

# Interferential Therapy Electrode Placement Technique in Acute Low Back Pain: A Preliminary Investigation

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**ABSTRACT.** Hurley DA, Minder PH, McDonough SM, Walsh DM, Moore AP, Baxter DG. Interferential therapy electrode placement technique in acute low back pain: a preliminary investigation. *Arch Phys Med Rehabil* 2001;82:485-93.

**Objective:** To determine the efficacy of interferential therapy (IFT) electrode placement technique compared with a control treatment in subjects with acute low back pain (LBP).

**Design:** Single-blind, randomized, controlled trial with a 3-month follow-up.

**Setting:** Outpatient physiotherapy departments in hospital and university settings.

**Patients:** A random sample of 60 eligible patients with back pain (28 men, 32 women) were recruited by general practitioners and self-referral for physiotherapy treatment and randomly assigned to 1 of 3 groups.

**Interventions:** (1) "IFT painful area" and *The Back Book*, (2) "IFT spinal nerve" and *The Back Book*, and (3) "Control," *The Back Book* only. Standardized IFT stimulation parameters were used: carrier frequency 3.85kHz; 140Hz constant; pulse duration 130 $\mu$ s; 30 minutes' duration.

**Main Outcome Measures:** Pain Rating Index, Roland-Morris Disability Questionnaire (RMDQ), and EuroQol were completed by subjects pretreatment, at discharge, and 3-month follow-up.

**Results:** All groups had significant improvements in all outcomes at follow-up. Subjects managed by IFT spinal nerve and *The Back Book* displayed both a statistically significant ( $p = .030$ ) and clinically meaningful reduction in functional disability (RMDQ), compared with management via IFT painful area and *The Back Book* combined or *The Back Book* alone.

**Conclusions:** The findings showed that IFT electrode placement technique affects LBP-specific functional disability, providing preliminary implications for future clinical studies.

**Key Words:** Interferential therapy; Low back pain; Pain measurement; Rehabilitation.

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**T**HE ECONOMIC BURDEN of back pain in the United Kingdom is now greater than any other disease for which economic analysis has been conducted.<sup>1</sup> Despite numerous randomized controlled trials (RCTs), there is still no strong evidence for the most efficacious and cost-effective treatment for this disabling condition.<sup>2</sup> Current physiotherapy management encompasses both evidence-based treatments advocated by clinical guidelines for low back pain (LBP), ie, manipulative therapy and general exercise therapy,<sup>3-5</sup> and other treatments for which there is only limited evidence. One such treatment is interferential therapy (IFT)—a medium frequency alternating current, modulated to produce low frequencies between 1 and 150Hz—which is widely used for its proposed hypoalgesic effects.<sup>6</sup>

Recent surveys have consistently reported that IFT is the most commonly used electrotherapeutic modality in Britain and Ireland for the physiotherapeutic management of patients with LBP.<sup>7-9</sup> Foster et al<sup>7</sup> observed that IFT was preferred by 44.1% of 813 physiotherapists they surveyed; furthermore, only 23.4% of respondents failed to report any use of IFT in the treatment of LBP conditions. This modality has widespread ownership, popularity, and usage among therapists in Australia<sup>10,11</sup> and Canada.<sup>12</sup> Despite a cost of approximately £2000 per machine, most hospital physiotherapy departments and private practices have at least 1 IFT unit. Factors related to the apparently high level of clinical usage are reported as its perceived effectiveness, ease of application, and time efficiency.<sup>10</sup>

Notwithstanding the popularity of IFT among clinicians, the literature supporting its proposed neurophysiologic and clinical effects is poor and limited.<sup>13</sup> Previous RCTs have reported significant improvements, but no significant differences in outcomes between subjects treated with IFT or alternative comparable treatments for LBP,<sup>14</sup> osteoarthritis of the knee,<sup>15</sup> and recurrent jaw pain.<sup>16</sup> It is evident that further RCTs investigating the efficacy and cost-effectiveness of IFT for the management of painful conditions, particularly LBP, are urgently required to justify the continued use of this modality in the clinical setting.<sup>13,17</sup>

An IFT treatment for an individual patient or clinical condition is defined in terms of a complex range of parameters: carrier frequency, stimulation (beat) frequency, pulse duration, swing pattern, 2 pole versus 4 pole, treatment time, and electrode placement technique. Many electrotherapy textbooks and IFT manufacturers' equipment manuals have published clinical recommendations for the treatment of acute, subacute, and chronic painful conditions, which (because of the lack of research) are based solely on anecdotal evidence.<sup>18-21</sup> Consequently, therapists are inconsistent in their use of IFT parameters, and it is likely that they administer treatment protocols on a trial and error basis.<sup>22</sup> A few parameters are predetermined by the manufacturers of IFT equipment (eg, carrier frequency); 2 and 4kHz are only available on most machines, owing to historical, not scientific reasons.<sup>23</sup>

Nonetheless, most parameters are at the discretion of the individual therapist, eg, electrode placement technique. The

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following range of electrode placement methods exist: "painful area," "spinal nerve root," "dermatome," "myotome," "sclerotome," "trigger point," and "peripheral nerve."<sup>24</sup> Survey work at this center has determined that local therapists most frequently select the "painful area" (86.4% of therapists) and "spinal nerve root" (53% of therapists) techniques in the treatment of patients with LBP, largely because of manufacturers' guidelines and advice from colleagues.<sup>25</sup> Less frequently used techniques were reported as "peripheral and central" (25.8%), "trigger points" (10.2%) and "acupuncture points" (5.3%). Marchand et al,<sup>26</sup> reporting on the extensive literature on transcutaneous electric nerve stimulation (TENS) for LBP conditions, have already shown that optimum electrode position must be established to achieve a good analgesic response. The effect of using different IFT electrode placement techniques for the management of LBP conditions has not been reported. It is evident that studies of the efficacy of IFT parameters are required to establish protocols for future RCTs and to enable clinicians to select treatment protocols based on sound scientific results.

