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Hypnosis Enhances the Effects of Pain Education in Patients With Chronic Nonspecific Low Back Pain: A Randomized Controlled Trial

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Abstract: **The potential benefits of combining pain education (PE) with clinical hypnosis (CH) has not yet been investigated in individuals with chronic pain. A total of 100 patients with chronic nonspecific low back pain were randomized to receive either: 1) PE alone, or 2) PE with CH. Outcomes were collected by a blinded assessor at 2 weeks and 3 months after randomization. The primary outcomes were average pain intensity, worst pain intensity (both assessed with 11-point numeric rating scales), and disability (24-item Roland Morris Disability Questionnaire) at 2 weeks. At 2 weeks, participants who received PE with CH reported lower worst pain intensity (mean difference = 1.35 points, 95% confidence interval [CI] = .32–2.37) and disability (mean difference = 2.34 points, 95% CI = .06–4.61), but not average pain intensity (mean difference = .67 point, 95% CI = –.27 to 1.62), relative to participants who received PE alone. PE with CH participants also reported more global perceived benefits at 2 weeks (mean difference = –1.98 points, 95% CI = –3.21 to –.75). At 3 months, participants who received PE with CH reported lower worst pain intensity (mean difference = 1.32 points, 95% CI = .29–2.34) and catastrophizing (mean difference = 5.30 points, 95% CI = 1.20–9.41). No adverse effects in either treatment condition were reported. To our knowledge, this is the first trial showing that additional use of hypnosis with PE results in improved outcomes over PE alone in patients with chronic nonspecific low back pain.**

Perspective: ***This study provides evidence supporting the efficacy of another treatment option for teaching patients to self-manage chronic low back pain that has a relatively low cost and that can be offered in groups.***

Key words: *Education, neurophysiology, hypnosis, low back pain, randomized controlled trial.*

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Chronic nonspecific low back pain is a common condition[33] that is associated with high financial costs[30,51] and disability.[3,16] The available biomedical interventions are typically not very effective at reducing pain or disability,[17] are often associated with negative side effects,[1] or involve treatment from a variety of different health care professionals, which increases costs.[26] A relatively simple intervention provided by physical therapists—patient education—has shown efficacy, but its effects tend to be modest.[6,13,35] One particular type of education is pain biology education, which seeks to help patients understand the biological processes related to

their pain experience.[31] This intervention has shown promise for reducing disability, catastrophizing, and increasing function.[32,41]

Hypnotic treatment for pain conditions has received more attention recently,[23,24,29] perhaps in part because of the lack of efficacy of more traditional biomedical interventions. When used for pain treatment, hypnosis typically involves an "induction" during which the clinician invites patients to experience a state of focused awareness, followed by suggestions for changes in the sensory, cognitive, and emotional domains of pain experience.[19]

The most recent systematic reviews conclude that hypnosis reduces pain intensity compared with usual care and when combined with other interventions for a variety of chronic conditions.[2,23,49] Only 3 studies have investigated the effects of hypnotic suggestion in patients with chronic low back pain.[36,48,50] Some authors have proposed that the beneficial effects of cognitive-behavioral therapy for patients with chronic pain could be enhanced by combining cognitive-behavioral therapy with hypnosis.[21,28] Combining pain education (PE) with hypnosis has not yet been investigated, however.[39]

With these considerations, we designed the current study to evaluate the effects of additional use of hypnosis with PE. We hypothesized that patients with chronic low back pain who received PE with hypnosis would report greater improvements in pain intensity and disability (primary outcomes) as well as patient-specific function, catastrophizing, and global perceived benefits (secondary outcomes), relative to those randomized to receive PE alone.

Methods

Study Design, Setting, and Participants

This trial was prospectively registered at clinicaltrials.gov: NCT02638753. There was no deviation from the original registered protocol. This was a 2-arm randomized controlled trial with the outcome assessor blinded to the group allocation (Fig 1). The primary source of participants was the waiting list of the outpatient physical therapy clinic of the Universidade Cidade de São Paulo, Brazil. The interventions were conducted in classrooms of the university from February to November 2016.

Potential participants were informed that they would be randomized to receive 1 of "two different widely used pain education programs that have been found to be helpful for patients with chronic pain." Patients were invited to participate if they had nonspecific low back pain of at least 3 months, were aged between 18 and 80 years old, and had a minimum score of 3 on 0 to 10 pain numeric rating scale (NRS) of average pain intensity. Patients who were receiving physical therapy at the time of recruitment, with any contraindication to exercise, serious spinal pathologies, previous spinal surgery, nerve root compromise, cardiorespiratory illness, pregnancy, hearing problems, low back pain as secondary complaint, illiteracy, or inability to attend treatment sessions were excluded. The institutional human ethics committee of the Universidade Cidade de São Paulo approved this trial. All study participants provided written informed consent.

