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Title Page

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

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Abstract

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

Objectives. To investigate the relative effectiveness of interferential therapy and manipulative 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 no evidence for interferential therapy and no study has investigated the effectiveness of interferential therapy combined with manipulative therapy.

Methods. Consenting subjects (n=240) were randomly assigned to receive a copy of the Back Book and either manipulative therapy (MT; n=80), interferential therapy (IFT; n=80) or combined manipulative therapy and interferential therapy (CT; n=80). Follow-up outcome questionnaires were posted at discharge, 6 and 12 months.

Results. The groups were balanced at baseline for low back pain and demographic characteristics. All interventions were found to significantly reduce functional disability and pain and increase quality of life at discharge and to maintain these improvements at 6 and 12 months. No significant differences were found between groups for reported LBP recurrence, work absenteeism, medication consumption, exercise participation and healthcare use at 12 months.

Conclusions. For acute low back pain, interferential therapy whether used in isolation or in combination with manipulative therapy was as effective as manipulative therapy alone (in addition to the Back Book).

Key Words: physiotherapy; effectiveness; low back pain; manipulation; interferential therapy; primary care; randomized clinical trial.
Key Points

- For acute low back pain, interferential therapy whether used alone or in combination with manipulative therapy was as effective as manipulative therapy alone.

- Physiotherapists should question the usage of the combination of interferential therapy and manipulative therapy for patients with acute low back pain.

- Physiotherapists with postgraduate qualifications in manipulative therapy provided all treatments.

- Future randomised controlled trials that compare the relative effectiveness of treatments should include a no treatment and placebo group to account for the potential effect of natural history and placebo.
Mini Abstract

A multi-center assessor-blinded randomized clinical trial was conducted to investigate the relative effectiveness of interferential therapy and manipulative therapy for patients with acute low back pain when used as sole treatments and in combination. At 12 month follow-up all interventions were found to significantly reduce functional disability, pain, work absenteeism and medication consumption and to increase quality of life and exercise participation.
**Introduction**

Simple backache (low back pain with no associated nerve root or serious spinal pathology) affects the majority of the population at some stage in their adult lives and constitutes a major public health problem in Western industrialised societies (Deyo 1998). Despite substantial advances in our understanding of low back pain (LBP) sources and pain mechanisms, it is claimed that up to 90% of cases do not have a demonstrable pathologic basis (Spitzer et al. 1987) and are therefore termed nonspecific LBP. Patients are typically classified as having ‘acute’ (i.e. current attack of less than three months) or ‘chronic’ LBP (i.e. current attack of more than three months duration, Waddell 1998).

Physiotherapists treat an estimated 1.6 million people with LBP each year in the UK and are more likely to treat LBP patients with poor prognostic indicators, for example moderate to high levels of self-reported disability due to LBP and pain radiating below the knee (Mielenz et al. 1997). In 1998, physiotherapists, chiropractors and osteopaths accounted for 37% of the Stg£1.6 billion direct healthcare costs of LBP, followed by the hospital sector (31%) and primary care (14%) (Maniadakis and Gray 2000). The results of several recent surveys of the physiotherapeutic management of LBP in Britain and Ireland (Foster et al. 1999; Gracey et al. 2002) found that a range of treatment strategies is being utilised: advice, Maitland mobilisations, McKenzie, abdominal exercises, and interferential therapy.

