led to greater reduction in back pain at 5, 10 and 26-week follow-up as well as activity limitation at 26 and 52-weeks. Between-group differences were likely to be clinically important.

Trial registration ACTRN12609000334202.

Keywords: Back pain; Manual therapy; Spinal manipulative therapy; Clinical trial; Zygapophyseal joint; Facet joint

Introduction

Low-back-disorders (LBD) are a major cause of disability adjusted life years [1] as well as being prevalent and costly [2]. Recent onset LBD improve rapidly but symptoms commonly persist and/or recur [3] and the identification of effective treatment is a high research priority [4].

Advice for LBD has demonstrated positive effects on clinical outcomes [5], is cost-effective [6], requires no additional

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training [7] and is commonly used in clinical practice. Advice is also recommended in clinical guidelines for LBD [4]. However, LBD can be complex and advice may not lead to positive outcomes for all patients [8,9].

Manual therapy is a common physiotherapy treatment for LBD [10,11] but evidence of effectiveness remains limited [12]. However, clinical trials often use a generic approach to manual therapy rather than individualising treatment based on pathoanatomical (e.g. nociceptive source of symptoms), psychosocial (e.g. fear avoidance), and neurophysiological (e.g. central sensitisation) barriers to recovery [13–16]. An individualised approach to manual therapy is more reflective of clinical practice and has been described as being more likely to demonstrate effectiveness in randomised controlled trials (RCTs) [13–16].

Preliminary evidence has been published in a systematic review supporting the effectiveness of individualised manual therapy for LBD [17]. However none of the RCTs identified evaluated a manual therapy program based on the commonly used [10] Maitland approach [18] in combination with addressing individual barriers to recovery such as altered motor control [19]. In addition no clinical trial has investigated the effectiveness of manual therapy on patients with a "regular compression" pattern of localised unilateral pain reproduced on lumbar extension and ipsilateral lateral flexion [20]. This commonly observed [21] presentation has been reported as responding in a consistent and predictable manner to manual therapy techniques [18,22,23] and may comprise features indicative of lumbar zygapophyseal joint pain [24].

The aim of this trial was therefore to report the findings of a preplanned subgroup analysis to determine the effectiveness of individualised manual therapy (IMT) plus guideline-based advice compared to advice alone in people with LBD and clinical features potentially indicative of lumbar zygapophyseal joint (LZJ) origin.

Table 1
Clinical features indicative of lumbar zygapophyseal joint dysfunction (LZJ) pain.

Unilateral symptoms
• Symptoms greater on one side of the body compared with the opposite side or central
A regular compression pattern
• Extension in standing must reproduce the participant's clinical pain
• Ipsilateral lateral flexion or quadrant in standing must reproduce the participant's clinical pain
• Contralateral movements must show either greater range of movement or a lesser degree/different type of pain compared to ipsilateral movements
Comparable sign
• Reproduction of clinical pain on ipsilateral passive posterior-anterior accessory movement applied through the transverse process or the zygapophyseal joint at one or two segments
• For the clinical pain to be greatest at that one or two segments compared to other segments
Positive response to a mini-treatment
• If a comparable sign is identified then a mini-treatment should be performed
• This mini-treatment should be sufficient to create a within-session change but not a between-session change.
• A positive response to a mini-treatment is a significant reduction in resting pain or a significant response to asterisk reassessments, for example increased range and quality of movement. We defined asterisks as key findings from the subjective and objective assessments that could be used for reassessment of treatment effect [30].

Methods

A multi centre parallel group randomised controlled trial was conducted at 16 private physiotherapy clinics across metropolitan Melbourne, Australia. Ethical approval was provided by the La Trobe University Human Ethics Committee and informed consent received from all participants prior to enrolment.

The trial was prospectively registered (ACTRN12609000334202). Recruitment and treatment occurred concurrently with four other trials, each targeting a different LBD subgroup. After registration, a decision was made to merge all of the five trials into one, creating the Specific Treatment of Problems of the Spine (STOPS) trial (ACTRN12609000834257), the protocol for which has previously been published [25]. Results from the STOPS trial provided evidence that 10 sessions of individualised physiotherapy was more effective than 2 sessions of advice alone in participants with low-back disorders of between 6-weeks and 6-months duration. Between-group changes in favour of intervention group were sustained at 12 months for activity limitation and 6 months for back and leg pain [26]. The present manuscript reports results obtained in the LZJ subgroup as a pre planned secondary subgroup analysis of the STOPS trial.

Participants

Volunteers were recruited through newspaper advertising, community notices and health practitioner referral. Eligible volunteers had a primary complaint of low back with or without referred leg pain, had symptom duration of 6-weeks to 6-months, were aged 18 to 65 years, were fluent in English and had three out of four clinical features indicative of LZJ pain (Table 1). Volunteers were excluded if they had: clinical features indicating membership of one of the other four STOPS subgroups including radiculopathy due to a confirmed spinal nerve root impingement on CT or MRI scan, a current LBD related compensation claim, cancer undergoing treatment, clinical or radiological features of cauda equina syndrome, pregnancy or childbirth (last 6-months), spinal

injections (last 6-weeks), a history of lumbar spine surgery, a pain intensity score of less than 2 on a 0 to 10 numerical rating scale (NRS), minimal activity limitation (defined as an ability to walk, sit and stand for at least one hour and no sleep disturbance), received more than five treatments with a study physiotherapist prior to enrolment, an inability to walk safely (e.g. from foot drop), and/or planned absence of more than 1-week during the intervention phase of the trial [27].

