Cognitive-behavioral therapy for insomnia improves attentional function in fibromyalgia syndrome: A pilot, randomized controlled trial

E. Miró¹, J. Lupiáñez¹, M.P. Martínez¹, A.I. Sánchez¹, C. Díaz-Piedra ¹, M.A. Guzmán², G. Buela-Casal¹

Abstract
This pilot, randomized controlled trial analyzed the effects of a cognitive behavioral therapy (CBT, n = 20) for insomnia vs a sleep hygiene (SH, n = 20) program on the three attentional networks (alertness, orienting, and executive function) and other additional outcome measures (sleep, pain, depression, anxiety, and daily functioning) of fibromyalgia patients. The CBT group showed significant improvement in alertness (F(1, 28) = 11.84, p = .0018), executive functioning (F(1,28) = 15.76, p = .00059), sleep quality (F(1, 38) = 6.33, p = .016), and a trend to improvement in daily functioning (p > .06), as compared with the SH group. The improvement in executive functioning was significantly related to the changes in sleep (r = 0.40, p = .026). A CBT for insomnia represents a useful intervention in fibromyalgia patients not only regarding sleep disturbance but also attentional dysfunction and probably daily functioning.

Keywords
attentional function, cognitive behavioral therapy, fibromyalgia, insomnia, randomized controlled trial

Introduction
Fibromyalgia (FM) is a chronic pain syndrome characterized by widespread musculoskeletal pain and multiple tender points (Wolfe et al., 1990). FM is estimated to appear in 2–5 percent of the population (female/male ratio 9:1) and can severely affect the individual’s quality of life, leading to substantial social and economic costs (Spaeth and Briley, 2009).

Cognitive complaints may affect up to 70 percent of individuals with FM and contribute to the global disability associated to the syndrome (Leavitt and Katz, 2009). Patients often complain of forgetfulness, blurring of mental activity, and diminished ability to concentrate or follow conversations, which are sufficient to impair life quality or occupational functioning.

¹University of Granada, Spain
²Virgen de las Nieves Hospital, Granada, Spain

Corresponding author:
Elena Miró Morales, PhD, Facultad de Psicología, Universidad de Granada, Campus Universitario de la Cartuja, s/n, CP. 18071, Granada, Spain.
Email: emiro@ugr.es
Overall, FM patients seem to have problems in working memory, episodic memory, and semantic memory access as compared to healthy controls (see Glass, 2009 for a review). Attention and concentration have also been analyzed in FM patients, with contradictory results (Glass, 2009). A main limitation of existing studies is that attention has been broadly defined and the tasks used to measure attention are not designed to cover all the main components of the attentional system.

Research on attention has identified three primary functions of attention, known as alerting, orienting, and executive functioning (Posner and Rothbart, 2007). The alerting network is in charge of keeping the cognitive system properly activated. The orienting network selectively allocates attention to a potentially relevant area of the visual field and/or object to enhance its perceptual processing. The executive component of attention is active in situations that involve planning, maintaining goal-relevant priorities and avoiding interference, making a decision, detecting an error, or overcoming habitual actions (Fan et al., 2002). In a recent study designed to analyze the three attentional networks in FM, observed impaired alertness (reduced vigilance) and executive control (greater interference) were observed in FM patients as compared to healthy controls (Miró et al., 2010). The ability to control distraction is part of the executive component of attention. In fact, it has been recently suggested that FM patients seem especially sensitive to distraction (Glass, 2009; Leavitt and Katz, 2009) and have some impairment in executive processes (Verdejo-García et al., 2009).

Cognitive problems are a real and troubling symptom for FM patients. However, very few studies have addressed whether cognitive dysfunction could be improved in FM. From a pharmacological approach, it is not yet known whether any of the medications used in FM are helpful to improve cognitive function. In a study with chronic pain patients, Dick and Rashiq (2007) found that cognitive function was not improved by short-term local analgesia in several tests of working memory and attention. Two recent studies have shown that exercise in a warm-water pool improves cognitive function in FM patients. Munguía-Izquierdo and Legaz-Arrese (2007) performed a randomized controlled trial comparing an exercise training group vs a control group. Their outcome measures included several memory tasks, attention and working memory assessed with the Paced Auditory Serial Addition Task (PASAT) and executive function in the Trail Making Test (TMT). After training, exercise improved all neuropsychological tests, pain, and severity of FM, while differences were not significant in the control group. In a later publication, Munguía-Izquierdo and Legaz-Arrese (2008) reported similar results, also finding that physical condition and subjective sleep quality improved in the exercise group, while anxiety remained unchanged during the trial.

