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Multicomponent Cognitive-Behavioral Group Therapy With Hypnosis for the Treatment of Fibromyalgia: Long-Term Outcome

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Abstract: This study compared the efficacy of 2 psychological treatments for fibromyalgia with each other and with standard care. Ninety-three patients with fibromyalgia (FM) were randomly assigned to 1 of the 3 experimental conditions: 1) multicomponent cognitive-behavioral therapy (CBT); 2) multicomponent CBT with hypnosis; and 3) pharmacological treatment (standard care control group). The outcome measures of pain intensity, catastrophizing, psychological distress, functionality, and sleep disturbances were assessed before treatment, immediately after treatment, and at 3- and 6-month follow-up visits. CBT and CBT with hypnosis participants received the standard pharmacological management plus 14 weekly, 120-minute-long sessions of psychological treatment. All but 1 session followed a group format; the remaining session was individual. The analyses indicated that: 1) patients with FM who received multicomponent CBT alone or multicomponent CBT with hypnosis showed greater improvements than patients who received only standard care; and 2) adding hypnosis enhanced the effectiveness of multicomponent CBT. This study presents new evidence about the efficacy of multicomponent CBT for FM and about the additional effects of hypnosis as a complement to CBT. The relevance and implications of the obtained results are discussed.

***Perspective:** This article highlights the beneficial effects of adding hypnosis in a multicomponent cognitive-behavioral group treatment of fibromyalgia patients. Also, this research showed that by adding hypnosis the length of treatment did not increase.*

***Key words:** Fibromyalgia, hypnosis, chronic pain, cognitive-behavioral therapy, psychological treatment.*

Fibromyalgia (FM) is a chronic pain syndrome characterized by widespread musculoskeletal pain and multiple symptoms, including fatigue, sleep disturbances, cognitive dysfunction, and psychological distress.[6,14] Because the etiology of FM is still unclear, it has received a great amount of attention from clinicians and researchers. This attention has focused on both discovering the etiology of FM and determining the optimal management of it.

The efficacy of cognitive-behavioral therapy (CBT) in treating various chronic pain disorders has been demonstrated in numerous studies and stated in numerous reviews and meta-analyses.[10,16,21,34,41,44,56-58,73-75] In FM in particular, CBT has been proven effective at producing modest outcomes across multiple domains, including pain, fatigue, physical functioning, and mood,[4,7,23,24,26,28,32,64,72,77] even when it is provided in a group format.[38,77] Nevertheless, some authors have questioned the usefulness of CBT in the treatment of some key symptoms of FM, such as pain, fatigue and sleep disturbances.[6,23,27]

Hypnosis can be understood as "a social interaction in which one person - designated the subject - responds to suggestions offered by another person - designated the hypnotist - for experiences involving alterations in perception, memory and voluntary action."[39] There is extensive evidence on the efficacy of hypnotic treatment in reducing acute and chronic pain.[2,3,18,22,25,31,36,42,46,52,53,59,68,69] Despite the benefits of hypnosis in the overall treatment of pain, few studies have examined its efficacy in the treatment of FM.[1,12,26,76]

The efficacy of hypnosis has also been proven when it is combined with CBT. In particular, a meta-analytic review[40] showed that hypnosis enhanced the efficacy of CBT. However, only 2 of the studies included in this meta-analytic review studied pain, and neither of those

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studies found that adding hypnosis produced better results than CBT alone.[48,49] More recent studies indicated that the combination of CBT and hypnosis was more effective than standard care in managing symptoms in breast cancer radiotherapy patients.[54,65] Additionally, in FM patients, 1 study showed that the combination of CBT and hypnosis was more effective at improving pain and functionality than CBT alone.[13] Unfortunately, that study did not provide information about the evolution of the results during a long-term follow-up. Further research is needed to determine whether and under what conditions hypnosis contributes to better outcomes when added to CBT intervention.

To add to the current data regarding this topic, we compared 2 psychological treatments for FM (multicomponent CBT and multicomponent CBT plus hypnosis) with each other and with standard care (pharmacological management). Additionally, we assessed the maintenance of therapeutic benefit at a 6-month follow-up visit. We hypothesized that the multicomponent CBT treatments (CBT alone and CBT plus hypnosis) would provide greater benefits than standard care. We also sought to determine whether adding hypnosis to the CBT treatment would enhance its efficacy, anticipating that if a difference were found, CBT plus hypnosis would be more effective than CBT alone.

Methods

Participants

Inclusion criteria for study participation were an FM diagnosis made according to the ACR diagnostic criteria[78] and an age between 18 and 65 years old. Exclusion criteria were 1 or more additional severe chronic medical pain conditions (eg, sciatica and complex regional pain syndrome), significant suicidal ideation, severe psychopathology (eg, psychosis), or moderate-to-severe cognitive impairment.

A total of 123 individuals with FM were initially screened, and 93 of these individuals were ultimately included in the study sample. Their average age was 49.6 years old (range: 35–65 years SD 6.8), and the average length of their pain history was 12.6 years (SD 8.3). Of this sample, 96.8% were women and the remaining 3.2% were men. The ethnic composition was 100% white. Regarding education, 54.8% had completed their primary education, 38.7% had completed secondary education and 6.5% had completed higher education. More specific demographic and pain-related data are detailed in Table 1.