Randomisation and blinding

Eligible participants were randomised to receive either IMT plus guideline-based advice or advice alone. A researcher not involved in treating participants in the trial developed a computer generated randomisation schedule in advance using a web based randomisation program. Permuted block randomisation with random block lengths were used to ensure approximately equal numbers of participants in each group [28,29]. Randomisation was stratified by treatment centre. The allocation spreadsheet was held by an administrative assistant offsite who had no involvement in the recruitment, screening, assessment, enrolment or treatment of the participants thereby ensuring adequate allocation concealment [29] following participant enrolment in the trial. Blinding of participants and therapists was not possible, but data entry was performed by a researcher who was blinded to treatment allocation.

Interventions

Treatment was provided by 14 physiotherapists across 14 centres. Participants randomised to IMT received 10 × 30-minute treatment sessions over 10-weeks. In addition to advice similar to the comparison group, treatment was individualised based on specific manual therapy techniques as well as other barriers to recovery (contributing factors) for each participant (e.g. altered neural mechanosensitivity, contributions from adjacent joints such as the hip). This method is commonly used by physiotherapists in clinical practice and provides direction regarding application of individualised treatment based on pathoanatomical and hypothesised causal mechanisms [30]. The primary treatment was manual therapy individualised according to the principles of Maitland [18] such as identifying segmental comparable signs, within treatment evaluation of effectiveness and providing treatment based on the importance of pain vs stiffness. Available techniques included unilateral passive accessory movements, passive physiological rotation mobilisation and high velocity thrust rotation manipulation [31]. Detailed clinical reasoning processes [24] were facilitated via electronic clinical notes to assist physiotherapists in selecting the most appropriate manual therapy technique, and then progressing that technique based on the participant's clinical response [31].

Motor control training [32] targeting the local/deep muscles around the lumbar spine (transversus abdominis, lumbar multifidus and pelvic floor) were provided in non-weight bearing positions and progressed to a home based functional exercise program following commencement of manual therapy. A range of optional treatment components were also provided depending on identification of other pathoanatomical, psychosocial or neurophysiological barriers to recovery. These treatment components have previously been described in detail [24].

Participants allocated to guideline-based advice attended 2 × 30-minute physiotherapy sessions comprising a pathological explanation of the participant's pain, reassurance regarding prognosis, advice to remain active, and instruction regarding lifting technique [5].

To ensure a high level of treatment integrity, trial physiotherapists received 16-hours of training and were provided with a detailed treatment manual, participant information sheets and electronic clinical notes designed to ensure provision of treatment was consistent with the protocol. Clinical notes were reviewed and feedback provided to trial physiotherapists individually and at monthly case reviews.

Outcomes

Outcomes were measured using reliable and valid self-administered questionnaires that were mailed to participants at baseline and 5, 10, 26 and 52-weeks post randomisation. Primary outcome measures were activity limitation (Oswestry Disability Index [33,34]) as well as back pain and leg pain (NRS [35]). Secondary outcome measures were global rating of change [36,37], satisfaction with physiotherapy treatment and with treatment results [38], the Sciatica Frequency and Bothersomeness Scale [39,40], self-reported number of LBD related work days missed [38,41], degree of interference with work [38,41], Örebro Musculoskeletal Pain Questionnaire score [42,43] and health-related quality of life (EuroQol-5D) [44]. Adverse events were documented by trial physiotherapists in the clinical notes and by participants on postal questionnaires [45]. Co-intervention data and medication use was collected via the postal questionnaire.

Statistical analysis

The original sample sizes was calculated to be 148 participants, but following merging of the studies into one large trial (with a sample size of 300) only 64 participants were included in this analysis. An initial sample size calculation estimated that 148 participants would be required to detect a between-group difference of 10/100 points on the Oswestry, assuming a standard deviation of 20 and a 15% loss to follow-up (two tailed hypothesis, alpha = 0.05, power = 0.80). However, after the LZJ participants became a subgroup of the larger STOPS trial, the sample size was dictated by the STOPS trial target of n = 300.

Data were analysed via intention-to-treat. Missing continuous data were accounted for by restricted maximum likelihood estimation within the linear mixed models [46]. A sensitivity analysis was performed using last observation carried forward for missing outcomes [27].

