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Psychological treatments for fibromyalgia: A meta-analysis

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ABSTRACT

The aims of the present analysis were to investigate the short- and long-term efficacies and treatment moderators of psychological interventions for fibromyalgia. A literature search using PubMed, PsychINFO, the Cochrane Library, and manual searches identified 23 eligible studies including 30 psychological treatment conditions and 1396 patients. Meta-analytic integration resulted in a significant but small effect size for short-term pain reduction (Hedges's $g = 0.37$, 95% confidence interval (*CI*): 0.27–0.48) and a small-to-medium effect size for long-term pain reduction over an average follow-up phase of 7.4 months (Hedges's $g = 0.47$, 95% *CI*: 0.3–0.65) for any psychological intervention. Psychological treatments also proved effective in reducing sleep problems (Hedges's $g = 0.46$, 95% *CI*: 0.28–0.64), depression (Hedges's $g = 0.33$, 95% *CI*: 0.20–0.45), functional status (Hedges's $g = 0.42$, 95% *CI*: 0.25–0.58), and catastrophizing (Hedges's $g = 0.33$, 95% *CI*: 0.17–0.49). These effects remained stable at follow-up. Moderator analyses revealed cognitive-behavioral treatment to be significantly better than other psychological treatments in short-term pain reduction (Hedges's $g = 0.60$, 95% *CI*: 0.46–0.76). Higher treatment dose was associated with better outcome. Publication-bias analyses demonstrated that the effect sizes were robust. The results suggest that the effects of psychological treatments for fibromyalgia are relatively small but robust and comparable to those reported for other pain and drug treatments used for this disorder. Cognitive-behavioral therapy was associated with the greatest effect sizes.

1. Introduction

Fibromyalgia (FM) is a chronic pain syndrome defined by widespread pain [72]. Additionally, FM patients report other symptoms, predominantly disturbed sleep, fatigue, and depressed mood [6,7,65].

FM affects 2–7% of the general population [3,5,6], and recent epidemiological studies demonstrate the disorder's alarming socioeconomic burden [58]. Although the exact etiology and pathogenesis of FM are still unknown, there is increasing evidence supporting an integrative biopsychosocial model [32,65,71].

Treatment of FM is regarded as challenging, and the prognosis for recovery is poor [23,25]. There is some evidence that FM can be effectively treated with drug therapies [25,30,31,43]. However, pharmacological interventions often led to treatment discontinuation because of adverse events, suggesting that FM patients may be intolerant to medication side effects [43]. Furthermore, the positive effects of drug therapy appear to dissipate after treatment discontinuation [66]. The evidence concerning other monotherapies for FM is also conflicting [1]. A meta-analysis based on 9 studies suggested that multimodal therapy provides greater benefit than single interventions [1,29].

Psychological interventions are known to be effective in treating other pain disorders [17,68] and therefore, could be a promising treatment for FM. Only a few systematic reviews on this subject exist and their authors came to divergent conclusions [4,25,53,56,66,60]. In addition, none of these reviews applied meta-analytic methods to quantify the size of the treatment effect. Rossy and colleagues [53] and Sim and Adams [56] performed the first systematic qualitative reviews of non-pharmacological interventions for FM. Rossy et al. [53] concluded that cognitive behavior therapy (CBT) proved effective, while Sim and Adams [56] found that there was no strong evidence to support any single intervention. Four recent systematic reviews also arrived at disparate conclusions: Goldenberg et al. [25] stated that there is a strong evidence for the long-term efficacy of CBT and patient education on alleviating fibromyalgia symptoms, whereas van Koulil et al. [66] concluded that the effects of CBT for FM are limited and positive outcomes do not persist in the long-term. Bennett and Nelson [4] stated that CBT does not seem to provide pain relief in fibromyalgia patients and that the primary utility of CBT might be in improving symptoms other than pain. In contrast, Thieme

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and Gracely [60] identified 27 studies on psychological FM interventions and concluded that CBT and operant-behavioral therapy were "highly effective" for treating FM pain.

A closer examination of these qualitative reviews reveals that the conclusions drawn are based on very different study samples and focus on different treatment techniques due to divergent definitions of psychological treatment or CBT. Additionally, some authors interpret only the effects of psychological treatments in comparison to control groups [60], whereas others also take pre–post effects into consideration [66].

In sum, it remains unclear whether psychological treatments, such as CBT, are effective in reducing symptoms of FM. We conducted a meta-analysis with two primary goals: (1) to quantify the size of controlled and uncontrolled short-term and long-term treatment effects of psychological treatments on FM symptoms and (2) to identify treatment moderators.

2. Methods

2.1. Search procedure

The meta-analysis was performed according to the QUORUM guidelines [10], taking the recent update ("PRISMA guidelines" [42]) into account. Studies were identified by searching PubMed, PsycINFO, and the Cochrane Library. Extensive searches were conducted for studies published between the first available year and June 1, 2009, using the search term *fibromyalgia* combined with the term *treatment*. Additionally, a manual review of reference lists of relevant studies and review papers extracted from the database searches was conducted. A priori decisions were made to search only for published work. These searches generated 1530 unique articles. Each article was further examined by two independent reviewers (JG and KK, all decisions reviewed by JAG) for potential inclusion in the meta-analysis.

