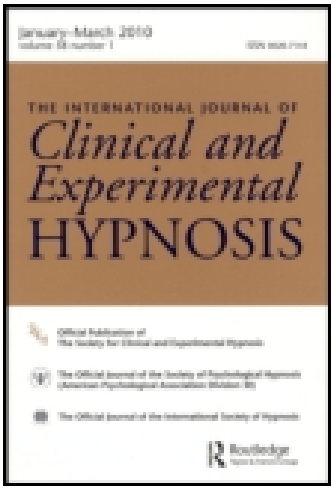

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Hypnosis for Management of Fibromyalgia

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HYPNOSIS FOR MANAGEMENT OF FIBROMYALGIA[1]

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Abstract: This randomized, controlled trial contrasted the effects of 5 not-standardized sessions of hypnosis over 2 months in 59 women with fibromyalgia who were randomly assigned to treatment ($n = 30$) or a wait-list control group ($n = 29$). Patients in the treated group were encouraged to practice self-hypnosis. Fibromyalgia Impact Questionnaire (FIQ), MOS–Sleep Scale, Multidimensional Fatigue Inventory (MFI), Cognitive Strategy Questionnaire (CSQ), and Patient Global Impression of Change (PGIC) were administered at baseline, 3 months (M3), and 6 months (M6) after inclusion. Compared to the control, the hypnosis group reported better improvement on PGIC ($p = .001$ at M3, $p = .01$ at M6) and a significant improvement in sleep and CSQ dramatization subscale (both at M6).

Fibromyalgia (FM) is a poorly understood chronic-pain syndrome, characterized by widespread musculoskeletal pain, nonrestorative sleep, fatigue, cognitive impairment, psychological distress, and specific regions of localized tenderness (Yunus, 2007). The etiology of FM is unclear, although many data suggest that central sensitization is one mechanism involved in dysfunctional pain processing in FM patients (Julien, Goffaux, Arsenault, & Marchand, 2005; Mease et al.,

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2007). The triggering and maintenance of FM appear to require both genetic disposition and environmental influences such as emotional or physical stressors or illness (Bennett, Jones, Turk, Russell, & Matallana, 2007). The recent European League Against Rheumatism (EULAR) recommendations suggest that multimodal therapies provide greater benefit than isolated intervention. Among these, nonpharmacologic approaches are recommended (Carville et al., 2008). Assessment of complementary and alternative approaches in FM is limited by a dearth of clinical trials and an effort to evaluate their benefit is needed.

Hypnosis has been largely evaluated in the setting of acute and chronic pain and was generally found to be more effective than nonpharmacological interventions such as attention, physical therapy, and education (Huet, Lucas-Polomeni, Robert, Sixou, & Wodey, 2011; Jensen et al., 2011; Jensen & Patterson, 2006; Lew, Kravits, Garberoglio, & Williams, 2011; Nusbaum et al., 2011; Patterson, Jensen, Wiechmann, & Sharar, 2010). There is growing interest in understanding the effects of hypnosis on the sensory and affective components of pain. The results of the various investigations are not totally conclusive on this point, and it seems to be accepted that hypnosis has greater influence on the affects of pain than on the sensation of pain (Jensen, 2009; Paterson & Jensen, 2003; Rainville, Carrier, Hofbauer, Bushnell, & Duncan, 1999).

At the moment, only two published clinical studies have been conducted to evaluate hypnosis in the context of FM (Castel, Pérez, Sala, Padrol, & Rull, 2007; Haanen et al., 1991). Although positive, the results of these studies need confirmation from additional research. In the first study, Haanen et al. only used visual analog scales (VAS) for the study's primary outcome, which was an overall assessment by the patient. In the second study by Castel et al., the evaluation took place immediately after treatment and did not include any long-term follow-up.

The current study was performed to evaluate the effect of hypnosis on reducing FM symptoms in recently diagnosed FM patients. We chose to screen relevant domains that more fully constitute FM for use in a clinical trial as proposed by a workshop for Outcome Measures in Clinical Rheumatology trials (OMERACT 9). The study was carried out with validated screening tools well adapted to evaluate the impact of treatment in FM patients (Mease et al., 2009). An active treatment was compared with a neutral control (waiting list). Besides these methodological improvements, we also included hypnosis suggestions that extended beyond pain relief and relaxation.