The present study was conducted in preparation for a proposed RCT, which will compare the efficacy of IFT with current evidence-based treatments for LBP; the sample size of which will be based on power calculations from this data. The main purpose of this study was to investigate the efficacy of commonly used IFT electrode placement techniques for the management of subjects with LBP: "painful area" and "spinal nerve root" in combination with an evidence-based patient education booklet, *The Back Book*,<sup>27</sup> compared with a "control" treatment, *The Back Book* alone.

## METHODS

### Recruitment Procedure

Sixty subjects (28 men, 32 women; mean age  $\pm$  standard deviation [SD],  $34.6 \pm 11.7$ yr; range, 19–62yr) were recruited from the staff and students of the university, and from patients referred by general practitioners for physiotherapy treatment at a large acute care, general hospital. No reimbursement or reward was offered to subjects for participation. Subjects aged 18 to 65 years, with LBP with or without pain radiation into 1 or both lower limbs for 1 to 3 months were eligible for inclusion. Acute LBP has been defined as a current episode of less than 3 months duration.<sup>28</sup> Because the median recurrence rate of LBP is 26 weeks,<sup>29</sup> only subjects who had no similar episodes in the previous 6 months were eligible for inclusion. Subjects were given a detailed information sheet, and after written informed consent, were screened for exclusions by the trial coordinator. Exclusions were pacemaker (or indwelling stimulator); breaks in the skin or lack of normal skin sensation under the area where the electrodes were to be placed; epilepsy; pregnancy; previous spinal surgery or fractures of the vertebrae; known medical, neurologic or musculoskeletal disorders; or reflex and/or motor signs of nerve root compression. Approval was obtained from the university's research ethics committee before the study commenced.

Randomization was achieved using a predetermined list based on an alpha numeric code, drawn up by a member of the research team not involved in the day-to-day running of this study. Thus, neither the trial coordinator nor the treating physiotherapists were involved in randomization. Consenting subjects were randomly assigned to 1 of 3 treatment groups by means of sealed envelopes: (1) "IFT painful area": IFT painful area electrode placement technique and *The Back Book* ( $n = 18$ ; 7 men, 11 women; mean age,  $33.3 \pm 12.1$ yr); (2) "IFT spinal nerve": IFT spinal nerve root electrode placement tech-

nique and *The Back Book* ( $n = 22$ ; 10 men, 12 women; mean age,  $35.5 \pm 12.1$ yr); and, (3) "control": *The Back Book* only ( $n = 20$ ; 11 men, 9 women; mean age,  $34.7 \pm 13.5$ yr).

### Outcome Measures

Before commencing treatment and after a detailed verbal explanation, consenting subjects were requested to complete 3 self-administered valid and reliable questionnaires, to establish baseline LBP severity, LBP-specific functional disability, and generic health. Total completion time for all self-administered questionnaires was approximately 10 minutes. The treating physiotherapists were blind to the scores achieved on the outcome measure questionnaires.

Pain severity was measured by the McGill Pain Questionnaire (MPQ),<sup>30,31</sup> a valid and reliable measure of pain intensity; this yields the Pain Rating Index (PRI), a composite score consisting of 4 subscales measuring the sensory, affective, evaluative, and miscellaneous components of pain, with a score range from 0 (no pain) to 78 (extreme pain severity). The MPQ has been recommended as the leading pain measurement scale available.<sup>32</sup>

LBP-specific functional disability was measured by the Roland-Morris Disability Questionnaire (RMDQ),<sup>33</sup> a short, simple, reliable, and sensitive measure of functional disability resulting from LBP, derived from the Sickness Index Profile. The RMDQ has shown good validity and responsiveness to small changes in health in people with LBP,<sup>34</sup> and is well supported by several critical reviews of LBP-specific self-administered functional disability questionnaires.<sup>35,36</sup> Twenty-four items related to the subject's functional disability were checked on the day of completion, yielding a total score ranging from 0 (no complaint) to 24 (extreme disability). Stratford et al<sup>37</sup> determined that the minimum level of detectable change for the RMDQ was a change score of 4 (initial scores, 4–11; 16–20) or 5 (initial scores, 12–15) RMDQ points, such that any observed change in a patient that is less than this value is indistinguishable from measurement error, and it is therefore considered that the patient has not undergone change.