2.2. Determination of outcome variables

The Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) [15,63] recommends the inclusion of a set of core outcome domains in clinical trials of pain treatments (pain, physical functioning, emotional functioning, participant global rating of self-improvement and adverse events). Following these recommendations, we included average pain intensity as a primary outcome [64] and as a measure of the core outcome domain "pain", functional status as a measure of the core outcome domain "physical functioning", and depression as a measure of core outcome domain "emotional functioning". Additionally, there are several cognitive, physical and behavioral FM symptoms that are typically described in the literature and regarded as relevant [5,6], including sleep disturbances and catastrophizing. Sleep disturbances and catastrophizing were included as additional outcome variables in the analyses.

2.3. Study selection

To be included, studies were needed to meet the following inclusion criteria:

(1) included patients with a diagnosis of FM based on the criteria of the American College of Rheumatology [69];
(2) included an adult sample (aged 18–65);
(3) employed a psychological treatment of any kind (defined as "the relief of distress or disability in one person by another, using an approach based on a particular theory or paradigm, and that the agent performing the therapy has had some form of training in delivering this" [21]) that accounted for at least 60% of treatment time in cases of multimodal programs;
(4) reported measures of at least one of the main outcome variables at both pre- and post-intervention;
(5) provided sufficient data to perform effect size analyses.

Studies meeting the following exclusion criteria were excluded:

(1) employed a pharmacological treatment as a cointervention ("drug intake as usual" or general advice about medication during treatment was tolerated);
(2) the length of the psychological treatment was insufficient (e.g., only therapist contact time was during the diagnostic assessment);
(3) the study was a case study or included less than six patients;
(4) the sample overlapped either partially or completely with the sample of another study meeting inclusion criteria for the meta-analysis.

If available, follow-up data (from the longest available follow-up) and data for control groups were included. For studies that included a wait-list control group and an active control group other than a psychological treatment, the data of the active control group were included. In the case of two or more groups receiving different psychological interventions within one study, all groups were independently included. Publications in English, German, Spanish, Italian and Polish were considered.

2.4. Validity assessment

Regarding the methodological quality of the studies, no additional inclusion criteria were applied and randomized controlled trials (RCTs) as well as uncontrolled or nonrandomized studies were included. To control for the possible confounds of effect size [24] we rated the quality of each study on a validity scale and analyzed it as a moderator of the study findings. The validity scale was developed by three of the authors (JAG, JG, KK)[1] by adapting Jadad criteria for pharmacological trials [38] and following PRISMA recommendations [42]. The validity scale takes into account relevant aspects of internal, external, and construct validity and consists of 20 dichotomous items with a maximum validity score of 20. For each study, validity was assessed independently by two reviewers (JG and KK) and inter-rater reliability was measured. Disagreements were resolved through discussion.

2.5. Data extraction

For each study, two of the authors (JG and KK) independently selected psychometrically validated measures of pain intensity, sleep disturbance, depression, catastrophizing, and functional status. Two of the authors (JAG and WR) decided which measures had adequate psychometric properties to be included in the analyses. Numerical data were extracted from the studies by two of the authors (JK and KK) in order to analyze changes from pre to post-treatment and from pre-treatment to follow-up.

2.6. Quantitative data synthesis

All analyses were completed manually or by using the software program Comprehensive meta-analysis, version 2 [8]. We analyzed intention-to-treat (ITT) data when available and completer data in

[1] The full version of the validity scale is available upon request from the first author.

all other cases. Separate effect sizes for continuous measures of pain intensity, sleep disturbance, depression, catastrophizing, and functional status were calculated using pre–post-treatment differences (within-group) for all studies and also for all controlled studies using Hedges's *g* and its 95% confidence interval. Hedges's *g* is a variation of Cohen's *d* that corrects for biases due to small sample sizes [33]. Within-group effect size was calculated using the following formula: $d = (\frac{\overline{Y_1}-\overline{Y_2}}{S_{\text{Difference}}})\sqrt{2(1-r)}$, where $\overline{Y_1}$ is the pre-treatment sample mean, $\overline{Y_2}$ is the post-treatment sample mean, $S_{\text{Difference}}$ is the standard deviation of the difference, and *r* is the correlation between pre- and post-treatment scores. Hedges's *g* can be computed by multiplying *d* by correction factor $J(df) = 1 - \frac{3}{4df-1}$, where *df* is the degree of freedom to estimate the within-group standard deviation.

The controlled effect sizes were computed using the following formula: $g = \frac{\overline{\Delta}_{PSY}-\overline{\Delta}_{CONT}}{\sqrt{\frac{(n_{PSY}-1)SD^2_{CONT}+(n_{CONT}-1)SD^2_{PSY}}{(n_{total}-2)}}} \times (1 - \frac{3}{4(n_{PSY}+n_{CONT})-9})$, where $\overline{\Delta}$ is the mean pre- to post-treatment change, *SD* is the standard deviation of post-treatment scores, *n* is the sample size, *PSY* refers to the psychological treatment condition, and *CONT* refers to the control condition.