Method

Participants

All female patients referred to the pain clinic who fulfilled the criteria for entry into the study were asked if they wished to take part in

the investigation. Study inclusion criteria were women with FM syndrome for at least 6 months who were diagnosed by a rheumatologist following the criteria of the American College of Rheumatology (Wolfe et al., 1990). Study exclusion criteria were patients who presented with chronic inflammatory arthritis and/or peripheral or central neuropathic pain, who were treated with opioids, and/or who presented severe psychiatric illness, including major depression or major personality disorders according to the *Diagnostic and Statistical Manual of Mental Disorder*, fourth edition (Cantor & Genero, 1986), or who had a history of substance abuse. The sample size calculation was done on the basis of a previously published study (Arnold et al., 2002) in which the mean score for the Fibromyalgia Impact Questionnaire (FIQ) was 43 $\pm$ 14, with an expected difference of 12 (-30% of the control), a Type I error of 5%, and a 95% power in unilateral hypothesis. It was then determined that 30 patients per group were necessary.

Procedure

The referent research ethic committee (CPP Sud Est VI) approved this study, and 62 patients attending the pain clinic (from March 2008 to November 2009) and who fulfilled the criteria for entering the study were invited to sign a consent form. Before randomization, patients were informed that they possibly would have to be included in the wait-list group. Then, each patient was randomly assigned to either the hypnosis trial group or the waiting list control group. We offered participants courtesy treatment with hypnosis after their participation if they were in the wait-list group. The person performing this randomization and preparing envelopes was on a separate site from the study and had nothing to do with the study participants or the collection of data. Demographic data and the first outcome measure assessments were filled out on the day of randomization. Follow-up assessments were then performed during a consultation 3 and 6 months postrandomization by the same medical doctor who was not blind to the study condition. At home, the 62 patients were asked to evaluate their pain intensity once a week during the previous 8 days on a 10-point numeric rating scale (NRS). After randomization, each patient in both groups underwent an educative consultation with the same nurse. During this consultation, participants were educated about FM and questions about hypnosis were answered if necessary. Participants were allowed to continue to take their pain medications and antidepressants if necessary, but they were discouraged from starting new treatment or any other form of complementary therapy.

Intervention

Hypnosis began 5 to 8 days after randomization and consisted of five 1-hour sessions. The time interval between each session was 8,

15, 21, and 28 days, respectively. Each patient received five hypnosis interventions, which were conducted by the same psychologist qualified in hypnotherapy. The hypnosis interventions were directed toward enhancing patient competence and mastery in managing pain and stress related to disease.

Each session involved a hypnotic induction including focusing on body sensation and breathing, developing a trance state, and connecting to a safe place. Various suggestions both analgesic and nonanalgesic were provided, including reinterpreting pain sensation as numbness through the use of imagery, improving individual coping with the emotional consequences of pain, improving stress-management skills in daily life according to their needs, and changing their relationship with the disease in order to improve acceptance of it.

Inside this framework, the script was unrestricted; each patient's intervention was tailored to the patient's personal needs; and all freedom to create was encouraged.

Patients were also instructed to practice self-hypnosis on a daily basis outside the session.

Outcome Measures

The Fibromyalgia Impact Questionnaire (FIQ; Burckhardt, Clark, & Bennett, 1991) total score at Month 6 was the primary outcome variable. The FIQ is a 20-item disease-specific instrument to assess the overall effect on FM symptomatology. The FIQ measured physical function and daily activities as well as the severity of pain, fatigue, stiffness, and anxiety/mood. Individual item scores excluding the two scores dealing with work status were combined into a total impact score ranging from 0 to 80. Higher scores indicate a patient is more affected by fibromyalgia.

FIQ was evaluated at the time of randomization and 3 and 6 months later. The French-validated version of the FIQ was used (Perrot, Dumont, Guillemin, Pouchot, & Coste, 2003).

We evaluated the effect of treatment on important secondary outcome domains, including pain, fatigue, patient global multidimensional function, and sleep disturbance, as proposed by a workshop for OMERACT 9 with a specific fibromyalgia syndrome module (Mease et al., 2009). These secondary outcomes were assessed using validated questionnaires.