Interferential therapy (IFT) has the highest ownership and usage of all electrotherapeutic modalities in the United Kingdom and the Republic of Ireland (Pope et al. 1995; Cooney et al. 2000) being predominantly employed for its hypoalgesic effects, ease of application and time efficiency (Lindsay et al. 1990; Noble 1998). Despite being used by up to 44% of therapists for LBP management (Moore 1998; Foster et al. 1999; Gracey et al. 2002), the complete absence of any evidence of effectiveness necessitated its omission from
recent LBP clinical guideline documents (Waddell et al. 1999). A previous randomised controlled trial (RCT) involving patients with acute and chronic LBP by Werners and colleagues (1999) reported that IFT alone was no more (or less) effective than lumbar traction with massage in reducing LBP-related functional disability or pain up to 3 month follow-up. Interferential therapy is usually used in combination with other forms of treatment (typically advice and manipulative therapy) for LBP management (Moore 1998; van Tulder 1999b; Gracey et al. 2002) and consequently investigations into the effectiveness of IFT within a multimodal (physiotherapeutic) treatment regime have been advocated (van Tulder 1999b). Therefore, a randomised controlled trial that compared the effectiveness of IFT when used in isolation and, as part of a multimodal package for patients with acute LBP would contribute significantly to its limited evidence base.

Clinical guidelines advocate the use of manipulative therapy (MT) in acute LBP conditions (Waddell et al. 1999) which incorporates both mobilisation (low velocity manual force that does not involve a thrust) and manipulation (high velocity range-expanding thrust) techniques. Within current physiotherapy practice in Britain and Ireland, the most well recognised and used approaches are those of Geoffrey Maitland (Maitland 1986) and Dr James Cyriax (Cyriax 1984; Foster et al. 1999; Gracey et al. 2002), being preferred by up to 62% of physiotherapists for their hypoalgesic and mobilising effects. However, despite a total of 38 RCTs investigating the effectiveness of various types of MT, systematic reviews have not consistently detected positive effects for spinal manipulation in people with acute LBP compared to placebo and a range of other active treatments (Shekelle et al. 1992; Bigos et al. 1994; Evans and Richards 1996; Koes et al. 1996; van Tulder et al. 1997; Mohseni-Bandpei et al. 1998; Bronfort 1999). Further large-scale rigorous RCTs of patients with clinically homogeneous LBP syndromes, who receive well-defined MT interventions and who
are assessed for response with valid outcome measures have been recommended (Shekelle et al. 1992).

Furthermore, the recommendations of the UK Clinical Guidelines regarding the promotion of early return to normal activities and the avoidance of bed rest were encompassed into the Back Book (1996), an evidence-based patient education booklet. It has been successfully piloted in primary care and shown to be readily acceptable and understandable to individuals with LBP, and to create a positive shift in beliefs about LBP (Burton et al. 1996). The developers believe it is more likely to have an impact as part of a combined treatment package (Burton et al. 1999), and thus it was an appropriate standardised co-intervention for the proposed RCT.

The aim of this RCT was to investigate the relative effectiveness of interferential therapy and manipulative therapy when used as sole treatments and in combination (in addition to the Back Book advocated by current clinical guidelines) for patients with acute low back pain.
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 aged 18 to 65 years 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 1 to 3 months 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 (manipulative therapy, interferential therapy, combined therapy) using an allocation schedule generated from a random numbers table. 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 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.

Interventions. Only chartered physiotherapists who had successfully completed the Society of Orthopaedic Medicine (SOM) membership examination, a postgraduate qualification in manipulative therapy, recognised by the Chartered Society of Physiotherapy (CSP) and the International Forum of Orthopaedic Manipulative Therapists (IFOMT), were eligible to administer the treatment protocol. Sixteen physiotherapists met the criteria and were willing
to participate in this study (100% participation rate); i.e. 4 physiotherapists within each of the 4 participating hospitals. All treatments were provided to an individual patient by the same therapist.

*The 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.

**Manipulative Therapy (MT) Group.** Subjects assigned to this group were treated by the MT protocol, which was defined as techniques for the spine described by Maitland (1986) and Cyriax (1984). Each physiotherapist was limited to using only these techniques but had free choice of which to use and when, and the spinal regions to which they were applied.