The magnitude of Hedges's *g* may be interpreted using Cohen's [11] recommendations of small (0.2), medium (0.5), and large (0.8).

The correlation between pre- and post-treatment measures is needed in order to calculate the pre–post effect sizes, but could not be determined from the study reports. Therefore, we followed the recommendation by Rosenthal [52] and assumed a conservative estimate of $r = 0.7$.

Effect size estimates for average pain intensity, sleep disturbance, depression, catastrophizing, and functional status, respectively, were pooled across studies in order to obtain a summary statistic. It was decided a priori (based on previous pain research results) that effect sizes for single studies that exceeded Hedges's $g > 3.0$ would be regarded as outliers and would be excluded from the analyses. These studies and the specific reasons for their exclusion are described below. The effect size estimates were calculated using a random-effects model rather than a fixed-effects model because the studies included were not functionally identical [34,44]. Effect size estimates for follow-up data were also calculated in the manner described above.

2.7. Sensitivity analysis

Results of a meta-analysis may be biased due to the fact that studies with non-significant results are less likely to be published than those reporting significant results. In order to address this potential publication bias, we computed the *fail-safe N* [52] using the following formula: $X = \frac{K(K\overline{Z}^2-2.706)}{2.706}$. In this formula, *K* is the number of studies in the meta-analysis and $\overline{Z}$ is the mean *Z* obtained from the *K* studies. The effect size can be considered robust if the required number of studies (*X*) to reduce the overall effect size to a non-significant level exceeds $5K + 10$ [52]. Additionally, for the pre–post effect size for pain intensity we constructed a funnel plot. The Trim and Fill method examines whether negative or positive trials are over or under-represented, accounting for the sample size (i.e., where the missing studies would need to fall to make the plot symmetrical). This information can then be used to re-calculate the effect size estimate.

2.8. Moderator analysis

Three potential moderating variables were determined based on previous research and the characteristics of the investigated treatments. Quality of studies (assessed with a validity score), treatment dose (total number of hours spent in psychological interventions) and treatment type were chosen as potential moderators. The moderating effect of treatment type was tested by dividing the studies into the following six classes of psychological treatments: (1) CBT, including cognitive interventions combined with respondent and/or operant interventions; (2) Relaxation interventions, defined as respondent treatment including diverse types of relaxation training and/or biofeedback/neurofeedback[2]; (3) Educational interventions; (4) Behavioral treatments, including mainly operant interventions; (5) Mindfulness-based treatments, including mainly mindfulness meditation and mindfulness-based stress reduction; and (6) other treatments (e.g., Eye movement desensitization and reprocessing [EMDR]). For the purpose of our analysis, we followed Turk's [62] suggestion to differentiate between CBT for chronic pain and its single component and to label interventions as CBT only when cognitive, operant and/or respondent techniques were combined.

The classification of studies into one of the treatment groups described above was based on information provided in the publications and discussion between three of the authors (JAG, JG, and KK). Moderating effects were examined using meta-regression analyses. To investigate the effects of categorical moderator variables, we examined 95% confidence intervals.

3. Results

3.1. Study selection

Our study selection process is illustrated in Fig. 1. Of the 1530 articles identified in our initial searches as potentially relevant, 24 studies met our selection criteria. One study that fulfilled the inclusion criteria had to be excluded because it reported unusually high effect sizes ($g > 3.0$) for all treatment conditions and outcome measures [19]. This study as well as other conditions that were regarded as outliers concerning specific outcomes or treatment conditions will be discussed below. Twenty-three studies including 30 treatment conditions were included in the meta-analysis (see Tables 1 and 2). These studies included a total of 1396 patients who fulfilled the American College of Rheumatology diagnostic criteria for fibromyalgia. All included studies provided data for continuous measures of relevant outcome variables at pre- and post-treatment.

3.2. Characteristics of the study sample

3.2.1. Studies and patient characteristics

The characteristics of the included studies and treatment conditions are shown in Table 2. Our analysis included 23 studies with 30 psychological treatment conditions, of which 8 ($n = 213$ participants) were identified as CBT, 8 ($n = 225$ participants) as relaxation treatments, 6 ($n = 200$ participants) as educational treatments, 5 ($n = 199$ participants) as behavioral treatments, 2 ($n = 115$ participants) as mindfulness-based treatments, and 1 ($n = 6$ participants) as an EMDR treatment. In three treatment conditions individual treatment was administered, all other treatment conditions provided group therapy or a combination of group and individual therapy. The number of hours spent in psychological interventions ranged from 2 to 120 ($M = 26.9$, $SD = 29.9$). Most

[2] One may argue that combining biofeedback and relaxation into one subgroup is not appropriate since biofeedback is often used to enhance discrimination rather than induce relaxation. However, the studies included in the analysis that employed biofeedback also taught patients relaxation (e.g. van Santen [67] "muscle relaxation"). Additionally, moderator analyses were performed with "type of treatment" = biofeedback/neurofeedback vs. relaxation as moderator to make sure that we could summarise these three studies under "relaxation". The moderator analyses were not significant (e.g. for pain intensity $B = -0.0211$, $SE = 0.028$, $p = 0.46$), justifying our decision to subsume biofeedback and relaxation into one treatment-type subgroup.