The Medical Outcomes Study–Sleep Scale (MOS–Sleep; Hays & Stewart, 1992) is a patient-rated questionnaire consisting of 12 items that assess key constructs of sleep; two sleep problems indexes were calculated. Fatigue was assessed with the Multidimensional Fatigue Inventory (MFI; Smets, Garssen, Bonke, & De Haes, 1995), a 20-item, self-report instrument designed to measure fatigue. The MFI total score ranges from 20 to 100 with greater scores indicating

more fatigue. Anxiety and depression were assessed by the Hospital Anxiety and Depression scale (HADS; Zigmond & Snaith, 1983), a self-reported, 14-item measure with seven items forming a depression subscale and another seven measuring anxiety. Catastrophizing was assessed by the Pain Catastrophizing Scale (PCS; Sullivan, Bishop, & Pivik, 1995), a self-report measure comprising 13 items measuring the degree to which people experiencing pain catastrophize and to adopting a negative or aversive orientation towards their pain. Pain-coping strategies were measured using the French version of the Coping Strategies Questionnaire (CSQ–F; Irachabal, Koleck, Rascle, & Bruchon-Schweitzer, 2008), consisting of 21 items that yield scores of five coping subscales (distraction, catastrophizing, reinterpreting pain sensations, ignoring pain sensations, praying and hoping). Overall treatment experience and efficacy of chronic pain treatments were assessed by the Patient Global Impression of Change (PGIC; Guy, 1976), a self-reported, 7-point instrument. All these secondary outcomes were evaluated at the time of randomization and 3 and 6 months later. Besides this evaluation, patients were invited to evaluate each week, on the same day, the pain intensity of the 8 previous days measured on a 10-point NRS ranging from *no pain* (0) to *the most intense pain imaginable* (10).

Statistical Analysis

Data analysis was carried out with the SAS system V8.02. Baseline characteristics of patients were summarized by mean (+/− standard deviation) for continuous variables and by frequency (percentage) for categorical variables. Comparisons of continuous variables between groups were made using *t* tests and analysis of variance (ANOVA). Comparisons between two categorical variables have led to the Chi-squared test and, if necessary, to the Fisher's Exact test. Pearson's correlation coefficients were calculated to evaluate the association between two continuous variables. Significance level was set at 5%.

Results

Among the 62 patients who were randomized, 3 were excluded after randomization because 2 of them (wait-list group) committed themselves to a physical rehabilitation program, and 1 patient (hypnosis group) who experienced the treatment felt it would not give her any benefit. Of the 59 remaining patients, 30 were in the hypnosis group and 29 in the wait-list group. Both groups were similar with respect to patient demographics, FM history, impaired functioning, and other clinical baseline characteristics (see Table 1).

Table 1
Key Patient Demographic and Clinical Characteristics at Baseline

	Wait List ($n = 29$)	Hypnosis ($n = 30$)
Age (yrs)	49.3 (8.5)	48.1 (9.3)
Chronic pain duration (yrs)	6.8 (4.8)	9.7 (10.5)
FM duration (yrs)	2.6 (2.1)	2.6 (2.4)
Work activity	16	11
Menopausal status	8	13
FIQ total score	50.1 (13.6)	49.5 (11.6)
NRS (out of 10)	6.80 (1.5)	7.16 (0.5)
MFI total	70.2 (11.8)	72.6 (11.9)
HADs Score Anxiety	10.8 (3.7)	9.9 (4.1)
Score Depression	12.1 (4.0)	12.0 (4.6)
PCS	29.1 (10.5)	30.5 (13.2)

Note. Data are expressed as mean (*SD*) or number of patients.
Abbreviations: FIQ: Fibromyalgia Impact Questionnaire; VAS: Visual Analog Scale; MFI: Multidimensional Fatigue Inventory; HAD: Hospital Anxiety Depression scale; PCS: Pain Catastrophizing Scale; NRS: Numeric Rating Scale.

Table 2 shows the outcomes for both groups. FIQ total score at Month 6, which was the primary outcome, did not change. Compared to baseline, the difference was –4.6 (11.6) in the hypnosis group and -0.7 (13) in the control group. This difference was not statistically significant ($p = .25$). Mean weekly NRS scores monitored throughout the 24-week study were significantly better in the hypnosis group ($p = .05$) but this difference was not clinically relevant (0.6/10).

