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Effects of Self-Hypnosis Training and Emg Biofeedback Relaxation Training on Chronic Pain in Persons with Spinal-Cord Injury[1]

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Abstract

Thirty-seven adults with spinal-cord injury and chronic pain were randomly assigned to receive 10 sessions of self-hypnosis (HYP) or EMG biofeedback relaxation (BIO) training for pain management. Participants in both treatment conditions reported sub-stantial, but similar, decreases in pain intensity from before to after the treatment sessions. However, participants in the HYP condition, but not the BIO condition, reported statistically significant decreases in daily average pain pre- to posttreatment. These pre- to posttreatment decreases in pain reported by the HYP participants were maintained at 3-month follow-up. Participants in the HYP condition, but not the BIO condition, also reported significant pre- to posttreatment increases in perceived control over pain, but this change was not maintained at the 3-month follow-up.

Chronic pain is a significant problem in many persons with spinal-cord injury (SCI). Not only does a substantial proportion (about one third) of patients with SCI experience severe, ongoing pain but longitudinal research indicates that once a person with SCI develops pain it rarely resolves (Ehde et al., 2003; Jensen, Hoffman, & Cardenas, 2005). Moreover, chronic SCI pain is refractory to pain treatment; the majority of pain treatments available to persons with SCI have been shown to benefit only a subset of patients (Cardenas & Jensen, 2006; Warms, Turner, Marshall, & Cardenas, 2002). In short, there continues to be a need to develop effective pain treatments for persons with SCI.

There is growing evidence that hypnosis treatment can reduce pain intensity in at least some patients with SCI and otherwise refractory chronic pain. For example, in one small case series, 4 patients with SCI and chronic pain reported substantial decreases in pain and sleep disturbance pre- to posthypnosis treatment (Jensen & Barber, 2000). At 1-year follow-up, 2 of these patients had maintained their treatment gains. In a subsequent larger case series, in which 33 patients with a number of disabilities (13 of whom had SCI) and chronic pain participated, hypnosis treatment resulted in significant pre- to posttreatment changes in average pain intensity (Jensen, Hanley, et al., 2005). Moreover, most of the patients who benefited from treatment maintained those benefits at the 12-month follow-up point, with 23% of the otherwise refractory sample reporting clinically meaningful decreases in pain relative to their pretreatment levels (Jensen et al., 2008). Also, a large majority of the patients, including many who did not report substantial decreases in daily average pain, reported that they were highly satisfied with the hypnosis treatment (Jensen et al., 2008).

When those patients who did not report large decreases in pain with treatment were questioned about the apparent discrepancy between (a) their lack of substantial decrease in daily pain and (b) their high level of treatment satisfaction, most reported that they used the self-hypnosis strategies they learned in treatment to obtain temporary relief from pain, even if this did not translate into substantial *permanent* decreases in average pain (Jensen et al., 2006). For example, at 12-months posttreatment, when they practiced self-hypnosis skills, the participants in the case series reported an average pain relief of 5.5 (on a 0 = *no relief* to 10 = *complete relief* scale) following use of self-hypnosis and that the pain relief they achieved lasted for an average of 4.1 hours (Jensen et al., 2008).

These findings suggest two types of outcomes of hypnosis treatment among participants in our previous studies. First, although hypnosis treatment may not provide a "cure" for chronic pain (e.g., no patient in the clinical case series reported that he or she was pain-free after treatment), the fact that a substantial subset of patients reported clinically meaningful decreases in average daily pain suggests that hypnosis treatment can produce long-lasting changes in daily pain for some patients. Second, both (a) the large number of patients who continued to use self-hypnosis 12 months after treatment and (b) the significant pain relief that reportedly followed the practice of self-hypnosis suggest a second, more common, outcome of self-hypnosis training; that is,

training in self-hypnosis appears to provide patients with a tool to help decrease their experience of pain on a short-term basis. These patients appeared to use self-hypnosis like they might an effective analgesic medication. However, unlike many analgesic medications that can produce negative side effects such as constipation and sedation, the "side effects" of self-hypnosis are overwhelmingly positive and include such additional benefits as increased feelings of wellbeing, improved sleep, and an increased sense of control over pain (Jensen et al., 2006).

The positive initial findings concerning the efficacy of hypnosis treatment for pain in persons with SCI need to be confirmed in randomized controlled trials. However, the design of the control condition for such trials poses significant challenges to the hypnosis researcher (Jensen & Patterson, 2005). Such challenges are due largely to the fact that, unlike medication trials in which a placebo treatment can be disguised as an active treatment (and even produce side effects when active placebos are used) and can therefore be administered in a double-blind fashion, it is very difficult to design control treatments in hypnosis trials that look convincingly like hypnosis and, at the same time, do not include hypnotic components. This means that the experimental and control treatments in hypnosis trials can probably not be administered in a double-blind fashion. Because of this methodological challenge, we have argued that, rather than seek to design the single placebo-controlled definitive study that can prove or disprove the efficacy of hypnotic treatment, investigators need to compare hypnotic interventions to a variety of control conditions, each of which might control for different factors that could explain the effects of hypnosis (Jensen & Patterson). From a growing body of such research, conclusions can then be drawn about both the efficacy (if it works) and mechanisms (why it works) of hypnotic analgesia.

In the current study, we used what we thought would be a minimally effective treatment as the control condition (Jensen & Patterson, 2005); that is, an intervention that might have some limited benefit for persons with pain and would elicit a similar degree of outcome expectancy but that also did not share some critical features unique to hypnosis. We chose EMG-assisted biofeedback relaxation training because it had the following features: (a) it could be administered in a way that was similar to hypnosis (e.g., in the same number of face-to-face sessions, so it would control for therapist attention and time); (b) it could be described using exactly the same words used to describe a hypnotic-analgesia training intervention—that is, "As one of two treatments you will be randomly assigned to that contains both relaxation and hypnotic components, such as focused attention;" and (c) it has a history of use for pain treatment and so could be described, like the hypnosis intervention, as an intervention that "… has demonstrated efficacy for benefiting persons with chronic pain." Thus, an EMG biofeedback control treatment can be administered in a way that elicited the same outcome expectancies as the hypnosis treatment. We predicted that if hypnotic analgesia had specific effects beyond its effects on physical relaxation or expectancy, we would observe a larger effect for the hypnosis intervention than for the biofeedback intervention.

In addition, an intriguing finding from one of our previous case series studies concerns a possible difference in response to hypnotic-analgesia treatment as a function of diagnosis. Specifically, we found that persons with pain and acquired amputation reported greater pre-to posttreatment decreases in average daily pain (43% average decrease) than those with multiple sclerosis (MS; 10% decrease) or SCI (17% decrease; Jensen, Hanley, et al., 2005). Moreover, in that study, more patients with amputation reported clinically meaningful decreases in daily pain than patients with either SCI or MS (60% for amputation versus 27% or 33% for SCI and MS, respectively; Jensen, Hanley, et al., 2005). These results suggest the possibility that pain from different sources or causes could potentially be differentially responsive to hypnotic treatment. To examine this issue further, we recruited participants into this study with both neuropathic pain (pain related to dysfunction in or damage to nerves) and nonneuropathic pain

(pain related to dysfunction in or damage to other physical structures, such as muscle, skin, or bones) to allow for comparisons in outcome between these two types of pain.