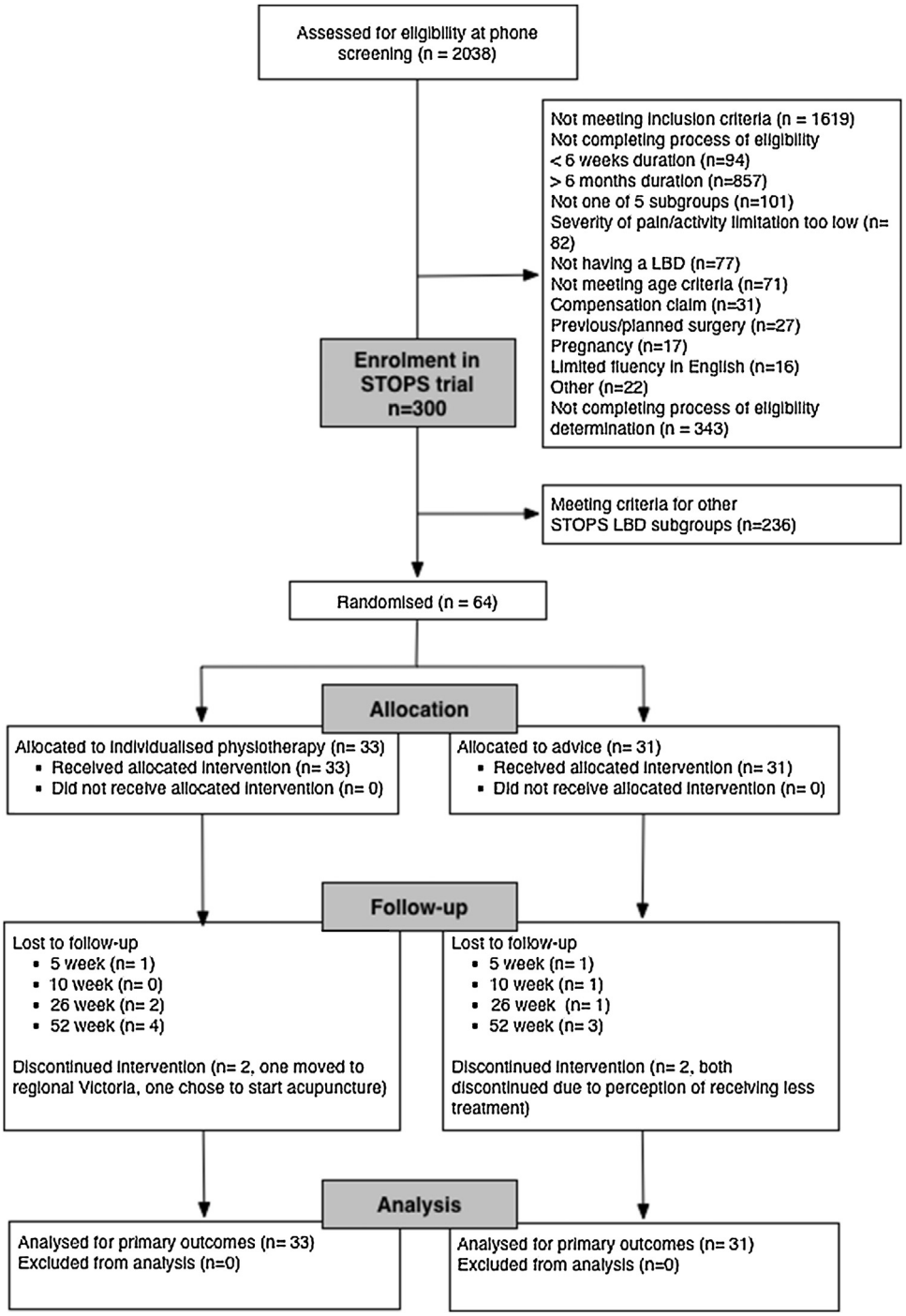

Fig. 1. Flow of participants through the randomised controlled trial.

Analyses focused on detecting between-group effects (with 95% confidence intervals [CI]) at each time-point. Using SPSS Version-21, continuous data were analysed by linear mixed models (group × time interaction, with time modeled as a repeated measure) adjusting for baseline score [27]. Ordinal data were analysed using the Mann–Whitney U test. At each time-point (5, 10, 26 and 52-weeks), participants were dichotomised according to whether they achieved the MCID on outcome measures or not. Risk ratio, risk difference and number needed to treat were calculated with 95% CI and statistical significance evaluated using Chi-square analyses [27]. The MCID for individual patients was defined as 10/100 points for the Oswestry, 2/10 for the NRS pain scales, at least "much improved" on the global rating of change scale, and "very satisfied" on the treatment satisfaction scales [27]. Given these values may be too low in some contexts, we repeated the analyses using a threshold of 50% reduction in Oswestry and NRS pain scores [27].

Table 2
Baseline characteristics of participants included in the trial.

Characteristics	Individualised manual therapy	Advice
Age in years: mean (SD)	42.9 (11.8)	46.4 (11.2)
Sex (M:F)	13/20	13/18
Smoker	4/33 (12%)	3/31 (10%)
Duration of back pain in weeks: mean (SD)	16.5 (6.5)	14.4 (6.0)
Duration of leg pain in weeks: mean (SD)	16.2 (11.4)	16.1 (19.2)
Number of participants with back pain only	13/33 (39%)	8/31 (26%)
Number of participants with back and leg pain	20/33 (61%)	23/31 (74%)
Number of participants experiencing a previous episode of low back pain	20/33 (61%)	25/31 (81%)
Number of participants meeting each LZJ criteria		
Unilateral low back pain	29/33 (88%)	27/31 (87%)
Regular compression pattern	21/33 (64%)	21/31 (68%)
Comparable palpatory finding	33/33 (100%)	31/31 (100%)
Positive response to mini-treatment	29/33 (88%)	26/31 (84%)
Number of participants meeting all criteria	13/33 (39%)	12/31 (39%)
Number of participants meeting 3 out 4 criteria	20/33 (61%)	19/31 (61%)
Primary outcome measures at baseline		
Back pain = NRS): mean (SD)	4.9 (1.8)	5.1 (1.8)
Leg pain (NRS) mean (SD)	4.1 (2.7)	4.3 (2.6)
Activity limitation (ODI): mean (SD)	24.2 (9.9)	22.7 (8.9)
Other key outcomes at baseline		
Psychosocial score (Orebro): mean (SD)	91.4 (24.0)	88.3 (18.6)
Sciatica frequency score: mean (SD)	11.1 (5.9)	11.3 (5.7)
Sciatica bothersomeness score mean (SD)	11.5 (6.0)	10.7 (5.2)

Baseline characteristics presented as n (%) unless otherwise stated.
LZJ = lumbar zygapophyseal joint. NRS = numerical rating scale. ODI = Oswestry Disability Index. SD = standard deviation.

