Enhanced Therapeutic Alliance Modulates Pain Intensity and Muscle Pain Sensitivity in Patients With Chronic Low Back Pain: An Experimental Controlled Study

Jorge Fuentes, Susan Armijo-Olivo, Martha Funabashi, Maxi Miciak, Bruce Dick, Sharon Warren, Saifee Rashiq, David J. Magee, Douglas P. Gross

Background. Physical therapy influences chronic pain by means of the specific ingredient of an intervention as well as contextual factors including the setting and therapeutic alliance (TA) between provider and patient.

Objective. The purpose of this study was to compare the effect of enhanced versus limited TA on pain intensity and muscle pain sensitivity in patients with chronic low back pain (CLBP) receiving either active or sham interferential current therapy (IFC).

Design. An experimental controlled study with repeated measures was conducted. Participants were randomly divided into 4 groups: (1) AL (n=30), which included the application of active IFC combined with a limited TA; (2) SL (n=29), which received sham IFC combined with a limited TA; (3) AE (n=29), which received active IFC combined with an enhanced TA; and (4) SE (n=29), which received sham IFC combined with an enhanced TA.

Methods. One hundred seventeen individuals with CLBP received a single session of active or sham IFC. Measurements included pain intensity as assessed with a numerical rating scale (PI-NRS) and muscle pain sensitivity as assessed via pressure pain threshold (PPT).

Results. Mean differences on the PI-NRS were 1.83 cm (95% CI=14.3–20.3), 1.03 cm (95% CI=6.6–12.7), 3.13 cm (95% CI=27.2–33.3), and 2.22 cm (95% CI=18.9–25.0) for the AL, SL, AE, and SE groups, respectively. Mean differences on PPTs were 1.2 kg (95% CI=0.7–1.6), 0.3 kg (95% CI=0.2–0.8), 2.0 kg (95% CI=1.6–2.5), and 1.7 kg (95% CI=1.3–2.1), for the AL, SL, AE, and SE groups, respectively.

Limitations. The study protocol aimed to test the immediate effect of the TA within a clinical laboratory setting.

Conclusions. The context in which physical therapy interventions are offered has the potential to dramatically improve therapeutic effects. Enhanced TA combined with active IFC appears to lead to clinically meaningful improvements in outcomes when treating patients with CLBP.

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Nonspecific low back pain (LBP) is defined as pain, muscle tension, or stiffness localized below the costal margin of the back and above the inferior gluteal folds, with or without leg pain (sciatica).[1] When LBP persists for 12 weeks or more, the condition is described as chronic (CLBP).[2] This condition is a highly prevalent problem that represents a challenge for health care providers and society.[3–5] Patients with CLBP are commonly treated by physical therapists, yet the mechanisms by which physical therapy interventions influence chronic pain are complex. Variables associated with the clinician, patient, and setting may influence clinical outcomes in addition to the specific physical interventions. These factors make up the "context" and can be described as "nonspecific" or "contextual."[6] When contextual factors positively influence clinical outcomes, they are known as contextual, nonspecific, or placebo effects. The placebo effect is thus the positive psychosocial and neurobiological effect that the treatment context has on clinical outcomes.[7,8] Although in clinical practice both specific and nonspecific effects may work together, the quantification of the placebo effect, or contextual factors that surround a therapy, has not traditionally been a primary focus of investigation in the physical therapy literature. However, a comprehensive analysis of all factors that potentially could influence physical therapy's clinical efficacy is needed, especially in the management of chronic pain.[9]

Among the diverse contextual factors, the therapeutic alliance (TA) is fundamental to the therapeutic process and the placebo effect. The TA can be defined as the working rapport or positive social connection between the patient and the therapist.[10] More specifically, during rehabilitation, TA relies on "a complex interplay of technical skill, communicative competence, and the reflective capacity of the therapist to respond to the patient in the moment of therapy."[11(p873)] The TA is more than the communication between the patient and the therapist. For example, the TA involves the sense of collaboration, warmth, and support that are critical aspects of this construct.[12]

The TA has been correlated with treatment adherence and positive outcomes in several disciplines, including medicine, psychotherapy, and physical rehabilitation.[13–20] Although an identifiable "practitioner effect" has been documented in LBP and neck pain intervention trials,[21] this phenomenon has not been systematically investigated in treatments aimed at modifying musculoskeletal pain. In physical rehabilitation, a positive TA has been correlated with improved pain, reduced disability, and higher treatment satisfaction.[20] Recently, the TA was found to be more strongly associated with disability and function compared with pain outcomes in CLBP.[22] Experimental manipulation of the TA construct is needed to confirm a causal effect during physical therapy intervention for musculoskeletal conditions. To date, no randomized controlled study has adequately tested the role of TA in physical therapy clinical outcomes for CLBP.

In physical therapy, the application of electrophysical agents is commonly associated with therapeutic procedures involving application of technologically impressive equipment. Because the placebo response is influenced by the invasiveness of the procedure and the way the treatment is applied (ie, therapeutic device versus pill),[23–25] it is plausible that electrophysical agents may be more prone to the influence of placebo effects. The protocol of this study was based on a previous study that explored the active and placebo effects of interferential current therapy (IFC) in experimentally controlled conditions.[26] The results of the study suggested that IFC has some clinical efficacy but that the therapeutic context in which IFC was applied influenced muscle pain sensitivity.[26] Therefore, the current study attempted to confirm this finding in patients with chronic painful conditions.

The aim of this study was to compare the effect of an enhanced TA versus a limited TA on pain intensity and muscle pain sensitivity in patients with CLBP receiving either active or sham IFC. Also, the use of IFC allowed us to apply an adequate sham intervention needed for 2 of the groups included in this study.