Procedure

Our study was conducted in agreement with the Joan XXIII University Hospital Clinical Research Ethical Committee, and all candidates signed the study consent form. Patients were randomly assigned to 1 of 3 treatment conditions: standard pharmacological care (control), standard pharmacological care with CBT, and standard pharmacological care with cognitive-behavioral therapy plus hypnosis (CBT plus hypnosis). The psychological treatments (CBT and CBT plus hypnosis) were conducted in a group format. The number of subjects in each group ranged from 4 to 6 participants. Demographic data were collected, and several instruments were administered to obtain pretreatment measures. In the week immediately after treatment completion, the same instruments were administered again to obtain the post-treatment outcome measures. The same assessment instruments were administered at the 3- and 6-month follow-up visits. All outcome measures were administered by a psychologist who was blinded to the participants' group assignment.

Treatment Conditions

The participants in the standard care control group received conventional pharmacological treatments, including analgesics, antidepressants, anticonvulsants. and myorelaxants, as appropriate. The participants assigned to the CBT-alone treatment condition received the standard pharmacological management plus 14 weekly, 120-minutes CBT treatment sessions. All sessions were conducted in a group format except Session 2, which was individual. The CBT program included education about FM and pain perception theory (Session 1), Schultz Autogenic Training[66] (Session 2), cognitive restructuring skills training (Sessions 3 to 5), cognitive-behavioral therapy for primary insomnia[19] (Sessions 6 to 8), assertiveness training (Sessions 9 and 10), activity pacing and pleasant activity scheduling training (Sessions 11 and 12), goal setting (Session 13), and life values and relapse prevention (Session 14). The participants in this group were given a patient's manual describing the contents of the program and an audio CD to practice Schultz Autogenic Training at home. They also received record sheets to register their practices of the CBT contents (cognitive restructuring skills training, cognitive-behavioral therapy for primary insomnia, and goal-setting) and these record sheets were discussed in the CBT sessions.

The participants assigned to the CBT plus hypnosis condition received the standard pharmacological management and the same 14 weekly, 120-minute sessions provided to the CBT-alone participants. As in the CBT-alone intervention, all sessions were conducted in a group format except Session 2, which was an individual session. In this session, instead of autogenic training, the participants received analgesic self-hypnosis training. The analgesia suggestions included imagining an analgesic liquid stream that filtered through the skin and reached different parts of the body. Additionally, self-hypnotic training was extended as an adjunct of other components of the CBT program. Specifically, cognitive therapy was complemented with hypnosis through visualization of the most complex situations chosen by the participant. During hypnosis, the patient modified the belief or emotion caused by the concrete situation and ended with a covert self-reinforcement. The CBT for primary insomnia was complemented with the visualization of a blind lowering and with a relaxing suggestion. The assertiveness training was complemented with the participant's visualization of a situation

Table 1. Demographic and Clinical Data

Variables	Control Group (N = 30)	CBT Alone (N = 34)	CBT Plus Hypnosis (N = 29)
Age (years)	48.7 (SD 6.5)	50.0 (SD 7.6)	50.2 (SD 6.2)
Sex			
Male	0 (0%)	2 (6%)	1 (3.4%)
Female	30 (100%)	32 (94%)	28 (96.6%)
Marital status			
Single	3 (10%)	1 (3%)	2 (7%)
Married	21 (70%)	29 (85%)	18 (62%)
Widow	0 (0%)	1 (3%)	4 (14%)
Separated	6 (20%)	3 (9%)	5 (17%)
Work Status			
Currently employed	19 (63%)	15 (44.1%)	14 (48.3%)
Homemaker	8 (27%)	14 (41.2%)	10 (34.5%)
Unemployed	3 (10%)	3 (8.8%)	3 (10.3%)
Working compensation	0 (0%)	2 (5.9%)	2 (6.9%)
Formal education			
Low	18 (60%)	20 (58.8%)	13 (44.8%)
Mid	10 (33.3%)	11 (32.4%)	15 (51-7%)
High	2 (6.7%)	3 (8.8%)	1 (3.4%)
Pain duration (years)	11.6 (SD 6.9)	13.6 (SD 9.2)	12.5 (SD 9.0)

NOTE. Continuous variables (mean and standard deviation); qualitative variables (number of subjects and percentage). Low education = primary education; mid education = secondary education; high education = higher education.

in which he/she used an adaptive, assertive style and with the suggestion of positive emotions and covert self-reinforcement. Finally, the activity pacing, pleasant activity scheduling training, and goal-setting components were complemented with the visualization of achieving short-term goals using future projection and visualization of the necessary steps to attain the goal. Hypnosis exercises were performed at the end of each session in place of the autogenic training provided in the CBT-alone program. Participants from the CBT plus hypnosis group were also given the patient's manual describing the program's contents. The participants also received record sheets to register their practice of the program's contents, which were also discussed in the sessions. All participants in the CBT plus hypnosis group received an audio CD for home practice. This CD only contained the analgesic self-hypnosis exercises. The CBT plus hypnosis program did not require longer sessions or a longer duration than the CBT-alone program.