Randomization

A simple randomization sequence was generated using the Microsoft Excel (Redmond, WA) program by one of the study investigators who was not directly involved with the study assessments or treatment. During the baseline assessment, participants received information about the study and signed a consent form to participate in the study. After the baseline assessment the therapist opened the randomization envelope and the participant was allocated to 1 of the 2 treatment groups. The allocation was concealed by using consecutively numbered, sealed, opaque envelopes. The envelopes were opened when the participants arrived for treatment, and the first session was conducted immediately after the baseline assessment that same day.

Blinding

The outcome assessor was blind to group allocation. Because of the nature of interventions, it was not possible for the therapist or the study participants to be blind to treatment condition.

Interventions

Participants from both groups received PE on the basis of information from the *Explain Pain* book,[5] and the second group received additional hypnotic suggestions. Both interventions were provided in the same group setting. The interventions were carried out in a group with up to 7 participants per class (varying from 1 to 7 participants). The frequency (4 sessions, twice a week) and content of PE were standardized in both groups. Participants from both groups received a workbook with the same PE content given in each class. The clinician who treated the patients from both groups (R.R.N.R.) is a physical therapist with 13 years of clinical experience, including 6 years of experience in the delivery of PE and clinical hypnosis (CH) for pain. The therapist was certified in hypnotherapy and received guidance from a psychologist certified by the American Society of Clinical Hypnosis.

PE Group

The PE group classes used the same pictures, stories, metaphors, and examples described in the *Explain Pain* book.[5] Participants were encouraged to ask questions during the classes. At the end of each class, the information presented was reviewed. A workbook was given to the participants with the same content offered during the classes, and the participants were asked to read the content after each class at home. Information provided during the classes included: pain as a normal experience (first class); components and function of the danger alarm system, and modulation of danger messages at the spinal cord level (second class); altered central nervous system alarms, and response systems in the pain

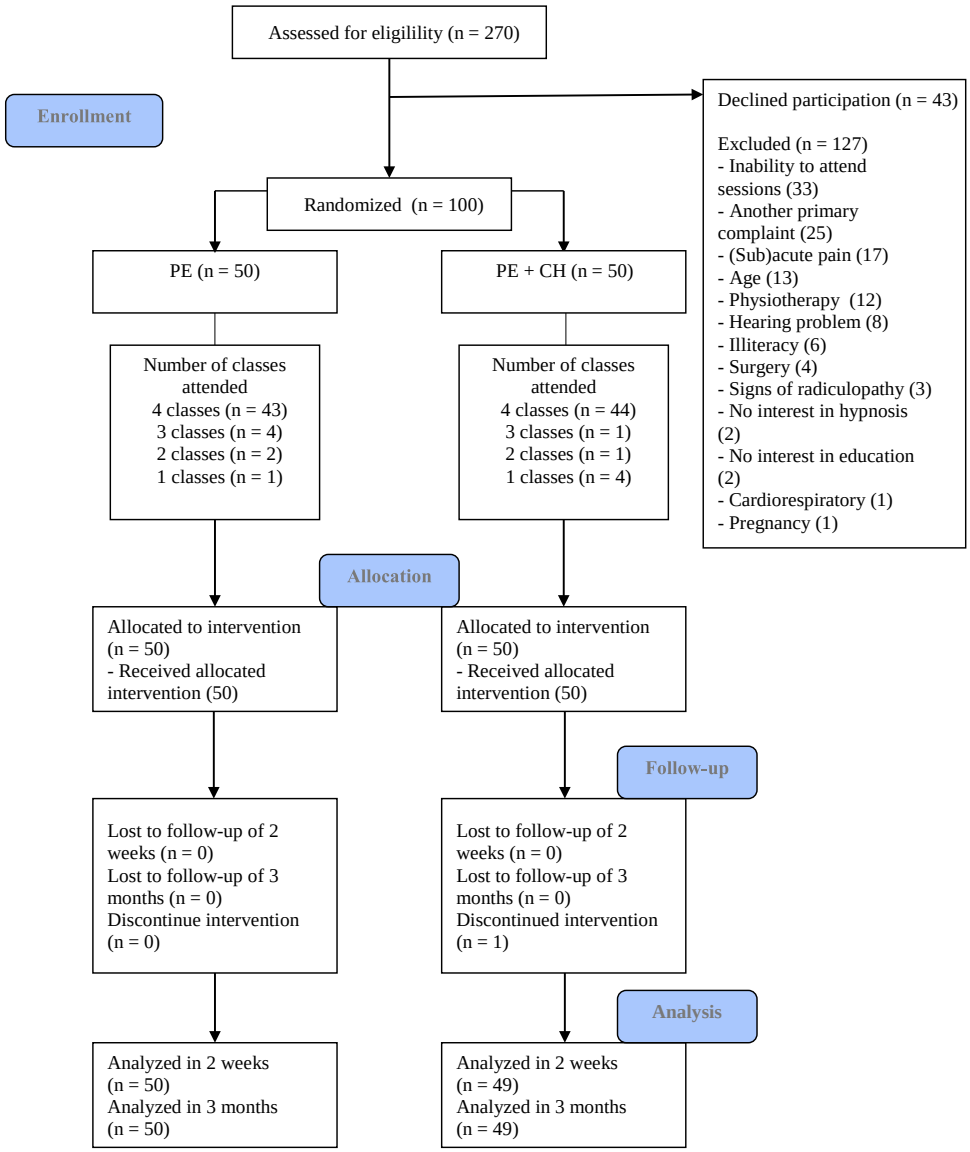

Figure 1. Participant flow diagram. All patients received the treatments as allocated. Overall follow-up response rates were 99% (n = 99) at 2-week and 3-month follow-ups.