However, to our knowledge, no study to date has analyzed the impact of a psychological therapy on cognitive function in FM. Since the etiology of FM is unknown, the relationship between its different symptoms is currently not well understood and there is no definitive treatment for the condition (Häuser et al., 2010). It is not clear whether cognitive deficits can be attributed to central nervous system dysfunction or may instead be due to the influence of psychological variables such as emotional distress or pain (see Glass, 2009 for a review).

The relationship between sleep and cognitive deficit has not been generally assessed. This is surprising, if we consider that fatigue and sleep disturbances may affect up to 99 percent of FM patients and are particularly distressing to them (Hamilton et al., 2008). The inability to obtain restorative sleep produces an impairment in the cortical function (Lim and Dinges, 2010), especially in the prefrontal cortex involved in alertness and executive functioning (Jones and Harrison, 2001). In our previous research, sleep dysfunction was the measure that correlated the strongest with attention (Miró et al., 2010). Thus, a therapy focused on sleep may improve cognitive function. Accumulating evidence supports
the idea that sleep disturbances have a reciprocal influence on pain, fatigue, mood, and cognitive functioning in FM patients (see Moldofsky, 2010 for a review). A randomized clinical trial with FM patients suffering from chronic insomnia showed that a cognitive-behavioral therapy (CBT) for insomnia significantly improves sleep quality (57 percent of improvement) as compared with sleep hygiene (SH) instructions (17%) and usual care (0%) (Edinger et al., 2005). In addition, the CBT group showed improvement in mood state as compared with the other groups. Non-pharmacological therapies currently recommended in the evidence-based guidelines for the management of FM are aerobic exercise, cognitive-behavioral therapy, and multicomponent treatment (Häuser et al., 2010). However, in CBT, sleep disturbances in FM are ignored or only dealt with SH at the most.

In this trial we analyzed the effects of a CBT for insomnia on the cognitive function of FM patients. The objectives of the study were the following: (1) to compare the effect of a CBT for insomnia vs an SH education program on our primary outcomes (overall reaction time, alertness, orienting, and executive function) and other secondary outcomes (sleep, pain, depression, anxiety, and daily functioning) in FM patients with chronic insomnia; and (2) to determine the relationships between possible changes observed over time as a result of the therapy in the different outcome measures.

Method
Design and participants
The clinical sample was selected from the Rheumatology Service and Pain Unit of Virgen de las Nieves Hospital in Granada, Spain. Since FM is infrequent in males and it is not clear whether FM has differential characteristics depending on gender, only women were recruited. Women who fulfilled the inclusion criteria to participate in the pilot study were referred from the hospital to the Clinical Psychology Unit of the School of Psychology. All patients met the diagnostic criteria for FM (Wolfe et al., 1990) and the criteria for insomnia (APA, 2000).

Exclusion criteria, designed to exclude patients whose insomnia and/or cognitive dysfunction were better explained by other comorbid conditions were as follows: (1) being pregnant; (2) having a medical history of significant head injury or neurological disorder; (3) having major concomitant medical conditions; (4) having major depressive disorder with suicide ideation or other major Axis I diagnoses (APA, 2000); (5) having symptoms of sleep-disruptive comorbidities with insomnia; (6) having an apnea-hypopnea index or periodic limb movement-related arousal index of 15 or more per hour of sleep; (7) having a severe hypnotic dependence, suggested by the use of a hypnotic in a higher than recommended dosage or repeated episodes of rebound insomnia on withdrawal (Edinger et al., 2005); and (8) being treated with another psychological or physical therapy at the moment of the study.

