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A Randomized Clinical Trial of Manipulative Therapy and Interferential Therapy for Acute Low Back Pain

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Study Design. A multicenter assessor-blinded randomized clinical trial was conducted.

Objectives. To investigate the difference in effectiveness of manipulative therapy and interferential therapy for patients with acute low back pain when used as sole treatments and in combination.

Summary of Background Data. Both manipulative therapy and interferential therapy are commonly used treatments for low back pain. Evidence for the effectiveness of manipulative therapy is available only for the short-term. There is limited evidence for interferential therapy, and no study has investigated the effectiveness of manipulative therapy combined with interferential therapy.

Methods. Consenting subjects (n = 240) recruited following referral by physicians to physiotherapy departments in the (government-funded) National Health Service in Northern Ireland were randomly assigned to receive a copy of the *Back Book* and either manipulative therapy (MT; n = 80), interferential therapy (IFT; n = 80), or a combination of manipulative therapy and interferential therapy (CT; n = 80). The primary outcome was a change in functional disability on the Roland Morris Disability Questionnaire. Follow-up questionnaires were posted at discharge and at 6 and 12 months.

Results. The groups were balanced at baseline for low back pain and demographic characteristics. At discharge all interventions significantly reduced functional disability (Roland Morris scale, MT: −4.53; 95% CI, −5.7 to −3.3 *vs.* IFT: −3.56; 95% CI, −4.8 to −2.4 *vs.* CT: −4.65; 95% CI, −5.8 to −3.5; $P = 0.38$) and pain (McGill questionnaire, MT: −5.12; 95% CI, −7.7 to −2.5 *vs.* IFT: −5.87; 95% CI, −8.5 to −3.3 *vs.* CT: −6.64; 95% CI, −9.2 to −4.1; $P = 0.72$) and increased quality of life (SF-36 Role–Physical, MT: 28.6; 95% CI, 18.3 to 38.9 *vs.* IFT: 31.4; 95% CI, 21.2 to 41.5 *vs.* CT: 30; 95% CI, 19.9 to 40; $P = 0.93$) to the same degree and maintained these improvements at 6 and 12 months. No significant differences were found between groups for reported LBP recurrence, work absenteeism, medication consumption, exercise participation, or healthcare use at 12 months ($P > 0.05$).

Conclusions. For acute low back pain, there was no difference between the effects of a combined manipulative therapy and interferential therapy package and either manipulative therapy or interferential therapy alone.

Key words:manipulative therapy, interferential therapy, low back pain, effectiveness, physiotherapy, primary care, randomized clinical trial. **Spine 2004;29:2207–2216**

Physiotherapists treat an estimated 1.6 million people with low back pain (LBP) each year in the United Kingdom and in 1998, along with chiropractors and osteopaths, accounted for 37% of the Stg£1.6 billion direct healthcare costs of LBP.[1] Recent surveys of the physiotherapeutic management of LBP in Britain, Ireland, the United States, and Canada found that a range of treatment strategies is being used: advice, spinal mobilization, active exercise, and electrical stimulation (interferential therapy [IFT]).[2–6] Although national clinical guidelines from at least 11 countries on acute LBP (current episode < 12 weeks) agree on the need to reassure patients, promote early and progressive physical activation, and discourage bed rest, there are differences in the recommendations for exercise therapy and manipulative therapy (MT), while electrical stimulation is not advocated at all.[7]

MT incorporates both mobilization (nonforceful, oscillatory technique of high or low velocity) and manipulation (low amplitude range-expanding thrust of high velocity) techniques that aim to reduce pain and increase joint range of movement.[8] The risks are low provided that patients are selected and treated properly by trained therapists; in Britain and Ireland, the most popular MT postgraduate programs are those based on the work of Geoffrey Maitland and Dr. James Cyriax.[9,10] Although spinal MT is not recommended by the Dutch, Australian, and Israeli guidelines for acute LBP, the remaining eight

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national guidelines support its use, although they report different time frames for its application. For example, the U.K. Guideline advises: "consider spinal manipulation for patients who need additional help with pain relief or who are failing to return to normal activities."[11] The lack of agreement between clinical guidelines is partly attributable to the conflicting evidence from systematic reviews for the effects of spinal manipulation compared to placebo and a range of other active treatments for acute LBP.[12] Therefore, there is a need for further large-scale rigorous trials of patients with clinically homogeneous LBP syndromes, who receive well-defined MT interventions and who are assessed for response with valid outcome measures.[13]

IFT is a form of electrical stimulation produced using the principle of amplitude modulation whereby two medium frequency currents (in the kilohertz range, *e.g.*, 4,000 Hz), which are slightly out of phase, are mixed (either within the tissues or within an electrical stimulator) to produce a low frequency current (0–250 Hz).[14] The resultant current produces less impedance in the tissues, and its intensity is perceived as being more comfortable to patients than that produced by low frequency stimulators such as a transcutaneous electrical nerve stimulation (TENS) machine.[15] In the British Isles, IFT has the highest ownership and usage of all electrotherapeutic methods by physiotherapists[16,17] and is the most popular form of electrical stimulation for LBP management (44% of therapists), being predominantly used for its hypoalgesic effects.[3,4,18] Nonetheless, insufficient evidence of effectiveness necessitated its omission from recent acute LBP clinical guideline documents.[11,19,20] The current literature includes two randomized controlled trials (RCTs) with 3-month follow-up of patients with LBP that reported significant improvements but no difference in outcomes with treatment using IFT compared with either lumbar traction/massage[21] or the *Back Book*.[22] Nonsignificant differences were also reported in trials of IFT compared with other active treatments for osteoarthrosis of the knee[23] and soft tissue shoulder disorders.[24] Therefore, the current evidence base to properly determine the effectiveness of this electrotherapeutic modality is inadequate and high-quality trials are warranted.[25]

While both MT and IFT are popular treatments for LBP management, their effects have not been directly investigated in a randomized clinical trial. Previous trials of chiropractic manipulation and TENS for subacute LBP have produced conflicting results, with one study reporting positive effects up to 3 weeks for manipulation[26] while another detected no significant differences between these interventions.[27] However, IFT has been shown to be considerably more popular than TENS for LBP management; thus, research into any difference in effectiveness relative to MT is warranted.