experience (third class); and education and understanding that "hurt does not necessarily equal harm," pacing and graded exposure (fourth class).[5]

PE With CH Group

Participants allocated to the PE with CH (PE + CH) group received a total of 6 hours and 15 minutes of treatment. The only difference between the PE and the PE + CH groups was the additional use of a total of 2 hours and 15 minutes of hypnosis distributed over the 2 weeks of treatment, and a hypnosis workbook to read at home with the same hypnotic suggestions offered in the classes. To ensure that the content of the PE treatment component was the same for both groups, the hypnotic suggestions were added to the PE components. For this reason, the total duration of sessions was different between groups.

To increase acceptability of hypnosis to the participants, the PE content was interspersed with hypnotic suggestions. For example, the participants were told, "Each hypnotic experience is intended to adjust each part of the danger alarm system." The hypnotic inductions started with stories and metaphors related to the PE content. After this, the participants were invited to focus their attention while looking at a spot on the wall in front of them. Brief summaries of the content of each hypnotic session are described in the following 4 sections (more detailed information about the content of the hypnotic suggestions are provided in Appendix 1).

First Class: Addressing Hypnosis Myths and Benefits[20]

The first hypnotic experience was intended to suggest an openness to the possibility of change. The suggestions reinforced the idea that the brain has many capacities that can be used to create comfortable experiences. Some brief suggestions explored the capacities of relaxation, dissociation (between body and mind),

analgesia, and age regression to previous pleasant experiences.

Second Class

Patients had 2 hypnotic experiences during the second class. The first experience was connected to the idea expressed in the *Explain Pain* book that "… sensors are often replaced by new and fresh ones."[5] We offered through hypnotic suggestions that an adaptation in the sensors is possible.[45] The second hypnotic experience was related to the content of descending inhibitory modulation at the level of the spinal cord. The suggestion was adapted hypnotic analgesia,[20] which invites patients to experience analgesic sensations in their body.

Third Class

Patients were given 2 hypnotic suggestions during the third class. The first was connected to the idea that "the brain can receive amplified messages from the tissues, even when there is nothing wrong with the structure of the body,"[5] and included suggestions for decreased pain unpleasantness, which invited participants to experience comfort even with the presence of some sensations in their body.[20] The second hypnotic suggestion was related to the idea of "the brain orchestra can play a different song."[5] We offered "sensory substitution" suggestions,[20] which invited participants to experience a comfortable sensation of their hands spreading to other parts of the body.

Fourth Class

During the fourth class, the participants were given 3 different hypnotic suggestions. The first 2 were related to the motor responses. The first was a "deep relaxation" suggestion,[20] during which participants were invited to relax each muscle of their body. The second was an "age regression and progression" suggestion,[20] during which participants were invited to bring adaptive pain responses from the past or the future into the present. Both of these hypnotic suggestions reinforced the importance of physical movement as a way to extend the benefits. The last hypnotic experience of this class offered a metaphor to help the patients use some of the information they had learned to manage negative thoughts during the day. After each class, the participants were asked to read the hypnosis workbook and to practice self-hypnosis briefly at home. The *Explain Pain* workbook was also provided during the last session.

Follow-up

Patients were evaluated by an assessor who was blind to treatment allocation at baseline and after 2 weeks and 3 months after randomization. Patients who did not finish all interventions in 2 weeks had an opportunity to complete the sessions in the following 2 weeks. After this period, the first follow-up assessment (2-week follow-up) was concluded. All baseline assessments were conducted in person. Participants who completed all 4 sessions were evaluated in person, and participants who did not complete all 4 sessions were evaluated via telephone at 2 weeks. All patients were contacted at 3 months via telephone to collect follow-up data.

Measures

The primary outcome measures were pain intensity (average and the worst pain over the past week, measured using a 0–10 pain NRS)[7,22] and disability (measured using the 0–24 Roland Morris Disability Questionnaire [RMDQ])[8,42] at 2 weeks after randomization. The secondary outcome measures were: 1) pain intensity (average and worst pain)[7,22] and disability[8,42] assessed at 3 months after randomization, 2) catastrophizing (measured using the 0–52 Pain Catastrophizing Scale,[47] 3) function (measured using the 0–10 Patient-Specific Function Scale),[7,18] and 4) global impression of change (measured using the −5 to +5 Global Perceived Effect Scale)[27] at 2 weeks and 3 months after randomization. Sociodemographic and clinical information and expectation of improvement with the treatment were obtained at baseline. During all telephone follow-up interviews, the occurrence of potential adverse effects was assessed by asking: "Since you started receiving this treatment, have your symptoms become worse?" To assess the expectation of improvement with the treatment, the follow question was asked: "In your opinion, what is your expectation that your symptoms will improve with this treatment (measured using the 0–10 expectation numeric rating scale)?"[11] All outcome measures used in this trial were cross-culturally adapted into Brazilian Portuguese and successfully tested for their measurement properties.[7,8,18,42,47] There were no changes made to the outcome measures after trial commencement.