Assessment Instruments

Numeric Rating Scale (NRS)

The patient indicates the maximum, minimum, and usual intensities of pain suffered in the last week using a numerical scale with values ranging from 0 to 10. A value of 0 indicates "no pain," while a value of 10 indicates "the maximum pain possible." The average of these 3 scores was obtained and used as a measure of retrospective pain intensity. This procedure has demonstrated a high degree of reliability as a measure of the pain suffered during a specific period of time.[15,37]

Subscale of Catastrophizing From the Coping Strategies Questionnaire (CSQ)[62,63]

This subscale measures catastrophizing related to pain. The questionnaire is widely used in clinical settings and research contexts and has shown adequate reliability and validity in different chronic pain pathologies,[62] including FM.[9]

Hospital Anxiety and Depression Scale (HADS)[79]

This scale evaluates the presence of anxiety and depression. It consists of 14 items, 7 for each dimension. For this study, we used the HADS Spanish adaptation,[71] which has shown adequate reliability and validity. The HADS total score was used as an indicator of psychological distress.[30]

Fibromyalgia Impact Questionnaire (FIQ)[8,61]

The FIQ is a 10-item instrument that assesses FM's impact on physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue, and well-being. The test generates 1 total score. The higher the FIQ score, the higher the impact of FM on the patient's life. The FIQ is widely used as an outcome measure for patients with FM, and its reliability and validity have been demonstrated.[7,25,64]

Medical Outcomes Study (MOS) Sleep Scale[29,60]

This questionnaire is a patient-reported measure consisting of 12 items that assess the quality and duration of sleep. The scale has been found to be a reliable and valid assessment of sleep disturbances in patients with FM.[11,43] Although the complete scale was administered, only the quantity of sleep and sleep problems dimensions were considered for the purposes of this study.

Data Analysis

We compared the demographic and pretreatment outcome variables of the 3 treatment groups using chi-squared analyses for categorical variables and analysis of variance for continuous variables. An intent-to-treat analysis was performed that included subjects who dropped out of the trial. Participants with missing data were included in the analysis, and missing final outcome variable values were replaced with the last known value before the participant was lost to follow-up.[33] Overall statistical comparisons of the treatments were performed using a Student's t-test with Bonferroni correction. Linear mixed model analysis was performed to determine the effects of the reported treatments on changes in outcome measures. The analysis focused on the fixed effects considering whether there was and interaction between time and group, and a random effect for subject. Any statistically significant interaction was broken down by exploring pairwise comparisons. Finally, the percentage of patients that experienced a clinically significant change was also evaluated. A cutoff of 30% was accepted for pain intensity[20] and a cutoff of 14% was accepted for the FIQ total score.[4] Chi-squared analyses and odds ratios (OR) were performed to compare these percentages among the different groups. All the analyses were performed with SPSS v.15 and statistical significance was accepted at P value < .05.

Results

No statistical significant differences were found between the 3 experimental groups on age, gender distribution, pain duration, marital status, educational level, or work status as well as on pretreatment measures of pain intensity, catastrophizing, psychological distress, FIQ total score, and sleep quantity and sleep problems index domains of the Medical Outcomes Study (MOS) Sleep Scale (Table 1). Not differences were found when attendance at the therapy sessions was compared between CBT alone and CBT plus hypnosis groups. Participants of the CBT alone group attended a mean of 12.3 sessions (SD 1.7) and participants of the CBT plus hypnosis group attended a mean of 12.0 sessions (SD 2.6).

Of the 93 treated patients, 87 (93.5%) finished the treatment. At 3-month follow-up, the number of participants decreased to 81 (87.1%), and at 6-month follow-up, the number of participants decreased to 71 (76.3%). If we consider the groups separately, at the post-treatment, the 96.7% of the control group participants, the 91.2% of the CBT group participants, and the 93.1% of the CBT plus hypnosis group participants were assessed. At 3-month follow-up, the percentage was respectively the 76.7%, the 94.1%, and the 89.6%. Finally, at 6-month follow-up, the 73.3% of the control group participants, the 76.5% of the CBT group participants, and the 79.3% of the CBT plus hypnosis group participants were assessed (Fig 1).

Overall statistics comparison using analysis of variance corrected by Bonferroni method showed a significant difference between CBT alone and control group on pain intensity (P < .0001), catastrophizing (P < .0001), psychological distress (P < .0001), FIQ total score (P < .0001), sleep quantity (P < .0001), and sleep index problems (P < .0001). Also, significant differences were found between CBT plus hypnosis and control group on pain intensity (P < .0001), catastrophizing (P < .0001), psychological distress (P < .0001), FIQ total score (P < .0001), sleep quantity (P < .0001), and sleep index problems (P < .0001). Finally, significant differences were found between CBT plus hypnosis and CBT alone on psychological distress (P < .05).