Combinations of treatment methods rather than the delivery of any mode of therapy in isolation represent the norm for a typical LBP physiotherapy session.[4,5] Some of the most popular combinations in a survey of Northern Ireland physiotherapists were "advice and Maitland mobilizations" and "advice, Maitland mobilizations and IFT."[4] No previous trial has investigated the combined use of MT and IFT for acute LBP, although investigations into the effectiveness of IFT within a multimodal (physiotherapeutic) treatment regimen have been advocated.[28]

Table 1. Exclusion Criteria

Previous spinal surgery
Recent motor vehicle accident
Systemic disease
Concurrent medical or musculoskeletal conditions
Contraindications to manipulative therapy or interferential therapy
Reflex and/or motor signs of nerve root, spinal cord, or cauda equina compression
Episodes of LBP in the previous 6 months
Physiotherapy treatment for LBP in the previous 12 months
History of psychological or psychiatric illness
Lack of fluency in English
Roland Morris Disability Questionnaire score <4 points
Pregnancy

This randomized clinical trial assessed the difference in short- and long-term effectiveness of two commonly used conservative physiotherapy approaches for acute LBP: MT and IFT. The effectiveness of the two therapies was tested against each other as well as against the results for a group that received the two treatments in combination as a multimodal package. In this study, the authors aimed to answer two research questions:

What was the difference in effectiveness of MT compared to IFT alone?

What was the difference in effectiveness of a combined MT and IFT package compared with either MT or IFT alone?

■ Materials and Methods

Selection of Patients. Patients were recruited within the British government-funded National Health Service (NHS) in Northern Ireland in four of the United Hospitals Health and Social Services Trust Hospitals' (Antrim, Whiteabbey, Mid Ulster, and Waveney) physiotherapy departments. All patients 18 to 65 years of age referred by general practitioners (GPs) for treatment of LBP with or without pain radiation into the buttock and/or one or both lower limbs, of between 4 and 12 weeks' duration were invited to participate. The first author, who was principal investigator, was responsible for verifying eligibility, providing detailed written and verbal explanations regarding the nature of the study and obtaining written consent. All subjects signed a consent form before admission to the study. The Research Ethical Committee of the University of Ulster approved the study protocol. Consenting subjects were screened for any exclusion criteria, as detailed in Table 1.

Randomization. Subjects were randomly allocated to one of three groups (MT, IFT, combined therapy) using an allocation schedule generated from a random numbers table.[29] This was drawn up by a member of the research team not involved in the day-to-day running of the trial (S.Mc.D.). Based on this schedule, the group allocation of each consenting, numbered subject

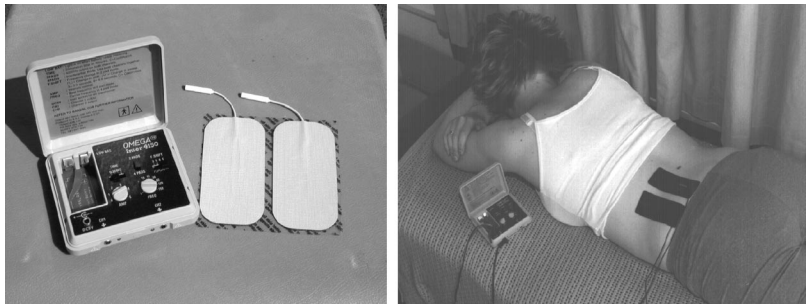

Figure 1. Interferential therapy unit, self-adhesive electrodes and patient set-up for IFT Group (Spinal Nerve Root Electrode Placement Technique).

was communicated to the relevant treating physiotherapist by telephone contact with the research group secretary. The principal investigator was not involved in any aspect of randomization and the allocation schedule was concealed from her until all interventions were assigned and data analysis completed.

Therapists. Only chartered physiotherapists who had successfully completed the Society of Orthopedic Medicine (SOM) membership examination, a postgraduate qualification in MT, recognized by the Chartered Society of Physiotherapy (CSP), and the International Forum of Orthopedic Manipulative Therapists (IFOMT), were eligible to administer the treatment protocols. Sixteen physiotherapists met the criteria and were willing to participate in this study (100% participation rate); *i.e.*, four physiotherapists within each of the four participating hospitals. All treatments were provided to an individual patient by the same therapist.

Clinical Interventions. Study participants were requested to continue normal activities and to avoid other forms of treatment for the duration of the study, apart from routine physician management and analgesics. Therapists other than the designated protocol were not permitted to administer any other forms of MT, electrotherapy or other techniques (spinal traction, heel raises, corsets, acupuncture, injection therapy, or taping) during the intervention period of the trial. Given the nature of the treatments, it was not possible to blind subjects or therapists with respect to the content of the interventions, but the clinicians were equally positive in their delivery[30] and recorded all treatments' provided to verify adherence to the protocol. The procedures for each intervention were standardized as detailed below.