Sample Size

We designed the study to detect a between-group difference of at least 1 point in pain intensity measured using the NRS, with an estimated SD of 2 points, and a between-group difference of 4 points for disability measured using the RMDQ, with an estimated SD of 5 points.[9,34] The specifications were: a power of 80%, an α coefficient of .05, and a possible loss to follow-up of up to 15%.[37] Therefore, a total of 100 participants were enrolled in the study. The estimates for powering the study were lower than the minimal clinical important difference for patients with low back pain.[43] The rationale for powering the study to detect a change in pain that is less than the minimally clinically important difference was that most published clinical trials of PE have not achieved this effect size. Therefore, we designed the study to be sufficiently powered to be able to detect at least the effect sizes shown in earlier studies.

Statistical Analyses

Statistical analyses were conducted using intention to treat principles. The between-group differences and their respective 95% confidence intervals (CIs) were calculated using linear mixed models. We also estimated the number needed to treat for the primary outcomes by

dichotomizing patients who had reached the minimal clinically important difference compared with those who had not reached minimal clinically important difference. The cutoffs used for determining minimal clinically important differences in pain intensity (a reduction of at least 2 points or 30% on the NRS scale, relative to baseline) and disability (a reduction of at least 5 points or 30% on the RMDQ, relative to baseline) was determined on the basis of previous studies relating these scales to global assessments of change.[4,12,14] We used SPSS version 22 for Mac (IBM Corp, Armonk, NY) for all statistical analyses.

Results

Two hundred seventy patients who were seeking care for low back pain at the physical therapy clinic from February to November, 2016, were approached for possible participation. Forty-three (16%) of these declined participation, 127 (47%) were excluded and 100 (37%) were eligible and agreed to participate (Fig 1). The primary reasons for exclusion were inability to attend treatment sessions (n = 33), low back pain as secondary complaint (n = 25), presence of an acute low back pain episode (n = 17), being younger than 18 years old or older than 80 years old (n = 13), receiving physical therapy at the time of recruitment (n = 12), having hearing problems (n = 8), being illiterate (n = 6), having a history of previous spinal surgery (n = 4), presence of signs of nerve root compression (n = 3), having no interest in hypnosis (n = 2), having no interest in PE (n = 2), the presence of cardiorespiratory illness (n = 1), and pregnancy (n = 1).

All patients received the treatments as allocated. In the PE group, 86% (n = 43) of the patients attended all classes, 8% (n = 4) attended 3 classes, 4% (n = 2) 2 classes and 2% (n = 1) only 1 class of the program. In the PE + CH group, 88% (n = 44) attended all 4 classes, 2% (n = 1) 3 classes, 2% (n = 1) 2 classes, and 8% (n = 4) attended only 1 class of the program. Overall follow-up response rates were 99% (n = 99) at 2 weeks as well as 3 months. One of the patients in the PE + CH group dropped out of the study and was lost to follow-up.

The baseline sociodemographic and clinical characteristics were similar in both groups (Table 1). Most participants in both groups were women, with secondary level education, with a median duration of pain of 4 years and with moderate levels of average pain intensity and disability. Participants in both groups started treatment with a high expectation of improvement.

Primary Outcomes

There was no significant differences between the groups in average pain intensity at 2 weeks (mean difference [MD] = .67 point, 95% CI = –.27 to 1.62) or 3 months (MD = .09 point, 95% CI = –.85 to 1.04). However, patients enrolled in the PE + CH group reported lower worst pain intensity at 2 weeks (MD = 1.35 points, 95% CI = .32–2.37) as well as 3 months (MD = 1.32 points, 95% CI = .29–2.34). They also reported significantly greater reductions in disability at 2 weeks (MD = 2.34 points, 95% CI = .06–4.61; Table 2).