Results

Recruitment took place between 28th April 2009 and 30th March 2012. When the STOPS trial reached its target enrolment, 64 participants with LZJ pain had been enrolled from a total 2038 screened volunteers. Fig. 1 presents the flow of participants through the trial. The most common reason for exclusion was duration of symptoms >6 months ($n = 857$), duration of symptoms <6 weeks ($n = 94$), meeting the eligibility criteria of one of the other four STOPS subgroups ($n = 236$), or not meeting eligibility criteria of any of the STOPS subgroups ($n = 101$). Participants in the IMT and advice group were generally well matched at baseline (Table 2).

The mean (SD) number of treatment sessions attended by participants receiving IMT was 9 (2) and 2 (0.2) in the advice group. Overall 17% of participants ($n = 11$) discontinued treatment, 14% ($n = 9$) from the IMT group and 3% ($n = 2$) from the advice group. There were no serious adverse events recorded.

Participants in both groups improved over time on all primary outcomes, most rapidly in the first 10-weeks following randomisation (Fig. 2 and Table 3). There was a statistically significant improvement in back pain (NRS) at 5, 10, and 26-weeks in favour of the IMT group, however this was not maintained at 52-weeks. There was also a statistically significant improvement in activity limitation (Oswestry) at 26 and 52-weeks in favour of the IMT group. There was no statistically significant difference in leg pain at any time-point. For the most part the results of the sensitivity analysis with imputed values did not differ from the primary analysis.

Secondary outcomes (Tables 3 and 4) also showed significant improvements in favour of the IMT group for global rating of change (5, 10 and 26-weeks), satisfaction with physiotherapy care and the results of treatment at all time-points, Sciatica Frequency (26 and 52-weeks) and Bothersomeness Scales (10, 26 and 52-weeks), the Örebro Musculoskeletal Pain Questionnaire (10, 26 and 52-weeks), self-rated health score (10, 26 and 52-weeks) and health related quality of life on the EuroQol-5D utility score (26 and 52-weeks). The only outcome that was non-significant across all time-points was work interference and absence.

Table A (supplementary material) presents the proportion of participants who achieved our predetermined thresholds of clinical importance for primary outcomes at each time-point. Participants in the IMT group achieved a 2/10 reduction on the NRS for back pain at 5-weeks, and 10/100 points on the Oswestry at 52-weeks. However achieving at least 50% improvement from baseline for back pain (NRS) was significantly in favour of the IMT group at 5, 10 and 26-weeks and activity limitation (Oswestry) at 26 and 52-weeks. All secondary outcomes apart from work showed a significantly greater number of participants achieving the clinically important thresholds when receiving IMT compared to advice at almost all time-points (Table B, supplementary material).

There were no statistically significant between-group differences on the basis of the amount or type of medication taken by participants at any time-point. The advice group