Our primary study hypothesis was that a hypnosis intervention would result in greater immediate and long-lasting decreases in pain intensity than an EMG-assisted biofeedback relaxation training control treatment. In addition, as we have done in previous studies (e.g., Jensen, Hanley, et al., 2005; Jensen et al., 2008, 2009), we examined the effects of treatment on a number of secondary outcome measures, including pain unpleasantness, depressive symptoms, pain interference, and perceived control over pain. Based on our previous findings (Jensen, Hanley, et al.), we predicted that the hypnosis intervention would be more effective than the biofeedback control condition in reducing pain unpleasantness and increasing perceived control over pain but that the two interventions would have the same effects on depressive symptoms and pain interference. In a series of additional exploratory analyses, we also examined: (a) differences between the two interventions on global satisfaction with treatment; (b) for patients who received hypnosis, the frequency and effects of use of self-hypnosis for pain management 3 months after treatment; (c) the association between treatment outcome and two variables hypothesized to influence the effects of hypnotic interventions (global hypnotizability and patient expectations concerning treatment outcome); and (d) whether efficacy of the treatments varies as a function of pain diagnosis (i.e., neuropathic versus nonneuropathic pain).

METHOD

Participants

Potential participants in this study were identified from a list of participants in previous survey studies of chronic pain (Jensen, Hoffman, et al., 2005) who had agreed to be contacted about future research studies and met eligibility criteria for the current study. Participants were also recruited from flyers and brochures distributed in clinics frequented by persons with SCI, from newsletters, or by word of mouth. The inclusion criteria for this study were: (a) having an SCI for at least 6 months; (b) reporting chronic daily pain that was bothersome; (c) being 18 years old or older; (d) being able to speak, read, and write English; and (e) expressing an interest in participating in a clinical trial comparing two treatments for chronic pain. Exclusion criteria were: (a) evidence of severe psychopathology (i.e., symptoms of psychosis on interview or endorsement of active suicidal ideation with intent within the past 6 months) and (b) a score of 21 or greater on the Telephone Interview of Cognitive Status (Brandt, Spencer, & Folstein, 1988), indicative of severe cognitive deficits that could potentially interfere with the focused attention required for hypnosis.

Of 71 potential participants who contacted us or were contacted by us about the study, 37 were found to be both eligible for the study and interested in participating once the study was described to them. Pretreatment data were collected from all 37 of these participants, and they were then randomized into one of the two treatment conditions, hypnosis (HYP) or biofeedback (BIO). Three participants (2 from the HYP and 1 from the BIO conditions) subsequently dropped out of the study during treatment, so posttreatment data were available for only 34 participants. Pain intensity and pain unpleasantness data from the 3-month follow-up assessment were available for 31 participants (3 BIO participants and 3 HYP participants were entirely lost to follow-up at the 3-month follow-up assessment point), and data concerning the other outcome variables from all three assessment points were available for 30 participants (due to the fact that 1 participant was contacted at follow-up for the three shorter interviews in which pain intensity and unpleasantness were assessed but could not be contacted for the longer interview in which the other outcome variables were assessed).

Of the 37 participants randomized to the two treatment conditions, 28 completed all 10 treatment sessions and were classified as treatment completers. Two participants (both in the HYP condition) completed one treatment session only, 1 participant (in the HYP condition) completed two sessions, 2 participants (both in the BIO condition) completed three sessions, 1 participant (in the BIO condition) completed seven sessions, and 3 participants (2 in the HYP and 1 in the BIO condition) completed eight treatment sessions. The 9 participants who completed eight or fewer sessions were classified as treatment noncompleters (5 had been assigned to the HYP condition and 4 to the BIO condition). All analyses were conducted for both (a) the entire sample for which data were available, whether or not they completed treatment (intent to treat [ITT] analyses) and (b) for those participants who completed treatment (efficacy analyses).

The mean age of the 37 randomized study participants was 49.5 years (range = 19–70 years). Twenty-eight (76%) of the participants were men, and 9 (24%) were women. Most (35, or 95%) described their ethnicity as Caucasian, and 2 (5%) described their ethnicity as Native American. A medical evaluation, performed by one of the study investigators (DDC), classified the primary pain problem as one of six types (SCI pain, transition zone pain, radicular pain, visceral pain, mechanical spine pain, overuse pain; see Cardenas, Turner, Warms, & Marshall, 2002). Seventeen had one of three types of neuropathic pain: 12 of these had SCI pain, defined as a neuropathic diffuse pain below the level of injury in areas without normal sensation and not affected by position; 4 had transition zone pain, defined as bilateral allodynia at the level of injury; and 1 had radicular pain, defined as pain at any dermatomal level, usually unilateral, usually radiating, related to activity, affected by position, and not worse with light touch. Twenty of the participants had one of three types of nonneuropathic pain: 4 had visceral pain defined as pain in the abdomen not related to activity or affected by position or made worse with light touch; 9 had mechanical spine pain, defined as pain in the back or neck, often bilateral, related to activity and sometimes position but not worse with light touch; and 7 had overuse pain, often above the injury in areas of normal sensation or below in incomplete injury, related to activity, sometimes affected by position, and not worse with light touch.

Intervention Protocols

The HYP intervention protocol consisted of 10 sessions of hypnotic analgesia and self-hypnosis training administered as frequently as daily (i.e., over the course of 2 weeks) or as infrequently as weekly, depending upon the availability and preferences of the participant. All of the sessions were based on a protocol written by three of the study investigators (MPJ, JB, and DRP).[3] All study clinicians (MPJ, JMR, MAH, KAR, IRM, JME, TLO, BLS) were given clinical supervision by a study investigator with more than 30 years of clinical experience in the hypnotic treatment of chronic pain (JB). To maximize standardization of suggestions across clinicians, the intervention-protocol scripts were used by the study clinicians during each treatment session; although minor wording changes in the scripts were allowed if the clinician judged that this would facilitate the verbal flow of the script.

The intervention script for the first two treatment sessions took approximately 40 minutes and began with an induction followed by five specific suggestions for analgesia or comfort/relaxation. The five suggestions given were for (a) decreased pain, (b) deep relaxation, (c) hypnotic anesthesia, (d) decreased unpleasantness, and (e) sensory substitution. After the first suggestion, participants were asked to return to a fully alert state and then underwent a second induction followed by a second suggestion. This process was repeated until all five analgesic suggestions were administered. The order of the five analgesic suggestions was randomized using a Latin-square design, so that each suggestion had an equal chance of being administered

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[3]Copies of the entire protocol script are available from the first author.

in each position. A final induction was administered after the fifth analgesia suggestion, after which the participants were given posthypnotic suggestions for self-hypnosis and extended analgesia efficacy. Each induction was preceded by a cue ("Take a deep breath … hold it … hold it for a moment … and let it out. Notice how comfortable that feels …"), so that the cue was linked to the induction and subsequent analgesia suggestions; participants were also instructed to begin each home practice session with this cue to enhance this association further. Participants received all five analgesia suggestions plus the posthypnosis suggestions during the first two sessions.

