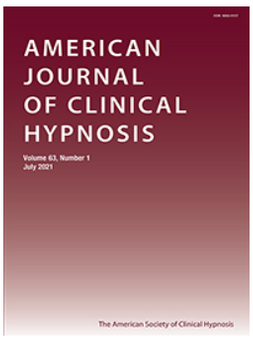

American Journal of Clinical Hypnosis

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/ujhy20

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To cite this article: Valentina Aravena , Felipe E. García , Arnoldo Téllez & Patricio R. Arias (2020) Hypnotic intervention in people with fibromyalgia: A randomized controlled trial, American Journal of Clinical Hypnosis, 63:1, 49-61, DOI: 10.1080/00029157.2020.1742088

To link to this article: https://doi.org/10.1080/00029157.2020.1742088

Published online: 03 Aug 2020.

AMERICAN JOURNAL OF CLINICAL HYPNOSIS
2021, VOL. 63, NO. 1, 49–61
https://doi.org/10.1080/00029157.2020.1742088

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Hypnotic intervention in people with fibromyalgia: A randomized controlled trial

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ABSTRACT

Fibromyalgia affects the quality of life of the patients, as well as their family. It also affects their social, labor, physical, and psychological dynamics. We aimed to evaluate the effectiveness of audio-recorded hypnosis in ameliorating fibromyalgia symptoms. We enrolled 97 individuals with fibromyalgia (mean age: 45 years) and randomly distributed them to two groups (48 in the experimental group and 47 in the control group). Individuals in both groups maintained their standard pharmacological treatment and continued their usual physical or psychological activities. The experimental group received an audio-recorded hypnosis intervention in the first session; subsequently, they received another audio hypnosis session to use for daily practice for a month. We evaluated the pre- and post-intervention pain intensity, pain interference, fatigue intensity, fatigue interference, depressive symptomatology, and satisfaction with life. We found that the self-administered audio-recorded hypnotic intervention significantly decreased the intensity and interference of pain and fatigue, as well as the depressive symptomatology. Audio-recorded clinical hypnosis techniques could provide an effective, practical, and economical alternative for reducing fibromyalgia-related symptoms.

KEYWORDS

Depressive symptomatology; fatigue; fibromyalgia; hypnosis; pain; satisfaction with life

Fibromyalgia is a complex syndrome characterized by generalized musculoskeletal chronic pain (Talotta et al., 2017). This pain is usually accompanied by other symptoms, including severe fatigue, morning stiffness after resting, sleep disorders, paresthesia in limbs, subjective inflammation, tension headache, irritable bowel syndrome, as well as genitourinary, vegetative, and functional symptoms. Moreover, it is accompanied by psychological symptoms, including cognitive disorders, psychological stress, depression, and anxiety (Wolfe et al., 2010).

The worldwide prevalence of fibromyalgia is approximately 2.7% (Queiroz, 2013). In Chile, approximately 5.4% of patients admitted to the Clinical Hospital of the Universidad de Chile have fibromyalgia (Lizama-Lefno & Rojas-Contreras, 2019). Symptom intensity and progression vary for each patient, sometimes invalidating common daily life activities (Ayán, 2009), like taking a shower, getting dressed, eating, as well as labor and leisure activities (Arnold et al., 2008; Del Río, Palacios, & Arbona, 2014).

Currently, there is increasing attention on fibromyalgia by health professionals and researchers given the significant increase in its prevalence in the general population, the

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scarcity of knowledge available regarding it, and the absence of effective medical treatment (Rivera et al., 2006). The latter leads to patients with fibromyalgia receiving multiple therapies involving physical, pharmacological, and cognitive regimens (Talotta et al., 2017). Currently, combining tricyclic antidepressants, cardiovascular exercise, cognitive behavioral therapy, and psychoeducation is considered effective in reducing fibromyalgia symptoms. However, they collectively incur a large economic cost. Therefore, there is a need to develop new therapeutic interventions that are not only effective but also are inexpensive and easily accessible (Talotta et al., 2017). From this perspective, hypnotic interventions provide a viable alternative.

Hypnosis can be defined as a special consciousness state produced by concentrated attentional focus, which is characterized by increased ability to respond to suggestions (Elkins, Barabasz, Council, & Spiegel, 2015; Téllez, 2007), leading to changes in perception and memory. This consciousness state renders alternative cognitive control systems available (Unestahl, 2018).