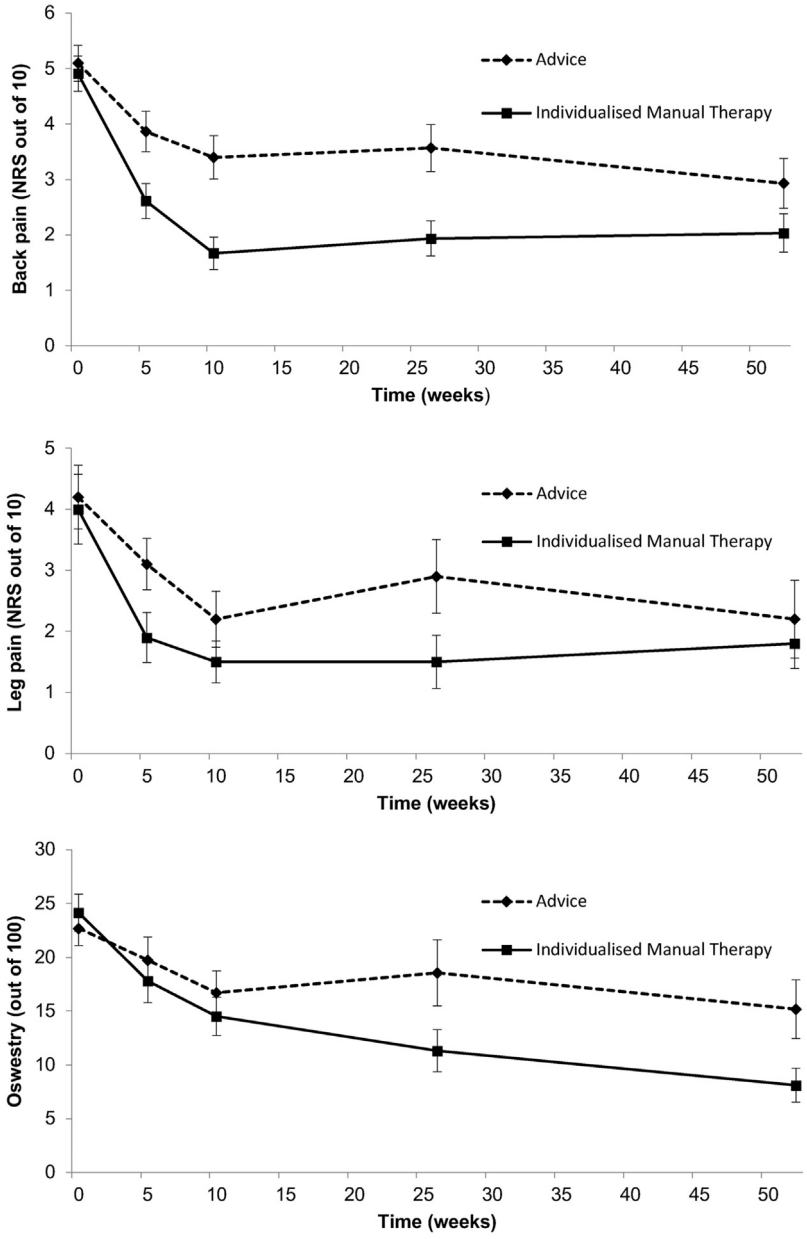

Fig. 2. Group mean scores (error bars indicate standard errors) for primary outcomes at baseline and 5, 10, 26 and 52-week time-points.

Table 3
Effects of individualised manual therapy vs advice on continuous outcomes.

Outcome	Number included (IMT/advice)	Unadjusted mean score (SD)		SMD (95%CI)	Adjusted between group difference (95% CI)[a]	*P*-value
		IMT	Advice			
Back pain (0 to 10 numerical rating scale): primary outcome						
Baseline	33/31	4.9 (1.8)	5.1 (1.8)			
5 weeks	32/30	2.6 (1.8)	3.9 (2.0)	**0.5 (0.02 to 1.0)**	**1.0 (0.6 to 2.0)**	0.04
10 weeks	33/30	1.7 (1.7)	3.4 (2.1)	**0.8 (0.3 to 1.3)**	**1.5 (0.5 to 2.4)**	**<0.01**
26 weeks	31/30	1.9 (1.8)	3.6 (2.3)	**0.7 (0.2 to 1.2)**	**1.4 (0.4 to 2.3)**	**<0.01**
52 weeks	29/28	2.0 (1.9)	2.9 (2.4)	0.3 (−0.2 to 0.8)	0.7 (−0.3 to 1.6)	0.19

Table 3 (*Continued*)