**Interferential Therapy (IFT) Group.** Subjects assigned to this group were treated by the IFT protocol based upon the results of a previous study by the researchers (Hurley et al. 2001a). Omega™ *Inter 4150* portable IFT units* were utilised to deliver standardised IFT stimulation parameters: i.e. carrier frequency 3.85 kHz; beat frequency 140 Hz constant; pulse duration 130 µs; treatment time 30 minutes; using the spinal nerve root electrode placement method via two Reply 658 carbon silicone self-adhesive electrodes (50x100mm) (Figure 1).

**Combined Therapy (CT) Group.** Both the MT and IFT protocols were provided to subjects assigned to the CT group with the MT protocol preceeding the IFT protocol.

Apart from the designated protocol, the participating physiotherapists were not permitted to administer any other forms of MT, electrotherapy or other techniques (spinal traction, heel raises, corsets, acupuncture, injection therapy, taping, McKenzie) during the intervention period of the RCT. Subjects were requested to continue normal activities and to avoid other treatments for the duration of the RCT apart from routine GP management.

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* TensCare Ltd, 89 Robin Hood Way, London, SW15 3PW.
analgesics and the advice contained in the Back Book. Subjects were requested to attend twice per week, to receive a minimum of 6 and a maximum of 10 treatments over a period of 8 weeks (Hurley et al. 2000). Discharge was at the discretion of the treating therapist. Patients who failed to attend for three successive appointments (or who requested it), were considered noncompliant and 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. 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 physiotherapists were equally positive in the delivery of each protocol as recommended by Koes and Hoving (1998).

Outcome Measurement and Follow-up Procedures. A range of valid and reliable outcome measure questionnaires and a patient-centered questionnaire (Hurley et al. 2001b) were used to collect outcome data at baseline, discharge, 6 months and 12 months (Table 2). All follow-ups were conducted by post (using self-addressed envelopes) and administered by the principal investigator. Non-respondents were sent a postcard reminder after two weeks, and a second copy of the questionnaires and self-addressed envelopes after four weeks. The principal investigator, who assessed all the outcomes, was blind to group allocation until completion of data analyses. The treating physiotherapists were not involved in any aspect of outcome assessment.

Data Analysis. All data were analysed using the Statistical Package for the Social Sciences (Windows 9.0). Analyses were performed according to the ‘intention-to-treat’ principle. An alternative analysis that accounted for dropouts (i.e. nonrespondents) at follow-up was conducted whereby missing values were replaced with imputed values generated by a series of linear regression equations (Sim and Wright 2000). The comparability of groups at
baseline and the patient-centered questionnaire data were assessed using Chi-Square tests for discrete nominal variables and one-way analysis of variance for continuous interval variables if the assumptions for parametric statistics held; otherwise the Kruskal-Wallis H test was used. Differences between two groups (i.e. respondents and non-respondents; compliers and noncompliers) were assessed using Chi-Square tests for discrete nominal variables and unrelated t tests for continuous interval variables; otherwise the nonparametric equivalent, the Mann-Whitney U test was employed. For the functional disability, pain and quality of life continuous variables change scores were calculated for the differences from baseline at discharge, 6 months and 12 months. The effects of the interventions on these outcome measures were estimated using univariate analyses of covariance with the change score as the dependent variable and the baseline score as the covariate. **Why not a mixed Ancova?** For all comparisons, a probability of <0.05 was considered to be statistically significant (two-tailed).

Where multiple comparisons of variables were conducted, significance levels for each individual variable were determined, and the Bonferroni correction for multiple tests of significance was then performed. Exploratory analysis of Roland Morris Disability Questionnaire change scores determined if subjects had achieved the relevant minimal clinically important difference (MCID) value according to their baseline score: 0-8 (MCID = 2), 9-16 (MCID = 4), 17-24 (MCID = 8) (Stratford et al. 1998). **Don’t understand this.**