Hypnosis has been widely used to treat pain since it produces a state of relief and mental absorption, which influences the subjective pain experience (Alladin, 2010; Elkins, Jensen, & Patterson, 2007; Jensen & Turk, 2014). Moreover, the application of hypnosis with other treatments increases their efficacy (Capafons, 2001). Contrary to popular belief, the main hypnosis objective is not pain alteration; rather, it is to teach the personal skills and strategies for altering pain intensity perception and its effects on daily life (Jensen & Patterson, 2006). Some studies have reported that all hypnoses are self-hypnosis (Unestahl, 2018), i.e., it more primarily lies on the skill of the hypnotized person rather than that of the hypnotist.

Studies on the use of hypnosis for treating pathologies associated with chronic pain have reported that it is effective for managing different pain aspects, including intensity (Jones, Cooper, Miller, Brooks, & Whorwell, 2006; Rizzo et al., 2018), perceived control (Jensen, 2009), sensation (Abrahamsen, Zachariae, & Svensson, 2009), duration (Simon & Lewis, 2000), and pain interference (Jensen et al., 2009).

Self-administered audio-recorded hypnotic interventions are commonly used for pain control with the objective of learning self-applied hypnotic analgesia techniques that require daily practice for better results (Pellicer, 2016).

Hypnotic analgesia provides an option with efficacy for symptomatology management; specifically, acute and chronic pain reduction (Jensen, 2009) and fibromyalgia treatment (Castel, Cascón, Padrol, Sala, & Rull, 2012; Castel, Pérez, Sala, Padrol, & Rull, 2007; Derbyshire, Whalley, Seah, & Oakley, 2017; Moioli-Montenegro, 2017; Zech, Hansen, Bernardy, & Häuser, 2017). Unestahl (2018) has found no difference between audio-recorded hypnotic elicitations and *in vivo* elicitations, however, some studies have recommended assessing the efficacy of regular hypnosis training at home using audio recordings (Zech et al., 2017).

Hypnosis and self-administered audio-recorded hypnotic interventions have been suggested as complementary regimens for pharmacological and non-pharmacological treatments for pain management (Sánchez, Téllez, Juárez-García, García, & García, 2018); further, they have been recommended for the fibromyalgia symptom management. Developing a self-administered audio-recorded hypnotic intervention is considered important given its easy application and low cost.

We aimed to administer a self-administered audio-recorded hypnotic intervention to patients with fibromyalgia for 1 month. We hypothesized that the intervention would

reduce the intensity and interference of pain, fatigue, and emotional discomfort (depressive symptoms), as well as increase the wellbeing (satisfaction with life) of the patients compared to the control group.

Methods

Design

This experimental randomized clinical trial, which involved pre- and posttest measurements (Hernández, Fernández, & Baptista, 2014), was performed according to the recommendations of the CONSORT statement (Begg et al., 1996; Moher, Schulz, & Altman, 2001). We randomly allocated the participants to two groups; namely, the experimental and control (in the waiting list) group. The participants were assessed using self-applied questionnaires and scales at the beginning and end of the intervention, as well as 6 months upon completion.

Participants

We enrolled 97 individuals with fibromyalgia and randomly allocated them to either the control or intervention group. This sample size exceeded the minimum amount recommended by the American Psychological Association (APA) for experimental studies (Chambless & Hollon, 1998).

All the enrolled patients were older than 18 years, had been diagnosed with fibromyalgia at a health center, and had provided consent for study participation. We excluded individuals with a formal diagnosis of severe psychopathology or presenting any terminal organ impairment or painful chronic disease. We randomly assigned the enrolled participants as follows: 48, the experimental group (EG); 49, the control group (CG). Figure 1 shows the randomization diagram according to the CONSORT protocol. Table 1 shows the socio-demographic characteristics of the participants.

Instruments

To assess satisfaction with life, we used the Satisfaction with Life Scale (Diener, Emmons, Larsen, & Griffin, 1985; translated by Arias & García, 2018), which assesses general cognitive judgments about one's own life. It is composed of five items scored on a 5-point Likert-type scale (1: strongly disagree, 5: strongly agree). The study by Arias and García (2018) reported a Cronbach's alpha of.81.