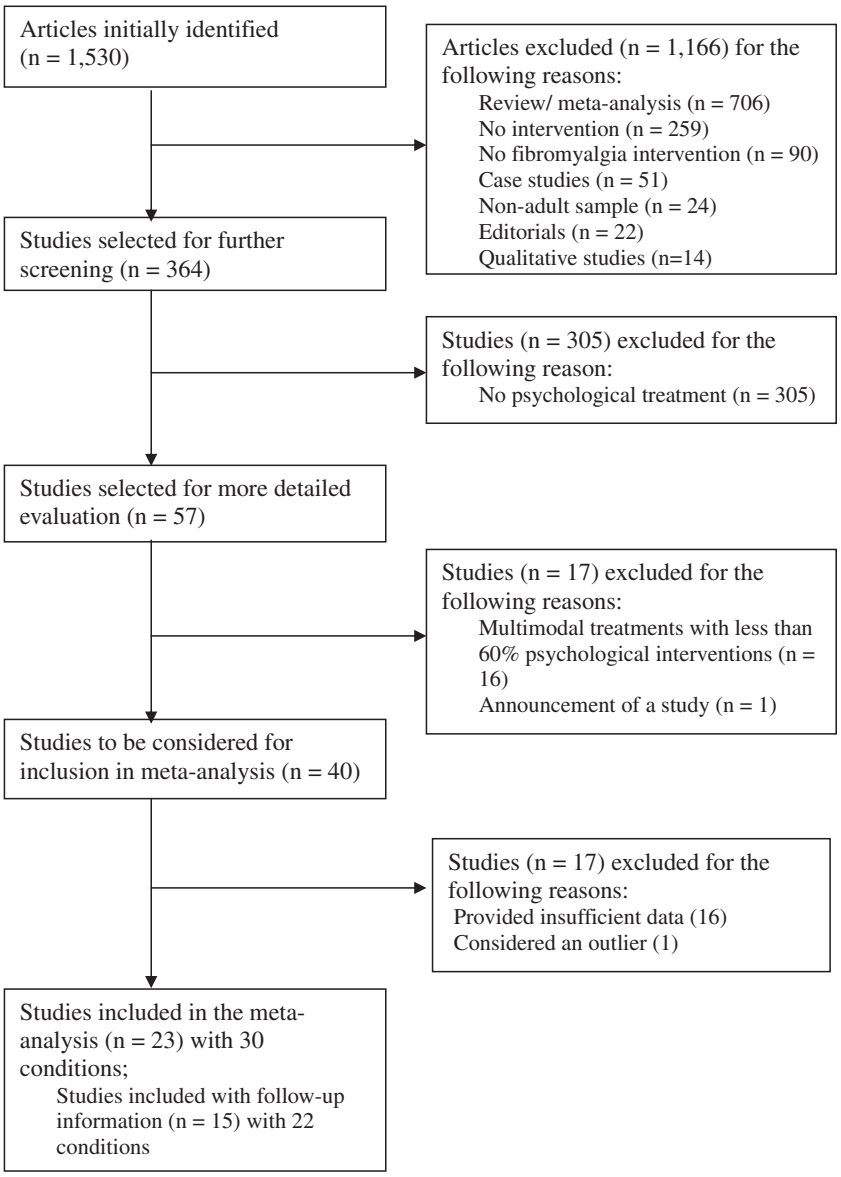

Fig. 1. Study selection process.

studies did not report any cointervention and were regarded as purely psychological, but in some cases ($n = 8$ treatment conditions) additional exercise, Yoga, or Qi Gong was applied, accounting for 16–40% of treatment time. Twelve treatment conditions were uncontrolled or employed another psychological condition as a control condition ($n = 6$). Three control conditions included physical or balneotherapies, 3 included exercise conditions, 8 included wait-list control or treatment as usual conditions, and 4 included placebo (attention/support placebo or sham neurofeedback) conditions. Because patients in the wait-list control conditions (WLC) typically received treatment-as-usual (TAU), we merged studies employing a WLC condition with those employing a TAU control condition for the purpose of moderator analyses.

For 21 of the treatment conditions, follow-up data were reported. The follow-up periods ranged from 2 to 48 months ($M = 7.4$, $SD = 3.6$).[3] The total number of patients across all studies and all treatment and control groups was 1396 with 958 patients in treatment and 438 patients in control groups. The samples were predominantly female (92% of patients). Twenty-seven treatment conditions ($n = 921$ patients), and 12 control conditions ($n = 364$ patients), included sufficient data to compute drop out rates from pre- to post-treatment. A total of 192 patients (20.85%) and 73 patients (20.06%) dropped out of psychological treatment and control conditions, respectively, indicating that the drop out rates for treatment and control conditions were comparable. Eleven studies reported ITT data at post-treatment.