**Power Analysis.** Sample size was determined by the statistician (M.D.) in accordance with the procedures described by Buchner et al. (1997). Estimates of variability for the primary endpoint were obtained from a previous RCT conducted by the researchers (Hurley et al. 2001a) that also concurred with the recommendations of the original developers of the Roland Morris Disability Questionnaire for a change score of 2 or 3 points for sample size calculations for RCTs (Roland and Fairbanks 2000). Calculations determined that a
minimum of 50 subjects would be required for each intervention group to provide at least 90% probability, at an alpha of 0.05, of detecting the MCID of 2 points in the mean change of the Roland Morris Disability Questionnaire (in either direction) if such an effect existed. 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

Ninety-seven GPs from 36 primary care practices in Northern Ireland referred patients to the RCT. From May 1999 to May 2000 a total of 240 subjects who met the inclusion criteria were randomly assigned to one of three groups: (1) MT (n=80; 35 male, 45 female; mean age=39.6 years, ±SD=11.6 years) (2) IFT (n=80; 30 male, 50 female; mean age=40.2 years, ±SD=12.1 years) and (3) CT (n=80; 32 male, 48 female; mean age=40.5 years, ±SD=11.3 years). The trial flow diagram is shown in Figure 2; five subjects deemed ineligible after randomisation were excluded from the study and subsequent analysis as recommended by Pocock (1983). One patient randomly assigned to the IFT group was mistakenly treated according to the MT protocol and consequently 234 subjects received treatment as allocated. Subjects received an average of five physiotherapy treatments (±SD=2.5; range = 1 to 10), over a period of five weeks (±SD=2.3; range = 1 to 10), 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.

No adverse effects of treatment were reported in any of the study groups. Follow-up data were obtained from 194 (83%) subjects at discharge, 166 (71%) at 6 months and 158 (67%) at 12 months. Respondents and nonrespondents were comparable for all baseline variables apart from smoking status with a higher percentage of current smokers within the nonrespondent (NR) group compared to respondents (R) at 6 months (NR:50.7%, n=35; R:31.3%, n=52; P = 0.02) and 12 months (NR:50.6%, n=41; R:29.8%, n=46; P = 0.007). One patient died between the discharge and 6 month follow-up points due to a cause unrelated to LBP or physiotherapy.
Subject characteristics

Sociodemographic, clinical characteristics and outcome measure scores at baseline were well balanced for the three arms of the trial (Table 3).

Treatment compliance

A total of 35 subjects (15%) were considered noncompliant with the study protocol and there was no difference between groups for the level of noncompliance ($\chi^2 = 1.91$, df = 1, $P = 0.39$) as illustrated in Figure 2. 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; $t$ (df) = -3.78, $P = 0.001$; 95% CI of difference = −11.71 to −3.69).

Outcomes

Table 4 shows the mean change in outcome measures over time for each group from randomization to follow-up at discharge, 6 months and 12 months. The values of the mean adjusted change scores suggested that subjects in all groups had experienced clinically meaningful improvements in functional disability, pain and quality of life at discharge, which were largely maintained at 6 and 12 month follow-up (Figure 3). The results of univariate analysis of covariance found no significant differences between groups in the magnitude of the change scores at discharge, 6 months and 12 months 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 significantly greater differences and 95% confidence intervals in favour of CT over MT for SF-36 Physical Functioning (mean difference = -12; 95% CI of difference = -23.59 to −0.41; $P = 0.04$; Figure 4) and Bodily Pain (-13; -24.55 to −0.62; $P = 0.036$) scales, and for CT over IFT in the Mental Health (-9.5; -18 to −0.97; $P = 0.023$) scale.
While there was no significant difference between groups for the primary outcome, the Roland Morris Disability Questionnaire, the majority of subjects in all groups displayed the minimal clinically important difference value of at least 3 points for this measure at 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, 17-24 (Stratford et al. 1998).