We used the Brief Pain Inventory-Short Form (De Andrés Ares et al., 2015) to assess pain. It is composed of nine items scored on a 10-point Likert-type scale (0: no pain/does not interfere with the daily life, 10: as bad as you can imagine/completely interfere with the daily life). This scale assesses the intensity and impact of pain and analgesic treatment effects. It has a Cronbach's alpha of .93 (De Andrés Ares et al., 2015).

Fatigue was assessed using the Brief Fatigue Inventory (Mendoza et al., 1999; translated by Valenzuela et al., 2012), which evaluates the fatigue level and its interference with daily activities. It is comprised of nine items with the first three assessing the individual's "current", "usual", and "worst levels" of fatigue experienced using a 10-point scale (0: no fatigue, 10: as bad as you can imagine). The remaining items evaluate fatigue

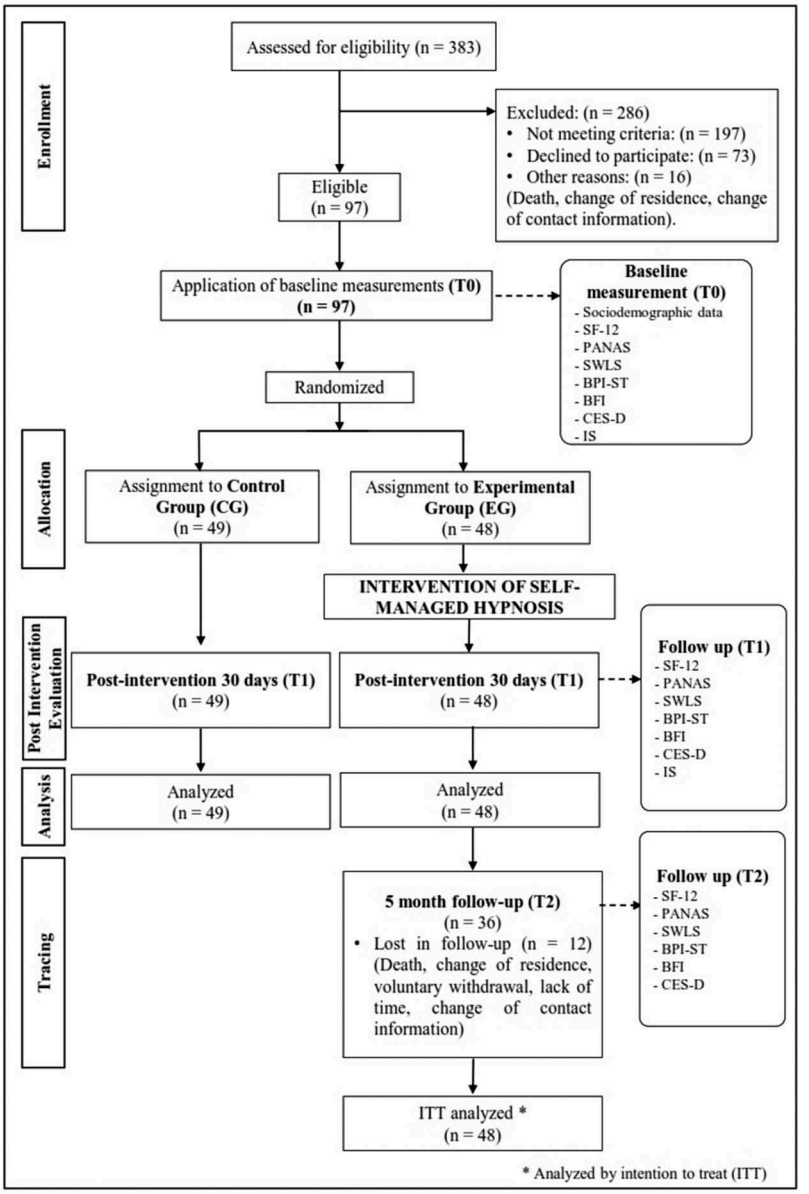

Figure 1. Progress flow chart (CONSORT 2010)
Source: Own creation.

interference on different life aspects on a scale from 0 "does not interfere" to 10 "completely interferes". Using a Chilean population, it was reported to have a Cronbach's alpha of .97 (Lorca, Sacomori, & Puga, 2016).