The EuroQol (EQ-5D),<sup>38,39</sup> a valid and reliable questionnaire to measure the health of a population and to detect differences in subgroups of the population,<sup>40</sup> was used as a short, simple, self-administered measure of generic health. The descriptive profile from the EQ-5D consists of 5 items: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression, which represent an individual's health, and related quality of life. Responses to these items have been weighted to produce a single index for describing and valuing health states, which ranges from  $-.59$  (extreme poor health) to 1 (full health).<sup>41</sup>

### Materials

**The Back Book.** *The Back Book* is an evidence-based patient education booklet developed as an adjunct to the UK's Royal College of General Practitioners guidelines for the management of acute LBP.<sup>42</sup> Early return to normal activities and participation in low-impact activities such as walking, swimming, and cycling are emphasized. *The Back Book* has been shown to be readily accepted and understood by individuals with LBP and to create a positive shift in beliefs about LBP.<sup>43,44</sup> However, no significant difference was shown between it and a traditional educational booklet for reduction of pain or functional disablement.<sup>44</sup> Therefore, *The Back Book* served as the control treatment in this study, was given to subjects in all groups, and the message reinforced by the treating physiotherapist.

**Interferential therapy.** Portable IFT units (Omega™ Inter 4150<sup>a</sup>) were used to deliver standardized IFT stimulation pa-

rameters, based on previous work at this center,<sup>45-47</sup> ie, carrier frequency 3.85kHz, 140Hz constant; pulse duration 130 $\mu$ s; for 30 minutes. Before commencement of the study, the stimulation parameters were calibrated for each unit using an oscilloscope.<sup>b</sup> Two carbon silicone self-adhesive electrodes<sup>a</sup> (45 × 102mm) were used to deliver the above treatment parameters. Individual subjects were always treated with the same IFT unit and electrodes.

Figure 1 shows the IFT painful area electrode placement technique. Two electrodes were placed unilaterally or bilaterally at the peripheries of the LBP painful area. In subjects with unilateral pain, the cathode (–) electrode was positioned at the proximal extent and the anode (+) electrode at the distal extent of the painful area. Treatment of subjects with bilateral LBP involved paraspinal application of the cathode and anode electrodes at the lateral limits of the painful area, parallel to the vertebral column (fig 1), as recommended.<sup>24</sup>

Figure 2 shows the IFT spinal nerve root electrode placement technique, which involved placement of the midpoint of the cathode and anode electrodes lateral to the intervertebral foramen of the target spinal nerve, parallel to the vertebral column. For unilateral symptoms, the proximal cathode was placed 2cm lateral to the intervertebral foramen and the distal anode electrode was placed 2cm further laterally (fig 2). Treatment of subjects with bilateral LBP involved paraspinal application of the cathode and anode electrodes parallel to the vertebral column at the level of the intervertebral foramen of the paraspinal target spinal nerves.

### Treatment Procedure

Physiotherapists received instructions on the treatment allocation of individual subjects by means of sealed envelopes so that the trial coordinator was blinded and had no influence over the treatment received by any subjects. Therefore, double-blind conditions were fulfilled. All treatments to an individual subject were conducted by the same physiotherapist. After routine physiotherapy assessment,<sup>48</sup> subjects were positioned on a treatment plinth in their preferred position of comfort, ie, prone lying or side lying. After a detailed explanation by the treating physiotherapist, the IFT unit was switched on, and the current amplitude gradually increased until the subject reported first a “mild tingling sensation” and then a “strong but comfortable sensation.” To maintain a continuous level of intensity, the amplitude was increased by the physiotherapist when the subject reported a diminution of the IFT current sensation. All IFT treatments were 30 minutes long.

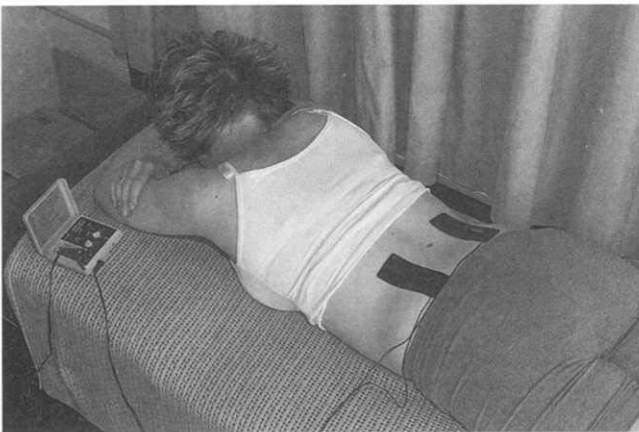


Fig 1. IFT “painful area” electrode placement technique.

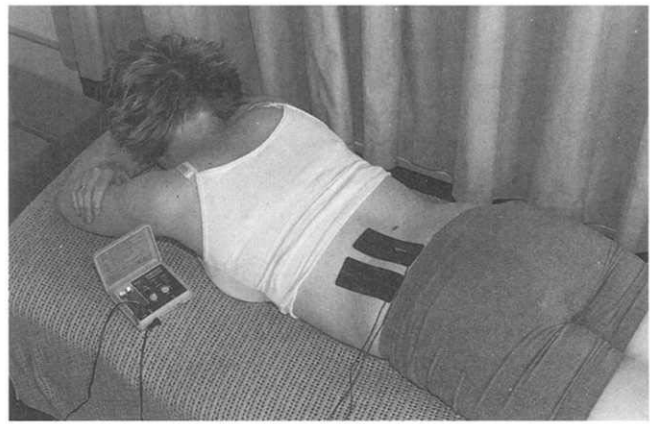


Fig 2. IFT spinal nerve root electrode placement technique.