MOS-Sleep was significantly better at Month 6 in the hypnosis group ($p = .01$ for Index 1 and $p = .005$ for Index 2). CSQ dramatization subscale improved significantly at Month 6 in the patients who benefited from hypnosis ($p = .01$). This improvement was parallel to that noted in the PCS scale (but the latter was not significant). PGIC was reported as "minimally improved" in the hypnosis group and "no change" in the control group. This difference is statistically significant at the 3-month ($p = .001$) and 6-month follow-ups ($p = .01$). Results of patients' characteristics associated with treatment response did not demonstrate any correlation either with self-hypnosis practice, pretreatment FIQ score, or pretreatment HADS.

Discussion

This is the first study to address the effects of hypnosis on FM using adapted and validated tools. Regarding the FIQ, we found no statistically significant difference between patients who received hypnosis

Table 2
Primary and Secondary Outcomes at 3 and 6 Months, Expressed in Difference Baseline Values

	M3			M6		
	Wait-List	Hypnosis	*p*	Wait-List	Hypnosis	*p*
FIQ total Score	0.19	−0.9	.77	−0.7	−4.6	.25
MFI total Score	−1.4	−4.7	.3	−0.77	−5.2	.31
MOS Sleep						
Index I	−2.3	−5.8	.36	1.7	−8.6	.01
Index II	−1.9	−7.2	.15	1.6	−9.2	.005
CSQ						
Praying/Hoping	−0.08	−0.1	.48	−0.19	−0.36	.35
Diverting attention	0.04	0.21	.23	0	0.2	.15
Reinterpreting pain	0	0.11	.54	0.12	0.22	.63
Catastrophizing	−0.1	−0.3	.22	−0.06	−0.47	.01
Ignoring pain	−0.02	0.14	.27	0.3	0.08	.15
HADs						
A	−0.74	−0.86	.87	−0.5	−1.2	.3
D	−0.39	−1.12	.35	−0.1	−1.4	.06
PCS	−2.6	−5.9	.19	−3	8.7	.057
PGIC	3.8	2.9	.001	3.9	2.9	.01
Mean weekly NRS (24 weeks)				6.64	6.04	.05

Note. Abbreviations: FIQ: Fibromyalgic index questionnaire; MFI: Multidimensional Fatigue Inventory; MOS–Sleep: Medical Outcome Study; CSQ: Pain Coping Strategy Questionnaire; HADs: Hospital Anxiety Depression scale; PCS: Patient Catastrophizing Scale; PGIC: Patient Global Impression of Change; NRS: Numeric Rating Scale.

treatment compared to those in the nontreatment group. Regarding pain, the effect of hypnosis was statistically significant but clinically minor, since the improvement was only half a point of the NRS. More clinically interesting is the improvement of the other variables reflecting the quality of sleep, catastrophizing, and patient global impression of change. These changes were especially visible at the 6-month follow-up. These results suggest that hypnosis has a more positive effect on the cognitive and/or affective side of FM than on the pain itself.

The findings of the current study vary in consistency with the limited number of previous investigations. Previous reports showed an effect of hypnotic treatment on pain felt by FM patients (Castel et al., 2007; Haanen et al., 1991) and other chronic pain conditions (Jensen & Patterson, 2006; Montgomery, Duhamel, & Redd, 2000). The two published studies concerning FM and hypnosis are quite different from our study. In the study by Castel et al., hypnosis based on analgesia suggestions was followed by pain evaluation before and just after the hypnosis session. Therefore, the study only evaluated the very short-term effect of hypnosis. In Haanen et al., most outcome measures, including overall

assessment by the patient, were assessed with the VAS, which is obviously not adapted to the complex clinical problem including many symptoms that represent FM. These two studies did not evaluate the FIQ since they focused on pain.

The improvements in the study sample appeared to be largely focused on the cognitive and affective side effects of fibromyalgia.

Although pain was not affected by hypnosis in this study, other variables, such as quality of sleep, catastrophizing in CSQ, and patient global impression of change, were significantly improved. In addition, the improvement of the PCS score almost reached the significance level, underlining that hypnosis corrected maladaptive thoughts. These cognitive and behavioral modifications take time to be effective, explaining the better results at 6-months posttreatment than at 3-months.