We assessed depressive symptomatology using the Center for Epidemiological Studies Depression Scale (Radloff, 1977; translated by Gempp, Avendaño, & Muñoz, 2004). It is comprised of 20 self-report items that indicate the frequency of each symptom within the

Table 1. Baseline socio-demographic characteristics of the study participants

Results	EG M(SD) (n = 48)	CG M(SD) (n = 49)	p-value
Age (years)	M = 45.79; SD = 12.11	M = 45.33; SD = 10.79	.84
Sex			.57
Female	47 (97.9%)	47 (95.9%)	
Male	1 (2.1%)	2 (4.1%)	
Marital Status			.17
Single	11 (22.9%)	12 (24.5%)	
Married	16 (33.3%)	21 (42.9%)	
Cohabiting	3 (6.3%)	5 (10.2%)	
Separated/Divorced	15 (31.3%)	11 (22.4%)	
Widow	3 (6.3%)	0 (0%)	
Educational Level			.83
Primary School	2 (4.2%)	1 (2.0%)	
Secondary School	20 (41.7%)	20 (40.8%)	
Technical College	14 (29.2%)	20 (40.8%)	
University	12 (25.0%)	8 (16.3%)	
Work Situation			.22
Student	4 (8.3%)	5 (10.2%)	
Worker	16 (33.3%)	24 (49.0%)	
Unemployed	18 (37.5%)	12 (24.5%)	
Normal age retirement	6 (12.5%)	5 (10.2%)	
Disability retirement	4 (8.3%)	3 (6.1%)	
First symptoms	M = 12.71; SD = 12.37 years	M = 10.16; SD = 6.70 years	.21
Obtaining of diagnosis	M = 4.83; SD = 4.18 years	M = 4.41; SD = 3.70 years	.60
Specialist			.33
General Practitioner	8 (16.7%)	8 (16.3%)	
Rheumatologist	31 (64.6)	26 (53.1%)	
Orthopedic Surgeon	4 (8.3)	8 (16.3%)	
Neurologist	2 (4.2%)	4 (8.2%)	
Family Physician	2 (4.2%)	0 (0%)	
Intern	1 (2.1%)	1 (2.0%)	
Psychiatrist	0 (0%)	2 (4.2%)	

EG: experimental group (n = 48), CG: control group (n = 49), M: median, SD: standard deviation.

last week using a four-choice scale ("rarely or none of the time" to "most of the time"). Using a Chilean population, it was reported to have a Cronbach's alpha of .87.

We ad-hoc created a socio-demographic questionnaire to collect information regarding age, academic level, marital status, labor situation, as well as clinical and health variables.

Procedures

We contacted two local associations of individuals with fibromyalgia to provide information about the objectives and implications of this study; subsequently, we invited the individuals to participate in the study.

Initially, we conducted a pilot phase study using five women volunteers meeting the inclusion criteria to obtain feedback regarding the instruments and self-assessments. This allowed the final phase to be conducted using more precise instructions regarding the use of the scales.

Subsequently, we contacted participants for the final study. Each member of the associations received a phone call; further, we published adverts on social media to invite more people to participate in the intervention.

Ninety-seven participants met the inclusion criteria. We arranged meetings where they received information regarding the study characteristics, including confidentiality and

willingness to participate. Next, they provided signed informed consent forms. Subsequently, we applied the set of instruments for the basal measurement (T0).

After conducting basal measurements, we randomly assigned the participants to the EG or CG by creating a table with unrepeated random numbers using MS Excel. Subsequently, we provided hypnosis audio recordings to the EG accompanied by instructions regarding their use and the application self-register. Upon completion of the 30-day intervention period, we obtained post-intervention measurements (T1) from both groups. Moreover, we obtained follow-up measurements (T2) after 6 months (Refer to Figure 1).