The study flow of participants is shown in Fig. 1. Eighty-two eligible Spanish-speaking women from 25 to 60 years old with FM were initially screened by a psychologist just before the medical examination. From these patients, 53 women with FM who fulfilled the inclusion criteria were admitted for evaluation. The complete evaluation was carried out by CD and included, in this order, interviews (two sessions), questionnaires (to be completed at home after the first interview), a neuropsychological test (performed at the end of the second session), and a polysomnographic study. After the evaluation, a final sample of 44 women with FM was randomly assigned to either a cognitive-behavioral treatment (CBT, n = 22) for insomnia, or a sleep hygiene (SH, n = 22) group. Simple randomization (1:1) was implemented by a computerized number generator designed by a researcher with no clinical involvement in the trial. Finally, 16 patients in the CBT group and 15 patients in the SH group completed the whole trial and were included in the analysis of the ANT-I. All participants...
gave their informed consent prior to their inclusion in the study. The study received ethical approval from the University of Granada Ethics Committee.

**Treatments**

Three female CBT experts with experience in FM (EM, MPM, and AIS) provided the therapy guided by a treatment manual designed for the study. Each therapist applied both CBT and SH. All sessions were delivered in groups (five to six participants) once a week for six weeks, and lasted about 90 minutes. Patients in the CBT and SH therapy groups continued with their usual medical treatment for FM. All participants were on stable doses of medication during the trial (see Table 1).
The contents and format of the CBT program were designed according to the work of Edinger et al. (2005) and met the recommendations of the American Academy of Sleep Medicine (Morgenthaler et al., 2006). In the first session, patients received information about the relationship between sleep and FM, basic notions about sleep (sleep stages, sleep functions, circadian rhythms, sleep needs, effects of sleep deprivation on wake functioning, and explanation of insomnia) and sleep hygiene education. In the second session, the therapist provided sleep restriction and stimulus control instructions. The third session was devoted to relaxation training (a combination of passive relaxation and imagery training). The fourth and fifth sessions focused on cognitive therapy for the dysfunctional beliefs related to insomnia. Finally, the sixth session was devoted to maintaining achievements and preventing relapses. The SH group worked only with sleep hygiene rules. In the first session, participants were given the same information about sleep as the CBT group. The second session was devoted to sleep hygiene rules related to environmental factors. The third session focused on some lifestyle factors that influence sleep (consumption of stimulants and other substances). The fourth and fifth sessions were devoted to providing information about diet and physical exercise, respectively. The sixth session was similar in both groups.

At the beginning of the first session (CBT and SH groups), the therapist provided patients with a written manual with a summary of the information presented in every session and homework. Participants in the SH group were offered CBT after their Post-treatment assessment.

**Measures**

The assessment of the outcome measures was performed within one week after the intervention by an examiner (CD) who was blinded to group assignment.

**Polysomnography (PSG).** A domiciliary PSG recording (with a SomnoScreen PSG-Tele, SomnoMedics) was used to exclude subjects with sleep-disruptive comorbidities. The recording included electroencephalography in the frontal, central, parietal, and occipital regions (FZ/A1, CZ/A1, PZ/A1, OZ/A1), bilateral electrooculography, bilateral submental and anterior tibial electromyography, and respiratory variables (nasal/oral airflow, thoracic effort, snoring, and pulse oximetry). Sleep stages were scored visually according to Rechtschaffen and Kales’ (1968) standard criteria.

**Neuropsychological task.** The ANT-I (Attentional Network Test-Interactions) task developed by Callejas et al. (2004) explores the efficiency and interactions of the three attentional networks (alertness, orienting, and executive functioning). The ANT-I task was performed with a laptop computer with a 15” color screen monitor, with Windows Vista and E-Prime 2 software. Participants were instructed to respond to the direction of the target stimulus by pressing one of two possible keys on the keyboard. A fixation point was followed by the 50 ms alerting signal (a 2000 Hz sound), presented only in half of the trials. The orienting cue (an asterisk) was presented 400 ms later for 50 ms above or below the fixation point in two-thirds of the trials. After another 50 ms ISI, the target and flankers were shown at the same location of the previous orienting cue in 50 percent of the trials and at the opposite location in the remaining 50 percent of cue-present trials. Participants were to press the ‘C’ key on the keyboard if the central arrow pointed to the left and the ‘M’ key if it pointed to the right, while ignoring the flanking arrows. Target and flankers were congruent (i.e. showed the same direction) in 50 percent of the trials and incongruent (i.e. pointed in opposite directions) in the remaining 50 percent.