Following the first two sessions, the treating clinicians selected the analgesia suggestion to which the participant appeared most responsive to (in addition to the decreased-suffering suggestion) and then provided that suggestion along with the decreased-suffering suggestion for each subsequent session. The decreased-suffering suggestion was included in each session based on our clinical experience that many patients respond well to it, including those with minimal hypnotic talent, given its focus on the meaning of pain. For example:

> You may already be aware that the pain intensity, and the distress that pain can produce are two different things… . It is possible to be aware of a painful sensation, but not be bothered by it… . Maybe it helps to remember that these sensations don't really mean you need to do anything… . You really don't need to pay attention to them, and you certainly don't need to feel bothered by them.

Sessions 3 and 4 were recorded, and a tape or CD of these sessions was given to the participant for practice, with the instructions that they listen to the tape or CD "at least" once a day, and more if they were able. Participants were also encouraged to practice on their own, without the use of the recording, as often as they would like and found helpful. More details of the hypnosis-treatment condition are provided in Jensen, Hanley, et al. (2005), and the entire script of the HYP intervention is available from the first author. Finally, the electrodes used to assess physiological responding in the BIO subjects (see below) were also placed on the HYP participants to ensure as much similarity between the treatment conditions as possible.

The BIO intervention consisted of 10 sessions of EMG biofeedback, using a J & J Engineering I-330 C-2 biofeedback module and program, which is run by a laptop computer, for monitoring and feedback. At the beginning of the biofeedback sessions, the clinician prepped the participant's skin where electrodes were to be placed by cleaning it with rubbing alcohol and then placed two active electrodes (with conductive paste) on the participant's forehead (one just above each eye) and one ground electrode on the patient's nondominant hand. Once the electrodes were in place, the clinician administered the pretreatment measures (i.e., pain intensity ratings, treatment expectations, and motivation) to allow for a period of rest and habituation. Throughout the subsequent session, frontalis EMG activity was assessed, processed by the software and then fed back to the participants as a repeating tone, which lowered in frequency as EMG activity decreased. Also throughout each session, the clinician provided ongoing encouragement and praise when the tone became lower.

In order to make the HYP and BIO conditions as comparable as possible in terms of the study procedures, participants in the BIO condition were also given an audio recording at the third session. This recording, made by the clinician outside of the session, included a relaxation exercise with no direct suggestions for pain relief. The exercise asked participants to systematically imagine relaxing all the muscle groups in the body and was similar to the deep relaxation instructions that were part of the HYP condition (see above). These recordings were burned onto CDs or recorded onto audiotapes. They were then given to the BIO participants with the same instructions as those given to the HYP participants when the HYP participants were given their recordings (i.e., to listen to the recording "at least" once a day, and more if they are able). Also, like the HYP participants, the participants in the BIO condition were

encouraged to practice relaxation on their own, without the recordings, as often as they would like to and found helpful. The rationale given to participants in the BIO condition was that practice with the audio recording could help extend any benefits they received from the biofeedback intervention.

Randomization

All study participants were randomized to either the HYP or BIO treatment conditions using a computer program, written so that about two thirds of the participants would receive HYP and one third BIO, with every participant having at least some chance of participating in either condition when randomization occurred. We recruited more participants into the HYP condition to help ensure an adequate number of subjects for analyses involving the prediction of response to HYP treatment, as well as to help ensure adequate statistical power to be able to compare the rates of response to HYP in the current study to those of other samples in future studies. In all, 23 (63%) participants were assigned to the HYP treatment and 14 (37%) to the BIO treatment.

The participants in each treatment condition were compared on all demographic and pretreatment outcome variables to determine the success of the randomization procedures in creating equivalent groups, using chi-square analyses for categorical variables and t tests for continuous variables. The results of these analyses indicated similarity between participants assigned to the two treatment conditions for a number of variables (presession average pain intensity, pre- and post-first-session treatment outcome expectancies, sex, ethnicity, hypnotizability score, pain type). However, a number of the pretreatment outcome variables differed between participants assigned to the two treatment conditions, such that those assigned to the HYP treatment reported significantly more average daily pain intensity, Mean (SD) = 5.72 (1.87) versus 3.95 (2.04), $t(35)$ = 2.71, $p < .05$; less perceived control over pain, Mean (SD) Survey of Pain Attitudes Control scale score = 1.70 (0.90) versus 2.41 (0.87), $t(35)$ = 2.34, $p < .05$; more depression, Mean (SD) Center for Epidemiological Studies Depression scale score = 21.99 (11.68) versus 11.64 (8.37), $t(35)$ = 2.89, $p < .01$; and more pain interference, Mean (SD) Brief Pain Inventory Pain Interference scale score = 4.91 (2.46) versus 3.01 (2.59), $t(35)$ = 2.24, $p < .05$; than those assigned to the BIO condition. Thus, the randomization procedures did not result in completely equivalent groups on all study measures before treatment.

Measures and Assessment Procedures

Primary outcome measures—The two primary outcome domains of this study were (a) average daily pain intensity, assessed at pretreatment, posttreatment, and at 3-month follow-up, and (b) current pain intensity, assessed just before and just after each treatment session. Both types of pain were measured using 0–10 numerical rating scales (NRS), with 0 = *no pain sensation* and 10 = *the most intense pain sensation imaginable*. The 0–10 NRS has been recommended as the best measure to use for pain intensity in pain clinical trials (Dworkin et al., 2005) because of (a) the strong evidence for its validity as evidenced by its strong associations with other measures of pain intensity and responsivity to analgesic treatment, (b) understandability and ease of use, and (c) ease of administration and scoring (Jensen & Karoly, 2001).

Average daily pain intensity was assessed via four telephone interviews made during a 7-day window at each of three assessment points (pretreatment, posttreatment, and 3-month follow-up). During these interviews, participants were asked to rate their average pain intensity over the past 24 hours on the NRS, and the ratings of 24-hour average pain intensity were combined into composite scores representing their usual daily pain (average of the ratings from the four interviews). If a participant could not be contacted four times within a 7-day period by the

research assistant, the composite scores were created by averaging the ratings that could be obtained. The immediate treatment effects on pain were examined by asking participants to rate their current pain intensity on 0–10 NRSs before and after each treatment session. Pre- to postsession change scores were then computed for each session and then averaged across all sessions.

In addition to the primary outcome domains, a number of secondary outcome domains were assessed. These included: (a) average daily pain unpleasantness, pain interference, depressive symptoms, perceived control over pain; (b) global satisfaction with treatment; and, for those who were given self-hypnosis training; and (c) the frequency and effects of self-hypnosis practice.

Average daily pain unpleasantness was assessed using the same procedures used to assess average daily pain intensity; that is, via four telephone interviews made during a 7-day window at pretreatment, posttreatment, and 3-month follow-up. To assess this outcome domain, participants were asked to rate their average pain unpleasantness over the past 24 hours on a 0–10 NRS, with 0 = *not bad at all* and 10 = *the most intense bad feeling possible for me*. The four ratings of 24-hour average pain unpleasantness were combined into composite measures.