Back Book. Following assessment, all subjects received the *Back Book* from their treating physiotherapist, who reinforced its positive messages during the first visit, by encouraging early return to normal activities and participation in low impact activities such as walking, swimming, and cycling.[31] The UK Clinical Guideline recommendations regarding physical reactivation are encompassed in the *Back Book*,[31] which has been shown to be readily acceptable and understandable and to create a positive shift in beliefs about LBP.[32] It is reported to be more likely to have an impact as part of a treatment package[33]; thus, it was an appropriate standardized cointervention for the RCT.

MT Group. Subjects assigned to this group were treated by the MT protocol, which was defined as any "mobilization" or "manipulation" techniques' for the lumbar spine that passively move an intervertebral joint within or beyond its existing range of movement, respectively, described by Maitland[10] or Cyriax.[9] Maitland mobilization (Grade I, II, III, or IV) and manipulation (Grade V) techniques refer to the application of oscillatory or glide techniques, while Cyriax mobilization (Grade A or B) and manipulation (Grade C) techniques refer to the application of rotational and extension maneuvers; both approaches use short- and long-lever arms. On the basis of normal clinical practice, each physiotherapist had free choice of which mobilization and manipulation techniques to use and when, and the spinal levels to which they were applied on the basis of the initial and progressive assessment of each patient's lumbar joint dysfunction.

IFT Group. Study participants assigned to this group were treated by the IFT protocol based on the results of a previous study by the researchers.[22] Omega *Inter* 4150 portable IFT units (TensCare Ltd, London) were used to deliver standardized IFT stimulation parameters (*i.e.*, carrier frequency 3.85 kHz; beat frequency 140 Hz constant; pulse duration 130 microseconds; treatment time 30 minutes) using the spinal nerve root electrode placement method via two Reply 658 carbon silicone self-adhesive electrodes (50 × 100 mm) (Figure 1).

Combined Therapy (CT) Group. Both the MT and IFT protocols were provided to subjects assigned to the CT group at each treatment session with the MT protocol preceding the IFT protocol.

Compliance. On the basis of the findings of a previous survey that established the routine physiotherapy management of people with LBP in the United Hospitals Trust, it was determined that subjects in all groups in this RCT should receive a minimum of four and a maximum of 10 treatments over a period of 8 weeks.[34] Noncompliance was defined as receipt of three or less treatments and these participants were withdrawn from the study and treated "as necessary" by the same physiotherapist but were included in all subsequent follow-ups for the purposes of intention-to-treat analysis.

Outcome Measurement and Follow-up Procedures. Several recommended valid and reliable outcome measure questionnaires[7] with proven psychometric properties for LBP-specific functional disability (Roland Morris Disability Questionnaire),[35] pain (Visual Analogue Scale,[36] McGill Pain Questionnaire[37]), and quality of life (EQ-5D,[38] Short-Form 36[39]) and a multidimensional patient-centered questionnaire (LBP recurrence, work absenteeism, exercise participation, analgesic medication consumption, additional health care)[40] were used to collect outcome data at baseline, discharge, 6 months, and 12 months. All follow-ups were conducted by post (using self-addressed envelopes) and administered by the prin-

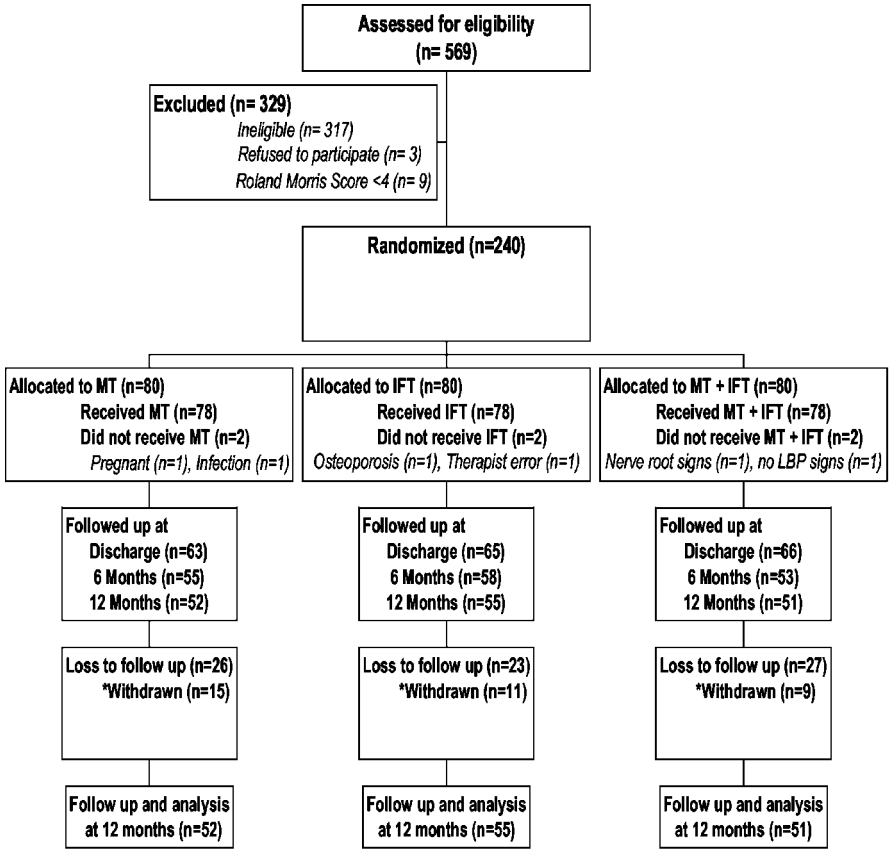

Figure 2. Progression of participants through the trial including withdrawals and losses to follow-up.