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- **eFigure:** Carbon Rubber Electrodes Placed Over Lumbar and Sacral Areas
- **eTable:** Pair-wise Comparisons Among Groups for Expectations Difference and Therapeutic Alliance
- A **video** showing the limited and enhanced clinician-patient interactions used in the study.
- **Discussion Podcast** with Paulo Ferreira and author Jorge Fuentes. Moderated by Steven George.

Method

The report of this trial followed the guidelines established for the CONSORT statement.[27]

Study Design

This was a double-blind, placebo-controlled experimental study with repeated measures. Participants were randomly divided into 4 groups: (1) AL (n=30), which received active IFC combined with a limited TA; (2) SL (n=29), which received

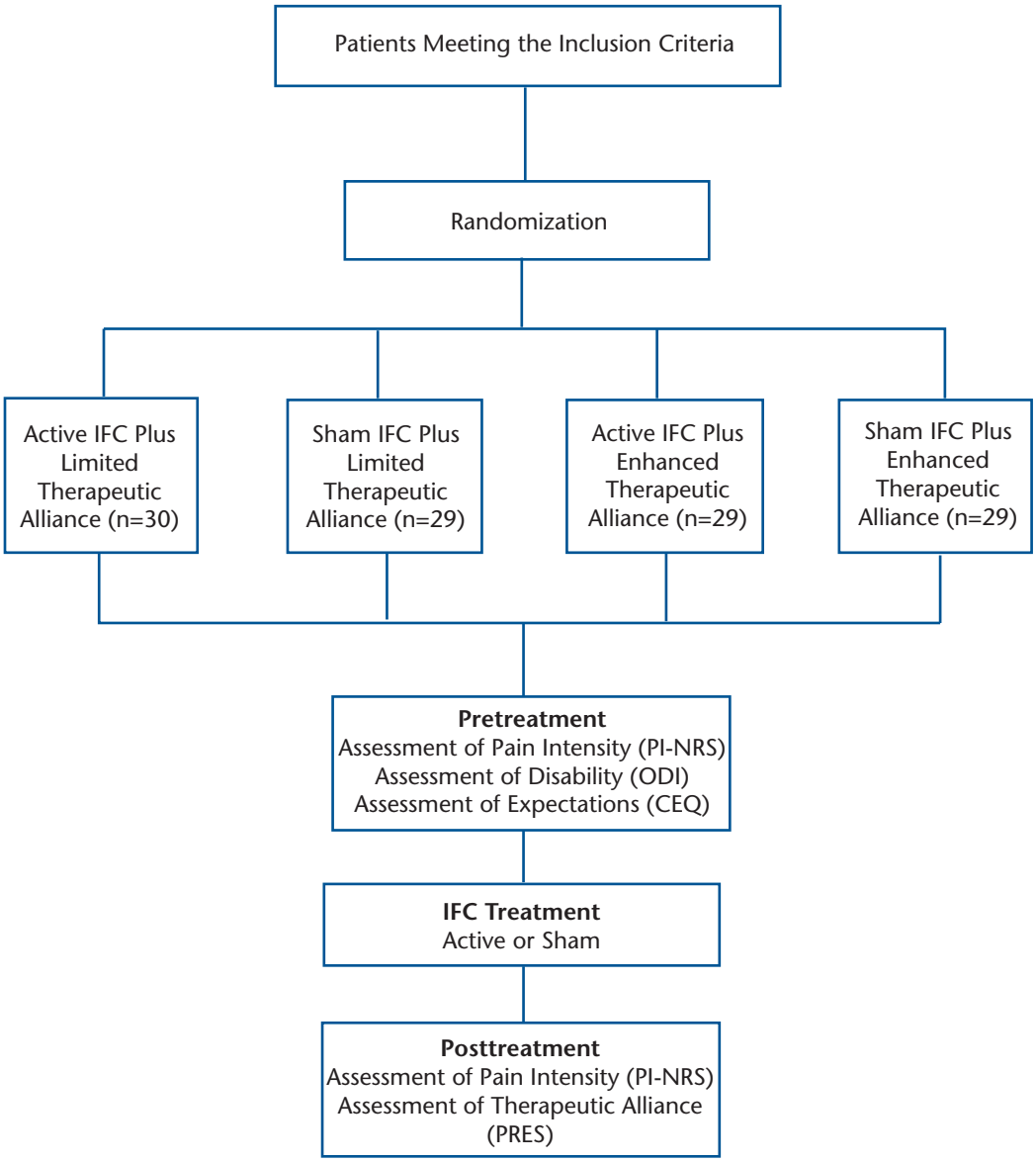

Figure 1.
Flowchart and schematic sequence of the study procedure. IFC=interferential current therapy, PI-NRS=pain intensity numerical rating scale, ODI=Oswestry Disability Index, CEQ=Credibility Expectancy Questionnaire, PRES=Pain Rehabilitation Expectations Scale.

sham IFC combined with a limited TA; (3) AE (n=29), which received active IFC combined with an enhanced TA; and (4) SE (n=29), which received sham IFC combined with an enhanced TA (Fig. 1).

All patients acknowledged their understanding and willingness to participate by providing signed consent, but the consent disclosure omitted certain descriptors and information about the methods to protect the study's scientific validity. For example, neither the word "placebo" nor the word "sham" was mentioned. Also, to avoid biasing their opinions of interactions with the treating therapist, participants were not told about the different levels of TA associated with the treatments. Participants were informed that the study was aimed at determining the difference in effectiveness between the standard electrotherapy treatment for LBP (ie, active IFC) and a new treatment based on a subthreshold level of electrical stimulation (ie, sham IFC).

Randomization

A randomization sequence stratified by sex was computer-generated by

a research assistant not involved in the study. This assistant distributed the results of the sequence into consecutively numbered, opaque, and sealed envelopes. Participants were allocated to the treatment groups by a physical therapist who opened the next available envelope prior to each treatment session.