3.2.2. Quality of included studies

The validity scores for each study are displayed in Table 1. Scores ranged from 5 to 16 points (out of 20; $M = 11.22$, $SD = 2.96$). Two independent ratings of validity criteria were conducted; inter-rater reliability was $r = .73$.

Twenty-one of the 23 studies described their interventions sufficiently and defined adequate outcome measures. Eighteen studies described drop out rates for each group as well as relevant baseline characteristics. Eight of the 23 studies did not describe adequate inclusion and exclusion criteria. Nine of the 23 studies

[3] Mean and standard deviation computed after the exclusion of one outlier (Wigers et al., 1996; 48-month follow-up).

Table 1
Effect size analysis of studies/treatment conditions examining the efficacy of psychological treatment on pain, sleep disturbance, depressive symptoms, functional status and catastrophizing in fibromyalgia patients.

Author, publication year	Type of treatment	Intent to treat (ITT) data	Targeted symptom	Hedges's *g*	95% Confidence interval	*p*-Value
Astin et al. (2003) [2]	Mindfulness-based treatment		Pain	0.44	0.17–0.72	0.01
			Sleep	NA[a]		
			Depression	0.46	0.18–0.74	<0.01
			Functional status	0.62	0.33–0.91	<0.01
			Catastrophizing	NA		
Creamer et al. (2000) [12]	CBT[b]	ITT	Pain	0.53	0.23–0.83	<0.01
			Sleep	0.32	0.03–0.61	0.03
			Depression	0.32	0.03–0.61	0.03
			Functional status	0.68	0.37–0.95	<0.01
			Catastrophizing	0.41	0.02–0.12	<0.01
Edinger et al. (2005) [18]	CBT		Pain	0.44	0.05–0.83	0.03
			Sleep	2.84	1.97–3.71	<0.01
			Depression	NA		
			Functional status	NA		
			Catastrophizing	NA		
Edinger et al. (2005) [18]	Education		Pain	0.40	0.03–0.76	0.03
			Sleep	6.21[c]	4.55–7.86	<0.01
			Depression	NA		
			Functional status	NA		
			Catastrophizing	NA		
de Voogd et al. (1993) [14]	Behavioral treatment		Pain	0.20	−0.06–0.46	0.13
			Sleep	0.01	−0.25–0.27	0.93
			Depression	0.34	0.08–0.61	0.01
			Functional status	NA		
			Catastrophizing	NA		
Field et al. (2002) [20]	Relaxation		Pain	0.46	0.03–0.89	0.04
			Sleep	0.46	0.03–0.90	0.04
			Depression	0.07	−0.34–0.48	0.74
			Functional status	NA		
			Catastrophizing	NA		
Friedberg (2004) [22]	EMDR		Pain	0.26	−0.28–0.79	0.34
			Sleep	NA		
			Depression	NA		
			Functional status	NA		
			Catastrophizing	NA		
Günther et al. (1994) [26]	Relaxation		Pain	0.52	0.10–0.95	0.02
			Sleep	0.69	0.29–1.09	<0.01
			Depression	NA		
			Functional status	NA		
			Catastrophizing	NA		
Hammond and Freeman (2006) [27]	Education	ITT	Pain	0.09	−0.02–0.27	0.34
			Sleep	0.24	0.06–0.42	0.01
			Depression	0.05	−0.13–0.23	0.60
			Functional status	0.46	0.27–0.65	<0.01
			Catastrophizing	NA		
Hammond and Freeman (2006) [27]	Relaxation	ITT	Pain	0.07	−0.13–0.26	0.51
			Sleep	0.18	−0.01–0.37	0.06
			Depression	0.02	−0.17–0.21	0.85
			Functional status	0.05	−0.14–0.24	0.60
			Catastrophizing	NA		
Hassett et al. (2007) [28]	Relaxation/ Biofeedback		Pain	NA		
			Sleep	0.47	0.04–0.90	0.03
			Depression	0.47	0.03–0.90	0.04
			Functional status	0.39	0.811–1.781	0.08
			Catastrophizing	NA		
Keel et al. (1998) [40]	Relaxation		Pain	0.13	−0.26–0.51	0.52
			Sleep	0.31	−0.08–0.70	0.12
			Depression	NA		
			Functional status	NA		
			Catastrophizing	NA		
Keel et al. (1998) [40]	Education		Pain	0.19	−0.21–0.59	0.34
			Sleep	0.25	−0.15–0.65	0.22
			Depression	NA		
			Functional status	NA		
			Catastrophizing	NA		
Kravitz et al. (2007) [41]	Relaxation		Pain	0.43	0.14–0.71	0.01
			Sleep	0.76	0.45–1.07	<0.01
			Depression	0.14	−0.13–0.41	0.32
			Functional status	0.16	0.43–1.15	0.25
			Catastrophizing	NA		
Nicassio et al. (1997) [45]	Behavioral treatment		Pain	0.17	−0.08–0.42	0.19
			Sleep	NA		

Table 1 (*continued*)