**Withdrawn* represents those who were noncompliant with the protocol, but participated in follow-up and analysis.

cipal investigator who was blind to group allocation until completion of data analyses. Nonrespondents were sent a postcard reminder after 2 weeks, and a second copy of the questionnaires and self-addressed envelopes after 4 weeks.

Data Analysis. All data were analyzed using the Statistical Package for the Social Sciences (Windows 9.0) according to the "intention-to-treat" principle. Baseline characteristics and the patient-centered questionnaire data were compared using $\div^2$ tests for categorical variables and one-way ANOVA or Kruskal-Wallis *H* test for continuous variables. For the functional disability, pain and quality of life continuous variables, within-subjects repeated-measure ANOVA determined significant differences over time for the whole sample, and between-within repeated measures ANCOVA assessed significant differences between and within groups over time using the relevant baseline score as the covariate. The differences from baseline were calculated for the continuous variables and the effects of the interventions at each follow-up point were estimated using univariate ANCOVA. For all comparisons, a probability of $<$ 0.05 was considered to be statistically significant (two-tailed). Where multiple comparisons were conducted, the Bonferroni correction for multiple tests of significance was used. Exploratory analysis of Roland Morris Disability Questionnaire change scores determined the percentage of subjects that had achieved the minimal clinically important difference (MCID) value of 3 points and the MCID value according to baseline score: 0–8 (MCID = 2), 9–16 (MCID = 4), and 17–24 (MCID = 8).[41] An alternative analysis that accounted for dropouts at follow-up was conducted whereby missing values were replaced with imputed values generated by a series of linear regression equations; subjects' previous scores were used to determine a predicted value that reduced the variance of the value for each variable.[42]

Power Analysis. Sample size was determined by the statistician (M.D.) in accordance with the procedures described by Buchner *et al*.[43] Estimates of variability for the primary outcome (Roland Morris Disability Questionnaire scores at 12 months) were obtained from a previous trial conducted by the researchers[22] that also concurred with the recommendations of the original developers of the questionnaire for a change score of 2 or 3 RMDQ points for sample size calculations.[44] A minimum of 50 subjects was required for each intervention group to provide at least 90% probability, at an alpha of 0.05, of detecting a MCID of 2 points in the mean change of the Roland Morris Disability Questionnaire (in either direction) between groups if such an effect existed and based on a between-within repeated-measures ANOVA design. Allowing for 15% attrition at three follow-up points increased the minimum sample size for each group to 76 subjects; total sample size was a minimum of 228 subjects.

■ Results

Participant flow and retention are shown in Figure 2. From May 1999 to May 2000, a total of 240 subjects

Table 2. Patient Characteristics at Baseline

	Global (n = 240)	Manipulative Therapy (n = 80)	Interferential Therapy (n = 80)	Combined Therapy (n = 80)
Mean age (yr, SD)	40 (11.6)	39.6 (11.6)	40.2 (12.1)	40.5 (11.3)
Gender (% female)	144 (60%)	46 (57%)	50 (62%)	48 (60%)
History of LBP [no. (%)]				
Previous LBP*	158 (66)	49 (61)	53 (66)	56 (70)
Previous treatment for LBP	118 (49)	40 (50)	38 (47)	40 (50)
Previous physiotherapy for LBP	72 (30)	25 (31)	23 (29)	24 (30)
Previous motor vehicle accident	91 (38)	31 (39)	30 (38)	30 (38)
LBP after motor vehicle accident	32 (35)	11 (35)	10 (33)	11 (37)
Current episode of LBP				
Duration of problem (weeks) [mean (SD)]	8.0 (2.9)	7.5 (3.1)	7.6 (3.0)	8.3 (2.8)
Self-reported cause of LBP [no. (%)]				
Work-related incident	73 (31)	31 (39)	15 (19)	27 (34)
Non work-related incident	39 (16)	10 (12)	12 (15)	17 (21)
Idiopathic	128 (53)	39 (49)	53 (66)	36 (45)
Employed or self-employed	191 (80)	65 (81)	62 (77)	64 (80)
Work absenteeism due to LBP				
None	49 (26)	15 (23)	19 (31)	15 (23)
≤30 days	112 (59)	39 (60)	38 (61)	35 (55)
>30 days	30 (16)	11 (17)	5 (8)	14 (22)
Participation in exercise†	115 (48)	37 (46)	39 (49)	39 (49)
Use of analgesics for LBP‡	185 (77)	63 (79)	63 (79)	59 (74)
Use of analgesics (days)§ [mean (SD)]	4.0 (2.9)	4.2 (2.9)	4.1 (2.9)	4.0 (3.0)
No. (%) of non-smokers	104 (43)	39 (49)	34 (42)	31 (39)
Outcome variables [mean (SD)]				
Primary outcome				
Roland Morris Disability Score	10.05 (4.81)	10.70 (4.86)	9.04 (4.45)	10.41 (5.01)
Secondary outcomes				
VAS score (mm)				
Average back pain	51.32 (26.09)	52.08 (24.49)	52.06 (24.93)	49.84 (28.91)
Average leg pain	31.69 (33.51)	30.68 (33.26)	32.70 (35.33)	31.70 (32.28)
Worst back pain	57.74 (30.76)	58.24 (30.17)	58.97 (29.54)	56.03 (32.80)
Worst leg pain	34.05 (36.01)	32.69 (35.89)	36.16 (37.13)	33.33 (35.37)
McGill Pain Questionnaire Score	16.52 (9.68)	15.85 (9.12)	17.44 (9.93)	16.28 (10.02)
EQ-5D Weighted Health Index Score	00.52 (0.29)	00.51 (0.30)	00.52 (0.28)	00.54 (0.28)
Short-Form 36 Score				
Physical Functioning	52.60 (22.3)	50.64 (20.75)	55.65 (21.17)	51.46 (24.61)
Role–Physical	14.10 (27.8)	10.90 (22.65)	17.72 (31.30)	13.61 (28.53)
Bodily Pain	28.90 (15.4)	27.12 (13.91)	30.57 (16.02)	28.97 (16.07)
General Health	66.90 (18.7)	67.48 (18.48)	68.24 (16.48)	65.06 (20.92)
Vitality	42.7 (19.7)	39.17 (17.23)	45.44 (19.63)	43.33 (21.60)
Social Functioning	56.6 (25.9)	52.56 (24.70)	60.92 (25.58)	56.33 (27.14)
Role–Emotional	45.3 (45.8)	44.02 (45.74)	48.52 (46.16)	43.46 (46.03)
Mental Health	65.1 (18.4)	64.00 (18.78)	66.43 (18.68)	64.94 (17.88)