Table 1. Demographic and Clinical Characteristics of the Participants at Baseline (N = 100)

Characteristics	PE (n = 50)	PE + CH (n = 50)
Female sex, n (%)	36 (72)	44 (88)
Age, years	48.4 (12.60)	51.7 (14.46)
Duration of pain, months	50 (102)	48 (98)
Weight, kg	73.99 (12.94)	71.44 (15.55)
Height, m	1.64 (.06)	1.62 (.06)
Marital status, n (%)		
Single	17 (34)	14 (28)
Married	27 (54)	19 (38)
Divorced	6 (12)	15 (30)
Other	0 (0)	2 (4)
Education status, n (%)		
Elementary school	10 (20)	18 (36)
Secondary school	22 (44)	25 (50)
University	18 (36)	7 (14)
Use of medication	31 (62)	32 (64)
Physically active	17 (34)	13 (26)
Smoker	7 (14)	10 (20)
Work compensation	1 (2)	3 (6)
Treatment expectation (0–10)	8.46 (1.69)	8.37 (1.85)
NRS average (0–10)	7.20 (1.61)	6.63 (1.57)
NRS worse (0–10)	8.18 (1.57)	8.31 (1.41)
RMDQ (0–24)	13.44 (5.02)	14.88 (5.10)
PCS (0–52)	28.16 (12.83)	28.92 (13.75)
PSFS (0–10)	3.63 (1.80)	4.38 (1.89)
GPE (–5 to +5)	–2.34 (2.67)	–2.29 (2.78)

Abbreviations: PCS, Pain Catastrophizing Scale; PSFS, Patient-Specific Function Scale; GPE, Global Perceived Effect Scale.
NOTE. Categorical variables are expressed as n (%), continuous variables are expressed as mean (SD), and duration of pain is expressed as median (interquartile range).

Secondary Outcomes

With respect to the secondary outcomes, there was significant difference in favor of the PE + CH group for catastrophizing at 3 months (MD = 6.78 points, 95% CI = 2.08–11.48) and global perceived benefits at 2 weeks (MD = 1.98 points, 95% CI = –3.25 to –.71; Table 2). The numbers needed to treat were 2.9 (95% CI = .3–.7) for the worst pain intensity and 5.1 (95% CI = .4–1.0) for disability at 2 weeks in favor of the PE + CH group.

The expectation of improvement between the groups were very similar at 2-week (MD = –.00 point, 95% CI = –.70 to .68) and at 3-month follow-ups (MD = –.23 point, 95% CI = –.92 to .46).

Participants in both groups reported similar frequency of home practice at 3 months (never or little: 14% in the PE and 20% in the PE + CH group; somewhat: 50% in the PE and 40% in the PE + CH group; much: 36% in the PE and 38% in the PE + CH group).

Adverse Effects

The percentage of patients who reported increased pain at 3-month follow-up was 12% (n = 6) in the PE group, and 8% (n = 4) in the PE + CH group (a nonsignificant difference; $\chi^2 = .40$, $P = .53$). No serious adverse effects were reported.

Table 2. Primary and Secondary Outcomes—Mean Change According to Treatment Group

	Unadjusted Mean Outcome (SD)		*Adjusted Treatment Effect (95% CI)*	
Measure	*PE (N = 50)*	*PE + CH (N = 49)*	*PE Versus PE + CH Adjusted MD*	P
Pain intensity average—NRS (0–10)				
Baseline	7.2 (1.61)	6.6 (1.57)		
2 Weeks	5.6 (2.21)	4.4 (2.14)	.67 (–.27 to 1.62)	.16
3 Months	5.1 (2.48)	4.4 (2.93)	.09 (–.85 to 1.04)	.84
Pain intensity worse—NRS (0–10)				
Baseline	8.1 (1.57)	8.3 (1.41)		
2 Weeks	6.8 (2.49)	5.5 (2.06)	1.35 (.32 to 2.37)	.01*
3 Months	6.1 (2.63)	4.9 (3.14)	1.32 (.29 to 2.34)	.01*
Disability—RMDQ (0–24)				
Baseline	13.4 (5.02)	14.8 (5.10)		
2 Weeks	9.6 (6.45)	8.9 (6.40)	2.34 (.06 to 4.61)	.04*
3 Months	7.6 (7.09)	7.2 (7.24)	2.07 (–.19 to 4.35)	.07
Catastrophizing—PCS (0–52)				
Baseline	28.1 (12.83)	28.9 (13.75)		
2 Weeks	17.9 (14.43)	16.2 (11.00)	2.38 (–1.72 to 6.48)	.25
3 Months	14.3 (14.89)	9.8 (9.22)	5.30 (1.20 to 9.41)	.01*
Function—PSFS (0–10)				
Baseline	3.6 (1.80)	4.3 (1.89)		
2 Weeks	5.4 (2.28)	6.0 (1.90)	.08 (–.84 to 1.00)	.86
3 Months	5.7 (2.30)	6.2 (2.58)	.16 (–.75 to 1.09)	.72
Global Perceived Effect—GPE (–5 to +5)				
Baseline	–2.3 (2.67)	–2.2 (2.78)		
2 Weeks	.5 (3.35)	2.6 (2.08)	–1.98 (–3.21 to –.75)	.002*
3 Months	1.8 (2.65)	2.4 (2.60)	–.47 (–1.69 to .75)	.31

Abbreviations: PCS, Pain Catastrophizing Scale; PSFS, Patient-Specific Function Scale; GPE, Global Perceived Effect.
NOTE. Unadjusted Mean Outcomes presented as Mean Difference (MDs) and Standard Deviation (SD). Adjusted Treatment Effect presented as MDs and Confidence Interval of 95% (95% CI). Positive scores for treatment effect favor pain neurophysiology education with hypnosis for outcomes of pain intensity, disability, catastrophizing, and function. Negative scores favor the pain neurophysiology education with hypnosis for the outcome of global perceived effect. Primary outcomes are highlighted in gray.
*$P < .05$.