Mixed linear model analysis showed a significant interaction group × time in catastrophizing [F = 2.446; P < .05], psychological distress [F = 5.361; P < .0001], FIQ total score [F = 5.466; P < .0001], sleep quantity [F = 3.955; P < .01] and sleep index problems [F = 8.854; P < .0001]. On the contrary, not significant interaction group × time was found in pain intensity. Post hoc comparisons were performed when the interaction term (group × time) was significant.

When outcomes were compared with baseline in each one of the groups, post hoc analyses adjusted with Bonferroni method showed that there was a significant effect of CBT plus hypnosis and CBT alone on catastrophizing, psychological distress, FIQ total score, sleep quantity, and sleep index problems (Table 2).

When treatments were compared, mixed model analyses showed significant differences between CBT alone and control group at post-treatment on catastrophizing (P < .05) and sleep index problems (P < .0001). At 3-month follow-up the differences between both groups were significant on psychological distress (P < .05), sleep quantity (P < .05), and sleep index problems (P < .0001). Finally, at 6-month follow-up the differences between CBT alone and control group were significant on psychological distress (P < .01), FIQ total score (P < .05), and sleep index problems (P < .0001). When CBT plus hypnosis and control group were compared, significant differences were found at post-treatment on catastrophizing (P < .0001), psychological distress (P < .0001), and sleep index problems (P < .0001). At 3-month follow-up the differences between CBT plus hypnosis and control group were significant on catastrophizing (P < .05), psychological distress (P < .01), sleep quantity (P < .05), and sleep index problems (P < .0001). Finally, at 6-month follow-up the differences between CBT plus hypnosis and control group were significant on psychological distress (P < .01) and sleep index problems (P < .0001). No differences were found between CBT alone and CBT with hypnosis when mixed model analysis was performed (Figs 2-4). When the male participants were removed from the sample, the linear mixed model analysis indicated a similar pattern of the effects.

Finally, the percentage of participant who met the standard criteria for minimal clinically significant difference in pain intensity and FIQ total score was calculated (Table 3). Significant differences were found between CBT plus hypnosis and CBT alone in pain intensity at post-treatment [χ^2 = 5.007; P < .05] [OR = 4.650; 95% CI: 1.121 to 19.284]. Also, significant differences were found in FIQ total score between CBT and control group