Overall ANOVAs and χ^2 tests were not statistically significant.
*Previous LBP represents the percentage of patients with any experience of back pain in the previous 12 months.
†Participation in exercise represents the percentage of patients who have participated in any form of physical exercise in the previous month (baseline).
‡Use of analgesics for LBP represents the percentage of patients who used analgesics in the previous week.
§Mean use of analgesics represents the no. of days that analgesics were used in the previous week.

were recruited following referral from 97 general practitioners in Northern Ireland. Follow-up data were obtained from 194 (83%) subjects at discharge, 166 (71%) at 6 months, and 158 (67%) at 12 months. A retrospective power analysis on the basis of the 12-month follow-up data showed the study achieved power of at least 90% to detect clinically significant differences for all the continuous variables (apart from EQ-5D and SF-36 Role–Physical). Five subjects deemed ineligible after randomization were excluded from the study and subsequent analysis.[29] A total of 234 subjects received treatment as allocated. One patient randomly assigned to the IFT group was mistakenly treated according to the MT protocol but was included in the intention-to-treat analysis.

Subjects received an average of five physiotherapy treatments (±SD = 2.5), over a period of 5 weeks (±SD = 2.3), and there were no significant differences between groups for the number of treatments ($P = 0.62$) or the number of weeks of treatment ($P = 0.84$) received. A total of 35 subjects (15%) were considered noncompliant with the study protocol. The level of noncompliance was comparable between groups ($\div^2 = 1.91$; $df = 2$; $P = 0.39$); noncompliers were significantly younger (mean, 33.31 years; SD, 10.53 years) than those who adhered to the protocol (mean, 41.01 years; SD, 11.2 years; t = −3.78, $df = 2$, $P = 0.001$; 95% CI of difference = −11.71 to −3.69). The 15% level of poor attendance by participants in this clinical trial was better than the 21% rate for routine patients attending physiotherapy in the participating hospitals during the same time period. No adverse effects of treatment were reported. One patient died between the discharge and 6-month follow-up points due to a cause unrelated to LBP or physiotherapy.