Pain interference with activities was assessed using a modified version of the Pain Interference Scale from the Brief Pain Inventory (BPI; Cleeland & Ryan, 1994; Daut, Cleeland, & Flannery, 1983). The original version of this scale asks respondents to rate the degree to which pain interferes with seven daily activities, including general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life. For use in the current study, we modified the BPI in two ways. First, we changed Item 3 (Walking ability) to read "Mobility, that is, your ability to get around," to be more appropriate for the participants in the current study, many of whom cannot walk. Second, in order to gain a broader perspective of the extent to which pain interfered with important activities, the current study added three items: self-care, recreational activities, and social activities. The BPI interference items are averaged to produce a total composite pain interference score. The original BPI Pain Interference scale has demonstrated validity through its strong association to pain severity across a number of samples of individuals with cancer and other diseases (Daut et al.; see also Cleeland & Ryan), and the modified version of this scale has demonstrated reliability and validity in samples of persons with disabilities, including persons with SCI, through its strong association with pain intensity and even stronger association with measures of physical disability (Osborne, Ehde, Jensen, & Kraft, 2006; Raichle, Osborne, Jensen, & Cardenas, 2006; Tyler, Jensen, Engel, & Schwartz, 2002). The modified BPI was administered once, by telephone, during each assessment window (pretreatment, posttreatment, and 3-month follow-up).

Depressive symptoms were assessed using the 20-item Center for Epidemiologic Studies-Depression Scale (CES-D; Radloff, 1977). The CES-D has demonstrated good reliability and validity as a measure of depression in a wide range of populations (e.g., Weissman, Sholomskas, Pottenger, Prusoff, & Locke, 1977), including patients with chronic pain (Geisser, Roth, & Robinson, 1997; Turk & Okifuji, 1994). The CES-D was administered once, by telephone, during each assessment window.

Perceived control over pain was assessed using the 10-item Control scale of the Survey of Pain Attitudes (SOPA; Jensen, Turner, Romano, & Lawler, 1994). Support for the reliability of this scale comes from previous research that has shown it to have adequate levels of internal consistency (Cronbach's alpha = .71) and test-retest stability over a 6-week period (r = .68; Jensen, Turner, Romano, & Lawler). The SOPA Control scale's validity has been supported through its ability to predict physical disability (Jensen, Turner, & Romano, 1994), as well as its responsivity to treatments thought to impact perceived control over pain (Jensen, Turner,

& Romano, 1994, 2001). The SOPA Control scale was administered once, by telephone, during each assessment window.

Global satisfaction with treatment was assessed by asking patients to rate, at posttreatment, "how satisfied or dissatisfied" they were with the treatment they received on a 1–7 Likert scale (*very satisfied*, *somewhat satisfied*, *slightly satisfied*, *neither satisfied nor dissatisfied*, *slightly dissatisfied*, *somewhat dissatisfied*, *very dissatisfied*).

The frequency and effects of self-hypnosis practice at 3-month follow-up were assessed by asking participants in the self-hypnosis condition to indicate (a) the number of days out of the last 30 they listened to an audio recording of one of their sessions; (b) the amount of immediate pain relief they obtained when they listened to the recording (on a 0 = *no relief* and 10 = *complete relief* NRS); and (c) the number of hours pain relief usually lasted after they listened to the recording. These same three questions were also asked about the frequency and effects of practicing self-hypnosis on their own without a recording.

Predictor measures—As we did in the previously published case series, we also assessed two variables to predict outcome: (a) general hypnotizability and (b) treatment outcome expectancies. In addition, we also used pain type (neuropathic vs. nonneuropathic) as an outcome predictor in this study.

A modified version of the Stanford Hypnotic Clinical Scale (SHCS; Hilgard & Hilgard, 1994) was used to assess general hypnotizability and administered by a trained research assistant at the time of study recruitment. The SHCS has demonstrated its validity through its positive association with other measures of hypnotizability (Hilgard & Hilgard). It consists of five suggestions used to elicit specific classic hypnotic responses, including hand lowering, suggested cough/throat clearing, amnesia, age regression, and a suggestion for having a dream. The hand-lowering item was modified to allow for alternative motor responses (e.g., moving the head to the right) if the participant had motor deficits in his or her arms.

Treatment outcome expectancy was assessed with the four-item Treatment Expectancy Scale (TES; Holt & Heimberg, 1990), with the TES items modified to address the treatment of pain. The items of the TES used in this study begin with the stem, "You will receive 10 sessions of a treatment for pain. Based on what you have heard about the treatment so far… ." Participants were then asked to rate the perceived logic of ("How logical does this type of treatment seem to you?"), their confidence in the treatment for themselves ("How confident would you be that this treatment will be successful in eliminating your pain?" and "How successful do you feel this treatment will be in decreasing your pain?"), and their confidence in the treatment for others ("How confident would you be in recommending this treatment to a friend who was experiencing a great deal of pain?") on 0–10 NRS. Participants were asked to respond to these items at the beginning of the first session (before they had a chance to experience the treatment protocol for the first time) and immediately after the first session, and the responses to the four TES items were averaged to form a treatment outcome expectancy composite score. The original version of the TES has been used successfully to compare the reliability of control treatments in treatment outcome research (cf. Heimberg, Dodge, Hope, Kennedy, & Zollo, 1990) and to determine the extent to which treatment credibility predicts treatment outcome (Chambless, Tran, & Glass, 1997; Safren, 1997).

Finally, each participant's pain type was classified into one of three neuropathic (SCI, transition zone, or radicular) or nonneuropathic (visceral, mechanical spine, or overuse) pain types by the study physician (DDC), as described previously (Cardenas, 1999; Cardenas et al., 2002). Pain type, coded as neuropathic or nonneuropathic, was also used as a predictor variable.

Data Analysis

Change in pain intensity following HYP versus BIO was examined using two analyses. First, the immediate impact of the two treatment conditions was examined by comparing pre- to postsession pain intensity change scores (averaged across all treatment sessions) between participants assigned to the HYP and BIO treatments, using a *t* test. Second, the pre- to posttreatment effects of HYP and BIO on average daily pain intensity was examined using a repeated measures analysis of variance, with average daily pain as the dependent variable and time (pretreatment, posttreatment) and treatment condition (HYP, BIO) as the independent variables. These analyses were run for both intent-to-treat (ITT; all participants randomized) and efficacy (all participants who completed treatment) samples.

In addition, because findings concerning average change in pain intensity across the study participants do not provide information concerning the rates of positive response in the sample (a moderate average change in pain for the sample as a whole could be obtained, for example, from a small to medium treatment response in all participants or from a large response in a very few participants), a responder analysis was conducted to estimate the number of participants who showed a clinically meaningful change in pain in both the ITT and the efficacy analysis samples. A pre- to posttreatment pain intensity change of 30% was used as the cutoff for identifying a clinically meaningful change, given previous research that has shown that improvements of such magnitude are associated with patient reports of meaningful change across a number of chronic pain conditions (Farrar, Young, LaMoreaux, Werth, & Poole, 2001).

Analyses were then performed to examine the effects of the two treatment conditions up to the 3-month follow-up assessment point on average daily pain intensity for the ITT and efficacy samples, using a similar repeated measures ANOVA strategy to that used in the primary analyses, except that the time variable covered three time points (pretreatment, posttreatment, 3-month follow-up) instead of two. Responder analyses for the 3-month assessment were also performed.