Catastrophizing has been broadly defined as an exaggerated negative orientation toward pain stimuli and pain experience (Sullivan et al., 1995). Numerous clinical and experimental investigations have shown that catastrophizing is associated with heightened pain experience (Sullivan, Stanish, Waite, Sullivan, & Tripp, 1998; Van Houdenhove & Egle, 2004). In a recent article, Schütze, Rees, Preece, and Schütze (2010) demonstrated the strong moderating effect of mindfulness on the relationship between pain intensity and pain catastrophizing. The ability to stay focused on present-moment experience with a nonjudgmental attitude (definition of mindfulness) predicted a weaker relationship between pain intensity and catastrophizing. It must be noted that patients in this study were suggested to undergo the state of mindfulness at the hypnosis induction step, before suggestions were done.

As indicated by the MOS–Sleep score, hypnosis improved sleep in our sample. Sleep disturbances affect 70% to 90% of patients with FM and may play an important role in the physiopathology of fibromyalgia (Harding, 1998). The multiple types of sleep problems and disturbances may account in part for FM patients' high levels of emotional distress. It was recently demonstrated that negative mood mediated the relationship between poor sleep and pain in a sample of chronic pain patients including FM (O'Brien at al., 2010).

The need for PGIC as a core outcome domain for clinical trials has been emphasized (Geisser et al., 2010; Turk et al., 2003). Therefore, the clear improvement seen with PGIC at the 3- and 6-month follow-ups is a major finding of the study. It is known that patients with FM associate pain, vitality, physical functioning, sleep, and cognitive-functioning improvement within PGIC ratings (Hudson et al., 2009). This confirms the role of cognitive and affective factors since pain and physical function could not influence the PGIC ratings recorded in this study as these factors (VAS and FIQ) did not improve significantly. Therefore, the other comorbid symptoms such as sleep alteration and cognitive impairment

(catastrophizing) must be the cause for the changes observed in PGIC ratings as these factors improved.

The results of the current study failed to demonstrate that the FIQ, a more broad-based measure of fibromyalgia symptoms, showed differences as a result of the intervention.

The FIQ is a specific instrument to assess the overall effect of pharmacological treatments on FM symptomatology and is currently considered as the gold standard (Burckhardt et al., 1991). The fact that it was not statistically improved may reflect the lack of consensus on whether or not it is relevant to evaluate nonpharmacological treatments. Some authors have pointed out that it is extremely difficult to detect a difference on generic measures such as the FIQ or Short Form Health Survey (SF–36) based on just about any type of specific intervention. Hypnosis, cognitive-behavioral pain therapy, and other interventions usually only show effects on very specific measures rather than broad-based ones (Garcia-Martinez, De Paz, & Marquez, 2011). The fact that we did not test for the patient's hypnotizability is another possible explanation for the lack of change in the values of this variable. It is known that hypnotic analgesia does not help everyone nor does it always provide complete pain relief in the setting of chronic pain (Jensen, 2009). Most of the studies evaluating hypnosis' effect on acute or chronic pain demonstrated a significantly greater decrease in pain scores in highly hypnotizable patients. With chronic pain, studies comparing hypnosis directly with other psychological strategies such as distraction, mental imagery, or placebo further demonstrated that hypnosis typically produced larger analgesic effects in highly hypnotizable subjects (De Pascalis, Magurano, Bellusci, & Chen, 2001; Rainville, 2008). Another explanation for the lack of change of FIQ scores lies in the choice of hypnosis methodology. Pain was not obligatorily considered as the main symptom on which hypnosis sessions focused. In this study, we chose to propose hypnosis as a way to not only focus on control or avoidance of symptoms but also to focus on the patient's relationship with symptoms from a perspective of acceptance of chronic pain and commitment to new emotional, physical, and social functioning. Maybe this choice prevented this trial from demonstrating an efficacy in the strict domains of symptoms.

In spite of some of the unique features of our study, a number of methodological limitations should be discussed. Our hypnotic procedure was not standardized as is proposed for all clinical trials of the effects of hypnosis. It has been suggested to examine the efficacy of hypnotic analgesia through different chronic pain conditions using more standardized hypnotic-intervention protocols, which would allow for better comparison between studies (Jensen & Patterson, 2006). This questions the foundation of hypnosis, which was classically defined as a state of consciousness characterized by a markedly increased

receptivity to suggestion and the capacity for modification of perception and memory. The experience of hypnosis creates an unusual relationship between the person offering the suggestions and the person receiving them. Through this special relationship, the person experiences a form of transference. This transferential quality of the hypnotic experience is a powerful determinant of clinical effectiveness (Barber, 1996). Although the procedure and some script parameters can be standardized, the relationship between therapist and patient, which is an important determinant of hypnosis, cannot be.