Setting

The study was conducted in the sports physical therapy laboratory of the Faculty of Rehabilitation Medicine at the University of Alberta, Edmonton, Canada. This laboratory is located within an academic building on the university campus. The laboratory is also used for treating varsity and professional athletes.

Participants and Recruitment

Volunteers with CLBP were recruited from the local community by a widely circulated poster advertisement. Inclusion criteria were nonspecific LBP of at least 3 months' duration, resulting in a mild to moderate level of disability (Oswestry Disability Index ≤60%); a pain intensity score between 3 and 8 points on a numerical rating scale (PI-NRS) ranging from 0 ("no pain") to 10 ("worst possible pain"); and age between 18 and 65 years. Exclusion criteria were any contraindications to the use of electrotherapy, neurological problems (central or peripheral, such as sciatica), concomitant physical therapy or chiropractic treatment, and previous experience with electrotherapy. Participants were asked to refrain from taking pain medications the day of the treatment session.

All patients acknowledged their understanding and willingness to participate by providing written informed consent, and each participant was reimbursed CAD$20 for participating in the study.

Intervention

Both the AL and AE groups included the application of active IFC. The intensity of the current was at sensory level.[26,28] The frequency was set at an amplitude-modulated frequency of 0 Hz.[26,28] The participants assigned to the SL and SE groups received sham IFC treatment. This intervention was delivered using the same equipment and the same electrode arrangement as per the active IFC groups, except that the lead wires of the equipment were disconnected from the output channel jack. Thus, the participants received no current output.

Output channel jacks were covered during the procedure, and the equipment screen displayed the same visual and output signals as in the active treatment groups. Thus, neither the participant nor the assessor was able to distinguish between active and sham treatments.

The intensity of the current for treatment application was a strong but comfortable sensory level, producing a "pins-and-needles–like sensation" without visible muscle twitches.[26,28,29] During sham application, the investigator's instructions were: "Today, I am going to apply a new treatment called therapeutic subthreshold current . . . as the level of stimulation is subthreshold, you might not be able to feel it beneath the electrodes."

In order to create the same level of positive treatment expectations, all participants received a similar instructional set (verbal suggestions) about the effectiveness of the intervention (ie, "The intervention you are going to receive is an effective pain-relieving treatment"). Therefore, expectations were not manipulated in an attempt to control the effect of expectations among groups.

AL group. In this group, a single 30-minute session of active IFC was applied. The limited interaction included about 5 minutes during which the therapist introduced herself and explained the purpose of the treatment. In addition, participants were told that this was a "scientific study" in which the therapist had been instructed not to converse with participants.[30] After setting up the treatment parameters, the therapist left the room and returned 15 and 30 minutes into the treatment to be present when the tester arrived to conduct outcome assessment.

SL group. In this group, the same protocol as described for the AL group was applied. The difference was that a sham IFC intervention was administered.

AE group. In this group, a single 30-minute session of active IFC was applied. During the first 10 minutes, each participant was questioned about his or her symptoms and lifestyle and about the cause of his or her condition. The therapeutic interaction was enhanced through verbal behaviors, including active listening (ie, repeating the patient's words, asking for clarifications), tone of voice, nonverbal behaviors (ie, eye contact, physical touch), and empathy (such as saying, "I can understand how difficult LBP must be for you."). This intervention model aimed to create an optimal patient-clinician relationship.[30,31] The therapist then stayed in the room during the entire treatment and during the measurement of outcomes. During this time, verbal interaction between the therapist and participant was encouraged. Finally, at the end of the session, few words of encouragement were given.

SE group. In this group, the same protocol as described for the AE group was applied. The difference was that a sham IFC intervention was used.

These treatment protocols were adapted from a previous trial explor-

ing the components of placebo effect in acupuncture for irritable bowel syndrome.[30]

Therapists and Training Methods

Three female physical therapists administered the experimental treatments. Their average clinical experience in the management of musculoskeletal disorders was 11.3 years. The therapists were formally trained in methods of patient-clinician interactions by a clinical psychologist to ensure they were able to create the 2 different therapeutic contexts (ie, limited TA and enhanced TA). The therapists were instructed in advance on the scripts for their interactions by means of a training manual and by role playing with simulated patients.[30] A video showing the limited and enhanced clinician-patient interactions used in the study is available online at ptjournal.apta.org.

Adherence to Treatment Protocols

Therapist adherence was based on how closely the therapists followed the experimental protocol.[30,32,33] Therapist adherence was assessed by videotaping all treatment sessions, of which 28 (20%) were randomly selected for evaluation. Two research assistants not involved with the study separately rated each session regarding treatment fidelity.

Procedure

At the beginning of the study, the treatment procedure was explained with a standard information sheet. Baseline measurements were then conducted. Level of disability, pain intensity, pressure pain thresholds (PPTs), and expectations of pain relief were assessed. Next, the IFC treatment was applied. After completing IFC treatment, pain intensity and expectations of pain relief were assessed again. Also, participants completed a measure of TA and a global rating scale (GRS).

All measurements under the 4 treatment conditions were made by the same trained investigator (J.F.) who was blind to the treatment applied and to the statistical analysis. Participants were blind to intervention status. To determine whether the active and sham IFC treatments were perceived differently, the difference in expectations of pain relief scores at baseline among the 4 treatments was calculated. In addition, after the session ended, participants were asked to guess the type of treatment received (ie, active IFC or sham IFC).

Outcome Measures

Pain intensity. The PI-NRS is a self-report measure of pain intensity.[34] The PI-NRS has been shown to be a reliable and valid measure of pain severity in CLBP.[35,36] The minimal clinically important difference (MCID) for LBP has been reported to range from 1.5 to 3.2 points.[37–41] Measurements of pain intensity (PI-NRS) were taken before treatment (ie, at baseline) and immediately following the end of the intervention.