Outcome	Number included (IMT/advice)	Unadjusted mean score (SD)		SMD (95%CI)	Adjusted between group difference (95% CI)[a]	*P*-value
		IMT	Advice			
Leg pain (0 to 10 numerical rating scale): primary outcome						
Baseline	24/25	4.0 (2.8)	4.2 (2.6)			
5 weeks	24/25	1.9 (2.0)	3.1 (2.1)	0.5 (−0.1 to 1.0)	1.0 (−0.2 to 2.1)	0.11
10 weeks	22/25	1.5 (1.6)	2.2 (2.3)	0.2 (−0.4 to 0.8)	0.4 (−1.0 to 1.8)	0.55
26 weeks	21/23	1.5 (2.0)	2.9 (2.9)	0.5 (−0.1 to 1.1)	1.2 (−0.3 to 2.7)	0.11
52 weeks	22/18	1.8 (1.9)	2.2 (2.7)	0.04 (−0.6 to 0.7)	0.1 (−1.4 to 1.7)	0.88
Activity limitation (Oswestry Disability Index, 0 to 100 scale): primary outcome						
Baseline	33/31	24.2 (9.9)	22.7 (8.9)			
5 weeks	32/29	17.8 (11.4)	19.7 (11.7)	0.3 (−0.2 to 0.8)	3.6 (−1.0 to 8.1)	0.12
10 weeks	32/30	14.5 (10.1)	16.7 (11.3)	0.4 (−0.1 to 0.9)	4.0 (−1.0 to 9.0)	0.14
26 weeks	31/29	11.3 (10.9)	18.6 (16.5)	**0.6 (0.08 to 1.1)**	**8.3 (2.6 to 14.2)**	**<0.01**
52 weeks	29/28	8.1 (8.5)	15.2 (14.4)	**0.7 (0.2 to 1.2)**	**8.2 (2.3 to 14.2)**	**<0.01**
Sciatica frequency score (0 to 30 scale, higher scores indicate greater frequency)						
Baseline	33/31	11.1 (5.9)	11.3 (5.7)			
5 weeks	32/30	6.3 (4.0)	7.7 (5.4)	0.3 (−0.3 to 0.8)	1.2 (−0.9 to 3.2)	0.26
10 weeks	33/30	4.8 (4.2)	7.0 (5.5)	0.4 (−0.1 to 0.9)	2.0 (−0.3 to 4.3)	0.10
26 weeks	29/30	3.8 (3.5)	7.7 (6.5)	**0.6 (0.1 to 1.1)**	**3.3 (0.9 to 5.6)**	**0.01**
52 weeks	25/26	3.3 (2.6)	6.8 (6.7)	0.5 (−0.1 to 1.0)	**2.5 (0.1 to 4.9)**	**0.04**
Sciatica bothersomeness score (0 to 30 scale, higher scores indicate symptoms more bothersome)						
Baseline	33/31	11.5 (6.0)	10.7 (5.2)			
5 weeks	32/30	6.4 (4.3)	7.8 (5.6)	0.5 (−0.03 to 1.0)	2.2 (−0.5 to 4.4)	0.06
10 weeks	33/30	5.1 (5.1)	7.0 (5.5)	0.5 (−0.03 to 1.0)	**2.5 (0.3 to 4.8)**	**0.03**
26 weeks	29/30	3.7 (4.1)	7.3 (6.6)	**0.7 (0.2 to 1.2)**	**3.8 (1.5 to 6.0)**	**<0.01**
52 weeks	25/26	3.1 (3.0)	6.7 (6.7)	**0.6 (.01 to 1.2)**	**3.2 (0.9 to 5.6)**	**<0.01**
Psychosocial score (Örebro 0 to 210 scale, higher scores indicating higher psychosocial distress)						
Baseline	33/31	91.4 (24.0)	88.3 (18.6)			
5 weeks	32/30	75.9 (26.3)	78.3 (25.6)	0.3 (−0.2 to 0.8)	7.2 (−2.5 to 17.0)	0.14
10 weeks	33/30	65.0 (23.3)	74.6 (25.5)	0.5 (0.0 to 1.0)	**12.3 (0.9 to 23.8)**	**0.04**
26 weeks	29/30	54.4 (26.9)	76.1 (31.0)	**0.7 (0.2 to 1.2)**	**20.2 (7.9 to 32.5)**	**<0.01**
52 weeks	26/26	50.0 (25.1)	74.5 (33.2)	**0.8 (0.2 to 1.4)**	**23.9 (10.7 to 36.9)**	**<0.01**
Health score (0 to 100 scale, higher scores indicate better health state)						
Baseline	33/30	66.2 (15.5)	70.7 (14.8)			
5 weeks	31/30	71.9 (16.9)	72.2 (17.8)	−0.3 (−0.8 to 0.2)	−4.9 (−12.1 to 2.3)	0.18
10 weeks	33/30	80.7 (12.6)	75.5 (20.3)	**−0.6 (−1.1 to −0.1)**	**−9.8 (−17.9 to −1.6)**	**0.02**
26 weeks	29/29	76.2 (21.8)	68.9 (21.7)	**−0.6 (−1.2 to −0.1)**	**−14.1 (−22.7 to −5.6)**	**<0.01**
52 weeks	26/25	84.1 (11.9)	74.4 (17.6)	**−0.9 (−1.4 to −0.3)**	**−13.2 (−22.3 to −4.2)**	**<0.01**

IMT = individualised physiotherapy.
Those with 0/10 leg pain at baseline and all follow-ups were excluded from this analysis.
[b]SMD = Hedges adjusted-*g* standardised mean difference.
[a] Between group mean differences and 95% confidence were obtained using a linear mixed model and adjusted for baseline score (bolded if statistically significant).

attended a greater number of additional physiotherapy sessions than the IMT group, but there were no other significant between-group differences in cointerventions.

Sample size calculations were based on conservative estimates [47] however our data shows that a smaller sample size was sufficient to detect significant effects.

Table 4
Effects of individualised manual therapy vs advice on ordinal secondary outcomes.

Outcome	Number included IMT/advice	Median (25th to 75th percentile)		*P*-value*
		IMT	Advice	
Global rating of change score (1 to 7 scale, lower scores indicating greater improvement)				
5 weeks	32/30	2.0 (2.0 to 3.0)	3.0 (3.0 to 4.0)	**<0.01**
10 weeks	33/30	2.0 (2.0 to 3.0)	3.0 (2.0 to 3.0)	**0.03**
26 weeks	31/30	2.0 (2.0 to 3.0)	3.0 (2.0 to 4.0)	**0.01**
52 weeks	29/28	2.0 (2.0 to 3.0)	3.0 (2.0 to 4.0)	0.24

Table 4 (*Continued*)