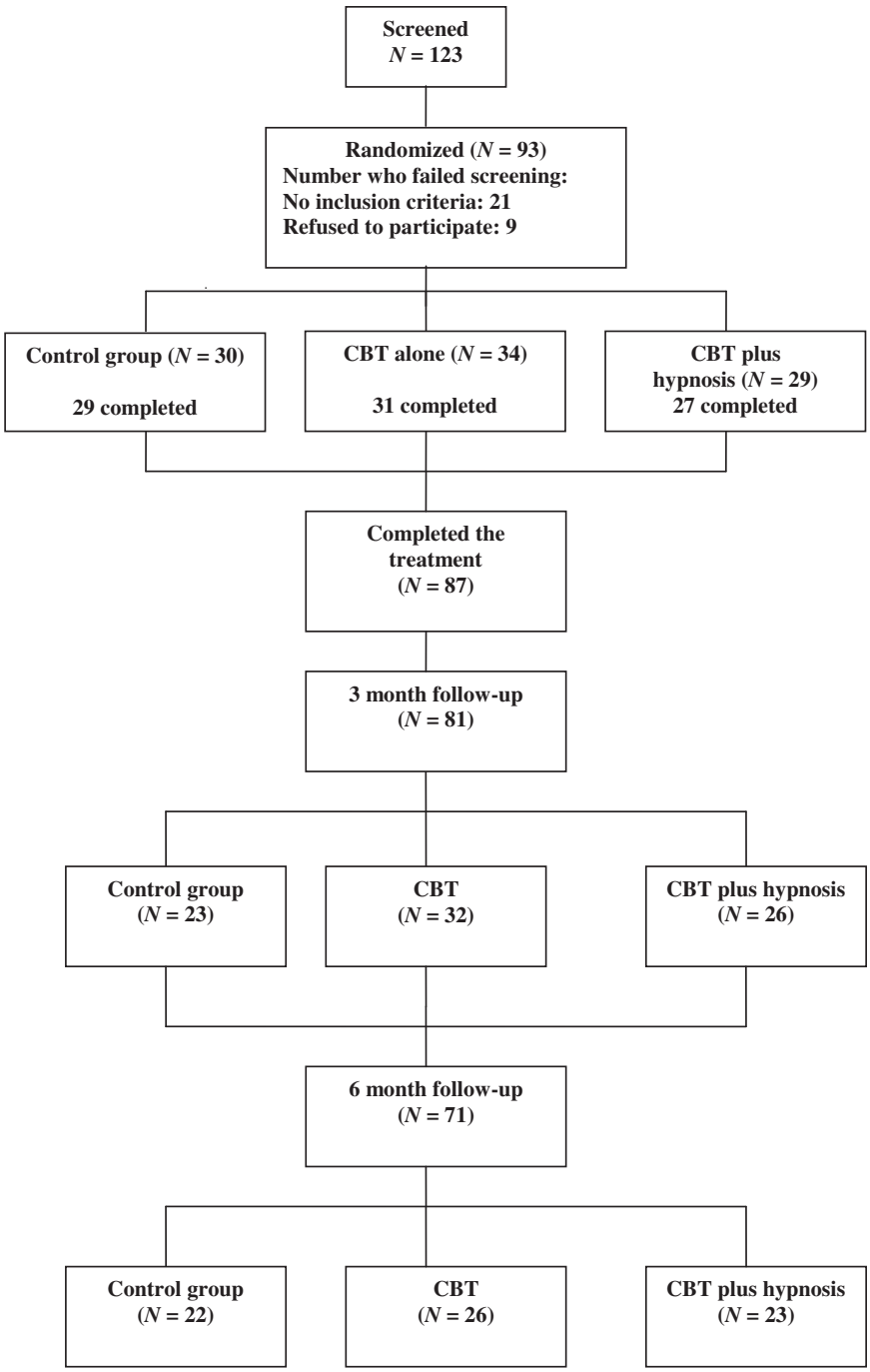


Figure 1. Trial profile.

at post-treatment [χ^2 = 7.0; P < .01] [OR = 4.162; 95% CI: 1.408 to 12.299], 3 month follow-up [χ^2 = 8.621; P < .01] [OR = 5.067; 95% CI: 1.650 to 15.558] and 6-month follow-up [χ^2 = 9.959; P < .01] [OR = 5.714; 95% CI: 1.854 to 17.810]. Finally, between CBT plus hypnosis and control group, significant differences were found in FIQ total score at post-treatment [χ^2 = 10.646; P < .01] [OR = 6.243; 95% CI: 1.994 to 19.542], 3-month follow-up [χ^2 = 14.344; P < .0001] [OR = 8.889; 95% CI: 2.701 to 29.257] and 6-month follow-up [χ^2 = 7.801; P < .01] [OR = 4.923; 95% CI: 1].

Discussion

The main results indicated that: 1) the patients with FM who received CBT alone or CBT plus hypnosis showed greater improvements in several outcomes than patients who received only standard care; and 2) adding hypnosis enhanced the effectiveness of CBT. Therefore, the obtained results support the study's hypothesis that multicomponent CBT for FM complemented with hypnosis was more beneficial than the same multicomponent CBT without hypnosis.

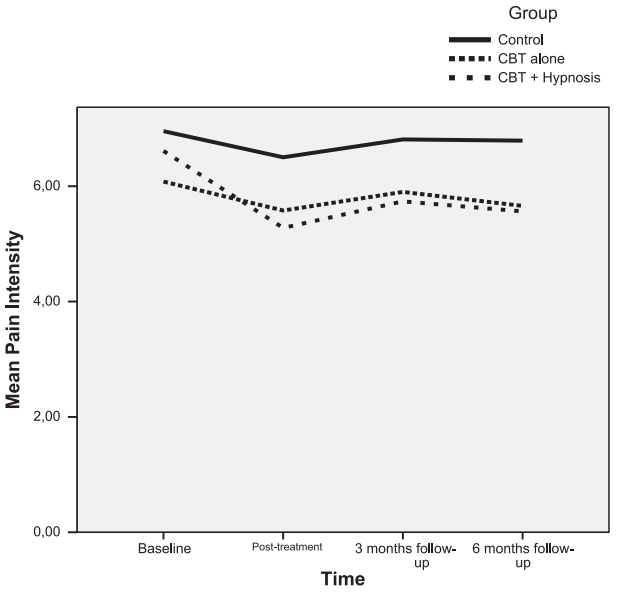
Table 2. Baseline, Post-Treatment, 3-Month Follow-Up, and 6-Month Follow-Up Outcome Measures of Participants in Each Treatment Condition