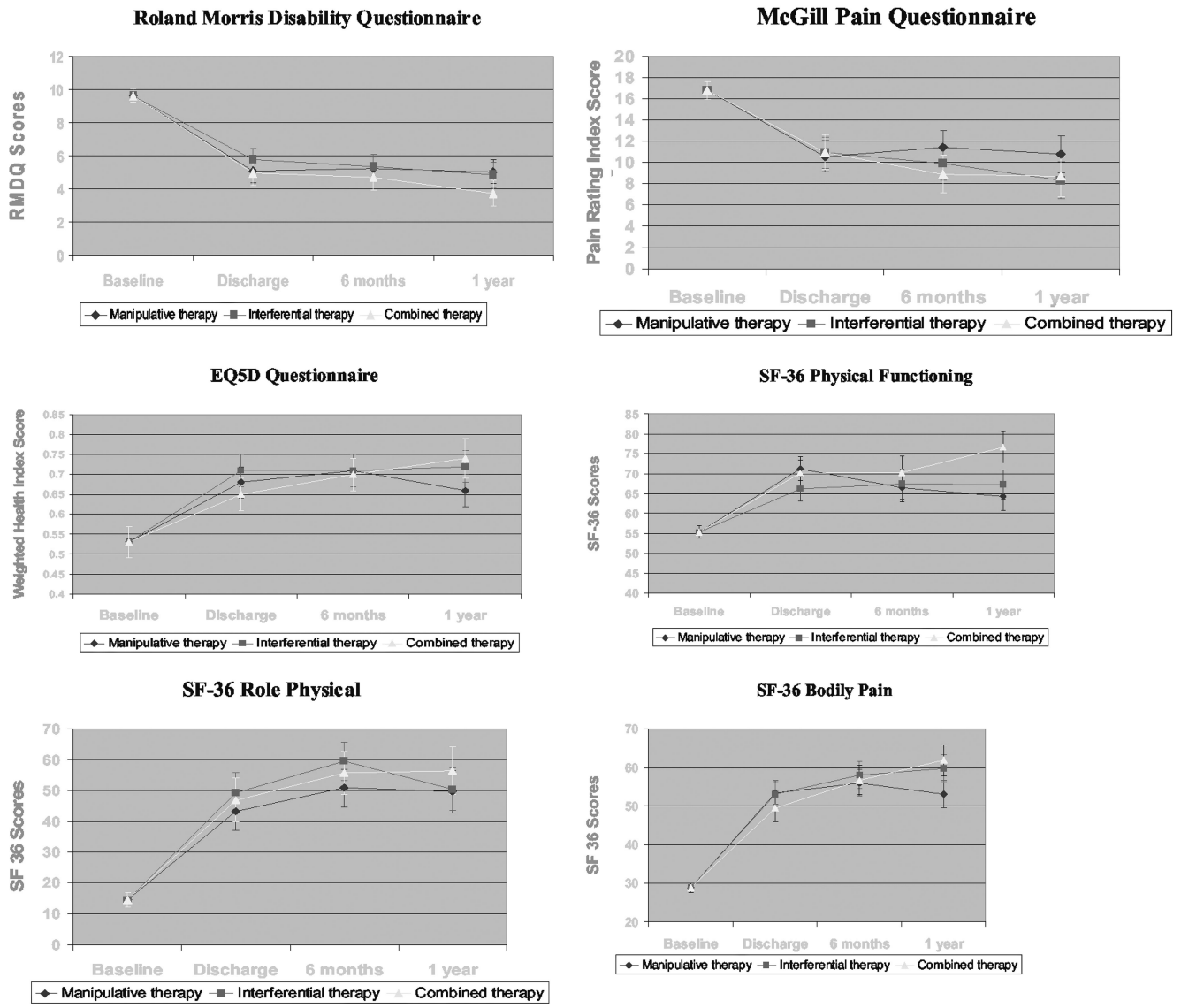

Figure 3. Mean (95% CI) change in primary and secondary outcomes from baseline to follow-up.

The baseline sociodemographic, clinical characteristics and outcome measure scores of participants were well balanced for the three arms of the trial (Table 2).

Outcomes

The mean changes in primary and secondary outcome measures of functional disability, pain, and quality of life from baseline at discharge, 6, and 12 months are illustrated in Figure 3. Repeated-measures ANOVA showed significant improvements at each follow-up point compared with baseline for all outcomes (except SF-36 General Health, which remained unchanged), while the discharge, 6-month, and 12-month values were not significantly different from each other. The repeated-measures ANCOVA analyses showed there were no significant differences between groups for the extent of these improvements over time on any of the outcome measures (Table 3, available for viewing on ArticlePlus).

Table 4 shows the mean changes in outcome measures over time for each group from randomization to discharge, 6 months, and 12 months; the values suggest that subjects in all groups experienced clinically meaningful improvements at discharge which were largely unchanged at the subsequent follow-up points. The results of univariate ANCOVA found no significant differences between groups for the magnitude of the change scores on any outcome measure at any time point, apart from SF-36 Physical Functioning ($P = 0.03$), Bodily Pain ($P = 0.04$), and Mental Health ($P = 0.03$) at 12 months. Pairwise comparisons found significant differences in favor of CT over MT for SF-36 Physical Functioning (mean difference = −12; 95% CI of difference = −23.59 to −0.41; $P = 0.04$) and Bodily Pain (−13; −24.55 to −0.62; $P = 0.036$) scales, and for CT over IFT on the Mental Health (−9.5; −18 to −0.97; $P = 0.023$) scale.

While no significant difference was detected between groups for the primary outcome, the majority of subjects in all groups displayed the minimal clinically important change of at least 3 points on the Roland Morris Disabil-

Table 4. Difference in Functional Disability, Pain, and Quality of Life Scores at Discharge, 6 Months, and 12 Months