Subjects in the IFT groups received treatment 2 to 3 times per week (on the basis of earlier work at this center),<sup>45,46</sup> whereas those in the control group were requested to attend biweekly for reassessment. On discharge, subjects were requested to complete all outcome measures by the relevant therapist. A 3-month postal follow-up was conducted, whereby subjects were sent copies of the outcome measure questionnaires and self-addressed envelopes. Nonrespondents were sent a postcard reminder after 2 weeks and a second copy of the questionnaires and self-addressed envelopes after 4 weeks. Subjects who failed to attend for 2 successive appointments, or who requested it, were withdrawn from the study and treated as necessary by the same physiotherapist but were included in all subsequent follow-ups.

### Data Analyses

Baseline data were coded and all outcome measure questionnaires scored by the trial coordinator. All data were entered into spreadsheets for analysis using the Statistical Package for the Social Sciences,<sup>c</sup> version 9.0 for Windows. An intention-to-treat analysis was carried out, whereby all patients once randomized were followed-up using the same endpoints. Between-group differences in baseline characteristics were calculated using Kruskal-Wallis (1-way analysis of variance [ANOVA]) tests. Similarly, differences in baseline characteristics between respondents and nonrespondents at 3-month follow-up were analyzed using Kruskal-Wallis (1-way ANOVA) tests. For pain (PRI), functional disability (RMDQ), and generic health (EQ-5D) data, descriptive statistics were used to establish median and interquartile range (IQR) values for the raw scores recorded at pretreatment, discharge, and follow-up for the 3 treatment groups. Difference scores between these time points (pretreatment: discharge, discharge: follow-up, pretreatment: follow-up) were determined and the significance levels within each group calculated by Wilcoxon matched-pairs signed-ranks tests. The significance of difference scores between groups was analyzed using Kruskal-Wallis (1-way ANOVA) tests. Power calculations were conducted to determine the sample size required for a proposed RCT, which would provide 90% power at the 5% significance level.<sup>49</sup>

### RESULTS

The study subjects reflected the heterogeneity of patients receiving physiotherapy for acute LBP in the British National Health Service, ie, slight female preponderance (53.3%), broad

Table 1: Baseline Characteristics of Study Subjects

	Painful Area (n = 18)	Spinal Nerve (n = 22)	Control (n = 20)	$\chi^2$	p*
Men (%)	38.8	40.9	55.0	1.1	.582
Median age (yr)	35.0	35.0	30.0	0.3	.863
Current smokers (%)	33.3	36.3	20.0	1.4	.498
Aerobic exercise (%)	66.6	59.0	80.0	2.5	.279
Employed (%)	55.5	72.7	70.0	1.9	.382
Current episode (wk)	5.0	7.0	4.0	5.9	.053
Analgesic usage (%)	61.1	72.7	63.1	1.2	.551
Median MPQ-PRI score	11.5	14.0	15.5	0.2	.920
Median RMDQ score	5.5	9.0	5.0	3.7	.156
Median EQ-5D score	.69	.76	.69	0.1	.971

\* p value determined by Kruskal-Wallis (1-way ANOVA).

age range (19–62yr), varied work statistics (employed 68.3%, unemployed 3.3%, students 23.3%, homemakers 5%), duration of current episode (mean,  $6.8 \pm 3.2$ wk), and analgesic medication consumption (66.7%). One subject was removed from the study (IFT spinal nerve group) because of development of another unrelated medical condition, which prevented continuation of treatment. The remaining subjects ( $n = 59$ ) received treatment until the relevant therapist considered maximal benefit had been achieved and were discharged after completion of the outcome measure questionnaires. There were no statistically significant differences between groups in the baseline characteristics evaluated (table 1).

The median number of treatment sessions was 3 (range, 2–10) for IFT painful area, 4 (range, 2–9) for IFT spinal nerve, and 3 (range, 1–4) for the control group. The 3-month follow-up yielded an 80% response rate ( $n = 48$ ). Respondents comprised the following: IFT painful area ( $n = 15$ ; 5 men, 10 women; mean age,  $33.4 \pm 8.7$ yr); IFT spinal nerve ( $n = 17$ ; 7 men, 10 women; mean age,  $35.6 \pm 12.0$ yr); and control ( $n = 15$ ; 8 men, 7 women; mean age,  $33.0 \pm 13.7$ yr). Table 2 shows that no significant differences were detected between respondents and nonrespondents (IFT painful area:  $n = 3$ ; 2 men, 1 woman; mean age,  $34.0 \pm 14.1$ yr; IFT spinal nerve:  $n = 4$ ; 2 men, 2 women; mean age,  $35.2 \pm 14.4$ yr; control:  $n = 5$ ; 3 men, 2 women; mean age,  $28 \pm 11.6$ yr) to 3-month follow-up, for gender, age, smoking status, employment status, duration of current episode, analgesic medication usage, and baseline PRI, RMDQ, and EQ-5D outcome measure scores ( $p > .05$ ). It was interesting to note that a significantly ( $p = .043$ ) higher per-

centage of respondents reported participation in aerobic exercise at baseline compared with nonrespondents.