Participants performed two practice trials followed by four blocks of 48 experimental trials each, which amounted to 16 trials per experimental condition. The test session lasted for about 40 m. with similar test conditions for all subjects. All participants’ self-reported chronotypes were estimated and participants were
tested at their optimal time (e.g. evening types in the evening).

The task had a 2 (Alerting Signal) × 3 (Orienting Cue) × 2 (Congruency) design. The Alerting Signal, used as an index of Attention-Alerting, had two levels: presence vs absence of the sound. The Orienting Cue, which measured Attention-Orienting, had three levels: no-cue trials (no orienting cue was presented, i.e. neutral trials), cued location trials (an orienting cue was presented at the same location as the subsequent target, i.e. valid trials), and uncued location trials (the orienting cue was presented but at the opposite side to the target, i.e. invalid trials). Lastly, Congruency was used to measure Attention-Executive functioning and had two levels: congruent trials (the target was flanked by arrows pointing in the same direction as the target) and incongruent trials (the flanker arrows pointed in the direction opposite to that of the target).

**Questionnaires**

**Pittsburgh Sleep Quality Index, PSQI (Spanish version of Royuela and Macías (1997)).** The PSQI includes 19 items that explore Sleep Quality, Sleep Latency, Sleep Duration, Habitual Sleep Efficiency, Sleep Disturbances, Use of Sleeping Medication, and Daytime Dysfunction. The present study used the total score (ranging from 0 = absence of perturbation to 21 = severe perturbation). The internal consistency of the PSQI ranged between .67 and .81 (Royuela and Macías, 1997).

**McGill Pain Questionnaire, MPQ (Spanish version of Lázaro et al. (2001)).** The MPQ assesses pain experience using 15 verbal pain descriptors (sensory and affective), a current pain index, and a visual analogue scale to assess pain intensity in the last week (from 1 = no pain to 10 = extreme pain). The present study used this last score. The Cronbach’s alpha of the MPQ was .74 (Lázaro et al., 2001).

**Hospital Anxiety and Depression Scale, HAD (Spanish version of Herrero et al. (2003)).** The HAD assesses anxiety and depression symptoms in non-psychiatric hospital contexts. The HAD includes 14 items (grouped into Anxiety and Depression dimensions) that are scored from 0 to 3. The Cronbach’s alpha was .84 for the Depression subscale and .85 for the Anxiety scale (Herrero et al., 2003).

**Fibromyalgia Impact Questionnaire, FIQ (Spanish version of Rivera and González (2004)).** The FIQ is composed of 10 items. The first item assesses functional capacity for daily living (ranging from 0 to 3). Items 2 and 3 ask the patients to mark the number of days they felt well/unable to work. Items 4 through 10 are scales marked in 10 levels which rate work difficulty, pain, fatigue, morning tiredness, stiffness, anxiety, and depression. The internal consistency of the FIQ showed an alpha coefficient of .82 (Rivera and González, 2004).

**Results**

Table 1 shows the demographic and clinical characteristics of the FM sample. The Student’s t-test, the Mann-Whitney U, and the $\chi^2$ tests were used to compare baseline measures between the CBT and SH groups. The two groups completing the ANT-I task (CBT; $n = 16$ vs SH; $n = 15$) differed significantly in terms of age ($t(29) = -3.31, p = .002$), but were similar in educational level, marital status, work status, and clinical variables such as years since the diagnosis of FM, and insomnia, or type of insomnia problem ($p > .2$ for all effects). The CBT ($n = 20$) and SH ($n = 20$) groups completing self-reported measures were similar in all demographic and clinical variables (all $ps > .37$).