Outcome	Control Group (N = 30)	CBT Alone (N = 34)	CBT Plus Hypnosis (N = 29)
Pain intensity			
Baseline	6.9 ± .3	6.1 ± .3	6.6 ± .3
Post-treatment	6.5 ± .3	5.6 ± .3	5.3 ± .3
3-month follow-up	6.8 ± .3	5.9 ± .3	5.7 ± .4
6-month follow-up	6.8 ± .4	5.7 ± .4	5.6 ± .4
All	6.8 ± .3	5.8 ± .3	5.8 ± .3
Catastrophizing			
Baseline	22.5 ± 1.7	19.6 ± 1.6	17.9 ± 1.8
Post-treatment	21.2 ± 1.8	11.6 ± 1.7***	9.0 ± 1.8***
3-month follow-up	19.4 ± 1.8	12.2 ± 1.7††	10.0 ± 1.8††
6-month follow-up	18.7 ± 1.7	11.7 ± 1.6‡‡	10.6 ± 1.8‡
All	21.0 ± 9.5	12.0 ± 9.8	9.0 ± 10.5
Psychological distress			
Baseline	24.2 ± 1.5	23.2 ± 1.4	21.3 ± 1.5
Post-treatment	23.1 ± 1.5	16.1 ± 1.4***	11.7 ± 1.5***
3-month follow-up	22.3 ± 1.4	15.4 ± 1.3†††	13.2 ± 1.4†††
6-month follow-up	23.7 ± 1.4	15.7 ± 1.3‡‡‡	14.2 ± 1.4‡‡
All	24.0 ± 7.4	17.0 ± 8.6	15.0 ± 8.7
FIQ			
Baseline	66.1 ± 3.0	62.7 ± 2.8	69.3 ± 3.0
Post-treatment	64.6 ± 3.5	52.2 ± 3.3*	49.0 ± 3.5***
3-month follow-up	66.3 ± 3.5	52.8 ± 3.3	51.1 ± 3.6†††
6-month follow-up	68.5 ± 3.7	50.5 ± 3.5‡‡	55.0 ± 3.8‡‡
All	68.0 ± 18.7	56.0 ± 18.6	58.5 ± 20.9
Sleep quantity			
Baseline	5.5 ± .3	6.0 ± .3	5.4 ± .3
Post-treatment	5.5 ± .3	6.6 ± .3	6.7 ± .3***
3-month follow-up	5.5 ± .3	6.9 ± .2†	6.9 ± .3†††
6-month follow-up	5.6 ± .3	6.7 ± .2	6.9 ± .3‡‡‡
All	5.3 ± 1.5	6.3 ± 1.5	7.0 ± 1.6
Sleep index problems			
Baseline	27.9 ± 1.6	30.4 ± 1.5	26.9 ± 1.6
Post-treatment	27.8 ± 1.4	39.8 ± 1.3***	40.7 ± 1.4***
3-month follow-up	28.8 ± 1.7	40.1 ± 1.6†††	40.7 ± 1.8†††
6-month follow-up	28.0 ± 1.6	39.9 ± 1.5‡‡‡	39.6 ± 1.6‡‡‡
All	27.5 ± 8.0	39.0 ± 9.6	37.0 ± 10.9

NOTE. Results are expressed in means and Standard Deviation. T-test *P* values were adjusted by Bonferroni Method.
Baseline-post-treatment significance: **P* < .05; ***P* < .01; ****P* < .001.
Baseline-3-month follow-up significance: †*P* < .05; ††*P* < .01; †††*P* < .001.
Baseline-6-month follow-up significance: ‡*P* < .05; ‡‡*P* < .01; ‡‡‡*P* < .001.
All: Overall statistics comparison.

The effectiveness of multicomponent CBT without hypnosis has been demonstrated for the modification of pain intensity, catastrophizing, psychological distress, functionality, and sleep disturbances in patients with FM. Improvements in self-efficacy, mood, and functionality were consistent with findings from meta-analyses of CBT in FM.[5,6] Additionally, the reduction in pain intensity was consistent with findings pertaining to CBT treatment in FM reported in another recent meta-analytic revision.[23] The sleep disorder improvement in the patients treated with CBT alone was probably related to different factors. First, relaxation has been shown to be an important component that enhances CBT's effects on insomnia in patients with fibromyalgia.[23] Second, autogenic training alone has demonstrated positive effects on functional sleep disorders.[67] Third, adding CBT content specifically oriented toward treating chronic primary insomnia has demonstrated significant improvements in sleep disturbances in patients with sleep problems and chronic pain,[55] including fibromyalgia.[17] Finally, it is important to note that our applied CBT for primary insomnia included some key aspects that probably enhanced its efficacy, such as sleep restriction and stimulus control.[70]

In terms of functionality, when the standard criteria for the minimal clinically significant difference was considered, the CBT participants improved progressively more over time compared with control group participants, as indicated by the odds ratio. One probable explanation for this progressive improvement in functionality is related to the decrease in sleep disturbances, which are strongly related to disability in patients who present with chronic pain, as described by Tang.[70]



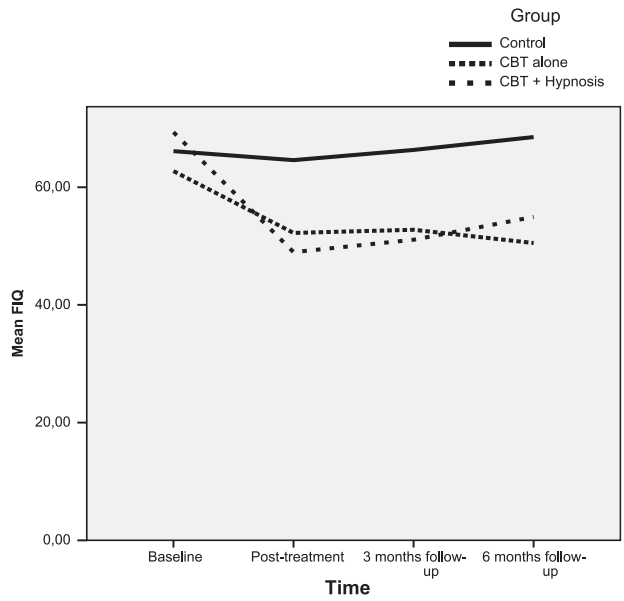
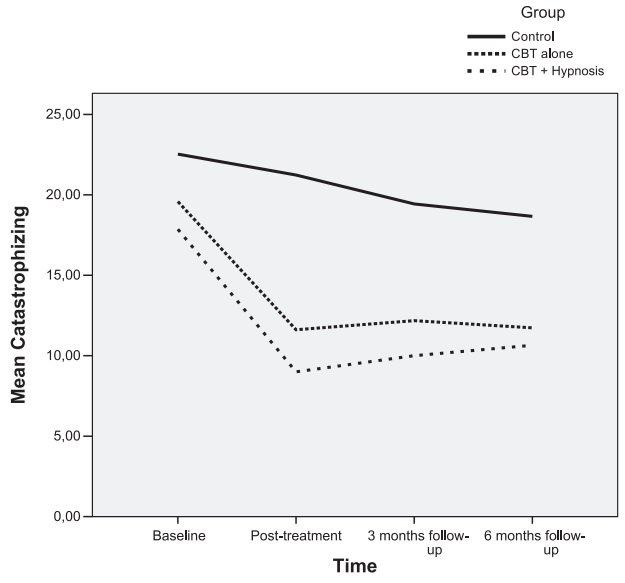