Intervention

We used two recordings. The first one, which lasted for 14 minutes and 44 seconds, was designed for the initial hypnosis session. It focused on preparing the patient for hypnosis and introducing them into the induction and experimentation with the ideodynamic approach (Cuadros & Vargas, 2009). Moreover, it seeks to allow the patient to have a positive attitude toward hypnosis and weakening of negative approaches that could interfere with the treatment (Schoenberger, Kirsch, Gearan, Montgomery, & Pastyrnak, 1997) and the conduction of direct and indirect eclectic hypnotic elicitation (Alden & Heap, 1998) through focused attention, imagery, dissociation, and confusion (Subizar-Cruz, Ramírez-Arias, & Rico-Ortiz, 2017). We instructed the participants to listen to the second session, which lasted 12 minutes, once per day for 30 days. It was aimed to improve the pain and stress management abilities and allow reinforcement of the automatic experience produced by the first recording (Moioli-Montenegro, 2017; Picard et al., 2013).

We created the script for the audio recordings and used the voice of a clinical psychologist who had specialized in hypnosis. Participants in both the EG and the CG maintained their usual medical treatment for fibromyalgia symptom management, including pharmacological treatments; physical, psychological, and alternative exercises; etc., which we recorded for each patient. This study protocol obtained ethical approval from the Ethics, Bioethics, and Biosafety Committee of the [Blinded], resolution CEBB 446–2019.

Data analysis

We conducted an intention-to-treat analysis to allow analysis independent of intervention adherence, which involved assessing participants even when they abandoned treatment and replacing lost data with the last known values. This contributed to the lack of changes in the number of participants in the EG and CG despite there being study withdrawals (Devereaux et al., 2002).

We conducted a descriptive analysis of the sociodemographic and psychosocial variables of each group. Next, we performed a normal distribution analysis of the variables using the Kolmogorov–Smirnov test. Subsequently, to test our hypotheses, we used Student's t-test for independent samples (for H1 and H2) and Student's t-test for related samples (for H3 and H4) to identify the effects of time (pre- and post-intervention) and the interaction effects between groups (EG and CG). We used the Cohen's d statistic to assess the effect size and interpreted it using Cohen's levels (1992), which propose that a d

value close to 0.20, 0.50, and 0.80 represents a small, medium, and large effect size, respectively.

We used the repeated-measures analysis of variance (ANOVA) test for the pre-, post-, and follow-up assessments. Here, we considered an n-value of 0.01, 0.06, and 0.14 as a small, medium, and large effect size, respectively (Téllez, García, & Corral-Verdugo, 2015). Data were analyzed using the SPSS 23 program.

Results

Baseline assessments indicated no significant between-group differences in the demographic characteristics and clinical variables. This allowed confirmation of correct sample randomization (see Table 1). In both groups, the proportion of women was higher than that of men (EG = 97.9%; CG = 95.9%). There was no significant between-group difference in the mean age. Table 1 shows the socio-demographic and clinical characteristics.

Table 2 shows the medians, standard deviations, and t-tests results for the pre- and post-assessment variables in both groups. There was a significant post-intervention decrease in the pain and fatigue intensity, as well as the depressive symptomatology in the EG. However, there was a numerical, but not significant, post-intervention increase in satisfaction with life in the EG. Regarding the effect sizes, the effect size for fatigue intensity was high (0.90) while those for pain intensity and depressive symptomatology were medium.

Intra-group comparisons of the pre- and post-intervention scores in the EG indicated that the intervention was effective at decreasing pain and fatigue intensity, as well as ameliorating depressive symptomatology. The effect sizes of the first two were medium while that for depressive symptomatology was small (see Table 3).

According to the participant´s self-registration of audio usage, the participants undertook the interventions for an average of 24.60 (SD = 4.19) days of the total 30 days. Table 4 shows the results of follow-up data analysis with repeated measures ANOVA in the EG, which indicated that the improvement was maintained. There were no significant differences between a majority of the post-intervention and follow-up variables except for