**Attentional measures**

Previous analyses showed that the main effects of each variable as well as the expected interactions were significant in the first session of the FM sample. Thus, the same results obtained with the original task were perfectly replicated (Callejas et al., 2004).
Group and treatment effects

Mean and standard deviations of outcome measures are shown in Table 2 and Figure 2. A first analysis showed that attentional measures at baseline were no different between the CBT and SH groups (all $p > .2$). After that, a $2$ (Alerting Signal) $\times 3$ (Orienting Cue) $\times 2$ (Congruency) $\times 2$ (Time; Pre- vs Post-treatment) $\times 2$ (Group; CBT vs SH) repeated measures ANCOVA was performed on the data from the two sessions to check whether the two groups differed across sessions in attentional functioning. Age was introduced in this analysis as a covariate to take into account age differences between the two groups. Age did not reach statistical significance in the ANCOVA, ($F(1, 28) = 2.31$, $p = .1401$). The analysis showed a significant interaction between Alerting Signal, Time, and Group ($F(1, 28) = 4.88$, $p = .0355$). It revealed that, whereas the CBT group reduced the alertness effect from the Pre- (63 ms) to the Post-treatment (31 ms)
session \( (F(1, 28) = 11.84, p = .0018) \), the SH group showed similar alertness effects in both sessions (47 and 46 ms, \( F < 1 \)). Similarly, the interaction between Congruency, Group, and Time was significant \( (F(1, 28) = 5.27, p = .0294) \). Again, whereas the CBT group showed reduced interference from the Pre- (114 ms) to the Post-treatment (88 ms) session, \( (F(1, 28) = 15.76, p = .0005) \), the SH group showed similar congruency effects in both sessions (114 ms and 104 ms, respectively, \( F < 1 \)).

The CBT group reduced overall reaction time (RT) in the second session to a greater extent than the SH group, although the Time \times Group interaction only approached significance \( (F(1, 28) = 2.97, p = .0956) \). Whereas the CBT group reduced overall RT significantly from the Pre- (717 ms) to the Post-treatment (88 ms) session, \( (F(1, 28) = 16.37, p = .0004) \), the SH group showed rather similar overall RT in both sessions (704 ms and 654 ms, respectively, \( F < 1 \)).

### Table 2. Mean (M) and standard deviations (SD) of the clinical variables obtained by the therapy groups at Pre- and Post-treatment

<table>
<thead>
<tr>
<th></th>
<th>CBT group (( n = 20 ))</th>
<th>Post-treatment M (SD)</th>
<th>SH group (( n = 20 ))</th>
<th>Post-treatment M (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MeanRT ( (1) )</td>
<td>717.45 (124.82)</td>
<td>617.00 (78.39)</td>
<td>703.68 (111.73)</td>
<td>653.60 (88.57)</td>
</tr>
<tr>
<td>Control ( (1) )</td>
<td>113.97 (33.74)</td>
<td>87.92 (29.13)</td>
<td>114.20 (49.81)</td>
<td>104.70 (33.84)</td>
</tr>
<tr>
<td>Orienting ( (2) )</td>
<td>54.88 (43.25)</td>
<td>66.17 (24.26)</td>
<td>59.70 (20.34)</td>
<td>58.15 (38.16)</td>
</tr>
<tr>
<td>Alerting ( (1) )</td>
<td>92.03 (74.17)</td>
<td>51.85 (31.33)</td>
<td>69.48 (47.39)</td>
<td>68.98 (44.81)</td>
</tr>
<tr>
<td>Sleep Quality (PSQI) ( (1) )</td>
<td>15.05 (3.39)</td>
<td>11.55 (4.29)</td>
<td>14.15 (3.11)</td>
<td>13.20 (3.12)</td>
</tr>
<tr>
<td>Pain Intensity (MPQ) ( (1) )</td>
<td>7.02 (1.92)</td>
<td>6.50 (2.46)</td>
<td>8.26 (1.70)</td>
<td>8.26 (1.48)</td>
</tr>
<tr>
<td>Anxiety (HAD) ( (1) )</td>
<td>10.60 (4.13)</td>
<td>10.95 (4.26)</td>
<td>11.60 (4.12)</td>
<td>11.55 (3.84)</td>
</tr>
<tr>
<td>Depression (HAD) ( (1) )</td>
<td>10.50 (3.69)</td>
<td>9.65 (4.39)</td>
<td>12.20 (3.73)</td>
<td>11.30 (4.61)</td>
</tr>
<tr>
<td>Daily Functioning (FIQ) ( (1) )</td>
<td>59.66 (12.83)</td>
<td>49.25 (21.38)</td>
<td>62.19 (13.97)</td>
<td>63.67 (16.08)</td>
</tr>
</tbody>
</table>

Note: (1) High scores indicate worse functioning; (2) High scores indicate better functioning.