Figure 2. Pain intensity and FIQ total score for mixed linear model analysis. NOTE. Intent-to-treat analysis (included participants who dropped out of the trial).



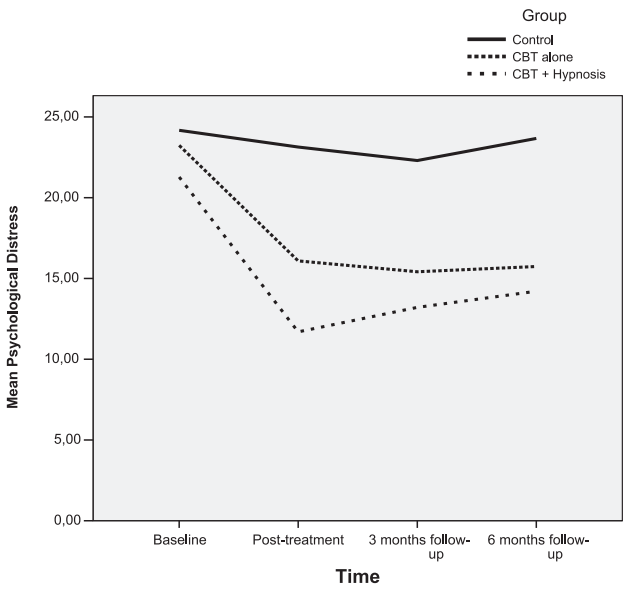


Figure 3. Catastrophizing and psychological distress for mixed linear model analysis. NOTE. Intent-to-treat analysis (included participants who dropped out of the trial).

As our results indicated, adding hypnosis increased CBT's effects on psychological distress. Also, when the percentage of patients who reported clinically meaningful improvement in pain intensity was analyzed at post-treatment, CBT with hypnosis was found to be superior than CBT alone. Nevertheless, no differences were found between CBT alone and CBT with hypnosis in the percentage of patients with clinically meaningful improvement in functionality, although both psychological treatments were superior to standard care control group.

The percentage of patients in our study treated with CBT plus hypnosis who reported clinically significant improvement in pain intensity was similar to that reported in other works realized in persons with chronic pain and a disability treated with hypnotic analgesia.[34,35] Specifically, our post-treatment percentage of patients who reported significant improvements ranged from 31 to 33.3% (Table 3), which is similar to results of the other study that reported a clinically significant post-treatment improvement percentage of 35%.[34,35] Nevertheless, in our study, the percentage of patients treated with hypnosis who reported clinically significant improvement ranged from 17.2 to 19.2% at the 3-month follow-up, and from 27.6 to 34.8% at the 6-month follow-up (Table 3). These percentages were different than those reported in the previously mentioned study[35] that were 27% at 3-month follow-up and 19% at the 6-month follow-up. These differences could be due to the different methods used to evaluate pain intensity, to differences in the treatment contents, or to differences in the study samples. Our results were consistent with those of other studies that examined the effect of hypnosis on pain intensity in chronic pain.[36,40,45,68]