Table 3 displays the median and IQR values for the raw outcome measure scores for the 3 treatment groups at each time point. Although no significant differences were detected between groups ( $p > .05$ ) at baseline, it is evident that the control group displayed the highest PRI value and the IFT spinal nerve group the greatest RMDQ score. Although the IFT painful area group recorded significantly ( $p = .049$ ) higher RMDQ raw scores at 3 months, the extremely low RMDQ scores in all groups represented minimal evidence of any functional disability.<sup>33</sup>

Wilcoxon matched-pairs signed-ranks tests showed significant differences within each group for all outcome measures ( $p < .01$ ; table 4). Table 5 details the specific difference scores for each outcome measure at the time points analyzed; a positive value indicates a reduction in PRI and RMDQ levels and a worsening in ED-5D status whereas, conversely, a negative value suggests an increase in PRI and RMDQ levels and an improvement in EQ-5D status. We plotted the change in outcome measure values (median) for each group at the 3 recording points: At discharge, the graphs show improvement in pain severity (PRI) (fig 3) LBP-specific functional disability (RMDQ) (fig 4), and generic health status (EQ-5D) (fig 5) in all groups, compared with pretreatment conditions. Analysis of between-group differences at discharge showed that the IFT spinal nerve group had a significantly higher RMDQ difference score (ie, 5 RMDQ points) than either the IFT painful area or control groups ( $\chi^2 = 6.3$ ,  $p = .042$ ; table 5). However, no

Table 2: Differences in Baseline Characteristics Between Follow-up Respondents and Nonrespondents

	Painful Area		Spinal Nerve		Control		$\chi^2$	p*
	Resp	Nres	Resp	Nres	Resp	Nres		
n	15	3	17	4	15	5	2.6	.109
Men (%)	33.3	66.6	47.0	50.0	53.3	60.0	0.9	.332
Median age (yr)	35.0	29.0	35.0	34.5	33.0	23.0	1.3	.246
Current smokers (%)	20.0	100.0	41.1	25.0	20	25.0	1.3	.255
Aerobic exercise (%)	66.6	66.6	70.6	25.0	93.3	50.0	4.1	.043*
Employed (%)	53.3	66.6	76.4	75.0	80.0	40.0	0.6	.436
Current episode (wk)	5.0	4.0	7.0	9.0	4.0	5.0	0.0	.913
Analgesic usage (%)	60.0	66.6	70.6	100.0	66.6	50.0	0.2	.669
Median MPQ-PRI score	11.0	20.0	15.0	13.5	16.0	15.0	1.0	.309
Median RMDQ score	5.0	12.0	10.0	7.5	5.0	5.0	0.7	.393
Median EQ-5D score	.69	.36	.76	.72	.76	.59	1.9	.169

Abbreviations: Resp, respondent; Nres, nonrespondent.

\* Kruskal-Wallis (1-way ANOVA),  $p < .05$ .

Table 3: Outcome Measure Raw Scores at Start, Discharge, and Follow-up

	Start (n = 60)				Discharge (n = 60)				3 Months (n = 48)			
	Pful	Spn	Cont	p*	Pful	Spn	Cont	p*	Pful	Spn	Cont	p*
MPQ-PRI												
Median	11.5	14.0	15.5		1.0	2.0	4.0		5.0	2.0	3.0	
IQR	11.8	12.5	14.7	.920	6.3	5.0	5.0	.246	14.0	10.0	5.0	.592
RMDQ												
Median	5.5	9.0	5.0		1.5	2.0	2.0		2.0	1.0	1.0	
IQR	6.3	8.0	4.5	.156	3.3	4.5	2.0	.912	3.0	5.5	1.0	.049*
EQ-5D												
Median	.69	.76	.69	.971	.80	.79	.93		.80	.80	1.0	
IQR	.14	.17	.20		.24	.31	.20	.363	.27	.31	.20	.054

Abbreviations: Pful, IFT painful area group; Spn, IFT spinal nerve group; Cont, control group.

\* Kruskal-Wallis (2-way ANOVA),  $p < .05$ .

significant differences were detected between groups in PRI or EQ-5D difference scores.

At 3 months, the graphs show that PRI scores increased in the IFT painful area group compared with the other groups; Wilcoxon matched-pairs signed-ranks tests confirmed this observation, showing that the PRI difference score significantly decreased in only the IFT painful area group ( $Z = -2.3$ ,  $p = .021$ ; table 4). For functional disability, the graphs show that the RMDQ score marginally increased in the IFT painful area group and decreased in the control group. Indeed, within-group analysis showed that the RMDQ difference score significantly increased in only the control group ( $Z = -2.6$ ,  $p = .01$ ; table 4). The EQ-5D difference scores were not significantly different in any group at follow-up.

Between-group difference analysis at follow-up showed a significantly greater RMDQ difference score in the control group (ie, by 1 RMDQ point) than either of the IFT treatment groups ( $\chi^2 = 6.2$ ,  $p = .045$ ; table 5). The IFT spinal nerve RMDQ difference score of 0 indicates no change from discharge, whereas the IFT painful area difference score of -1 suggests an overall worsening in functional disability level. Consistent with results at discharge, no significant differences were detected between groups in PRI or EQ-5D difference scores at this point.