Outcome	Manipulative Therapy*	Interferential Therapy*	Combined Therapy*
Functional Disability			
Roland Morris Disability Questionnaire			
Discharge	−4.53 (−5.7, −3.3)	−3.56 (−4.8, −2.4)	−4.65 (−5.8, −3.5)
6 mo	−4.66 (−6.1, −3.3)	−3.94 (−5.3, −2.6)	−4.62 (−6.0, −3.2)
12 mo	−4.71 (−6.1, −3.3)	−4.90 (−6.2, −3.6)	−6.50 (−7.8, −5.1)
Pain VAS (mm)			
Average back pain			
Discharge	−19.88 (−26.1, −13.7)	−21.38 (−27.5, −15.2)	−24.69 (−30.8, −18.6)
6 mo	−16.95 (−24.0, −9.9)	−24.55 (−31.5, −17.7)	−19.9 (−27.2, −12.7)
12 mo	−18.20 (−25.6, −10.7)	−26.50 (−33.8, −19.2)	−25.7 (−33.1, −18.1)
Average leg pain			
Discharge	−13.46 (−19.2, −7.7)	−13.44 (−19.1, −7.8)	−13.98 (−19.6, −8,3)
6 mo	−12.46 (−18.9, −5.9)	−12.80 (−19.1, −6.5)	−12.37 (−18.9, −5.7)
12 mo	−10.20 (−16.9, −3.4)	−14.40 (−21.0, −7.7)	−17.7 (−24.7, −10.9)
Worst back pain			
Discharge	−20.07 (−27.3, −12.8)	−23.56 (−30.7, −16.4)	−27.3 (−34.4, −20.2)
6 mo	−19.29 (−27.3, −11.3)	−28.28 (−36.1, −20.4)	−24.27 (−32.5, −15.9)
12 mo	−23.93 (−32.4, −15.5)	−29.51 (−37.8, −21.2)	−33.9 (−42.4, −25.4)
Worst leg pain			
Discharge	−13.78 (−20.5, −7.0)	−13.77 (−20.4, −7.1)	−14.03 (−20.6, −7.5)
6 mo	−10.09 (−17.4, −2.7)	−14.24 (−21.4, −7.1)	−12.12 (−19.7, −4.6)
12 mo	−12.69 (−19.9, −5.4)	−16.31 (−23.4, −9.2)	−22.9 (−30.3, −15.6)
McGill Pain Questionnaire-Pain Rating Index			
Discharge	−5.12 (−7.7, −2.5)	−5.87 (−8.5, −3.3)	−6.64 (−9.2, −4.1)
6 mo	−4.93 (−7.8, −2.0)	−6.89 (−9.7, −4.1)	−6.38 (−9.3, −3.4)
12 mo	−6.38 (−9.4, −3.3)	−8.32 (−11.3, −5.3)	−9.22 (−12.3, −6.1)
Quality of Life			
EQ-5D Weighted Health Index			
Discharge	0.16 (0.0, 0.2)	0.16 (0.0, 0.2)	0.15 (0.0, 0.2)
6 mo	0.17 (0.0, 0.2)	0.16 (0.0, 0.2)	0.16 (0.0, 0.2)
12 mo	0.15 (0.0, 0.2)	0.20 (0.1, 0.3)	0.25 (0.2, 0.3)
Short Form 36			
Physical Functioning			
Discharge	15.26 (−10.0, 20.5)	10.62 (5.5, 15.8)	14.31 (9.2, 19.4)
6 mo	12.60 (6.1, 19.1)	10.10 (3.7, 16.5)	14.38 (7.6, 21.2)
12 mo	9.36 (2.7, 16.0)	11.71 (5.2, 18.3)	21.4 (14.6, 28)
Role–Physical			
Discharge	28.58 (18.3, 38.9)	31.37 (21.2, 41.5)	30.01 (19.9, 40)
6 mo	36.78 (25.9, 47)	40.98 (30.3, 51.7)	39.43 (28, 51)
12 mo	36.9 (24.5, 49.4)	37.7 (25.5, 49.9)	49.1 (36.5, 61.6)
Bodily Pain			
Discharge	22.89 (17.2, 29)	22.68 (17.1, 28)	22.20 (16.7, 28)
6 mo	26.44 (20.3, 33)	26.71 (−20.7, 32.7)	24.53 (18.3, 31)
12 mo	23.81 (17, 30.7)	30.4 (23.8, 37.1)	36.4 (29, 43.4)
General Health			
Discharge	−1.25 (−5.4, 2.9)	−0.87 (−4.9, 3.2)	1.02 (−3.1, 5.1)
6 mo	−0.21 (−5.2, 4.8)	0.45 (−4.4, 5.4)	0.99 (−4.2, 6.2)
12 mo	−2.53 (−8.1, 3.0)	−2.69 (−7.9, 2.6)	0.74 (−4.8, 6.3)
Vitality			
Discharge	8.17 (3.4, 12.9)	6.32 (1.6, 10.9)	7.21 (2.5, 11.9)
6 mo	11.50 (5.9, 17)	9.85 (4.4, 15.3)	9.15 (3.5, 14.9)
12 mo	11.23 (5.5, 16.9)	9.40 (4.0, 14.8)	16.4 (10.622.1)
Social Functioning			
Discharge	15.56 (9.2, 21.9)	12.51 (6.2, 18.8)	15.39 (9.2, 21.6)
6 mo	19.02 (12.0, 26)	14.29 (7.4, 21.2)	19.8 (12.6, 27)
12 mo	24.4 (14.6, 34.1)	16.1 (6.7, 25.5)	24.2 (14.4, 33.9)
Role–Emotional			
Discharge	10.20 (−0.68, 21)	18.03 (7.6, 28.5)	22.05 (11.6, 33)
6 mo	24.02 (14.1, 34)	20.63 (10.9, 30.3)	34.28 (23.9, 45)
12 mo	21.3 (10.6, 32.2)	18.7 (8.3, 29.1)	29.5 (18.5, 40.5)
Mental Health			
Discharge	3.89 (0.1, 7.8)	1.54 (−2.4, 5.5)	6.35 (2.4, 10.3)
6 mo	6.53 (1.8, 11.2)	3.17 (−1.4, 7.8)	7.16 (2.3, 12.0)
12 mo	4.72 (−0.3, 9.7)	0.84 (−3.9, 5.6)	10.3 (5.3, 15.4)

Note: A favorable outcome is indicated by a negative value for the functional disability and pain measures, and a positive value for the quality of life measures.
*The change from baseline in mean (95% confidence intervals) scores on the continuous variables.

ity Questionnaire between baseline and each follow-up point (discharge: 67% MT, 60% IFT, 67% CT; 6 months: 64% MT, 71% IFT, 67% CT; 12 months: 77% MT, 74% IFT, 92% CT). Table 5 shows that the mean and 95% confidence interval of the RMDQ change scores for each group were in accordance with the recommended minimal clinically important difference values for each baseline score category; *i.e.*, 0–8, 9–16, and 17–24.[41]

The results of the patient-centered questionnaire showed that approximately 70% of subjects in each

Table 5. Roland Morris Disability Questionnaire Minimal Clinically Important Differences at 12 Months

Group	Initial RMDQ Score*	N	Mean Change†	95% CI†	MCID‡
MT	0–8	23	2.96	0.91, 5.01	2
IFT		33	2.70	0.98, 4.41	
CT		23	4.64	2.54, 6.74	
MT	9–16	21	4.65	2.45, 6.85	4
IFT		19	5.71	3.32, 8.10	
CT		22	7.91	5.81, 10.01	
MT	17–24	8	13.25	9.77, 16.73	8
IFT		3	11.33	5.64, 17.02	
CT		6	10.17	6.14, 14.19	