Discussion

To our knowledge, this is the first randomized controlled trial that has investigated the beneficial effects of combining CH with PE for patients with chronic pain. We found that the additional use of CH with PE resulted in improved outcomes of worst pain intensity, disability, and global perceived benefits in the short-term, compared with PE alone. Moreover, additional use of PE with CH maintained its superiority over PE alone for reducing the worst pain intensity at medium-term, and also showed additional benefits in reducing catastrophizing at medium-term.

We prospectively registered the worst pain intensity as a primary outcome because similar hypnotic suggestions have been shown to influence this outcome in other chronic pain conditions.[21] Jensen and colleagues compared CH with cognitive restructuring and did not find a statistically significant difference in the average pain intensity, but detected a statistical difference in the worst pain intensity.[21] The reasons for finding significant effects for worst pain intensity but not for average pain intensity are not entirely clear. It is possible that when rating average pain intensity, patients might consider different cognitive and emotional references than when rating worst pain intensity. Also, worst pain intensity tends to be more strongly correlated with pain interference (mood, social relationships, walking, work and enjoyment of life) than average pain.[10] Recently, a study showed that a scale for measuring pain intensity may reflect patients' perceptions about pain interference and beliefs about their pain, and not only pain intensity.[25] In our study, patients who received CH also evidenced a larger reduction in catastrophizing. There is evidence that catastrophizing may, at least in part, influence pain intensity in chronic pain conditions.[29,38] Overall, the findings suggest the possibility that a greater variety of pain experience domains might be influenced by CH than PE alone. Future studies could shed some light on this by testing the causal mechanisms that underlie the effect of CH on different pain-related outcomes, including worst pain intensity.

Previous studies that have evaluated the efficacy of hypnosis treatment (alone) for chronic low back pain showed no additional benefits for pain intensity, relative to other active psychosocial pain treatments such as PE, biofeedback, and relaxation.[36,48,50] The current findings suggest the possibility that combining different psychosocial interventions may boost their overall efficacy. However, it is important to keep in mind that the component parts of combination treatments may influence efficacy.[21,28,40,46] For example, exercise therapy has been shown to reduce the beneficial effects of pain neuroscience education in patients with chronic low back pain.[46] However, there is

also evidence that hypnosis can increase the beneficial effects of cognitive-behavioral therapy for reducing worst pain intensity in patients with chronic pain and multiple sclerosis.[21] Research is needed to help determine which treatment combinations are most effective for most patients.

This study has some important limitations that should be considered when interpreting the results. As is the case with all psychosocial interventions, neither the therapist nor the patients were blind to treatment condition. Thus, although the pain educational content and PE treatment time were the same in both treatment conditions, the participants in the PE with hypnosis condition received more therapist attention overall, because of the additional time needed for hypnosis. Further studies could compare the effects of PE with hypnosis versus PE with another intervention to control the potential effects of therapy time. In addition, a single therapist who was aware of the study hypotheses conducted the interventions; further research is therefore needed to determine if the current findings generalize to other therapists, including those who might not be aware of the study hypotheses.

Despite the study's limitations, it also has some important strengths. The trial was prospectively registered, used true randomization, concealed allocation, used outcome assessors who were blind to treatment condition, used an intent to treat analysis and had very high follow-up rates. In addition, a high percentage (87%) of attendance in all treatment interventions was observed. The interventions were clearly defined and standardized, and conducted by a therapist who had several years of experience delivering both interventions. The participants were seeking physical therapy services and were very similar to patients from previous clinical trials in back pain,[15,44] which increases the external validity of the study. Moreover, the expectation of improvement with the treatments was similar in both groups and at all assessment points. Thus, patient expectancies, either because of their beliefs about hypnosis or as might have been influenced by the therapist, do not appear to have had a biasing effect on the findings.

Conclusions

The findings from this study indicate that CH enhances the effects of PE, at least in the short- and medium-term. The study findings provide support for another option for the management of chronic low back pain; a treatment option that has a relatively low cost (compared with many other pain treatments) and that can be offered in group settings.

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Supplementary Data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jpain.2018.03.013.