The effects of the treatment conditions on the secondary outcome variables of pain unpleasantness, pain interference, depressive symptoms, and perceived control over pain were examined using the same ANOVA strategy used to assess the effects of treatment on average daily pain intensity, with each outcome measure as the dependent variable in each of four ANOVAs, and time (pretreatment, posttreatment, 3-month follow-up) and treatment condition (HYP and BIO) as the independent variables. Treatment satisfaction at posttreatment was compared between the HYP and BIO conditions using a *t* test.

To report on the frequency and effects of self-hypnosis practice at the 3-month follow-up assessment, we computed the frequencies of: (a) the number of days out of the past 30 that the participants who received HYP (1) listened to the audio recording of one of the sessions and (2) practiced self-hypnosis on their own without a recording; (b) the amount of pain relief obtained after (1) listening to an audio recording of a session or (2) practicing self-hypnosis without a recording; and (c) the number of hours of relief that occurred after (1) listening to an audio recording of a session or (2) practicing self-hypnosis without a recording.

The associations between hypnotizability and treatment outcome expectancy and treatment outcome were examined by computing correlation coefficients between pre- to posttreatment change scores in average daily pain and (a) the SHCS scale score and (b) the pre- and post-first-session outcome expectancy scores. Finally, the relative effects of the treatments on neuropathic versus nonneuropathic pain was examined by repeating the ANOVA analysis used to test the primary study hypothesis while including pain type as a second independent variable (in addition to treatment condition).

RESULTS

Primary Analyses: Effects of Treatment on Immediate Pain and Average Daily Pain Intensity

Pre- to postsession decreases in pain intensity scores (averaged across all of the treatment sessions) were very similar for both the HYP, Mean (SD) = 1.67 (1.59), and the BIO, Mean (SD) = 1.71 (1.33), treatments, and the difference in change scores between the two conditions was not statistically significant, $t(35) = 0.07$, $p = ns$. The ANOVA examining the relative effects of the two treatment conditions on pre-and posttreatment average daily pain intensity ratings in the ITT sample yielded a significant time effect, $F(1, 32) = 7.17$, $p < .05$, but no significant Time × Treatment Condition interaction, $F(1, 32) = 2.12$, $p = .16$. These results are reflected by a decrease in average daily pain for patients in both treatment groups (see Table 1). Although the Time × Treatment condition interaction effect in the ANOVA was not statistically significant, an examination of the pre- and posttreatment means of average daily pain in both treatment conditions suggested the possibility of a greater treatment effect in the HYP participants compared to the BIO participants. This possibility was explored by performing two paired t tests on the pre- to posttreatment changes in average daily pain in both groups. A significant effect emerged for the HYP participants, $t(20) = 3.08$, $p < .01$, but not for the BIO participants, $t(12) = 0.93$, $p = .37$; see Table 1. These results were essentially replicated in the efficacy sample, with a slightly larger effect size emerging for the time effect, $F(1, 26) = 7.90$, $p < .01$. As with the ITT sample, in the efficacy sample, follow-up univariate analyses indicated a statistically significant decrease in average daily pain for the HYP participants, $t(17) = 3.18$, $p < .01$, but not for the BIO participants, $t(9) = 1.18$, $p = .27$. Pre- to posttreatment responder analyses of the efficacy sample indicated slightly higher rates of responders in the HYP group compared to the BIO group; although the difference in rates between the two treatment conditions was not statistically significant (ITT sample: HYP responders = 4 or 19% and BIO responders = 2 or 15%; efficacy sample: HYP responders = 4 or 22% and BIO responders = 1 or 10%).

Secondary Outcome: Effects of Treatment on 3-Month Average Daily Pain and on Secondary Outcome Variables

The repeated measures ANOVA to test for longer-term effects of treatment on daily pain intensity in the ITT sample yielded a significant time effect, $F(2, 28) = 4.05$, $p < .05$, but not a significant Time × Treatment Condition interaction. These effects are illustrated by a pre-to posttreatment decrease in average daily pain that was maintained at the 3-month follow-up for both treatment groups (see Table 1). As with the pre- to posttreatment analyses, univariate analyses yielded significant pre- to posttreatment decrease in the HYP but not the BIO sample, and the decreases observed in the HYP sample were maintained at the 3-month follow-up. These results were replicated in the efficacy sample. Responder analyses at the 3-month follow-up assessment (i.e., rates of participants who reported a 30% or greater decrease in average daily pain relative to their pretreatment levels) yielded 8 (40%) responders in the HYP condition and 2 (20%) responders in the BIO condition for the ITT sample. These rates in the efficacy sample were 7 (31%) and 2 (22%) of the HYP and BIO participants, respectively. Although these findings suggest higher rates of responders to the HYP intervention, the difference in responder rates was not statistically significant.

The ITT ANOVA results for pain unpleasantness analyses were essentially the same as those found for average daily pain intensity, except that a statistically significant decrease was found in the univariate analyses of pain unpleasantness for the BIO sample (recall that no such effect was found for the BIO sample for average daily pain intensity) that was not maintained at the 3-month follow-up. In the efficacy sample, the pre- to posttreatment decreases in unpleasantness ratings found in both the HYP and BIO conditions were maintained in both treatment conditions at the 3-month assessment.

The ITT ANOVA results for depressive symptoms showed no significant effect for time, but a significant Time × Treatment Condition interaction did emerge (see Table 1). This interaction effect is associated with a slight pre- to posttreatment decrease in depressive symptoms in the HYP participants and a rather marked (and statistically significant) pre- to posttreatment *increase* in depressive symptoms among participants in the BIO condition. In both groups, however, the 3-month depressive symptom scores were not significantly different from the pretreatment scores. The pattern of results found for depressive symptoms in the efficacy sample was very similar to that found in the ITT sample (Table 1).

Although there was a slight pre- to posttreatment decrease in pain interference, as measured by the BPI Pain Interference scale, in the participants in the HYP condition, and a slight pre- to posttreatment increase in pain interference in the participants in the BIO condition, these differences between the two treatment conditions were not statistically significant in the ITT or efficacy samples. The time effect on perceived control over pain was not statistically significant, but a nonsignificant trend ($p < .10$) for a Time × Treatment Condition interaction effect in the ITT sample and a significant ($p < .05$) effect for this interaction in the efficacy sample did emerge. These effects are illustrated by the significant pre- to posttreatment increase in perceived control over pain in the HYP group and lack of significant pre- to posttreatment change in perceived control over pain in the BIO condition; although the change in this variable in the HYP group was not maintained at the 3-month follow-up point.

The *t* test comparing global satisfaction with treatment between the HYP and BIO groups in the ITT and efficacy samples indicated similar levels of satisfaction, Mean HYP and BIO satisfaction ratings in the ITT sample = 2.05 ($SD = 1.12$) and 2.18 ($SD = 1.17$), respectively, $t(30) = 0.32$, $p = .75$; Mean satisfaction ratings in the efficacy sample = 1.94 ($SD = 1.06$) and 2.33 ($SD = 1.23$), respectively, $t(25) = 0.86$, $p = .40$. Of the 32 participants who provided satisfaction ratings at posttreatment, the great majority in both treatment conditions (28 or 88%) expressed at least some satisfaction with treatment (12, or 32%, were highly satisfied; 10, or 27%, were somewhat satisfied; and 6, or 16%, were slightly satisfied). Three (8%) of the participants reported being neither satisfied nor dissatisfied with treatment, and only 1 (3%) reported that he was "slightly dissatisfied" with the treatment that he received. None were somewhat or highly dissatisfied.