*The baseline score categories of the Roland Morris Disability Questionnaire.
†Scores in relation to the baseline score at the 12-month follow-up.
‡The minimal clinically important difference (MCID) value according to baseline score.[41]

group reported recurrent episodes of LBP at 12 months (77% MT, 69% IFT, 64% CT), and there was no significant difference between groups ($\div^2 = 2.06$; $df = 2$; $P = 0.36$). The rate of work absenteeism for employed subjects was equally low among the groups at 12 months (none: 79% MT, 78% IFT, 82% CT, < 30 days: 9% MT, 14% IFT, 6% CT, > 30 days: 12% MT, 8% IFT, 12% CT; $\div^2 = 2.08$; $df = 4$; $P = 0.72$), while the percentage of subjects reporting participation in exercise was comparably high (73% MT, 77% IFT, 72% CT; $\div^2 = 0.36$; $df = 2$; $P = 0.84$). There were no significant differences between groups for the level of analgesic medication usage at discharge (56%, 45%, 48%, respectively; $\div^2 = 1.57$; $df = 2$; $P = 0.47$), or 12-month follow-up (46%, 42%, 32%, respectively; $\div^2 = 2.26$; $df = 2$; $P = 0.32$).

Alternative Analyses

The results of the alternative analysis were consistent with the intention-to-treat analysis; no significant differences were detected between groups over time for any of the outcome measures apart from SF-36 Physical Functioning ($P = 0.013$), Bodily Pain ($P = 0.018$), and Mental Health ($P = 0.003$) at 12 months.

■ Discussion

The main finding of this randomized clinical trial was that for patients with acute LBP there was no difference in the effects of MT or IFT, whether used in combination or in isolation (in addition to the *Back Book*). No previous trial has directly explored the effects of these treatments or investigated their combined use for acute LBP; thus, the findings contribute to the growing evidence base in this field. As the mean scores were unchanged at each follow-up point, the results suggest that the comparable positive short-term effects observed in each intervention group for functional disability, pain, and quality of life were well maintained in the medium- and long-term regardless of treatment.

The short-term equivalent effects of both interventions are consistent with the literature[12,21,22] and challenge the perception of therapists and patients that IFT as a sole treatment for LBP is unacceptable. This trial provides clinicians with an evidence-based IFT protocol on which to base treatment of similar LBP patients, to the benefit of both physiotherapy education programs and clinical practice alike.[45] Furthermore, the continued widespread use of IFT with MT,[4] which is costly and time-consuming, is questionable for acute LBP. Further research should establish the factors and barriers that influence patient preference and therapists' clinical reasoning in the selection of these interventions, particularly when used in combination.

The RCT design allowed for the control of confounders such as age, sex, duration of LBP, past history, and treatment, which could have distorted the results. Additionally, the comparable homogeneous patient groups, blinded randomization procedure, standardized interventions and follow-up procedures, the expertise of the physiotherapists, and use of the intention-to-treat principle should render these results valid. The patient sample exhibited characteristics similar to those of the archetypal patient with nonspecific acute LBP who presents to the health service for treatment, *i.e.*, mean age of 40 years, high recurrence rate, associated work-related disability, and utilization of previous treatment for LBP;[4,46–48] furthermore, outcome measure baseline values were within the limits of those previously reported.[21,22,27,33,47,49–55]

There are several limitations to the current investigation. In the absence of a control group, it may be that the observed improvements in functional disability, pain, quality of life, and a range of patient-related variables merely reflects the effect of natural history, regression to the mean, and placebo.[53] Nevertheless, a previous RCT by the researchers established that the IFT package used in this study yielded significantly greater reductions in functional disability compared with a group receiving the *Back Book* control treatment,[22] thus providing some evidence that the current intervention packages have a superior effect to this control. The placebo effect has been reported to account for 5% to 72% of the treatment effect,[56] and while participating physicians and physiotherapists were trained to be equally positive about the interventions,[30] it was impossible to control for the potential effect of patients' families', friends', and colleagues' expectations. A recent trial found significant positive outcomes for postoperative orthopedic knee surgery patients treated with home IFT *versus* placebo IFT, providing the first evidence for the efficacy of this modality for musculoskeletal conditions.[57] Thus, future researchers investigating the efficacy of IFT for LBP should include an adequate control or placebo group. Blinding of patients was not practicable,but every effort was made to minimize any expectation bias about the effectiveness of each intervention. The therapists were not blinded to the content of each protocol, not unusual in RCTs comparing the effectiveness of physiotherapeutic interventions[58] but detailed staff training aimed to standardize

delivery of the treatment protocols. There was a high dropout rate despite use of numerous recommended strategies; future RCTs may consider using repeated phone call reminders or monetary incentives. In view of the significantly younger age of noncompliers, extra emphasis needs to be placed on educating such patients about their role in the successful conduct of a clinical trial.

The findings of this study demonstrate for the first time the comparative short-and long-term positive effects of MT and IFT, two commonly used treatments for adult patients with nonspecific acute LBP, whether used as sole interventions or in combination (in addition to the *Back Book*). Future research should establish the factors that determine the clinical usage and cost-effectiveness of these treatments for patients with LBP, information that will be of particular significance to commissioners of health care.

■ Key Points

- For acute low back pain, there is no difference in the effect of a combined manipulative therapy and interferential therapy package and either manipulative therapy or interferential therapy alone.
- Both manipulative therapy and interferential therapy alone or in combination resulted in improvements in up to 12 months of follow-up in functional disability, pain, quality of life, analgesic medication consumption, and exercise participation.
- Physiotherapists should question the usage of the combination of manipulative therapy and interferential therapy for patients with acute low back pain.

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