Author, publication year	Type of treatment	Intent to treat (ITT) data	Targeted symptom	Hedges's *g*	95% Confidence interval	*p*-Value
			Depression	0.20	−0.05–0.45	0.11
			Functional status	NA		
			Catastrophizing	NA		
Nicassio et al. (1997) [45]	Education		Pain	0.29	0.04–0.55	0.03
			Sleep	NA		
			Depression	0.11	−0.17–0.36	0.41
			Functional status	NA		
			Catastrophizing	NA		
Nielson et al. (1992) [46]	CBT		Pain	1.09	0.72–1.47	<0.01
			Sleep	NA		
			Depression	1.22	0.83–1.62	<0.01
			Functional status	0.59	0.27–0.91	<0.01
			Catastrophizing	NA		
Redondo et al. (2004) [48]	CBT	ITT	Pain	0.51	0.13–0.90	0.01
			Sleep	0.48	0.09–0.86	0.02
			Depression	0.33	−0.05–0.70	0.09
			Functional status	0.55	0.20–0.89	<0.01
			Catastrophizing	NA		
Rodero et al. (2008) [51]	CBT	ITT	Pain	1.36	0.44–2.27	<0.01
			Sleep	NA		
			Depression	0.89	0.16–1.62	0.02
			Functional status	1.42	0.48–2.36	<0.01
			Catastrophizing	1.90	0.74–3.06	<0.01
Rucco et al. (1995) [54]	Relaxation		Pain	1.00	0.47–1.53	<0.01
			Sleep	2.91	1.88–3.95	<0.01
			Depression	NA		
			Functional status	NA		
			Catastrophizing	NA		
Sephton et al. (2007) [55]	Mindfulness-based treatment	ITT	Pain	NA		
			Sleep	NA		
			Depression	0.45	0.23–0.67	<0.01
			Functional status	NA		
			Catastrophizing	NA		
Soares and Grossi (2002) [57]	Behavioral treatment		Pain	NA		
			Sleep	0.14	−0.21–0.48	0.44
			Depression	NA		
			Functional status	0.17	−0.17–0.52	0.32
			Catastrophizing	0.26	−0.09–0.61	0.15
Soares and Grossi (2002) [57]	Education		Pain	NA		
			Sleep	0.06	−0.28–0.40	0.72
			Depression	NA		
			Functional status	0.04	−0.30–0.38	0.81
			Catastrophizing	0.07	−0.28–0.41	0.71
Thieme et al. (2003) [61]	Behavioral treatment		Pain	0.62	0.36–0.87	<0.01
			Sleep	0.47	0.22–0.72	<0.01
			Depression	0.92	0.63–1.20	<0.01
			Functional status	1.02	0.73–1.32	<0.01
			Catastrophizing	NA		
Thieme et al. (2006) [59]	CBT	ITT	Pain	0.62	0.37–0.87	<0.01
			Sleep	NA		
			Depression	0.35	0.11–0.59	<0.01
			Functional status	0.31	0.08–0.55	<0.01
			Catastrophizing	0.59	0.34–0.84	<0.01
Thieme et al. (2006) [59]	Behavioral treatment	ITT	Pain	0.09	−0.14–0.32	0.43
			Sleep	NA		
			Depression	0.10	−0.13–0.33	0.39
			Functional status	0.13	−0.10–0.35	0.28
			Catastrophizing	0.27	0.04–0.50	0.02
van Santen et al. (2002) [67]	Relaxation	ITT	Pain	0.02	−0.20–0.23	0.88
			Sleep	NA		
			Depression	NA		
			Functional status	NA		
			Catastrophizing	NA		
Vlaeyen et al. (1996) [69]	CBT		Pain	0.40	0.14–0.66	<0.01
			Sleep	NA		
			Depression	0.09	−0.16–0.34	0.46
			Functional status	NA		
			Catastrophizing	0.17	−0.08–0.42	0.19
Vlaeyen et al. (1996) [69]	Education		Pain	0.27	−0.01–0.55	0.05
			Sleep	NA		
			Depression	0.07	−0.20–0.34	0.63
			Functional status	NA		
			Catastrophizing	0.27	0.02–0.52	0.04

(*continued on next page*)

Table 1 (*continued*)

Author, publication year	Type of treatment	Intent to treat (ITT) data	Targeted symptom	Hedges's *g*	95% Confidence interval	*p*-Value
Wigers et al. (1996) [70]	CBT	ITT	Pain	0.48	0.13–0.82	0.01
			Sleep	0.27	−0.07–0.60	0.12
			Depression	0.65	0.29–1.01	<0.01
			Functional status	NA		
			Catastrophizing	NA		

Note. The table shows effect size estimates (Hedges's *g*), the 95% confidence intervals, and the significance test of changes in pain, sleep disturbance, depressive symptoms, functional status and catastrophizing from before to after a psychological treatment in fibromyalgia patients.

[a] NA = not available.

[b] CBT = Cognitive-behavioral therapy.

[c] Regarded as an outlier and excluded.

implemented a manualized or otherwise standardized intervention, and 3 studies reported of conducting a blind assessment of treatment outcome.