Regarding frequency and effect of practice of hypnosis at the 3-month assessment point, 12 (60%) of the 20 participants in the HYP condition for whom we have 3-month data reported listening to an audio recording of one of the hypnosis sessions at least once during the past 30 days (Range = 2 to 25 days; Median = 8 days). Sixteen (80%) reported practicing self-hypnosis on their own on at least one day during the previous 30 days (Range = 2 to 30 days; Median = 15 days). Average pain relief obtained following listening to a recording was 3.58 ($SD = 2.19$; Range = 0 to 8 on a 0–10 relief rating scale), and average relief after practicing self-hypnosis without a recording was 3.44 ($SD = 2.76$; Range = 0 to 10). Average hours of relief was 3.36 after listening to a recording ($SD = 3.07$; Range = 0.50 to 9.00 hours) and 1.42 after practicing self-hypnosis without a recording ($SD = 1.55$; Range = 0 to 6 hours).

Predicting Treatment Outcome

Hypnotizability, pre-first-session outcome expectancy, and post-first-session outcome expectancy all showed weak and nonsignificant associations with pre- to posttreatment change in average daily pain intensity in the efficacy sample as a whole, $rs = .18$, .22, and .22 (all $ps = ns$), respectively. The coefficients were also weak and nonsignificant when computed for each treatment group separately. Coefficients were not computed for the ITT sample, as there is no reason to expect that global hypnotizability or treatment outcome expectancy would be associated with treatment outcome among individuals who received only limited treatment.

Regarding possible variation in outcome as a function of pain diagnosis, we did find a significant Time × Treatment Condition × Pain Type interaction in the ANOVA predicting pre- and posttreatment average daily pain intensity, $F(1, 30) = 7.13$, $p < .05$. The means for each cell of this analysis are presented in Table 2. As can be seen, the significant three-way interaction can be explained by the significant reduction that occurred in pain among the participants with neuropathic pain who received hypnosis, and the lack of significant changes in pain among those with nonneuropathic pain who received hypnosis or among any of the participants who received biofeedback. A responder analysis of the ITT sample indicated that all of the individuals who responded to hypnosis had neuropathic pain (4, or 30%, of the HYP participants with neuropathic pain). None of the HYP participants with nonneuropathic pain responded to treatment. On the other hand, none of the participants in the BIO condition with neuropathic pain responded to treatment, whereas 2 (20%) of the BIO participants with nonneuropathic pain responded to treatment.

DISCUSSION

Change in Pain with Hypnosis Versus EMG Biofeedback

The primary hypothesis of this study was that participants in the HYP treatment condition would report greater decreases in pain than participants in the BIO treatment condition. This hypothesis was only partially supported. Participants in both treatment conditions reported similar pre- to postsession decreases in pain, and a significant Time × Treatment Condition interaction examining pre- and posttreatment average daily pain intensity composite scores did not emerge. On the other hand, in both the ITT sample (all participants randomized) and efficacy sample (only those participants who completed treatment), participants in the HYP condition reported a statistically significant pre- to posttreatment decrease in average daily pain (that was maintained at the 3-month assessment point), whereas participants in the BIO condition did not evidence a significant decrease in this variable. Although responder analyses indicated twice the rate of responders in the HYP group than the BIO group from pre- to posttreatment in the efficacy sample (22% versus 10%), the sample size was too low to be able to detect a statistically significant effect in rates of response to treatment.

Overall, the findings indicate that both hypnosis and biofeedback showed a similar *immediate* effect on pain intensity and that hypnosis was at least as effective as (but possibly more effective than) biofeedback, for reducing *daily average pain*. These findings are consistent with our prediction that hypnotic analgesia can reduce chronic pain in at least some individuals with SCI whose chronic pain has been refractory to other treatments. However, the results of this study do not provide definitive evidence that those effects are due to the specific effects of hypnotic treatment that are distinct from the biofeedback-assisted relaxation training control condition.

In hindsight, and as we observed the effects of the BIO treatment condition, we now believe that the control condition used was less than ideal for distinguishing the specific from nonspecific effects of hypnosis. First, the biofeedback procedures required that participants focus on a regular audio feedback signal ("beep … beep … beep") that was clearly absorbing for many patients, in part, perhaps, because it was linked to their own physiological response. The task of focusing one's attention on an absorbing biofeedback tone is similar to the focusing attention task that is common to many hypnotic inductions ("Listen closely to my voice …" or "Pay close attention to that spot on the wall …"), and focused attention is thought by many to be a critical part of facilitating hypnosis, if not central to the concept of hypnosis itself (e.g., Spiegel & Spiegel, 2004). Participants in the BIO condition were also provided with an audio recording that contained suggestions for relaxation; suggestions that might be viewed as incompatible with the experience of pain. In addition, in an effort to make the biofeedback condition credible, we described it as a treatment that has been shown to reduce pain. Thus,

participants in the BIO condition also received at least implicit suggestions for pain relief. It has long been known that hypnotic subjects can respond to implicit suggestions given prior to hypnotic inductions (e.g., Orne, 1959). The biofeedback control condition used in this study, which included both an opportunity for focused and absorbed attention, explicit suggestions for relaxation, and implicit suggestions for pain reduction, could therefore be viewed as a variant of a hypnotic intervention. In this study, we may have therefore compared a (full) hypnotic-analgesia intervention with another (albeit limited) hypnotic intervention. Our finding that the HYP condition may have resulted in greater pain reduction than the BIO condition (this conclusion is somewhat qualified because of the lack of significant interaction in the ANOVA, even though there was a statistically significant reduction in pain in the HYP group and not the BIO group) may be due to the greater number and variety of suggestions in the HYP condition compared to the BIO condition, rather than clear differences in mechanisms between the two conditions.

Longer-Term Effects of Treatment on Average Daily Pain and on Secondary Outcome Variables

The analyses examining the longer-term (up to 3 months) effects of treatment on average daily pain indicated that the significant decreases observed in this outcome variable among the HYP participants (in both ITT and efficacy samples) were maintained at 3 months, consistent with the results from our previous case series (Jensen, Hanley, et al., 2005). These findings confirm that hypnotic-analgesia treatment is associated with relatively long-lasting decreases in the intensity of chronic daily pain for some patients (in the current study, the responder analyses showed this rate to be 19% of the ITT sample and 22% of the efficacy sample). Although these responder rates are not large, the finding that a subset of patients with otherwise refractory pain reported substantial pain relief that was long-lasting, especially when considered in light of data from case series studies (e.g., Jensen & Barber, 2000; Jensen, Hanley, et al.), provides sufficient evidence, we believe, to justify offering this treatment to those patients with SCI and chronic pain who might be interested in this approach.