References

1. Abdel Shaheed C, Maher CG, Williams KA, Day R, McLachlan AJ: Efficacy, tolerability, and dose-dependent effects of opioid analgesics for low back pain: A systematic review and meta-analysis. JAMA Intern Med 176:958-968, 2016

2. Adachi T, Fujino H, Nakae A, Mashimo T, Sasaki J: A meta-analysis of hypnosis for chronic pain problems: A comparison between hypnosis, standard care, and other psychological interventions. Int J Clin Exp Hypn 62:1-28, 2014

3. Beattie P, Silfies P, Jordon M: The evolving role of physical therapists in the long-term management of chronic low back pain: Longitudinal care using assisted self-management strategies. Braz J Phys Ther 20:580-591, 2016

4. Bombardier C, Hayden J, Beaton DE: Minimal clinically important difference. Low back pain: Outcome measures. J Rheumatol 28:431-438, 2001

5. Butler D, Moseley L: Explain Pain. Adelaide, Australia, Noigroup, 2003

6. Clarke CL, Ryan CG, Martin DJ: Pain neurophysiology education for the management of individuals with chronic low back pain: Systematic review and meta-analysis. Man Ther 16:544-549, 2011

7. Costa LO, Maher CG, Latimer J, Ferreira PH, Ferreira ML, Pozzi GC, Freitas LM: Clinimetric testing of three self-report outcome measures for low back pain patients in Brazil: Which one is the best? Spine 33:2459-2463, 2008

8. Costa LO, Maher CG, Latimer J, Ferreira PH, Pozzi GC, Ribeiro RN: Psychometric characteristics of the Brazilian-Portuguese versions of the Functional Rating Index and the Roland Morris Disability Questionnaire. Spine 32:1902-1907, 2007

9. Costa LO, Maher CG, Latimer J, Hodges PW, Herbert RD, Refshauge KM, McAuley JH, Jennings MD: Motor control exercise for chronic low back pain: A randomized placebo-controlled trial. Phys Ther 89:1275-1286, 2009

10. Daut RL, Cleeland CS, Flanery RC: Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases. Pain 17:197-210, 1983

11. Devilly GJ: Psychometric properties of the credibility/expectancy questionnaire. J Behav Ther Exp Psychiatry 31: 73-86, 2003

12. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick C, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport BA, Rauschkolb C, Revicki DA, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S: Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain 9:105-121, 2008

13. Engers A, Jellema P, Wensing M, van der Windt DA, Grol R, van Tulder MW: Individual patient education for low back pain. Cochrane Database Syst Rev (1):CD004057, 2008

14. Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM: Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 94: 149-158, 2001

15. Garcia AN, Costa LC, Silva TM, Gondo FL, Cyrillo FN, Costa RA, Costa LO: Effectiveness of back school versus McKenzie exercises in patients with chronic nonspecific low back pain: A randomized controlled trial. Phys Ther 93:1-19, 2013

16. Global Burden of Disease Study 2013 Collaborators: Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: A systematic analysis for the Global Burden of Disease Study 2013. Lancet 386:743-800, 2015

17. Henschke N, Kuijpers T, Rubinstein SM, van Middelkoop M, Ostelo R, Verhagen A, Koes BW, van Tulder MW: Injection therapy and denervation procedures for chronic low-back pain: A systematic review. Eur Spine J 19:1425-1449, 2010

18. Horn KK, Jennings S, Richardson G, Vliet DV, Hefford C, Abbott JH: The patient-specific functional scale: Psychometrics, clinimetrics, and application as a clinical outcome measure. J Orthop Sports Phys Ther 42:30-40, 2012

19. Jensen MP: A neuropsychological model of pain: Research and clinical implications. J Pain 11:2-12, 2010

20. Jensen MP: Hypnosis for Chronic Pain Management: Therapist Guide. England, Oxford University Press, 2011

21. Jensen MP, Gertz KJ, Stoelb B, Dillworyh TM, Hirsh AT, Molton IR, Kraft GH: Effects of self-hypnosis training and cognitive restructuring on daily pain intensity and catastrophizing in individuals with multiple sclerosis and chronic pain. Int J Clin Exp Hypn 59:45-63, 2011

22. Jensen MP, Karoly P, Braver S: The measurement of clinical pain intensity: A comparison of six methods. Pain 27: 117-126, 1986

23. Jensen MP, Patterson DR: Hypnotic treatment of chronic pain. J Behav Med 29:95-124, 2006

24. Jensen MP, Patterson DR: Hypnotic approaches for chronic pain management: Clinical implications of recent research findings. Am Psychol 69:167-177, 2014

25. Jensen MP, Tome-Pires C, de la Vega R, Galan S, Sole E, Miro J: What determines whether a pain is rated as mild, moderate, or severe? The importance of pain beliefs and pain interference. Clin J Pain 33:414-421, 2017

26. Kamper SJ, Apeldoorn AT, Chiarotto A, Smeets RJ, Ostelo RW, Guzman J, van Tulder MW: Multidisciplinary biopsychosocial rehabilitation for chronic low back pain: Cochrane systematic review and meta-analysis. BMJ 350: h444, 2015

27. Kamper SJ, Ostelo RW, Knol DL, Maher CG, de Vet HC, Hancock MJ: Global Perceived Effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. J Clin Epidemiol 63:760-766, 2010

28. Kirsch I, Montgomery G, Sapirstein G: Hypnosis as an adjunct to cognitive-behavioral psychotherapy: A meta-analysis. J Consult Clin Psychol 63:214-220, 1995