Pressure pain sensitivity. Pressure pain sensitivity is the most commonly used method for quantitative analysis of local muscle pain and tenderness in pain research.[26,29,42–44] Pressure pain sensitivity was evaluated via PPT, or the minimum pressure that induces pain or discomfort.[45] This evaluation was done using a calibrated mechanical algometer (Wagner Instruments, Greenwich, Connecticut). Measurements of PPT have been shown to have good or excellent interrater (intraclass correlation coefficient [ICC]=.74–.90)[46] and intrarater reliability (ICC=.75–.99).[47–51] In addition, good values of sensitivity (0.77–0.88) and specificity (0.87–0.94) for conditions such as myofascial pain and fibromyalgia have been reported.[52,53] The minimum important difference (MID) has been reported to be $\geq$1.10 kg/cm^2/s.[26,54]

Before conducting the PPT assessment, participants were instructed in the application of the algometer and given a demonstration. A trained physical therapist assessor (J.F.) measured the PPTs by applying the algometer at a constant rate of force of 1 kg/cm^2/s. The algometer was applied perpendicularly over the right erector spinae muscle, landmarked 4 cm to the right of the spinous process of L4 for reproducibility (eFigure, available at ptjournal.apta.org). The force recorded was the minimum amount of pressure that evoked the first sensation of pain.[55,56] Participants were asked to say "stop" as soon as they felt a clear sensation of pain, distinct from pressure or discomfort.

Measurements of PPT were taken on 4 different occasions during the experimental procedure: M1 (10 minutes before treatment), M2 (time 0 or start of treatment), M3 (15 minutes into treatment), and M4 (at 30 minutes or end of treatment). On each occasion, 2 consecutive PPT measurements performed 60 seconds apart were collected and averaged for analysis.

TA. The TA between the therapist and the patient was measured using the working alliance subscale of the Pain Rehabilitation Expectations Scale (PRES). The PRES is a self-report, clinical intervention-specific assessment tool developed to measure proxy efficacy, motivation/expectations, and working alliance for rehabilitation interventions in patients with LBP.[57] Preliminary psychometric results validated the factorial structure of the PRES.[57] In addition, high values of internal consistency for each subscale (proxy efficacy, α=.93; motivation/expectations, α=.95; and working alliance, α=.96) have been reported.[57]

Level of expectations. Participants were asked to rate their expec-

Table 1.
Baseline Variables for the 4 Treatment Groups[a]

Characteristic	Group				*P*
	AL (n=30)	SL (n=29)	AE (n=29)	SE (n=29)	
Age (y)	30.5 (10.26)	30.3 (11.22)	29.7 (11.33)	29.8 (10.78)	.991
Height (cm)	170.9 (9.53)	168.2 (10.11)	169.1 (9.41)	169.4 (10.13)	.769
Weight (kg)	69.6 (18.64)	66.6 (11.99)	67.1 (13.28)	65.3 (18.64)	.695
Sex, n (%)					
Female	18 (60%)	17 (58.6%)	19 (65.5%)	17 (58.6%)	
Male	12 (40%)	12 (41.4%)	10 (34.5%)	12 (41.4%)	
PI-NRS	4.01 (0.91)	4.09 (0.10)	4.03 (0.92)	4.10 (0.12)	.986
CEQ baseline score	15.6 (2.69)	15.2 (4.51)	15 (2.73)	16 (4.80)	.898
Pain duration (mo)	45.3 (56.76)	51.1 (38.19)	51.21 (38.30)	47.28 (87.29)	.974

[a] Data are presented as mean (SD) unless otherwise specified. Significant differences at $P<.05$. The AL group received active interferential current therapy (IFC) combined with a limited therapeutic alliance (TA), the SL group received sham IFC combined with a limited TA, the AE group received active IFC combined with an enhanced TA, and the SE group received sham IFC combined with an enhanced TA. PI-NRS=pain intensity numerical rating scale, CEQ=Credibility Expectancy Questionnaire.

tations of pain relief using the Credibility and Expectancy Questionnaire (CEQ). The CEQ comprises 6 items (2 sets) and 2 factors (ie, credibility and expectancy). Items 1 to 3 measure credibility, and items 4 to 6 appraise expectancy.[58] The CEQ is considered to be a valid and reliable tool[59] to measure the expectancy construct. Expectations were assessed before treatment (ie, at baseline) and immediately after the intervention was completed.

GRS. Clinical significance and whether changes experienced were meaningful from the participant's perspective were assessed using the GRS. Patients respond by estimating the degree of change in pain experienced on a 15-point Likert scale (−7="a very great deal worse," 0="about the same," and +7="a very great deal better).[60] Changes of ±1 to 3 represent small changes, changes of ±4 to 5 represent moderate changes, and changes of ±6 to 7 represent large changes.[60]

Data Analysis

A 2-way repeated-measures multivariate analysis of variance (MANOVA) was used as the main test to evaluate the differences in PI-NRS and PPTs among treatment groups. In addition, a MANOVA test was used to evaluate differences in TA and differences in expectancies (before-after treatment) among groups after the interventions. Furthermore, a correlation between TA and differences in expectancies (before-after treatment) was conducted to determine the relationship between these variables using the Kendall tau correlation coefficient. In order to determine whether different therapists (ie, therapist effect) influenced the way that participants responded to the treatments, a 2-way MANOVA was performed. A Bonferroni post hoc test was used to determine significance between pair-wise comparisons. An a priori sample size of 116 participants (ie, 29 per group) was calculated for a 4-group MANOVA, with repeated measures to detect a change of ≥2 points on the PI-NRS with a power of 0.80, $\alpha=.05$, and a moderate effect size of 0.75 using established statistical guidelines.[61]

Calculation of effect size (Cohen *d*)[62] was conducted to determine the magnitude of the therapeutic effect and whether changes in outcomes were clinically meaningful. In addition, the calculation of MID has been commonly reported in studies aimed at evaluating the magnitude of immediate analgesic effects (ie, short follow-up) for an intervention in acute LBP[63] and CLBP.[64–66] Therefore, the MIDs for PPT and PI-NRS were calculated from the GRS following the guidelines established by Guyatt et al.[60]

SPSS version 17.0 (SPSS Inc, Chicago, Illinois) was used to perform the statistical analysis. The level of significance was set at $\alpha=.05$. The analyst was blinded to treatment allocation.