Outcome	Number included IMT/advice	Median (25th to 75th percentile)		*P*-value*
		IMT	Advice	
Satisfaction with physiotherapy care (0 to 4 scale, higher scores indicating greater satisfaction)				
5 weeks	32/30	4.0 (3.0 to 4.0)	2.0 (2.0 to 3.0)	**<0.01**
10 weeks	33/30	4.0 (4.0 to 4.0)	2.5 (2.0 to 3.0)	**<0.01**
26 weeks	29/27	4.0 (3.0 to 4.0)	2.0 (2.0 to 3.0)	**<0.01**
52 weeks	26/23	4.0 (3.0 to 4.0)	2.0 (2.0 to 3.0)	**<0.01**
Satisfaction with results of treatment (0 to 4 scale, higher scores indicating greater satisfaction)				
5 weeks	32/30	4.0 (3.0 to 4.0)	2.0 (2.0 to 3.0)	**<0.01**
10 weeks	33/30	4.0 (3.0 to 4.0)	2.5 (2.0 to 3.0)	**<0.01**
26 weeks	29/28	4.0 (3.0 to 4.0)	2.0 (2.0 to 3.0)	**<0.01**
52 weeks	26/21	4.0 (2.8 to 4.0)	2.0 (1.0 to 3.0)	**<0.01**
Satisfaction with enduring symptoms (0 to 4 scale, higher scores indicating greater satisfaction)				
5 weeks	32/30	1.0 (0.0 to 2.3)	0.0 (0.0 to 1.0)	0.05
10 weeks	33/30	1.0 (1.0 to 3.0)	1.0 (0.0 to 2.0)	0.07
26 weeks	29/29	3.0 (1.0 to 4.0)	1.0 (0.0 to 1.0)	**<0.01**
52 weeks	26/26	3.0 (1.0 to 4.0)	1.0 (0.3 to 2.8)	**<0.01**
Work interference (0 to 4 score, higher scores indicating greater interference with work)				
Baseline	26/26	2.0 (1.0 to 3.0)	1.5 (1.0 to 2.0)	0.47
5 weeks	25/26	1.0 (0.0 to 2.0)	1.0 (1.0 to 1.0)	1.0
10 weeks	26/26	1.0 (0.0 to 1.0)	1.0 (0.3 to 2.0)	0.61
26 weeks	22/26	0.0 (0.0 to 1.0)	1.0 (1.0 to 1.0)	0.06
52 weeks	19/23	0.0 (0.0 to 1.0)	1.0 (0.0 to 1.0)	0.08
Work absence (self-reported work days missed in the last 30 days)				
Baseline	24/24	0 (0 to 0)	0 (0 to 0)	0.74
5 weeks	25/25	0 (0 to 0)	0 (0 to 0)	0.27
10 weeks	23/24	0 (0 to 0)	0 (0 to 0)	0.13
26 weeks	22/23	0 (0 to 0)	0 (0 to 0)	0.29
52 weeks	18/20	0 (0 to 0)	0 (0 to 0)	0.17
EuroQol-5D utility score (0 to 1, higher scores indicating higher health-related quality of life)				
Baseline	33/31	0.7 (0.7 to 0.8)	0.7 (0.6 to 0.8)	0.31
5 weeks	33/31	0.8 (0.7 to 1.0)	0.8 (0.7 to 0.8)	0.43
10 weeks	33/31	0.8 (0.7 to 1.0)	0.8 (0.7 to 1.0)	0.61
26 weeks	33/31	0.9 (0.8 to 1.0)	0.8 (0.7 to 0.9)	**0.03**
52 weeks	33/31	0.9 (0.8 to 1.0)	0.8 (0.7 to 0.9)	**0.03**

IMT = individualised physiotherapy

* Significance value of Mann–Whitney U test (bolded if $P < 0.05$).

Discussion

This trial shows that people with LBD and clinical features indicative of LZJ experience greater and more rapid improvements in back pain (at 5, 10 and 26-weeks) and activity limitation (at 26 and 52-weeks) with IMT and guideline-based advice compared to advice alone. The size of between-group differences was close to the commonly accepted MCID [48]. To further explore clinical importance and in accordance with our a-priori statistical plan [27], a primary outcome responder analysis was conducted. This showed that participants receiving IMT had 1.8 to 2.5 times the chance of improving by 50% on back pain (at 5, 10 and 26-weeks) and 2.3 to 2.4 times the chance of improving by 50% on Oswestry (at 26 and 52-weeks) compared to those receiving advice.

Estimating clinical importance should also consider consistency of results, benefits/risks in relation to the treatments and the population being evaluated [49]. There was consistency of results across all primary and secondary outcomes apart from work. The responder analysis of secondary outcomes strongly supported the benefits of IMT over advice. There were no serious adverse events in either group. Between-group comparisons should also be interpreted in the context of large within-group improvements on all primary outcomes for both treatment groups [50]. Given the population sampled were >6-weeks post injury where spontaneous recovery is limited [3], it is likely that both treatments were effective, with IMT conferring substantial additional benefits over and above advice alone. These additional considerations strengthen the case for the clinical importance of adding IMT to guideline-based advice [49].

Our results support existing data suggesting that manual therapy when individualised to patient characteristics is more effective that other types of treatment [17]. This contrasts to the limited effectiveness when manual therapy is applied and evaluated without consideration of individualisation [12]. There are a range of possible mechanisms

behind the observed results. The IMT treatment focused on identifying a clinical pattern that was plausibly indicative of LZJ pain and providing a targeted treatment [24]. Diagnostic accuracy for LBD is challenging [51] and targeting pathoanatomy in the treatment of LBD has been criticised. However there is limited evidence to support exclusion of hypothesising on such mechanisms to assist clinical decision making [52].

The treatment protocol had explicit algorithms to assist decision making in accordance with well described clinical reasoning strategies [31]. Given the potential for clinical reasoning error in the health professions [53,54] it is possible that this approach combined with rigorous measures to maximise treatment integrity contributed to the positive results.

At baseline the sample recruited had a mean Örebro score of 90/210 in keeping with the eligibility criteria targeting people more likely to have a pathoanatomical or nociceptive driver of the LBD [55]. Between-group differences in Örebro outcome at 52-weeks were large and favouring IMT. The mean duration of back pain was 15.5 weeks which characterises the sample on average as falling within accepted definitions for chronic or persistent pain [56]. Commentary exists suggesting that manual therapy can reinforce illness behaviour and therefore may not be appropriate for persistent LBD [57,58] however our results suggest psychosocial risk of poor outcome is in fact substantially reduced by IMT in carefully selected patients.