As we found in our previous case series (Jensen, Hanley, et al., 2005), the hypnosis protocol used in this study produced similar effects on pain unpleasantness (the amount of "bothersomeness" of pain) as it did on pain intensity but did not have substantial effects on pain interference. A curious pre- to posttreatment increase in depressive symptoms among the BIO participants occurred (no significant change in this variable among the HYP participants occurred), but their depression scores returned to pretreatment levels at the 3-month follow-up. We have no reason to believe that EMG biofeedback treatment produces systematic and reliable short-term increases in depression symptoms, so we speculate that the change observed may have been associated more with random variation than a specific effect of treatment. Alternatively, it is possible that the increase in depression scores among the BIO participants might reflect short-term feelings of disappointment that the relaxation treatment was over and had not been as effective as the participants had hoped.

On the other hand, the changes observed in perceived control over pain (greater for the HYP group than the BIO group) are consistent with our previous case series (Jensen, Hanley, et al., 2005) and suggest that one of the immediate effects of the HYP protocol is to increase perceived control over pain. However, the significant increases in perceived control over pain observed in the HYP participants in this study did not maintain at the 3-month follow-up assessment point. Detecting longer-term effects on perceived control over pain may require a greater number of subjects than we were able to recruit for this study. Alternatively, it is possible that the chronic nature of SCI-related pain may erode immediate improvements in perceived control over pain that occur with treatment. Perhaps additional treatment components (e.g., cognitive-behavioral treatment, cf., Ehde & Jensen, 2004) may be needed to maximize the benefits of

hypnosis interventions on chronic pain across all outcome variables. Alternatively, it may be necessary to expand the suggestions made with hypnotic treatments in persons with pain to include suggestions concerning attributions of control and effects of pain on daily living, in order to impact variables in addition to pain intensity (Patterson & Jensen, 2003).

A large majority of participants in both of the intervention protocols reported satisfaction with the treatments, despite the lack of clinically meaningful decreases in average daily pain by many. This finding is consistent with our previous case series (Jensen, Hanley, et al., 2005) and could potentially be explained by the many beneficial "side effects" of hypnotic treatments, such as increased sense of well-being and perceived relaxation, and increased sense of control over immediate pain (Jensen et al., 2006). Indeed, in the current study, even 3 months after treatment, 60% of the participants who received HYP reported listening to the audio recordings of the treatment sessions, and 80% reported that they used the self-hypnosis skills taught during treatment on their own, without the assistance of the audio recording. Clearly, many more of the participants than only those whose average daily pain decreased substantially found the HYP intervention helpful. This finding provides further support for the importance of greater access to hypnotic-analgesia treatments for persons with SCI and chronic pain (indeed, for persons with chronic pain in general).

Predictors of Treatment Outcome

Neither general hypnotizability nor treatment outcome expectancy showed even moderate associations with outcome in this study. This finding is generally consistent with our previous research (e.g., Jensen, Hanley, et al., 2005); although it is not consistent with some of the previous studies that have found hypnotizability to be associated with response to hypnotic-analgesia treatment in the clinical setting (see review by Patterson & Jensen, 2003). One possible explanation for this discrepancy is that our group tends to examine the efficacy of hypnotic-analgesia interventions in samples of patients whose pain problems are highly refractory, so large reductions in pain can be very difficult to obtain. The refractory nature of pain in individuals with SCI can limit the variance in the outcome measure, and limited variability reduces the ability to detect real associations. It is also possible that in our samples, factors other than hypnotizability and/or expectancies, such as the specific type (e.g., neuropathic versus nonneuropathic) or history of the pain problem, play a much larger role in treatment outcome than they do in other samples of individuals with chronic pain. Another potential factor is our use of the Stanford Hypnotic Clinical Scale to measure global hypnotizability. This measure has only five items, as compared with other measures of hypnotizability that have more items, such as the Stanford Hypnotizability Scale, Form A or C, with 12 items each (Morgan & Hilgard, 1978–1979). The use of a brief hypnotizability measure may have limited our ability to detect associations between hypnotizability and outcome; although other investigators who have used this scale have found the measure to predict outcome (e.g., Freeman, Macaulay, Eve, Chamberlain, & Bhat, 1986; ter Kuile et al., 1994). In any case, our findings do suggest that, at least for persons with SCI pain, neither initial beliefs about outcome or treatment nor global hypnotizability should be used for screening patients out of treatment.

One interesting finding was the association between type of pain and treatment outcome. Among the study participants, responders to hypnotic analgesia were found only among those with neuropathic pain. On the other hand, the very few (2) responders to EMG-assisted biofeedback relaxation training were found only among those with nonneuropathic pain. These findings raise the intriguing possibility (only a possibility at this point, given the exploratory nature of the analyses, as well as the small sample size of this study) that the two treatments provided may be more or less effective for different types of pain problems. Our current view is that the final common pathway to the experience of pain is reflected in brain activity,

specifically activity in a number of interconnected cortical sites and networks, and that hypnotic-analgesia treatments can affect pain via any one or more of these sites and networks (Jensen, 2008). However, we also know that chronic pain can produce long-lasting changes in the cortex; changes that can than make a person more susceptible to interpret sensations as pain (e.g., Tinazzi et al., 2000; see also review by Melzack, Coderre, Katz, & Vaccarino, 2001). Perhaps some types of injury or disease processes are more likely than others to produce central (cortical) changes that contribute to the experience of pain, and pain due to central changes could potentially be more responsive to the effects of hypnotic treatments than pain caused by ongoing nociception. This (highly speculative) idea is consistent with (a) our findings that persons with amputations may be particularly responsive to hypnotic interventions (Jensen, Hanley, et al., 2005) and (b) amputation is known to produce significant central cortical changes (e.g., Flor et al., 1995; also see review by Elbert & Rockstroh, 2004). Future research is needed to explore the possibility that hypnotic analgesia produces a greater effect for some types of pain than others.

Limitations

The primary limitations of the study were: (a) participants in the two treatment conditions were not equivalent at pretreatment on all measures (the HYP group reported higher levels of average daily pain intensity, pain interference, and depression and less perceived control over pain compared to the BIO group); (b) the control condition used may have included components of hypnosis; and (c) the relatively low sample size of the study. The differences in the outcome measures at pretreatment could potentially explain the differences found between treatment conditions in outcome, due to regression to the mean. However, if a difference in pretreatment measures was the only factor that predicted or explained treatment outcome, one might expect to have seen differences between the treatment conditions on all outcome domains that differed (including pain interference and depression symptoms) and not just on pain intensity and perceived control over pain. Still, because of the nonequivalence of the treatment groups at pretreatment, one cannot conclude definitively, based on this study alone, that hypnosis treatment is more effective than EMG-assisted biofeedback relaxation for reducing pain and increasing perceived control over pain. Additional research is needed to help to clarify any differences in efficacy between hypnosis and relaxation training on chronic pain. In future studies, investigators should seek to assess and track pretreatment levels of the primary outcome variable (in this case, average daily pain) and to randomize participants in such a way as to ensure similarity between groups on this variable.