Role of the Funding Source

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Results

Participants

A total of 117 participants with CLBP were enrolled. The mean age was 30 years (SD=6.8, range=19–65). Complete data were available on all

Table 2.
Pair-Wise Comparisons for Muscle Pain Sensitivity (PPT) and Pain Intensity[a]

Measure	Group (I)	Comparison Group (J)	Mean Difference (I−J)	SE	P[b]	95% CI for Difference[b]	
						Lower Boundary	Upper Boundary
PPT	AL	SL	0.816	0.308	.05	−0.010	1.642
		AE	−0.856*	0.308	.03	−1.682	−0.030
		SE	−0.525	0.308	.54	−1.351	0.301
	SL	AL	−0.816	0.308	.05	−1.642	0.010
		AE	−1.672*	0.310	.00	−2.505	−0.839
		SE	−1.341*	0.310	.00	−2.174	−0.508
	AE	AL	0.856*	0.308	.30	0.030	1.682
		SL	1.672*	0.310	.00	0.839	2.505
		SE	0.331	0.310	1.00	−0.502	1.164
	SE	AL	0.525	0.308	.30	−0.301	1.351
		SL	1.341*	0.310	.00	0.508	2.174
		AE	−0.331	0.310	1.00	−1.164	0.502
Pain	AL	SL	7.623*	2.166	.00	1.806	13.440
		AE	−12.949*	2.166	.00	−18.766	−7.132
		SE	−4.673	2.166	.19	−10.491	1.144
	SL	AL	−7.623*	2.166	.00	−13.440	−1.806
		AE	−20.572*	2.184	.00	−26.439	−14.706
		SE	−12.297*	2.184	.00	−18.163	−6.430
	AE	AL	12.949*	2.166	.00	7.132	18.766
		SL	20.572*	2.184	.00	14.706	26.439
		SE	8.276*	2.184	.00	2.410	14.142
	SE	AL	4.673	2.166	.19	−1.144	10.491
		SL	12.297*	2.184	.00	6.430	18.163
		AE	−8.276*	2.184	.00	−14.142	−2.410

[a] Based on estimated marginal means. The AL group received active interferential current therapy (IFC) combined with a limited therapeutic alliance (TA), the SL group received sham IFC combined with a limited TA, the AE group received active IFC combined with an enhanced TA, and the SE group received sham IFC combined with an enhanced TA. SE=standard error, 95% CI=95% confidence interval, PPT=pressure pain threshold. Asterisk indicates the mean difference is significant at the .05 level.
[b] Bonferroni adjustment for multiple comparisons.

data points for all participants. Baseline characteristics were not significantly different among the groups on any variable (Tab. 1).

Differences (Pretreatment-Posttreatment) in Pain Intensity and PPT

Statistically significant differences were observed among groups on the mean change (pretreatment-posttreatment) of PPTs and pain intensity scores ($P<.05$). Results of the multiple comparisons among groups using the Bonferroni post hoc test for PPTs and pain intensity are displayed in Table 2.

Pain intensity. Mean differences on the PI-NPR were 1.83 cm (95% confidence interval [95% CI]=14.3–20.3), 1.03 cm (95% CI=6.6–12.7), 3.13 cm (95% CI=27.2–33.3), and 2.22 cm (95% CI=18.9–25.0) for the AL, SL, AE, and SE groups, respectively. Percentages of pain reduction were 45.6%, 24.5%, 77.4%, and 54.5% for the AL, SL, AE, and SE groups, respectively (Tab. 3). Significant differences ($P<.01$) were found between the SL group and the AL, AE, and SE groups (Fig. 2). The larger group differences occurred between the SL group and the 2 enhanced groups (AE, SE). When compared with the SL group, the differences were 23 mm (deemed clinically meaningful) and 11.9 mm for the AE and SE groups, respectively.

Muscle pain sensitivity. Mean differences in PPTs were 1.25 kg (95% CI=0.7–1.6), 0.39 kg (95% CI=0.2–0.8), 2.09 kg (95% CI=1.6–2.5), and 1.75 kg (95% CI=1.3–2.1), for the

Table 3.
Mean Differences (Baseline and Posttreatment) in Muscle Pain Sensitivity and Pain Intensity Scores for the 4 Treatment Groups[a]

Outcome Measure	Group			
	AL (n=30)	SL (n=29)	AE (n=29)	SE (n=29)
Pain intensity (PI-NRS), cm				
Baseline	4.01 (0.91)	4.09 (1.0)	4.03 (0.92)	4.10 (1.29)
Posttreatment	2.18 (1.17)	3.06 (1.27)	0.89 (0.98)	1.88 (1.44)
Difference	1.83 (0.85)	1.03 (0.65)	3.13 (0.97)*	2.22 (0.75)*
% of change (pain reduction)	45.6	24.5	77.4	54.5
Muscle pain sensitivity (PPT), kg/cm^2/s				
Baseline	3.89 (1.8)	3.76 (1.8)	4.11 (1.8)	4.5 (2.3)
Posttreatment	5.15 (2.6)	4.16 (1.6)	6.21 (2.6)	6.3 (2.8)
Difference	1.25 (1.3)*	0.39 (0.9)	2.09 (1.1)*	1.75 (1.3)*
% of change (increased PPT)	32.6	10.5	51.5	40.0

[a] Data are presented as mean (SD). The AL group received active interferential current therapy (IFC) combined with a limited therapeutic alliance (TA), the SL group received sham IFC combined with a limited TA, the AE group received active IFC combined with an enhanced TA, and the SE group received sham IFC combined with an enhanced TA. PI-NRS=pain intensity numerical rating scale, PPT=pain pressure threshold. Asterisk indicates findings were clinically important according to indexes based on distribution (ie, minimally important difference, standard error of measurement) reported in the literature.