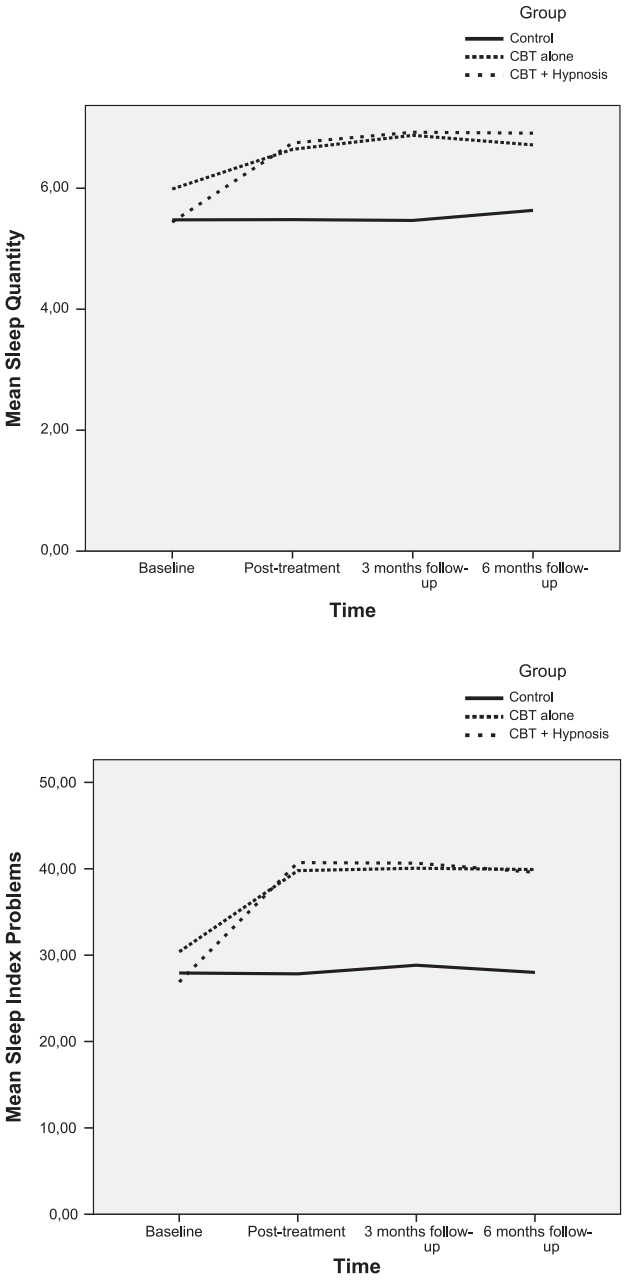


Figure 4. Sleep quantity and sleep index problems for mixed linear model analysis. NOTE. Intent-to-treat analysis (included participants who dropped out of the trial).

Table 3. Percentage of Participants With Minimal Clinically Significant Difference in Pain Intensity and FIQ Score at Post-Treatment, 3-Month Follow-Up, and 6-Month Follow-Up in Each Treatment Condition

Outcome	Control Group	CBT Alone	CBT Plus Hypnosis
Pain intensity			
Post-treatment	16.7%	8.8%	31%
3-month follow-up	10%	14.7%	17.2%
6-month follow-up	13.3%	17.6%	27.6%
FIQ			
Post-treatment	23.3%	55.9%	65.5%
3-month follow-up	20%	55.9%	69%
6-month follow-up	20%	58.8%	55.2%

It is important to note that CBT with hypnosis was superior than CBT alone, considering the equal number of sessions, length of sessions, and number of participants in each group. In fact, both programs (CBT alone and CBT plus hypnosis), with 28 hours of intervention, had a duration similar to those of other psychological treatments for FM. This is evident in the meta-analysis by Glombiewski et al,[23] in which the average psychological intervention took 26.9 hours.

On the other hand, although we could not determine gender-based differences in the response to the treatment due to the low number of men of our sample, we verified that the pattern of effects was the same when the males were removed from the analysis. This contributes to the generalizability of these results to the treatment of women with FM, which is relevant when we consider the high prevalence of women among those who suffer from this syndrome.[14]

There are some limitations of this study that should be considered when interpreting the results. One limitation involves the lack of previous assessment of the patients' expectations about the treatment. Response expectancies have been shown to mediate the effects of hypnotic and cognitive-behavioral pain interventions,[50,51] and the effects of presurgical hypnosis intervention on postsurgical pain in breast surgery patients.[53] It is possible that the differences we found were influenced by the differences in patients' expectations about each treatment condition. Nevertheless, other authors have reported that the relationship between treatment-outcome expectancy and treatment outcome was only moderate in the treatment of chronic pain with hypnosis.[35] Regardless, measuring expectancy would have allowed us to control for these possible effects in our study.[35,36,40] Another limitation concerns the lack of previous assessment of the hypnotic suggestibility of the patients in the CBT with hypnosis group. The quality of hypnosis has been shown to have a linear relationship with pain intensity reduction through hypnosis.[50,51] Likewise, the level of hypnotic suggestibility has been related to the decrease of pain in patients with chronic pain,[59] including FM.[13] Nevertheless, in clinical samples, hypnotizability did not have the same predictive value as in samples composed of healthy individuals.[35]

When the psychological interventions (CBT alone and CBT with hypnosis) were compared with the control group, we did not control for possible contact effects. Some of the obtained findings could be due to the different levels of time and attention the control group received in comparison with the psychological treatment groups. Nevertheless, the inclusion of a contact-controlled group would not have explained the differences between the 2 CBT treatment groups. A possible explanation for these differences could arise from the introduction of visualization under hypnosis conditions in

certain CBT with hypnosis sessions. As guided imagery has been shown to improve functionality in patients with FM,[47] it is possible that the therapeutic effects were improved by adding visualization to certain blocks of the treatment with hypnosis.

Despite the above limitations, the findings obtained are encouraging and in line with previous studies demonstrating the efficacy of CBT for patients with FM. Furthermore, this study provides new evidence about the additive effects of hypnosis as a complement to CBT. Nevertheless, future research should confirm these results and assess the relevance of some of the aspects discussed in this paper.

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