### Attentional indexes

Indexes of the efficiency of each attentional network were computed as the following subtractions (Callejas et al., 2004): Attention-Alerting = NoTone–Tone conditions (restricted to the no-cue condition); Attention-Orienting = Uncued location–Cued location trials, and Attention-Executive functioning = Incongruent–Congruent. These indexes were computed for both the Pre- and Post-treatment sessions. Overall RT in each session was also taken as an index of overall performance. Furthermore, differences between the Pre- and Post-treatment sessions were computed as an index of improvement in each measure. Specific \( t \)-tests comparing each Pre-Post attentional index against 0 for each group were computed to test whether the functioning of each attentional network changed after treatment for each group.

In the SH group, there was no change after treatment in any of the attentional indexes (all \( ps > .45 \)). In the CBT group, only the Alertness and Executive functioning attention indexes changed after treatment \( (t(16) = 2.16, p = .0470, d = .70 \) and \( t(16) = 2.65, p < .0183, d = .82 \), respectively), whereas no change was observed in the Attention-Orienting index \( (t(16) = -.82, p = .4271) \).
Self-report measures

Differences in self-reported measures between the CBT and SH therapy groups across sessions were compared using repeated-measures ANOVAs (Group; CBT vs SH × Time; Pre vs Post-treatment). Effect sizes were calculated via the partial $\eta^2$. For significant effects, Student’s $t$ test was computed for paired comparisons and Cohen $d$ was used to examine the effect sizes (small .2, medium .5, and large .8) (Cohen, 1988). The statistical power of the analysis performed with the self-report measures was 70 percent.

Repeated-measures ANOVAs for Sleep Quality (PSQI) showed a significant effect for Time ($(F(1, 38) = 19.29, p = .000, \eta^2 = .33)$) and for Time × Group interaction ($(F(1, 38) = 6.33, p = .016, \eta^2 = .14)$) but no significant effect for Group. Whereas the CBT group reduced sleep dysfunction from the Pre- (15.05) to the Post-treatment (11.55) session ($(t(19) = 5.01, p = .000, d = .90, \text{large effect size}$)), the SH group showed no differences in sleep dysfunction between both sessions (14.15 and 13.20, respectively, $(t = 1.29, p = .211)$). The ANOVA for Daily Functioning (FIQ) showed a significant Time × Group interaction ($(F(1, 38) = 4.09, p = .050, \eta^2 = .09)$), whereas the effect of Group or Time factors was not significant. CBT group changed the Daily Functioning (FIQ) from the Pre- (59.66) to the Post-treatment (49.25) sessions at a level that approached significance ($(t(19) = 1.94, p = .067, d = .59, \text{medium effect size}$)), whereas the SH group did not change (62.19 and 63.67, respectively). In short, 85 percent of the patients in the CBT group and 55 percent in the SH group showed significant clinical changes in Sleep quality (PSQI). Similarly, 60 percent of the patients in the CBT group and 30 percent in the SH group improved Daily Functioning (FIQ) to a clinically significant level. ANOVAs for Pain intensity (MPQ) and Anxiety and Depression (HADS) did not show any significant effects for Time, Group, and Time × Treatment interaction factors (between $F(1, 38) = .002, p = .961$ and $F(1, 38) = 2.93, p = .095$). Overall, these results show that the CBT group obtained greater improvement than the HS group in both Sleep Quality and Daily Functioning.