Finally, as regards overall progress, all 3 groups showed significant improvements from pretreatment to follow-up in self-reported pain severity, LBP-specific functional disability

and generic health levels, as shown in figures 3-5 ( $p < .01$ ; table 4). Analysis of between-group differences showed that the IFT spinal nerve group had significantly greater RMDQ difference score, ie, 6 RMDQ points, which is considered clinically meaningful,<sup>37</sup> than either the IFT painful area or control groups ( $\chi^2 = 7.0$ ,  $p = .030$ ; table 5). No significant differences were detected between groups for the PRI and EQ-5D difference scores recorded between these time points.

#### Power Analysis

Power analysis was conducted to determine the sample size required for a future RCT. Calculations, which were based on the IFT spinal nerve group RMDQ data, determined that to detect a 2-point difference between groups in the mean change on the RMDQ, 80 subjects would be required for a study for each treatment group (ie, 3 groups = total sample 240 subjects), allowing for 10% attrition at 3 follow-up points<sup>49</sup> (table 6). This sample size would provide 90% power at the 5% significance level.

#### DISCUSSION

Previous studies<sup>7,8</sup> at our center have established that IFT is the most widely used electrotherapeutic modality by physiotherapists in Britain and Ireland in the clinical management of LBP. This is so despite the absence of scientific evidence for its superiority over other treatment strategies, lack of research of its various treatment parameters, and the significant costs of an

Table 4: Within-Subject Differences in Outcome Measure Scores

	IFT Painful Area		IFT Spinal Nerve		Control	
	Z	p	Z	p	Z	p
MPQ-PRI Score						
Discharge	-3.7	.000*	-3.9	.000*	-3.3	.001*
3mo <sup>1</sup>	-2.3	.021*	-1.5	.131	-0.6	.508
3mo <sup>2</sup>	-3.0	.002*	-3.6	.000*	-3.3	.001*
RMDQ Score						
Discharge	-3.1	.002*	-4.0	.000*	-3.5	.000*
3mo <sup>1</sup>	-1.7	.087	-0.5	.612	-2.6	.01*
3mo <sup>2</sup>	-2.9	.004*	-3.6	.000*	-3.5	.000*
EQ-5D Score						
Discharge	-3.1	.002*	-2.8	.005*	-3.5	.000*
3mo <sup>1</sup>	-1.1	.271	-0.9	.331	-1.4	.151
3mo <sup>2</sup>	-2.6	.008*	-2.9	.003*	-3.3	.001*

Abbreviations: Discharge, median change (range) from pre- to posttreatment; 3mo<sup>1</sup>, median change (range) from posttreatment to follow-up; 3mo<sup>2</sup>, median change (range) from pretreatment to follow-up.

\* Wilcoxon's matched-pairs signed-ranks test,  $p < .01$ .

Table 5: Outcome Measure Difference Scores and Between-Subject Differences

	IFT Painful Area	IFT Spinal Nerve	Control	$\chi^2$	$p$
<b>MPQ-PRI Score</b>					
At start	11.5 (IQR = 11.7)	14.0 (IQR = 12.5)	15.5 (IQR = 14.7)	0.2	.920
Discharge	+11.0 (+1.0 to +53.0)	+11.0 (-4.0 to +56.0)	+10.0 (-5.0 to +55.0)	0.1	.971
3mo <sup>1</sup>	-3.0 (-18 to +3.0)	0.0 (-7 to +4.0)	+1.0 (-16 to +5.0)	4.7	.095
3mo <sup>2</sup>	+6.0 (-5.0 to +23.0)	+10 (+3.0 to +29.0)	+9.0 (-2.0 to +50.0)	1.5	.468
<b>RMDQ Score</b>					
At start	5.5 (IQR = 6.2)	9.0 (IQR = 8.0)	5.0 (IQR = 14)	3.7	.156
Discharge	+3.0 (-4.0 to +12.0)	+5.0 (+1.0 to +15.0)	+3.5 (-3.0 to +10.0)	6.3	.042*
3mo <sup>1</sup>	-1.0 (-3.0 to +2.0)	0.0 (-8.0 to +7.0)	+1.0 (-1.0 to +5.0)	6.2	.045*
3mo <sup>2</sup>	+3.0 (-2.0 to +12.0)	+6.0 (+2.0 to +14.0)	+4.0 (+1.0 to +11.0)	7.0	.030*
<b>EQ-5D Score</b>					
At start	.69 (IQR = .14)	.76 (IQR = .17)	.69 (IQR = .20)	0.1	.971
Discharge	-0.2 (-0.5 to +0.2)	-0.2 (-0.6 to 0.0)	-0.2 (-0.9 to -0.0)	2.3	.316
3mo <sup>1</sup>	0.0 (-0.2 to +0.3)	0.0 (-0.2 to +0.3)	0.0 (-0.3 to +0.2)	3.5	.176
3mo <sup>2</sup>	0.0 (-0.4 to +0.1)	0.0 (-0.6 to +0.1)	-0.2 (-0.8 to +0.2)	4.2	.129

Abbreviations: At start, median values (IQR) before randomization; Discharge, median change (range) from pre- to posttreatment; 3mo<sup>1</sup>, median change (range) from posttreatment to follow-up; 3mo<sup>2</sup>, median change (range) from pretreatment to follow-up.