3.3. Pre–post effect sizes and publication bias

The pre–post effect sizes (Hedges's *g*) for pain intensity reduction (based on 26 studies), sleep problems (based on 17 studies), depression (based on 20 studies), functional status (based on 14 studies) and catastrophizing (based on 8 studies) are displayed in Table 3. All pre–post effect sizes were significant. According to Cohen's interpretation recommendations, [11] the effect sizes were small with confidence intervals suggesting small- to medium-effects. For each effect size, using the Trim and Fill method the number of missing studies that would be needed to make the plot symmetric was $n = 0$ studies, so all values remained unchanged. The funnel plot for the variable "pain intensity reduction" is depicted in Fig. 2. The fail-safe *Ns* are displayed in Table 3. These analyses suggest that the effect size estimates for all considered outcome variables were unbiased.

3.4. Effects at follow-up

To examine the stability of the effects of psychological treatments, we further conducted an effect size analysis from pretreatment to the last available follow-up point (see Table 3). All follow-up effect sizes were small-to-medium and significant. For each effect size, using the Trim and Fill method the number of missing studies that would be needed to make the plot symmetric was $n = 0$ studies, so all values remained unchanged. The fail-safe *Ns* are displayed in Table 3. These analyses suggest that the effect size estimates for all considered outcome variables were unbiased.

3.5. Controlled effect sizes

For studies including control groups, we computed controlled effect sizes. For pain intensity, depression, and catastrophizing, the random-effects analysis of the controlled studies employing a WLC or TAU comparison condition yielded small to medium significant mean effect sizes (Hedges's *g*; see Table 3). According to publication-bias analyses these effects were robust for controlled studies employing an active treatment condition for pain intensity and depression. For all other variables the effects were non-significant or not robust according to fail-safe *N* analyses (see Table 3). The results should be regarded as preliminary due to a very small number of controlled conditions included in the analysis (range from $n = 10$ for pain intensity to $n = 2$ for catastrophizing).

3.6. Moderator analyses

In order to explore possible predictors of treatment outcome, we conducted moderator analyses for the within-subject data only using the following moderators: quality of studies, treatment dose, and treatment type.

3.6.1. Pain intensity

Hedges's *g* for pain intensity reduction was moderated by treatment dose ($B = 0.005$, $SE = 0.002$, $p = .003$) with higher treatment doses leading to greater effects. The effect size for pain intensity reduction was also moderated by the quality of studies ($B = -0.037$, $SE = 0.014$, $p = .008$) with studies employing less rigorous methodology (i.e., lower validity scores) reporting greater effect sizes. Hedges's *g* for pain intensity reduction was also moderated by type of treatment ($B = -0.064$, $SE = 0.023$, $p = .007$).

3.6.2. Sleep disturbances

Hedges's *g* for sleep problem reduction was moderated only by type of treatment ($B = -0.1$, $SE = 0.037$, $p = .008$).

3.6.3. Depression

Hedges's *g* for depression reduction was moderated by the quality of studies ($B = -0.035$, $SE = 0.013$, $p < .001$) with studies of lower validity scores reporting greater effect sizes. Hedges's *g* for depression reduction was also moderated by treatment dose ($B = 0.008$, $SE = 0.003$, $p < .001$) with higher treatment doses leading to greater effects.

3.6.4. Functional status

Hedges's *g* for functional status was moderated by the quality of studies ($B = -0.036$, $SE = 0.015$, $p = .02$) with studies of lower validity scores reporting greater effect sizes.

3.6.5. Catastrophizing

There were no significant moderators of Hedges's g for catastrophizing.

3.7. Sub analyses on "type of treatment"

3.7.1. Pain intensity

Given previous findings in pain research [35,68] and the fact that type of psychological treatment was a significant moderator of treatment efficacy, we hypothesised that CBT would prove to be a more effective treatment for chronic fibromyalgia pain than other psychological treatments. To examine this hypothesis we performed two separate analyses, one including only CBT and one including all other types of psychological treatments.

For CBT treatment alone ($n = 8$ treatment conditions), the average pre–post effect size for pain intensity reduction (Hedges's *g*) was 0.60 (95% *CI*: 0.43–0.76, $z = 7.03$, $p < .001$). This effect size

Table 2
Characteristics of included studies.