Relationships between outcome measures

For clinical variables that changed over time as a result of the therapy (CBT or HS), individual
changes were calculated with the Reliable Change Index (RCI) (Jacobson and Truax, 1991; Salaberría et al., 1996). Pearson’s analysis was performed to examine relations between changes (Reliable Change Index) in Sleep Quality (PSQI) and Daily Functioning (FIQ) and changes (rate of change) in subtraction indexes of the ANT-I. Results revealed a significant correlation between the Attention-Executive functioning and the Reliable Change Index of Sleep quality (PSQI) \( r = .40, p = .026 \). No significant correlations were observed between the Reliable Change Index of Sleep quality (PSQI) and Daily Functioning (FIQ) and the remaining indexes of the ANT-I (MeanRT, Alerting and Orienting) either at Pre- or Post-treatment \( (r \text{ between } .29, p = .104, \text{ and } -.24, p = .181) \), nor subtraction indexes of the ANT-I \( (r \text{ between } .19, p = .300 \text{ and } -.25, p = .162) \). These results show that the change in sleep quality was related to the improvement in executive functioning.

**Discussion**

This is the first study to our knowledge that demonstrates the positive effect of a CBT for insomnia on cognitive function of patients with FM. The CBT group showed significant improvement in alertness and executive functioning as compared with the SH group. In addition, the CBT group showed significant improvement in sleep quality and a trend to improvement in daily functioning, in contrast to the SH group. The analysis of relationships between changes in the ANT-I measures (alertness and control) and changes in psychological measures (sleep and daily functioning) showed that the improvement in executive functioning was significantly related to changes in sleep.

At Pre-treatment, participants with FM showed the expected impairment in Attention-Alerting and Attention-Executive functioning reported in our previous study (Miró et al., 2010). The two FM groups in the current study showed 115 and 119 ms Attention-Executive functioning, and 63 and 48 ms Attention-Alerting effects, while the control group in our previous study (Miró et al., 2010) showed 82 and 29 ms effects, respectively. The larger alerting effect is usually observed in populations with attentional deficits, and suggests that these subjects take greater advantage of the tone signal than healthy controls because they have difficulties in maintaining alertness without an external signal (Fan et al., 2002). After the treatment, the CBT group showed a significant reduction in the alertness effect as compared with the SH group. This seems to reflect an improvement in the capacity to endogenously maintain the level of activation that is necessary to perform the task, that is, an improvement in vigilance. This conclusion is somehow supported by the fact that, after treatment, the CBT also seems to decrease overall RT, a measure that is usually taken as an index of vigilance.

With regard to executive functioning, after the intervention, the CBT group showed a reduction in the interference effect as compared with the SH group. Sleep processes have strong relationships with executive functioning and attention (Lim and Dinges, 2010), and there is evidence that sleep therapy can lead to an improvement in most of these cognitive domains, as happens in people with sleep apnea or with insomnia (Altena et al., 2008).

Previously, two studies have shown that exercise in a warm-water pool improved attentional function and executive control in FM patients (Munguía-Izquierdo & Legaz-Arrese, 2007, 2008). This training in a warm-water pool included three sessions a week and lasted for 16 weeks, while our CBT program is composed of six sessions, one every week for six weeks. However, before concluding that CBT is more efficient than exercise therapy a detailed cost–benefit analysis is mandatory. As regards the self-reported measures, after treatment FM patients in the CBT group showed a significant improvement in sleep and showed a trend to improvement in daily functioning, as compared with subjects in the SH group. This finding is consistent with Edinger’s work, which showed a significant improvement in sleep quality in a
CBT group as compared with SH instructions and usual care (Edinger et al., 2005). Also, Munguía-Izquierdo and Legaz-Arrese (2008) reported an improvement in sleep quality in their exercise group vs the control group. Sleep disturbances in FM are usually treated with tricyclic antidepressants or sleep medications which provide very limited effects and often have adverse consequences (Häuser et al., 2010). Again, our results suggest that a CBT that includes sleep education and cognitive-behavioral strategies for insomnia may be both effective and efficient to improve sleep quality as compared with medications or the longer duration exercise therapy. However, much more research is needed before reaching conclusions about the efficacy of these treatments.