AL, SL, AE, and SE groups, respectively. Percentages of increased pain thresholds were 32.6%, 10.5%, 51.5%, and 40.0% for the AL, SL, AE, and SE groups, respectively (Tab. 3). Significant differences ($P<.05$) were found between the SL group and the AE and SE groups (Fig. 3). Larger group differences occurred between the SL group and the 2 enhanced groups (AE, SE). When compared with the SL group, the differences were 1.7 kg and 1.4 kg for the AE and SE groups, respectively (both clinically meaningful).

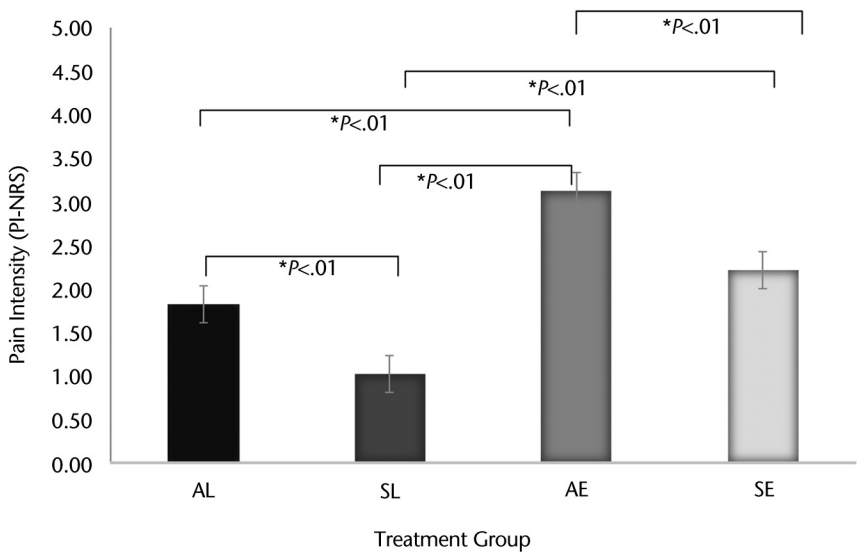

Figure 2.
Between-group differences for pain intensity scores. Results are shown as mean ± standard error of measurement. The AL group received active interferential current therapy (IFC) combined with a limited therapeutic alliance (TA), the SL group received sham IFC combined with a limited TA, the AE group received active IFC combined with an enhanced TA, and the SE group received sham IFC combined with an enhanced TA. PI-NRS=pain intensity numerical rating scale. Asterisk indicates significant at $P<.01$.

Differences in TA and Patients' Expectations

Mean (SD) scores for TA (PRES) assessed at the end of the treatment were 30.7 (6.0), 42.5 (2.7), 34.4 (4.5), and 42.8 (1.81) points for the SL, SE, AL, and AE groups, respectively. There were significant differences in TA among groups ($P<.05$). All of the groups differed with each other except for the comparison between the AE and SE groups (eTable, available at ptjournal.apta.org).

Mean differences (pretreatment-posttreatment) in expectation scores (CEQ) were 0.9, 2.9, 2.1, and 5.8 points for the SL, SE, AL, and AE groups, respectively. There were statistically significant differences in mean differences of CEQ scores among groups. Specifically, there were significant differences between the AL and AE groups and between the SL and AE groups (eTable).

The Kendall tau correlation coefficients indicated that there was a

very little association between TA and differences in expectancies (pretreatment-posttreatment) (τ=.24). Based on the coefficient of variation, it could be said that only 4% of the variance of expectancies was accounted for by the TA. Therefore, although expectations increased for the enhanced groups, it appears that this was not the main reason for the observed improvement.

Therapist Effect

No significant difference was observed among therapists (P=.18) or for the interaction between therapists and groups (P=.10) for either pain or PPT outcomes. In addition, TA scores among therapists were not different (P=.53). In other words, therapists were similar in providing the treatment and did not have an influence in the way that patients responded to different treatments.

Clinical Importance

Pain intensity. Group differences between pretreatment and posttreatment measurements for the AE group (3.13 cm) and the SE group (2.22 cm) exceeded suggested values for the MCID.[38–41] Clinically important effect sizes (Cohen d) were found between the AE and SL groups (d=2.51), SE and SL groups (d=1.73), and AL and SL groups (d=0.89). In the same way, large effect sizes were calculated between the AE and AL groups (d=1.36) and the AE and SE groups (d=1.0).

Muscle pain sensitivity. Differences for the AL group (1.2 kg/cm^2/s), AE group (2.0 kg/cm^2/s), and SE group (1.7 kg/cm^2/s) reached values deemed to be clinically meaningful.[26,54] In the same way, clinically important effect sizes (Cohen d) were found between the AE and SL groups (d=0.93) and the SE and SL groups (d=0.94). A moderate effect size (d=0.48) was calculated between the AL and SL groups.