The secondary outcomes measuring satisfaction showed large risk differences favouring IMT at 52-weeks. This included participants being at least very satisfied to endure symptoms for the rest of their life (57% for IMT and 16% for advice) as well as with physiotherapy care (73% for IMT and 29% for advice). Satisfaction is an important outcome reflecting patient perspectives [59] that increases the likelihood of a positive placebo effect [60]. However it is difficult to apportion the relative treatment effects of IMT to placebo or mechanisms of manual therapy given the lack of credible placebo treatments [61,62]. It has been argued that placebo effect in manual therapy is an important component of effectiveness provided it is ethically implemented [63]. The overall results of our trial combined with high levels of satisfaction with IMT support this perspective.

A key component of IMT was motor control training with a focus on specific activation of the local/deep muscles around the lumbar spine [32]. Our results support recent evidence that specific motor control training is an effective component when treating LBD [64]. It is possible that the initial rapid reduction in pain from IMT facilitated improved activation and effectiveness of the deep/local muscles thereby contributing to the 26 and 52-week improvements in activity limitation. This hypothesis is consistent with described although controversial [65] mechanisms underpinning the clinical application of motor control training [19]. However the multifactorial nature of IMT including motor control training limits conclusions on the effectiveness of the individual treatment components provided.

This subgroup analysis had several strengths including a low risk of bias and high follow-up rate providing confidence in the validity of the findings. The generalisability of the findings is increased as the sample was recruited from the community, multiple physiotherapists with varying clinical experience provided the treatment, and the treatment protocol has been published [66] enabling application of IMT in clinical practice. The inclusion criteria regarding the clinical features indicative of LZJ pain restrict the generalisability of the results, but in a manner consistent with current clinical practice by physiotherapists [21,67] and recommendations for research on LBD [68].

There are a number of potential trial limitations. It could be argued that the difference in the number of sessions, and hence attention, between the groups was a limitation in that the greater effects in the IP group could perceivably be attributed to the greater therapist attention. However, these session numbers reflect manual therapy clinical practice and protocols for advice in RCTs that have demonstrated effectiveness [5,69]. To address our primary aim of determining effectiveness of IMT compared to guideline-based advice an imbalance of treatment sessions therefore resulted. In addition trials with similar treatment imbalance show no difference between groups [70–72]. The treatment imbalance also has cost implications. However our analysis of the full STOPS trial data has demonstrated cost effectiveness for individualized physiotherapy compared to advice when accounting for all treatments provided as well as sick leave [73]. The 10 sessions required for IMT may have implications on generalisability of the results in some settings where access to no cost physiotherapy is limited. However, if the cost effectiveness of IMT compared to advice is confirmed in future studies, the case for expanded access to physiotherapy could be considered

As with most trials of physiotherapy it was not possible to blind therapists or participants to treatment allocation [74,75], although there was blinded scoring and entry of outcome questionnaires. This will have introduced some bias in the self-reporting of outcomes if participants had a preference for one treatment over the other.

The number of outcomes evaluated in this trial could result in increasing the type I error rate. However we decided not to adjust our α level given that all outcomes were defined a priori, multiple time-points were modeled as repeated measures within linear mixed models for continuous outcomes and considering the limitations and concerns about the use of Bonferroni adjustments [76]. The finding that the majority of short-term pain outcomes in this study were demonstrated to be significant indicates type I errors are an unlikely explanation for the results obtained. Alternatively, the study could be underpowered to detect all important effects given our reporting in this paper of a subgroup within a larger RCT. While obtained significant effects in this study cannot by definition be underpowered, the leg pain outcomes were underpowered (with power ranging from 5% to 40% across various timeframes) given that this outcome included only a propor-

tion of participants who had leg pain present. Sample size calculations were based on conservative estimates however our data shows that a smaller sample size was sufficient to detect significant effects on two of the three primary outcome measures.

Conclusion

In patients with clinical features potentially indicative of LZJ pain, IMT with guideline-based advice is more effective than advice alone for achieving faster improvements in back pain as well as faster and sustained improvement in activity limitation, but not for improvement in leg pain. The outcomes appear clinically important. Physiotherapists should consider providing IMT to patients with features potentially indicative of LZJ pain.

Key messages

- IMT is more effective than advice in patients who may have LZJ pain
- The outcomes appear clinically important
- Physiotherapists should consider IMT in patients with clinical features of LZJ pain

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Conflict of interest: JF reported being an employee and equity partner of the primary funding source (LifeCare Health). This funding arrangement was declared in our published trial protocol. No other LifeCare staff or equity partners had any involvement with the conduct of the trial including study design; in the collection, analysis, and interpretation of data; in the writing of this paper; and in the decision to submit the paper for publication. During the trial, five of the authors (AH, LS, AC, MR, SS) were subcontracted to LifeCare Health and were paid for treating participants with low back disorders and other musculoskeletal conditions. In order to minimise any potential for bias, all authors had full access to the study data, while both JF and AC had final responsibility for the decision to submit for publication. Three of the authors (JF, AH and AC) provide practitioner education programs that covers some of the treatments included in this trial.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.physio.2018.07.008.

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