Our data suggest that improvement in cognitive function seems to be related to a positive impact in daily functioning, although the effect was only marginally significant. No significant changes were found in anxiety, depression, or pain between both groups. In Edinger’s work, the CBT group showed an improvement in mood state as compared with the remaining groups, but Edinger used the Profile of Mood States while we used the HADS. As in the present study, Munguía-Izquierdo and Legaz-Arrese (2008) did not find any differences in anxiety either after their treatment using the State Trait Anxiety Inventory. The difference seems to lie in testing state vs trait. Improvements in trait rather than state may only appear after a longer period after treatment.

The absence of changes in pain may also be related to the instrument used to measure pain (MPQ). An objective measure of pain may be more sensitive to our intervention. Dick and Rashiq (2007) did not find any changes in the MPQ after procedures resulting in analgesia, while studies that have assessed pain with objective methods (dolorimeter) have found significant changes in the pain threshold after exercise training (Munguía-Izquierdo and Legaz-Arrese, 2007, 2008).

In addition, most studies of CBT that have achieved major psychological improvements in emotional distress and pain have used longer programs and include a much greater intervention (Hassett and Gevirtz, 2009). Moreover, it is important to consider that our results were obtained comparing a group of FM patients who received CBT vs a group of FM patients who received SH. Note that psycho-education is a feature of both interventions. If we had compared our outcome results with a control group, the benefits would probably have been greater. It is known that education conditions such as SH lead to greater improvement than a waiting-list control group (Edinger et al., 2005; Yang et al., 2010).

Regarding the relationships between attentional deficits and psychological measures, we found that changes in executive functioning – but not in alertness – were correlated with the improvement in sleep quality. The improvement in alertness may relate better with other sleep parameters that we have not considered in our study. Further research is needed to understand the relationships between sleep processes and cognitive functioning in FM. Accumulating evidence suggests that FM appears in response to chronic stressors (Oliveira and Costa, 2009) and is associated with a disorder of the neuroendocrine stress response that may influence cognitive function through effects of hypocortisolism on the brain (Sephton et al., 2003). Also, for example, chronic stress produces alterations in prefrontal cortical morphology that may underlie the observed deficits in executive control (Liston et al., 2006). In addition, chronic stress relates strongly to poor sleep quality (Hamilton et al., 2008; Moldofsky, 2010), and the inability to obtain a restorative sleep has been related with prefrontal cortex dysfunction (Jones and Harrison, 2001; Lim and Dinges, 2010).

Several methodological limitations of the present study should be taken into account in future research. First, our findings should be replicated with a larger sample recruited from other contexts. Although the diagnostic reliability of a sample collected from a hospital may be greater, these subjects may also have greater impairment than the participants recruited from
FM associations. Also, requiring participants to undergo many procedures and tests may have reduced the attendance to Post-treatment assessments (e.g. ANT-I). Follow-up assessments are necessary to clarify whether the observed benefits remain over time. In addition, it would be interesting for future trials to include objective measures of pain, a wide range of measures of emotional distress, and monitoring of therapy sessions to ensure fidelity of therapists to treatment protocols.

Furthermore, an added complication of the study of cognitive function in FM is the frequent use in the sample of multiple drugs. Although this might be considered a limitation of the study, it makes our study more representative of a general clinical population. It is important to note that medication was kept constant through all the trial. Nevertheless, the results of the present study should be treated with caution, and replication is called for.

In short, the present study showed that a CBT for insomnia represents a promising intervention not only for sleep disturbance in FM patients but also for attentional dysfunction, and probably for daily functioning. Our trial provides additional evidence for the relevance of sleep in FM. The results of the present study should encourage the use of a more structured intervention for insomnia such as CBT. Similarly, further research should address more specifically whether the combination of the usual CBT treatment with a CBT therapy for sleep may improve current management of FM syndrome.

Competing Interests
None declared.

Acknowledgements
This research was financially supported by the Spanish Ministry of Science and Innovation (research projects SEJ2006-07513, PSI2008-03595PSIC and PSI2009-1365PSIC). The cognitive task will be provided free of charge upon request to JL (jlupiane@ugr.es). Similarly, the therapy manual will be provided upon request to EM (emiro@ugr.es).

References


Herrero MJ, Blanch J, Peri JM, De Pablo J, Pintor L, and Bulbena A (2003) A Validation Study of the...