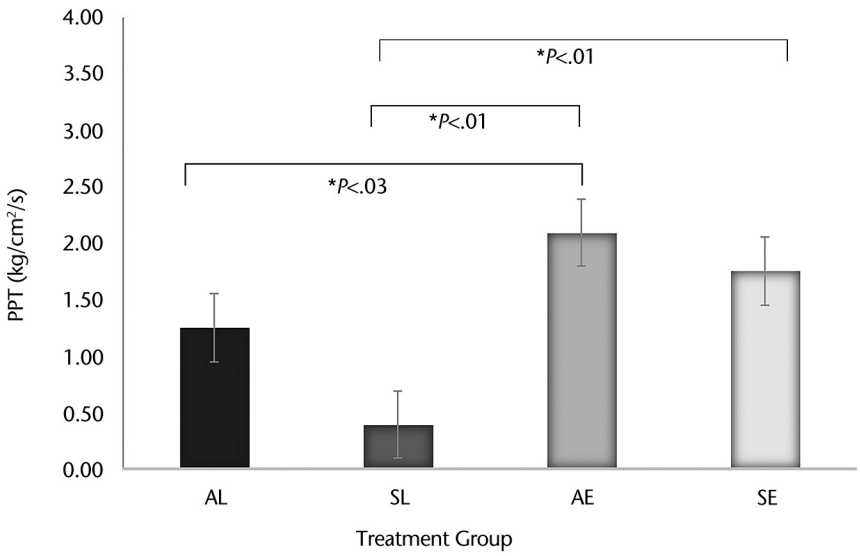

Figure 3.
Between-group differences for pressure pain threshold (PPT) measurements at baseline and posttreatment. Results are shown as mean ± standard error of measurement. The AL group received active interferential current therapy (IFC) combined with a limited therapeutic alliance (TA), the SL group received sham IFC combined with a limited TA, the AE group received active IFC combined with an enhanced TA, and the SE group received sham IFC combined with an enhanced TA. Asterisk indicates significant at P<.05.

GRS. The average change in GRS ratings reported by the participants was 4, 2, 5, and 4 points for the AL, SL, AE, and SE groups, respectively. Ninety percent of the participants in the AE group perceived the change as moderate (ie, ±4–5 points), whereas this change was reported in fewer than 5% of the participants in the SL group. The average pain intensity considered meaningful for participants was calculated to be 12 mm. The average PPT considered minimally important for participants was calculated to be 1.05 kg/cm^2/s.

Blinding Assessment

Differences in expectations at baseline among the 4 treatment groups were not significant (P=.90, Tab. 1). When participants were asked at the end of the session to guess the type of treatment (ie, active or sham IFC), 87% (n=25) of participants in the SL group and 97% (n=28) of the participants in the SE group thought they had been treated with an active intervention. In other words, only 8% (n=5) of all participants in both sham IFC groups (n=58) correctly guessed that they had not received an active treatment.

These findings suggest that the blinding procedures were adequate and that both active and sham treatments were perceived equally by the participants. No one in the active groups (AL, AE) thought that they had received a sham intervention.

Adherence to Treatment Protocols

Evaluation of videotaped interactions indicated that 86% of the sessions evaluated were rated as adherent to the protocol. Reliability of these ratings between the raters was considered excellent (ICC=.95, 95% CI=0.8–0.9, P<.01).

Adverse Effects

Two participants (one woman in the AL group and one man in the SL

group) reported an increase in their pain with no apparent reason after receiving the IFC treatment. No other adverse effects were reported.

Discussion

This study examined the impact of TA on clinical physical therapy outcomes in patients with nonspecific CLBP. The most striking result was the meaningful effect of enhanced TA when applied with active IFC on pain modulation. Thus, factors related to the therapist (ie, TA) appeared to be as important as the therapy (ie, IFC) in pain modulation, and their interaction may produce substantive clinical benefits.

Our results are in line with the findings of a recent study[30] that confirmed a supportive patient-practitioner relationship is a potent component of placebo effects in the management of irritable bowel syndrome. In that study, the magnitude of the effect for an augmented interaction (ie, 45 minutes' duration, including supportive, warm, active listening behaviors) between the practitioner and the patient was not only statistically but also clinically important compared with limited interaction (ie, 5 minutes) or a waiting list control group. Although methodological differences are present between the studies, similarities such as the intervention protocol and the use of subjective outcome measures make the comparisons between these 2 studies worth considering.

In physical therapy, it is conceivable that the patients' perceived differences in treatment responsiveness are likely related to the therapist's interpersonal skills rather than the appropriateness of the treatment. This notion may have some support considering the nature of therapeutic interventions in which features such as touch, care, and attention play a relevant role. The results of recent systematic reviews and meta-analyses about common nonpharmacological interventions used by physical therapists to treat patients with CLBP have shown similar and modest short-term benefit, but little long-term benefit.[67,68] In clinical settings, it is possible that treatments applied in a neutral or "business-like" manner (ie, limited contextual factors) may translate into less-than-optimal clinical outcomes.

In this study, therapists in the enhanced groups communicated (verbally and nonverbally) not only to translate information but also to engage with patients in meaningful ways. They communicated in order to convey broader concepts such as empathy, warmth, caring, encouragement, and support. These are widely accepted as critical aspects of TA.[12]

There is a difference between interacting and engaging and between connecting and meaningfully connecting. All require communication, but engaging and meaningfully connecting enhance the relationship. Thus, in this study, the interaction between patient and therapist was based on more than just improved therapist communication.

Magnitude of the Effect

The results of this study showed a clear dose-response effect. The largest beneficial effect was seen with the AE group, and the smallest effect was observed in the SL group. The magnitude of the effect in the AE group was larger than we had anticipated. On average, participants in the AE group had decreased pain intensity by 3.1 points on the PI-NRS. In addition, they increased their PPTs by 2.09 kg/cm^2/s. These values greatly exceeded what is considered a clinically meaningful difference for these outcomes.[26,54]

Clinical outcomes for participants in the SL group showed the smallest effect and are not considered clinically meaningful. Interestingly, the sham IFC with an enhanced TA (SE group) demonstrated better results than the active IFC with a limited TA (AL group). Although this difference was not statistically different, the question of whether a sham application (ie, no active ingredient) in an enhanced TA is better than an active intervention (ie, active ingredient included) in a limited TA would be worthwhile exploring further.