\* Kruskal-Wallis (1-way ANOVA),  $p < .05$ .

IFT machine.<sup>13,14</sup> This is the first report of the combined effect of *The Back Book* and IFT for subjects with acute LBP. Subjects in all groups displayed significant improvements in pain, functional disability, and generic health levels when treated with IFT and *The Back Book* in combination or *The Back Book* alone. Comparing between groups, our results most notably indicate that subjects managed by *The Back Book* and IFT using the spinal nerve root technique displayed both a statistically significant and clinically meaningful reduction in functional disability,<sup>37</sup> compared with management via *The Back Book* alone or in combination with IFT by the painful area technique. These results are unlikely to be attributable to spontaneous recovery in acute LBP, which is high in the first month of onset,<sup>50</sup> because subjects were required to have a current episode of at least 4 weeks to be eligible for inclusion. Thus, the results of the current study provide preliminary evidence

that the IFT spinal nerve root electrode placement technique should be used instead of the IFT painful area technique in future RCTs for subjects with acute LBP.

In contrast, Werners et al<sup>14</sup> failed to show a significant difference in functional disability between subjects treated with either IFT or motorized lumbar traction and massage. However, several methodologic differences are apparent between the 2 investigations. First, this study used only subjects with acute LBP, compared with the sample of subjects with acute and chronic LBP used in the latter study. Second, different outcome measures were used to record functional disability. Third, the comparative treatments differed markedly—a booklet in this investigation, traction and massage in their study. Finally, the IFT treatment parameters differed significantly, ie, bipolar spinal nerve or painful area electrode placement, 140Hz constant, and 30-minute<sup>7</sup> treatment time in this study, com-

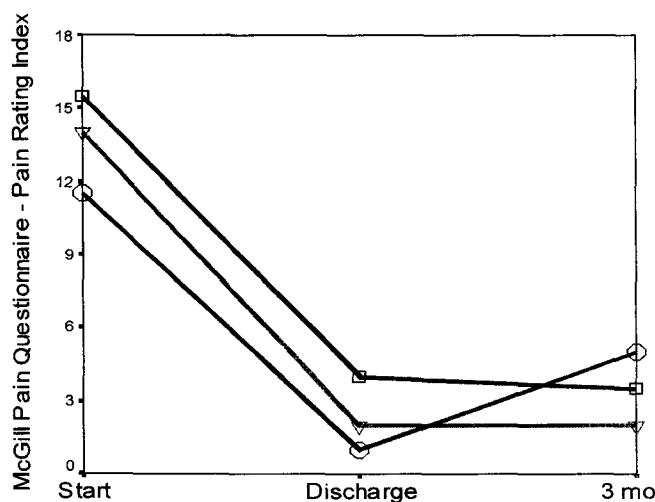


Fig 3. Outcome measure scores of PRI at pretreatment, discharge, and follow-up. A decrease in raw score value indicates an improvement in PRI, whereas conversely, an increase in raw score value suggests a deterioration in PRI. (○, painful area; ▽, spinal nerve root; □, control).

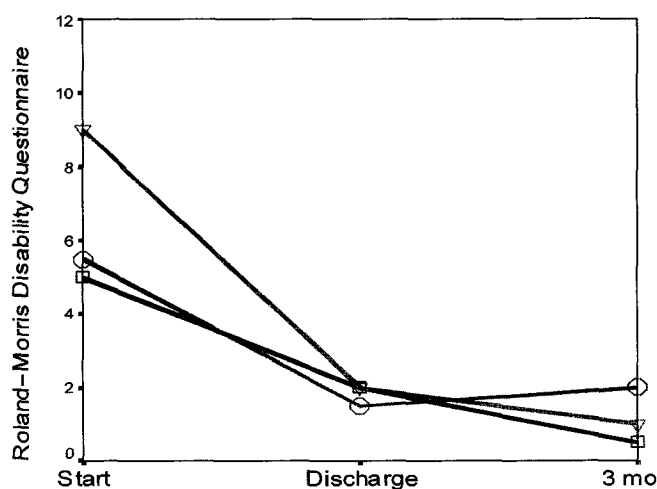


Fig 4. Outcome measure scores of RMDQ at pretreatment, discharge, and follow-up. A decrease in raw score value indicates an improvement in RMDQ levels, whereas conversely, an increase in raw score value suggests a deterioration in RMDQ levels. (○, painful area; ▽, spinal nerve; □, control).

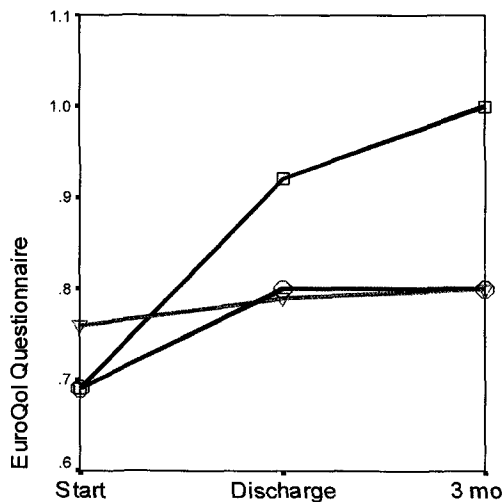


Fig 5. Outcome measure scores of EuroQol at pretreatment, discharge, and follow-up. Decreases in raw value indicates a worsening in EQ-5D status and vice versa (○, painful area; ▽, spinal nerve root; □, control).