A placebo control group is one of the key factors of evidence-based medicine. Which placebo can be used for hypnosis? The choice of a waiting list as a control group does not answer the question of whether the context effects are as effective or more effective than the intervention itself.

FM is a heterogeneous condition, and subgroups may exist that have different pathophysiologies with different response characteristics to treatment (Sommer, 2010). The heterogeneity of fibromyalgia patients renders a "one-size-fits-all" approach unlikely to be broadly efficacious. In the future, instruments assessing pretreatment levels of psychological distress or pain-coping strategies should be developed and used to identify subgroups of FM patients who might benefit differentially from specific interventions (Karsdorp & Vlaeyen, 2009).

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Hypnose im Fibromyalgiemanagement

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Abstrakt: Dieses randomisierte, kontrollierte Verfahren stellte die Effekte von fünf nicht-standardisierten Hypnosesitzungen über zwei Monate mit 59 Frauen mit Fibromyalgie, die randomisiert der Behandlung ($n = 30$) oder einer Wartelisten-Kontrollgruppe ($n = 29$) zugeteilt wurden, einander gegenüber. Patientinnen in der Behandlungsgruppe wurden dazu ermutigt, Selbsthypnose anzuwenden. Zu Beginn, 3 Monate (M3) und 6 Monate (6M) nach Aufnahme wurden der Fibromyalgia Impact Questionnaire (FIQ), die MOS-Schlaf Skala, das Multidimensional Fatigue Inventory (MFI), Cognitive Strategy Questionnaire (CSQ) und die Global Impression of Change (PGIC) angewandt. Verglichen mit der Kontrollgruppe berichtete die Hypnosegruppe eine Verbesserung im PGIC ($p = 0{,}001$ zum Zeitpunkt

M3, p = 0,01 zum Zeitpunkt M6) und eine signifikante Verbesserung in der Schlaf.- und CSQ-Dramatization Unterskala (beide zum Zeitpunkt M6).

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Le traitement de la fibromyalgie par l'hypnose

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Résumé: Cette étude randomisée contrôlée opposait les effets de 5 séances non standardisées d'hypnose pendant 2 mois chez 59 femmes souffrant de fibromyalgie, choisies au hasard pour recevoir un traitement (n = 30) ou pour être inscrites sur une liste d'attente (groupe témoin) (n = 29). Les patientes choisies pour recevoir le traitement étaient encouragées à pratiquer l'autohypnose. Au départ, après 3 mois (M3) et après 6 mois (M6), les patientes ont rempli les questionnaires suivants : l'évaluation de l'impact de la fibromyalgie (QIF), l'échelle de mesure du sommeil MOS, l'inventaire multidimensionnel de la fatigue (MFI), le questionnaire de stratégie cognitive (CSQ) et l'impression générale de changement du patient (PGIC). Comparativement au groupe témoin, le groupe de patientes hypnotisées a signalé une amélioration plus marquée de la PGIC (p = 0,001 à M3, p = 0,01 à M6), ainsi qu'une amélioration significative du sommeil et de la sous-échelle de dramatisation CSQ (toutes les deux à M6).

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La hipnosis para el manejo de la fibromialgia

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Resumen: Este ensayo, aleatorizado y controlado, contrastó los efectos de 5 sesiones no estandarizadas de hipnosis a lo largo de 2 meses con 59 mujeres con fibromialgia; quienes fueron asignadas aleatoriamente al tratamiento (n = 30) o al grupo control de lista de espera (n = 29). Se alentó a los pacientes en el grupo de tratamiento a practicar autohipnosis. El Cuestionario de Impacto de la Fibromialgia (FIQ), la Escala de Sueño MOS, el Inventario Multidimensional de Fatiga (MFI), el Cuestionario de Estrategia Cognitiva (CSQ), y la Impresión Global de Cambio del Paciente (PGIC) se administraron en la línea basal, a 3 meses (M3), y a 6 meses (M6) de la inclusión. Comparados con el grupo control, el grupo de hipnosis reportó mayor mejora en la PGIC (p = .001 en M3, = .01 en M6), y una mejora significativa en el sueño y en la subescala de dramatización del CSQ (ambos en M6).

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