29. Kjogx H, Kasch H, Zachariae R, Svensson P, Jensen TS, Vase L: Experimental manipulations of pain catastrophizing influence pain levels in patients with chronic pain and healthy volunteers. Pain 157:1287-1296, 2016

30. Lin IB, O'Sullivan PB, Coffin JA, Mak DB, Toussaint S, Straker LM: Disabling chronic low back pain as an iatrogenic disorder: A qualitative study in Aboriginal Australians. BMJ 3:e002654, 2013

31. Louw A, Diener I, Butler DS, Puentedura EJ: The effect of neuroscience education on pain, disability, anxiety, and stress in chronic musculoskeletal pain. Arch Phys Med Rehabil 92:2041-2056, 2011

32. Louw A, Zimney K, Puentedura EJ, Diener I: The efficacy of pain neuroscience education on musculoskeletal pain: A systematic review of the literature. Physiother Theory Pract 32:332-355, 2016

33. Maher C, Underwood M, Buchbinder R: Non-specific low back pain. Lancet 389:736-747, 2017

34. Maher CG, Latimer J, Hodges PW, Refshauge KM, Moseley GL, Herbert RD, Costa LO, McAuley J: The effect of motor control exercise versus placebo in patients with chronic low back pain [ACTRN012605000262606]. BMC Musculoskelet Disord 6:54, 2005

35. Malfliet A, Leysen L, Pas R, Kuppens K, Nijs J, Van Wilgen P, Huysmans E, Goudman L, Ickmans K: Modern pain neuroscience in clinical practice: Applied to post-cancer, paediatric and sports-related pain. Braz J Phys Ther 21:225-232, 2017

36. McCauley JD, Thelen MH, Frank RG, Willard RR, Callen KE: Hypnosis compared to relaxation in the outpatient management of chronic low back pain. Arch Phys Med Rehabil 64:548-552, 1983

37. Merrifield A, Smith W: Sample size calculations for the design of health studies: A review of key concepts for non-statisticians. N S W Public Health Bull 23:142-147, 2012

38. Meyer K, Tschopp A, Sprott H, Mannion AF: Association between catastrophizing and self-rated pain and disability in patients with chronic low back pain. J Rehabil Med 41:620-625, 2009

39. Moseley GL: Innovative treatments for back pain. Pain 158:S2-S10, 2016

40. Moseley LG: Combined physiotherapy and education is efficacious for chronic low back pain. Aust J Physiother 48: 297-302, 2002

41. Moseley LG, Nicholas MK, Hodges PW: A randomized controlled trial of intensive neurophysiology education in chronic low back pain. Clin J Pain 20:324-330, 2004

42. Nusbaum L, Natour J, Ferraz MB, Goldenberg J: Translation, adaptation and validation of the Roland-Morris questionnaire-Brazil Roland-Morris. Braz J Med Biol Res 34: 203-210, 2001

43. Ostelo RW, Deyo RA, Stratford P, Waddell G, Croft P, Von Korff M, Bouter LM, de Vet HC: Interpreting change scores for pain and functional status in low back pain: Towards international consensus regarding minimal important change. Spine 33:90-94, 2008

44. Parreira Pdo C, Costa Lda C, Takahashi R, Hespanhol LC Junior, Luz MA Junior, Silva TM, Costa LO: Kinesio taping to generate skin convolutions is not better than sham taping for people with chronic non-specific low back pain: A randomised trial. J Physiother 60:90-96, 2014

45. Rossi E, Ryan M, Sharp F: Healing in Hypnosis: The Lectures, Seminars, and Workshops of Milton H. Erickson, Vol. 1. New York, NY, Irvington, 1983

46. Ryan CG, Gray HG, Newton M, Granat MH: Pain biology education and exercise classes compared to pain biology education alone for individuals with chronic low back pain: A pilot randomised controlled trial. Man Ther 15:382-387, 2010

47. Sehn F, Chachamovich E, Vidor LP, Dall-Agnol L, de Souza IC, Torres IL, Fregni F, Caumo W: Cross-cultural adaptation and validation of the Brazilian Portuguese version of the pain catastrophizing scale. Pain Med 13:1425-1435, 2012

48. Spinhoven P, Linssen AC: Education and self-hypnosis in the management of low back pain: A component analysis. Br J Clin Psychol 28:145-153, 1989

49. Stoelb BL, Molton IR, Jensen MP, Patterson DR: The efficacy of hypnotic analgesia in adults: A review of the literature. Contemp Hypn 26:24-39, 2009

50. Tan G, Rintala DH, Jensen MP, Fukui T, Smith D, Williams W: A randomized controlled trial of hypnosis compared with biofeedback for adults with chronic low back pain. Eur J Pain 19:271-280, 2015

51. Thomas E, Silman AJ, Croft PR, Papageorgiou AC, Jayson MI, Macfarlane GJ: Predicting who develops chronic low back pain in primary care: A prospective study. BMJ 318:1662-1667, 1999