Table 2. Comparison of pre- and post-interventions variables in both groups

		Experimental	Control			
Variable	Period	M (SD)	M (SD)	ES Cohen´s *d*	*t*-value	*p*-value
Pain intensity	Pre	5.68 (1.63)	6.29 (1.50)		−1.884	.063
	Post	4.75 (1.54)	5.92 (1.43)	0.79	−3.882	<.001
Pain interference	Pre	6.71 (1.95)	7.13 (1.43)		−1.193	.236
	Post	5.34 (2.06)	6.96 (1.55)	0.89	−4.372	<.001
Fatigue intensity	Pre	7.02 (1.98)	7.20 (2.21)		−0.430	.668
	Post	5.65 (1.73)	7.22 (1.75)	0.90	−4.468	<.001
Fatigue interference	Pre	6.58 (2.07)	6.87 (1.78)		−0.761	.449
	Post	5.40 (2.15)	6.92 (1.76)	0.77	−3.815	<.001
Depressive symptomatology	Pre	51.33 (12.21)	52.35 (10.10)		−0.446	.657
	Post	46.60 (11.18)	53.12 (10.20)	0.61	−3.002	.003
Satisfaction with life	Pre	14.21 (5.30)	13.88 (5.42)		0.304	.722
	Post	14.54 (5.39)	14.49 (4.92)	0.00	0.050	.961

M: Median, SD: standard deviation, ES: effect size (Cohen's d).

Table 3. Intra-group comparison of the pre- and post-intervention variables in the experimental group

Variable	Period	M	SD	ES Cohen´s d	*t*-value	*p*-value
Pain intensity	Pre	5.69	1.63	0.59	3.779	<.001
	Post	4.75	1.54			
Pain interference	Pre	6.71	1.95	0.68	5.182	<.001
	Post	5.34	2.06			
Fatigue intensity	Pre	7.02	1.98	0.74	4.962	<.001
	Post	5.65	1.73			
Fatigue interference	Pre	6.58	2.07	0.56	4.23	<.001
	Post	5.40	2.15			
Depressive symptomatology	Pre	51.33	12.21	0.40	4.299	<.001
	Post	46.60	11.18			
Satisfaction with life	Pre	14.21	5.30	0.06	−0.697	.490
	Post	14.54	5.39			

M: Median, SD: standard deviation, ES: effect size (Cohen's d).

Table 4. Intra-group comparison of the pre-intervention, post-intervention, and follow-up variables using repeated measures ANOVA test

Variable	Period	*M*	*SD*	*η2*	*F* Value	*P* Value	Comparison
Pain intensity	Pre	5.69	1.63	0.233	7.003	.002	Pre > Post
	Post	4.75	1.54				Pre > Follow-up
	Follow-up	5.17	1.50				
Pain interference	Pre	6.71	1.95	0.372	13.630	<.001	Pre > Post
	Post	5.34	2.06				Pre > Follow-up
	Follow-up	5.76	1.61				
Fatigue intensity	Pre	7.02	1.98	0.356	12.699	<.001	Pre>Post
	Post	5.65	1.73				Pre>Follow-up
	Follow-up	5.94	1.64				
Fatigue interference	Pre	6.58	2.07	0.291	9.424	<.001	Pre > Post
	Post	5.40	2.15				Pre > Follow-up
	Follow-up	5.85	1.57				Post < Follow-up
Depressive symptomatology	Pre	51.33	12.21	0.285	9.189	<.001	Pre > Post
	Post	46.60	11.18				Pre > Follow-up
	Follow-up	47.92	8.87				
Satisfaction with life	Pre	14.21	5.30	0.073	1.824	.173	
	Post	14.54	5.39				
	Follow-up	14.91	4.87				

M, Median; SD, standard deviation; ES, effect size (Cohen's d),

fatigue interference, which showed a significant increase but did not reach pre-intervention levels.

Further, the comparison of post-intervention and follow-up measures did not indicate significant changes in the pain and fatigue intensity and interference, as well as depressive symptomatology. Regarding satisfaction with life, there were no significant changes between pre-, post-, and follow-up assessments.

Discussion

We aimed to assess the effect of a self-administrated audio-recorded hypnotic intervention on psychosocial and health variables (pain, fatigue, depression, and satisfaction with life) in individuals with fibromyalgia. Our findings indicated that the self-administrated audio-recorded hypnotic intervention effectively decreased pain and fatigue intensity and interference, as well as depressive symptomatology.

Compared with the CG and pre-intervention scores, there was a decrease in pain intensity in the EG. This is consistent with previous findings regarding hypnotic analgesia in fibromyalgia and as described by meta-analyses (Bernardy, Füber, Klose, & Häuser, 2011; Montgomery, DuHamel, & Redd, 2000) and other recent studies (Derbyshire et al., 2017; Moioli-Montenegro, 2017; Zech et al., 2017). Notably, hypnotic elicitations are mainly oriented to influence the pain: "… and allow your conscious to replace the discomfort and pain with a profound sensation of heat …". It has been reported that analgesia suggestions increase the pain threshold and decrease the perceived pain intensity (Potié, Roelants, Pospiech, Momeni, & Watremez, 2016).