Approximately 70% of subjects in each group reported recurrences at 12 months (77% MT, 69% IFT, 64% CT) and there was no significant difference between groups ($\chi^2 = 2.06; \text{df} = 2; P = 0.36$). The rate of work absenteeism for employed subjects was similar among the groups at 12 months (none: 79% MT, 78% IFT, 82% CT, < 30 days: 10% MT, 14% IFT, 6% CT, > 30 days: 12% MT, 8% IFT, 12% CT; $\chi^2 = 2.08; \text{df} = 4; P = 0.72$). The percentage of subjects reporting participation in exercise was similar (73% MT, 77% IFT, 72% CT; $\chi^2 = 0.36; \text{df} = 2; P = 0.84$), as were the percentages that reported additional treatment for LBP (33%, 29%, 24%, respectively; $\chi^2 = 3.04; \text{df} = 4; P = 0.55$). The most commonly sought treatments were visits to general practitioners (72%; n=33), NHS physiotherapy (21%; n=10), private chiropractic (14%; n=6), and hospital consultants (9%; n=4). There were no significant differences between groups for analgesic medication usage at discharge (56%, 45%, 48%, respectively; $\chi^2 = 1.57; \text{df} = 2; P = 0.47$) or 12-month follow-up (46%, 42%, 32%, respectively; $\chi^2 = 2.26; \text{df} = 2; P = 0.32$).

**Alternative analyses**

An intention-to-treat analysis is considered most valid when the dropout rate and number of missing values is low and there is no contamination bias (Koes et al. 1992). In this
study the results of the intention-to-treat analysis may be biased because of dropouts and missing values. Therefore, an alternative analysis was conducted in which missing values were replaced by values generated from a series of linear regression equations. The main underlying assumption for this analysis is that subjects’ previous scores are used to determine a predicted value that reduces the variance of the value for each variable (Sim and Wright 2000). The results of the alternative analysis were very similar to the intention-to-treat analysis. Univariate analysis of covariance found no significant differences between groups in the magnitude of the change scores at discharge, 6 months and 12 months apart from SF-36 Physical Functioning (P = 0.013), Bodily Pain (P=0.018), and Mental Health (P = 0.003) at 12 months. Pairwise comparisons found significantly greater differences and 95% confidence intervals for SF-36 Physical Functioning in favour of CT over MT (mean difference = -10.53; 95% CI of difference = -20.86 to –0.19; P = 0.04) and CT over IFT (-11.38; -21.58 to –1.19; P = 0.02). Similarly for SF-36 Bodily Pain the differences were in favour of CT over MT (-11.16; -22.24 to –0.08; P = 0.04) and CT over IFT (-11.41; -22.31 to –0.51; P = 0.04). For SF-36 Mental Health the difference was in favour of CT over IFT (-10.30; -17.56 to –3.05; P = 0.02).
Discussion

The main finding of this randomized clinical trial, was that MT and IFT whether used in isolation or in combination (in addition to the Back Book), were equally effective for patients with acute LBP. While, there were some significant differences on the SF-36 scales at 12 month follow-up in favour of the combined therapy group, the weight of evidence suggests that the positive short-term effects for functional disability, pain and quality of life were well maintained at 6 month and 12 month follow-up in all groups, providing evidence that all treatments were successful in the medium and long term. 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.

Despite dropouts due to nonrespondents, 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 MCID values for the RMDQ, VAS, MPQ, SF-36 Physical Functioning, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, and Mental Health variables. While the sample size exceeded the minimum established from power calculations, the large number of dropouts (particularly at 12 months) may have represented those who did not respond well to treatment. Thus an alternative analysis that replaced missing values with imputed values was conducted, which largely concurred with the intention-to-treat analysis findings thus strengthening their reliability.

The patient sample exhibited characteristics similar to those of the archetypal patient with acute LBP who presents to the health service for treatment of this common, disabling condition, i.e. a preponderance among the female population, mean age of 40 years, high
recurrence rate, and utilisation of previous treatment for LBP (Blomberg et al. 1992; Cherkin et al. 1998a; Gracey et al. 2002) and the outcome measure baseline values were within the limits of those described previously (Hsieh et al. 1992; Herman et al. 1994; Pope et al. 1994; Dettori et al. 1995; Hides et al. 1996; Cherkin et al. 1998; Kind et al. 1998; Seferlis et al. 1998; Burton et al. 1999; Chok et al. 1999; Werners et al. 1999; Hurley et al. 2001a).