pared with the standardized bipolar paravertebral electrode placement, 30 to 60Hz sweep, and 10-minute treatment duration of the other investigators.<sup>14</sup>

Consistent with the limited number of previous RCTs, our results show the significant hypoalgesic effects of IFT but no significant differences in pain reduction between subjects treated with this modality and a range of comparative treatments, ie, exercise, shortwave diathermy, traction, massage, and placebo IFT.<sup>14-16</sup> Thus, it remains to be proven scientifically that the hypoalgesic effects of IFT are superior to any other form of therapy, including an education booklet. The literature cites a range of hypoalgesic mechanisms attributable to IFT: stimulation of pain "gating" and opioid mechanisms,<sup>19</sup> stimulation of the reticular formation,<sup>21</sup> and removal of nociceptive substances.<sup>19</sup> The effect of IFT in relation to these hypotheses is largely speculative and requires detailed investigation in a placebo-controlled RCT.

Improvement in the level of functional disability is an important clinical outcome from the patients' perspective.<sup>51</sup> Despite the significantly greater reduction in RMDQ scores in the IFT spinal nerve group compared with the other groups, it should be acknowledged that this group displayed marginally higher baseline RMDQ values, reflecting greater functional disablement and thus more potential for change, which may in

part explain the significant finding. Conversely, the control group had slightly higher PRI values at baseline, representing greater pain severity, and perhaps a greater potential for significant improvement. It could also be argued that because the IFT spinal nerve and control groups had the highest baseline RMDQ and PRI values, respectively, they were equally difficult to treat. Although both the PRI and the EuroQol have been validated for use in subjects with LBP,<sup>32</sup> unlike the RMDQ, they are not LBP-specific and consequently may show less sensitivity to clinical change. It is evident from these results that the severity of an individual's LBP does not necessarily predict the degree to which that person is disabled,<sup>51</sup> emphasizing the need to consider both outcome variables in future clinical research and practice.

It is interesting to note that although no significant baseline differences were detected between groups, several known risk factors for chronicity showed varying distributions between the study groups and may have influenced the results. The control group had the lowest percentage of current smokers; a recent systematic review concluded smoking should be considered a weak risk factor but not a cause of LBP,<sup>52</sup> thus suggesting the IFT groups were at greater risk of poor outcome. There was a noticeably lower percentage of employed subjects in the IFT painful area group, compared with the other 2 groups. Numerous work-related factors can influence outcome from LBP, such as job satisfaction and compensation.<sup>53</sup> Finally, the IFT spinal nerve group reported the largest percentage of analgesic medication usage, and the control group had the highest number of subjects engaging in aerobic exercise. In categorizing pain coping strategies, Slade et al<sup>54</sup> considered analgesic medication usage a passive response and physical exercise participation an active coping strategy, which would suggest that the IFT spinal nerve group had the highest risk of LBP chronicity on entry to the study.<sup>55</sup> On a related theme, the significantly higher percentage of respondents who reported participation in aerobic exercise may suggest more positive health beliefs in this group compared with nonrespondents.

It is impossible to exclude the influence of such potential confounding variables on the findings, but equally it is extremely difficult to control fully for all such factors without stratification during the randomization procedure. In view of this and because of our power calculations, it is evident that a larger sample size will be required for a future RCT to investigate the efficacy and cost-effectiveness of the IFT spinal nerve protocol compared with other evidence-based approaches for acute LBP. This RCT should definitively establish any proposed additional benefits from IFT on pain and generic health and explore the impact of risk factors for chronicity on outcomes.<sup>55</sup>

## CONCLUSION

These results provide the first evidence that IFT electrode placement technique may be an important parameter affecting LBP-specific functional disability at 3-month follow-up. Specifically, treatment using *The Back Book* and IFT spinal nerve root electrode placement technique in combination resulted in a significantly greater and clinically meaningful reduction in RMDQ scores than management with *The Back Book* alone or in combination with the IFT painful area electrode placement technique. The results emphasize the need for additional investigations of this widely used electrotherapeutic modality to justify its continued use, eg, appropriate selection of IFT parameters and a comparative study of the efficacy and cost-effectiveness of IFT with TENS (which is considerably less expensive) for subjects with LBP.

Table 6: Power Calculations\*

	IFT Painful Area	IFT Spinal Nerve	Control
Pre-post RMDQ difference (mean ± SD)	3.66 ± 3.6	6.0 ± 3.38	4.21 ± 3.22

\* Based on Pocock,<sup>49</sup> using the following equation:

$$n = \frac{2\sigma^2}{(\mu_2 - \mu_1)^2} \times f(\alpha, \beta)$$

$$= \frac{2(3.38)^2}{(2)^2} \times (10.5)$$

= 60 (allowing for 10% attrition at 3 time points)

= 80 subjects per group

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#### Suppliers

- a. TensCare Ltd, 89 Robin Hood Way, London SW15 3PW, England.
- b. Gould Electronics Ltd, Instrument Systems, Roebuck Rd, Hainault, Ilford, Essex IG6 3UE, England.
- c. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.