Consistent with the pain intensity decrease, there was a decrease in pain interference in daily life, which has been found to ease the performance of activities, including walking, working, keeping social relations, sleeping, and enjoying life (Jensen et al., 2009; Moioli-Montenegro, 2017).

Compared with the CG and pre-intervention scores, there was a decrease in fatigue intensity and interference in the EG. This is consistent with findings regarding traditional hypnosis interventions (Hannen et al., 1991; Häuser & Bernardy, 2015) and self-hypnosis (Moioli-Montenegro, 2017) even when compared with other treatments, e.g., physiotherapy (Hannen et al., 1991). Although the hypnotic suggestions were not oriented for fatigue decrease, decreased pain intensity and depressive symptomatology have been associated with decreased fatigue in individuals with fibromyalgia (Parrish et al., 2008).

Compared with the CG, there was decreased depressive symptomatology in the EG, which is consistent with previous findings indicating that hypnosis is an effective depression treatment (Mendoza & Capafons, 2009). Interventions for fibromyalgia combined with hypnosis have been found to relieve both pain and depression (Jensen et al., 2006). Although the hypnotic elicitations were not oriented for decreasing depressive symptomatology, the observed finding could be attributed to the reported association between pain intensity and depressive symptomatology in individuals with fibromyalgia (Aguglia et al., 2011).

Regarding subjective wellbeing, there was no significant effect on the cognitive component (satisfaction with life). This could be attributed to the fact that the suggestions were expressly oriented more toward the affective component of wellbeing and not the cognitive one. This can be seen in the following example extracted from the hypnotic elicitation: "… and after each second ends, your relief will continue growing and you will not need to know how your unconscious mind takes advantage of the relief for your life to feel flooded with wellbeing and still continue living it with happiness …".

Our study has several limitations. First, our sample had a limited number of men, which impeded the determination of sex-based differences in the effects of the self-hypnosis intervention. However, the sample structure replicates the sex ratio of the fibromyalgia prevalence in the population with women being diagnosed nine times more than men (Katz, Mamyrova, Guzhva, & Furmark, 2010). Although we instructed the participants to maintain their standard treatment, we could not obtain information regarding the frequency of drug use during the study period and determine whether there were between-group differences. Finally, we excluded participants with other painful diseases, which is a common occurrence among individuals with fibromyalgia. Therefore, our sample does not necessarily represent that of patients with fibromyalgia receiving health care services.

Future studies should assess other distinctive variables of fibromyalgia, including catastrophizing, sleep disorders, and anxiety, as well as more affective wellbeing

components, e.g., the presence of positive emotions. Moreover, they should assess the efficacy of long-term hypnosis administration. It would be interesting to study if the patients of the EG continued using the audio-recorded hypnotic intervention, also if they would have learned to do self-hypnosis as a result of a lot of practice listening the audios. Further, they should provide the CG with an alternative audio-recording to determine that it is not just the hearing the recording (and its distractive effect) that produces the observed change. This because other studies using recordings with relaxation music have obtained similar results to those observed in the EG group (Sánchez et al., 2018). Finally, they could incorporate physical measurements in addition to self-reporting since fibromyalgia has been reported to be related to decreased vitamin D (Gheita, Sayed, Gheita, & Kenawy, 2016; Karras, Rapti, Matsoukas, & Kotsa, 2016). Therefore, measuring post-intervention Vitamin D levels could contribute additional information regarding its effects.

In conclusion, this study shows that audio-recorded hypnotic suggestions are an effective, accessible, and convenient psychological intervention for individuals with fibromyalgia. We found that it was effective for pain and fatigue management, as well as psychological discomfort caused by fibromyalgia. These results contribute to the existing knowledge regarding fibromyalgia and its mental and physical health consequences; further, it increases the knowledge regarding the hypnosis benefits for pain management.

Funding

This research was supported by the Conicyt/Fondecyt number 1180134. The authors have no conflicts of interest to report.

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