Given the number of variables examined the significant differences on the SF-36 Physical Functioning, Bodily Pain and Mental Health scales at 12 month follow-up in favour of the combined therapy group may be statistical artefacts. An alternative explanation may be related to variations between groups in the natural history during the follow-up period. Although not statistically significant, the combined therapy group had a lower recurrence rate compared to the manipulative therapy in particular and this may suggest some mutability of the LBP symptoms between treatment groups (Waxman et al. 2000). Furthermore, patients in the combined therapy group inevitably had a longer treatment time than the MT or IFT groups and this dose effect may have contributed to the differences recorded at 12 months. Finally, there may be uncontrolled factors unknown to the investigator that were related to these findings. Nonetheless, the weight of evidence suggests that there was little difference between the outcomes of the three treatment groups at 12 months.

While there is already strong evidence for the positive short-term effects of MT for functional disability (Postacchini et al. 1988; MacDonald and Bell 1990; Delitto et al. 1993; Blomberg et al. 1994; Erhard et al. 1994; Morton 1999) and pain (Hoehler et al. 1981; Farrell and Twomey 1982; Arkuszewski 1986; Postacchini et al. 1988; Blomberg et al. 1992; Morton 1999), including the recommendations of clinical guidelines (Waddell et al. 1999; Koes et al. 2001), interferential therapy lacks any evidence of positive short-term effectiveness compared to other active treatments (Werners et al. 1999; Hurley et al. 2001a). Fewer RCTs have evaluated the effectiveness of MT at long-term follow-up of 6 months or longer as advocated
by the Cochrane Collaboration Back Review Group for Spinal Disorders (vanTulder et al. 1997) and as a result, clinical guidelines and consensus reports do not discuss the change of effect over time (Skargren et al. 1998). Previous RCTs found equivalent (Berquist-Ullman and Larsson 1977; Arkuszewski 1986; Postacchini et al. 1988; Cherkin et al. 1998; Seferlis et al. 1998; Skargren et al. 1998), rather than positive (Meade et al. 1990; Blomberg et al. 1994) long-term effects for MT compared to other active treatments for reductions in disability, pain, work absenteeism, analgesic consumption and additional health care utilisation. Given the lack of any previous investigations of the long-term effectiveness of IFT, the findings of this RCT contribute substantially to the evidence base by demonstrating for the first time comparative short and long-term effectiveness for these two commonly used treatments for adult patients with non-specific acute low back pain whether used as sole treatments or in combination in addition to the Back Book.

Both MT and IFT are proposed to activate the large diameter, low threshold A beta afferent fibres causing pain relief through the ‘gate control’ theory of Melzack and Wall (1965). Similarly, activation of the descending pain suppression pathway, at segmental or supraspinal levels is attributed to both treatments, but while MT has been shown to produce concomitant physiological responses consistent with noradrenergic mediated sympathoexcitation, IFT is believed to cause simultaneous opioid-mediated sympathoinhibition (Wright and Sluka 2001). The placebo effect, a highly variable and complex phenomenon that is influenced by a myriad of factors other than the treatment has been reported to account for 5% to 72% of the treatment effect (Simmonds 2000) and may partly explain the findings. While, the participating GPs and physiotherapists were trained to be equally positive about each intervention (Koes and Hoving 1998), it was impossible to control for the potential effect of patients’, family, friends and colleagues. However the absence of a placebo group in this and the majority of previous RCTs of manipulative therapy
render this purely speculative and future researchers should endeavour to address this problem. Additionally, all patients received a copy of the Back Book, which may have had a potentially confounding effect on the observed outcomes, such that all patients benefited to a certain degree.