The large effect sizes (Cohen *d*) in pain intensity shown in this study for the enhanced groups (AE, $d=3.2$; SE, $d=1.6$) are in agreement with the results of previous meta-analyses studying the mechanisms of placebo analgesia.[69,70] In these studies, the manipulation of expectations through instructional sets or conditioning protocols also was able to produce large placebo effects ($d=0.95$,[70] $d=1.00$[69]). Thus, placebo effects appear to be larger when expectations and TA are experimentally manipulated, and these seem to be equally effective mechanisms to produce significant placebo responses.

Analysis of clinical importance from the patient's perspective showed that most participants rated their reduction in pain after the treatment as being clinically meaningful. Thus, average GRS scores were 5, 4, and 4 points for the AE, SE, and AL groups, respectively. These scores contrasted with the perception of change in pain rated in the participants in the SL group, where the average GRS score was 2 points, representing a small change.

Mechanisms

Personal characteristics of clinicians can influence treatment outcomes either positively or negatively. Some potential behavioral styles may favor or inhibit placebo responses. For

example, the clinician, by listening, sending appropriate messages, and physically contacting the patient during the clinical examination, may induce a strong placebo effect, whereas inappropriate comments may exacerbate symptoms.[71] Other therapeutic variables that enhance placebo responses include the amount of time the clinician spends with patients and a warm, empathic interaction.[30,32]

In this study, physical therapists in the enhanced groups were present for the whole treatment session, and they used behaviors such as active listening, empathy, and words of encouragement. Interaction between practitioner and patient has been considered central in determining outcome in back pain and neck pain.[72,73] The therapists in this study were skilled clinicians, empathetic and open to answering questions during the interaction with the participants while delivering the treatments. In addition, the enhanced communication skills and the concerned optimism exhibited about the patient by the physical therapist during the treatment session could potentially explain these results. Finally, available data suggest that the placebo-associated improvement is strongly influenced by the patient's awareness of the procedure and depends on the invasiveness of the procedure; elaborate rituals can produce effects that are greater than a simple pill ingestion.[24,74] Thus, the application of technologically impressive equipment such as an IFC machine may have resulted in a highly evocative and therapeutically potent agent for the patients in our study.

Therapist Effects

In this study, we did not find significant differences among the therapists or interaction between therapists and groups on clinical outcomes, which demonstrated that individual differences (ie, personality) among therapists did not influence the placebo response. This finding suggests that when different therapists adhere to a highly scripted and standardized treatment protocol, their personality attributes may not have an influence on the way patients respond to treatments. This finding also suggests that therapists who do not have great innate skills at building TA may achieve good results by following protocols.

Strengths and Limitations of the Study

To our knowledge, this is the first experimental controlled study aimed at exploring the effects of manipulating the TA in physical therapy treatment of chronic pain. The testing protocol was standardized to minimize bias, but this standardization made the environment somewhat different from routine clinical practice. Our study had high internal validity, as shown by adequate randomization, concealed allocation, baseline comparability among groups, and evidence of effective blinding of the research team and participants. Experienced clinicians delivered the interventions in accordance with a highly standardized study protocol designed to deliver different therapeutic contexts.

Although the results of this study are encouraging, any inference from this study needs to be tempered due to some limitations. First, the positive effects shown in the enhanced groups (ie, AE, SE) could have been due to the possibility that patients in these groups were more willing to please the therapist compared with the patients in the limited groups (ie, social desirability bias). Although this may be possible when reporting pain scores, we believe that in a less subjective outcome such as PPT, participants will not respond in the same socially desirable manner. Second, because we did not include a "no treatment" control group, the results of this study might warrant close scrutiny. It is possible that participants in the enhanced groups had a reduction in their pain due to natural variability in pain levels alone. However, this confounder (pain variability) would have equally affected all groups and thus would not account for the differences in the analgesic effect observed across groups. Third, in order to have a relatively homogeneous LBP sample, this study included a young and moderated disabled LBP population (average age=30 years, average Oswestry Disability Index score=22 points). Patients with more severe symptoms may have a more complex clinical presentation, and future research should explore the effect of TA in an older and more severely disabled population. Fourth, our study protocol aimed to test the immediate effect of the TA. Therefore, there is a need to determine whether these reported benefits could be sustained in the longer term. Future research is needed to overcome these limitations and expand the analysis of the existing evidence regarding the effects of TA as another therapeutic agent within clinical practice.

Implications for Practice

Our results call for a more in-depth consideration of contextual factors when delivering physical therapy. The results of this study suggest that maximizing TA during therapy is accompanied by significant therapeutic benefits. The effect of accepted interventions (ie, IFC) can be improved when clinicians interact positively with their patients.

Physical therapists should consider optimizing the psychosocial context in the clinical management of chronic pain conditions. In other words, the TA may be considered as another therapeutic agent. Therefore, physical therapists' awareness of this factor when delivering their interventions could lead to better outcomes.

Conclusion

The context in which physical therapy interventions are offered has the potential to dramatically improve therapeutic effects. Enhanced TA combined with active IFC appears to lead to clinically meaningful improvements in outcomes when treating patients with CLBP. Our results support efforts to foster enhanced alliance between patients and providers when delivering physical therapy interventions for chronic pain. Factors other than the specific ingredient of a treatment may have a large role in achieving positive clinical outcomes, and exploring them is central to physical therapist practice.

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