The weaknesses of the control condition selected for this study have already been discussed and include the fact that it contains what some might argue are "hypnotic" components (i.e., an invitation to focus one's attention on an absorbing stimulus coupled with direct suggestions for relaxation and implicit suggestions for decreases in pain). For the clinician, research comparing hypnotic-analgesia interventions to other pain interventions is very useful, even if those other interventions contain hypnotic components. Such research can help determine which interventions should be tried first (i.e., the one that shows the greater benefits on the largest number of patients). However, the EMG biofeedback condition used as a control condition in this study was not useful for answering questions concerning the specificity of hypnotic treatment. Because both the HYP and BIO interventions did appear to have some benefit, a substantial difference between the two interventions on outcome did not emerge. Had we been able to find a larger effect for the HYP condition compared with the BIO condition, we could have concluded that hypnosis' effects cannot be explained merely by its nonspecific effects (e.g., attention from a clinician, participation in a trial, and enlistment of positive outcome expectancies). A better control group for this type of research, if identifying the specific effects of the hypnosis intervention is a goal, would be one that: (a) does not contain any components related to hypnosis, (b) does not impact pain intensity significantly, and (c)

elicits similar outcome expectancies concerning effects on pain. Any one of a number of such control conditions can be envisioned (for example, training in sleep hygiene, with a rationale given to participants that the training would improve sleep, and that a subsequent reduction in disrupted sleep will result in reductions in daily pain).

Recruiting subjects for controlled trials is often a challenge and the current study was no exception. We were ultimately able to enlist and randomize 37 subjects in this trial, of which 28 completed treatment, and 29 provided complete data at all assessment points. A larger number of subjects would have provided greater power to detect significant effects that may exist in the population but that did not emerge in the present analyses. A larger sample size would also allow for greater confidence in the reliability of the results. Thus, although the findings suggest the possibility that hypnosis may be more effective than EMG biofeedback on average daily pain and on perceived control over pain, the findings are only suggestive and not definitive, in part because the low sample size limited the statistical power of the analyses.

SUMMARY AND CONCLUSIONS

Despite the study's limitations, the findings provide important information about the effects of hypnotic analgesia for chronic pain in persons with SCI. First, the findings are consistent with the hypothesis that hypnotic-analgesia treatment is effective for making substantial reductions in chronic daily pain intensity for a subset of patients with SCI—in this study, 19% of patients who began treatment and 22% of patients who completed treatment. The findings also confirm that most patients who receive hypnosis are satisfied with treatment. Also, most patients (80%) continue to use the self-hypnosis skills taught in training and to find that using these skills can provide pain relief that can last for hours. The study findings suggest that neither global hypnotizability nor outcome expectancies explain significant variance in treatment outcome but do suggest the possibility that patients with neuropathic pain may respond better to hypnotic-analgesia treatment than patients with nonneuropathic pain. This latter possibility warrants additional empirical evaluation. Finally, the current study's findings are consistent with a growing body of evidence that hypnotic-analgesia treatment for chronic pain can benefit a substantial subset of these patients and may be powerfully effective in a few.

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Table 1

Means and SDs for the Primary (Average Daily Pain Intensity) and Secondary Outcome Measures at Pretreatment, Posttreatment, and 3-Month Follow-Up, Intent-to-Treat, and Efficacy Analyses

Outcome Variable	Treatment Condition	Pretreatment		Posttreatment		3-Month Follow-Up		Time Effect $F(df)$	Time × Treatment Condition Effect $F(df)$
		Mean	SD	Mean	SD	Mean	SD		
Intent-to-treat analysis (n = 31)									
Daily average pain	Hypnosis	5.99_a	1.83	5.09_b	1.92	4.90_b	2.13	4.05^* (2, 28)	1.68(2,28)
	Biofeedback	3.44_a	1.48	3.36_a	1.28	3.13_a	1.42		
Pain unpleasantness	Hypnosis	6.83_a	1.69	5.10_b	2.12	5.13_b	2.71	8.56^{**} (2,28)	1.50(2,28)
	Biofeedback	3.91_a	2.07	2.88_b	1.02	2.80_a	1.59		
Depressive symptoms (CES-D)	Hypnosis	22.49_a	11.28	19.26_a	10.56	21.96_a	11.98	0.73 (2, 27)	5.89^{**} (2,27)
	Biofeedback	11.50_a	8.40	18.36_b	12.35	12.80_a	10.45		
Pain interference (BPI)	Hypnosis	5.23_a	2.49	4.58_a	2.57	4.54_a	2.40	0.19 (2, 27)	2.47 (2, 27)
	Biofeedback	2.33_a	1.68	3.05_a	2.06	2.87_a	2.33		
Perceived control	Hypnosis	1.82_a	0.90	2.24_{bc}	0.47	1.98_{ac}	1.18	1.14(2,27)	$3.19^{\dagger}$ (2, 27)
	Biofeedback	2.55_a	0.87	2.3_{ab}	0.41	2.82_{bc}	0.74		
Efficacy analysis (n = 26 for pain intensity and unpleasantness, n = 25 for all others)									
Daily average pain	Hypnosis	6.10_a	1.83	5.05_b	1.99	4.93_b	2.20	5.23^* (2, 23)	1.28(2,23)
	Biofeedback	3.38_a	1.41	3.17_a	1.33	3.78_a	1.20		
Pain unpleasantness	Hypnosis	6.92_a	1.74	5.13_b	2.21	5.25_b	2.83	8.62^{**} (2,23)	0.48 (2,23)
	Biofeedback	4.11_a	2.18	2.85_b	1.13	2.44_b	1.39		
Depressive symptoms (CES-D)	Hypnosis	23.46_a	11.28	18.72_{bc}	10.85	22.72_{ac}	12.37	0.08 (2, 22)	6.08^{**} (2,22)
	Biofeedback	11.38_a	8.21	17.38_b	11.95	12.38_a	10.08		
Pain interference (BPI)	Hypnosis	5.32_a	2.66	4.50_a	2.62	4.48_a	2.43	0.43 (2, 22)	0.68 (2,22)
	Biofeedback	2.48_a	1.82	2.67_a	1.88	2.47_a	2.15		
Perceived control	Hypnosis	1.76_a	0.92	2.25_{bc}	0.48	1.96_{ac}	1.12	1.25(2,22)	4.85^* (2, 22)
	Biofeedback	2.66_a	0.93	2.16_a	0.30	2.96_c	0.76		

[a] *Note.* Intent-to-treat analyses includes all participants who were randomized to treatment condition and for whom data at each assessment point was available, whether or not they completed treatment. Efficacy analyses includes only those participants who completed treatment (i.e., completed in 9 or 10 sessions). BPI, Brief Pain Inventory Pain Interference scale; CES-D, Center for Epidemiologic

Studies Depression scale; SOPA Control, Control scale of the Survey of Pain Attitudes; NRS-11, 1–10 Numerical Rating Scale of pain unpleasantness. Means with different subscripts aresignificantly different ($p < .05$) from one another.

†
p < .10

*
p < .05

**
p < .01.

Table 2

Means and SDs for Average Daily Pain Intensity for Participants With and Without Neuropathic Pain in Each Treatment Condition

Pain Type	Treatment Condition	Pretreatment		Posttreatment		t (df)
		Mean	**SD**	**Mean**	**SD**	
Neuropathic	Hypnosis	6.00	2.20	4.53	2.11	3.96** (12)
	Biofeedback	2.81	0.95	3.19	0.69	0.50 (2)
Nonneuropathic	Hypnosis	5.64	1.31	5.66	1.53	0.11 (7)
	Biofeedback	3.78	1.55	3.32	1.39	1.56 (9)

** $p < .01$.