Consistent with the recommendations of acute LBP clinical guidelines, all the participating physiotherapists had a recognised qualification in MT and thus the generalisability of these results are limited to therapists with similar qualifications. Postgraduate MT education is extremely popular amongst physiotherapists in Britain and Ireland (Foster et al. 1999; Gracey et al 2002), and these findings support continuation of this form of training. As interferential therapy is the most widely owned and used electrotherapeutic modality in Britain and Ireland for the physiotherapeutic management of patients with LBP, these findings provide for the first time an evidence-based protocol upon which to base the treatment of similar LBP patients that should benefit physiotherapy education programmes and clinical practice alike.

Several factors need to be considered in terms of the future clinical usage of manipulative therapy and interferential therapy including patient preference, the adverse effects of each intervention and therapist preference. In this RCT, patients did not have a bias towards one of the interventions, probably due to a lack of previous experience. However, in some clinical settings patients with frequent treatment episodes may prefer a manual or electrophysical intervention. While both MT and IFT treatments have been associated with unwanted side effects, they are considered rare for both interventions and were absent in this RCT. The risk of inducing cauda equina due to manipulation of the lumbar spine, estimated at between 10 and 100 million to one (Shekelle et al. 1992) has made therapists reluctant to utilise these techniques compared to mobilisation itself (Adams and Sim 1998; Foster et al. 1999). In Britain, IFT accounts for the highest percentage (approximately 33%) of adverse
reactions (e.g. burns, blisters, nausea) albeit in a small number of patients (Partridge and Kitchen 1999; Kitchen 2000a; Kitchen 2000b). Contraindications to IFT are predominantly based on ‘common sense’ due to the lack of evidence for current stimulation parameters (Johnson 1999) and the likely chance of adverse effects has not been established. Anecdotally many therapists report the use of IFT primarily to minimise treatment soreness due to MT and its provision as a sole treatment is perceived as being unacceptable to both clinician and patient. Further investigation of the factors and barriers that influence therapists’ clinical reasoning in the use of these interventions is warranted. Notwithstanding the results of such research, clinicians are challenged to consider the known advantages and disadvantages of each intervention before determining the most optimal treatment for individual patients.

There are several limitations to the current investigation, which should be considered and addressed where practicable in future RCTs of patients with acute LBP. Blinding of patients was hampered, as they knew which treatment they received but every effort was made to minimise any expectation bias about the effectiveness of each treatment protocol. The therapists delivering the treatment were not blinded to the content of each protocol, not unusual in RCTs comparing the effectiveness of physiotherapeutic interventions (van Tulder et al. 1997) but detailed staff training aimed to standardise delivery of the treatment protocols as already discussed. There was a high dropout rate despite use of numerous recommended strategies i.e. preliminary notification letter of scheduled follow-ups, repeated postal reminders at follow-up time points, and inclusion of a pre-paid return envelope with follow-up questionnaires (Yammarino et al. 1991). Future RCTs may consider using repeated phone call reminders or monetary incentives (Hsieh et al. 2002). The 15% level of non-attendance for treatment 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. In view of the significantly younger age of noncompliers, extra emphasis needs to be placed on educating
younger patients about the purpose of a RCT, and the importance of keeping treatment appointments. While difficult within a clinical context, the potential effect of natural history should be investigated in future RCTs involving LBP patients by the inclusion of a no treatment group. Finally, the lack of a valid, reliable and sensitive measure of patient satisfaction precluded its measurement in this RCT and as new tools become available (Hudak and Wright 2000) should be routinely included to complement the existing outcomes package.

Numerous systematic reviews have already highlighted the evidence base for MT in contrast to the lack of evidence for the effectiveness of IFT (van Tulder 1999b). The current results contribute to this evidence base by demonstrating for the first time the comparative short and long-term effectiveness of these two commonly used treatments for adult patients with non-specific acute LBP whether used as sole treatments or in combination (in addition to the Back Book). Future research should establish the cost-effectiveness of these interventions for patients with LBP, information that will be of particular significance to commissioners of healthcare.
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