Study Year	Type of treatment	Description of psychological intervention (*N*/*N*[a]) (*group treatment /individual treatment*)	Total number of hours of psychological intervention	Type of cointervention (% of time spent on cointervention)	Control Condition (*N*/*N*)	Latest follow-up in months	Measures	Quality Score (x/20)[b]
Astin et al. (2003) [2]	Mindfulness-based treatment	Mindfulness meditation training *(group) (64/32)*	20	Qi Gong (40%)	Placebo condition (education support group) *(64/33)*	6	Pain (MOS SF-36[c]) Depression (BDI[d]) Functional status (FIQ[e])	12
Creamer et al. (2000) [12]	CBT[f]	Educational/cognitive-behavioral sessions, relaxation and meditation *(group) (28/20)*	20	Qi Gong (40%)	No comparison condition	4	Sleep (VAS[g]) Pain (RAND[h]) Depression (BDI) Functional status (FIQ) Catastrophizing (CSQ[i])	8
Edinger et al. (2005) [18]	CBT	Cognitive-behavioral therapy: e.g., correcting misconceptions about sleep needs *(group) (18/15)*	2.75	None	Treatment as usual *(11/9)*	6	Pain (BPI[j]) Sleep (ISQ[k])	14
Edinger et al. (2005) [18]	Education	Sleep hygiene therapy: generic sleep education *(group) (18/17)*	2.75	None	Treatment as usual *(11/9)*	6	Pain (BPI) Sleep (ISQ)	14
de Voogd et al. (1993) [12]	Behavioral treatment	Psycho-motor therapy: behavioral therapy-oriented approach which refers to body-experience; marital counselling *(individual and group) (50/33)*	25	None	Waitlist *(50/NA)*	6	Pain (VAS pain) Sleep (VAS sleep) Depression (Subscale SCL 90R[l])	9
Field et al. (2002) [20]	Relaxation	Progressive muscle relaxation *(group) (12/NA)*	5	None	Massage Therapy *(12/NA)*	None	Pain (Likert Scale) Depression (CES-D[m]) Sleep (hours)	6
Friedberg (2004) [22]	Others (EMDR)[n]	EMDR *(individual) (6/6)*	2	None	No comparison condition	None	Pain (SUD[o])	10
Günther et al. (1994) [26]	Relaxation	Jacobson relaxation training *(group) (13/NA)*	Not reported (4 sessions)	None	Bath therapy *(12/NA)*	None	Pain (VAS) Sleep (Disrupted sleep due to pain)	8
Hammond and Freeman (2006) [27]	Education	Education based on social cognitive theory and self management cognitive-behavioral therapy approach *(group) (71/53)*	15	Exercise, stretching, Tai Chi (25%)	Control group consisted of psychological treatment[p]	8	Pain (FIQ subscale Pain) Sleep (FIQ subscale Rested in morning), Depression (FIQ subscale depression) Functional status (FIQ)	13
Hammond and Freeman (2006) [27]	Relaxation	Visualization, deep breathing other relaxation methods, group discussions *(group) (62/51)*	10	None	Control group consisted of psychological treatment	8	Pain (FIQ subscale Pain) Sleep (FIQ subscale Rested in morning) Depression (FIQ subscale Depression) Functional status (FIQ)	13
Hassett et al. (2007) [28]	Relaxation	Heart rate variability biofeedback training *(individual) (12/NA)*	Not reported (10 sessions)	None	No comparison condition	3	Depression (BDI-II[q]) Sleep (PSQI[r]) Functional status (FIQ)	5
Keel et al. (1998) [40]	Relaxation	Autogenic training *(group) (16/13)*	15	None	Control group consisted of psychological treatment	4	Pain (diary) Sleep (diary)	13
Keel et al. (1998) [40]	Education	Information, instruction in self-control strategies, group discussion *(group) (16/14)*	30	Gymnastics (20%)	Control group consisted of psychological treatment	4	Pain (diary) Sleep (Sleep disturbance diary)	13
Kravitz et al. (2007) [41]	Relaxation	Neurofeedback *(individual) (33/30)*	22	None	Placebo condition (sham neurofeedback) *(31/28)*	None	Pain (FIQ subscale Pain) Depression (FIQ subscale Depression) Sleep (FIG	16

(*continued on next page*)

Table 2 (*continued*)

Study Year	Type of treatment	Description of psychological intervention (*N*/*N*[a]) (*group treatment /individual treatment*)	Total number of hours of psychological intervention	Type of cointervention (% of time spent on cointervention)	Control Condition (*N*/*N*)	Latest follow-up in months	Measures	Quality Score (x/20)[b]
							subscale waking tired) Functional status (FIQ)	
Nicassio et al. (1997) [45]	Behavioral treatment	Behavioral treatment: education, relaxation, behavioral goal setting and active pacing, involvement of the support person, skill acquisition and practice, increasing social and physical activity *(group) (48/36)*	15	None	Control group consisted of psychological treatment	6[s]	Pain (FIQ, MPQ, Frequency/ intensity index) Depression (CES-D) Functional status (FIQ)	14
Nicassio et al. (1997) [45]	Education	Lectures on topics of general relevance to Fibromyalgia and other health-related issues, group discussions and support *(group) (38/35)*	15	None	Control group consisted of psychological treatment	6[r]	Pain (average score of FIQ subscale pain, MPQ[t], Frequency/ intensity index) Depression (CES-D) Functional status (FIQ)	14
Nielson et al. (1992) [46]	CBT	Relaxation training, cognitive techniques, pacing and enhancement of pain tolerance, family education, in vivo rehearsal of learned skills *(group) (30/25)*	Not reported	Aerobic exercises and stretching (16%)	No comparison condition	None	Pain (MPI[u]) Depression (CES-D) Functional status (MPI subscale life interence[u])	7
Redondo et al. (2004) [48]	CBT	Information, relaxation techniques, coping strategies, social abilities, sleep and resting, problem solving, prevention of relapses *(group) (21/16)*	24	None	Physical exercise *(19/ 15)*	12	Pain (VAS pain) Depression (BDI) Sleep (VAS) Functional status (FIQ)	13
Rodero et al. (2008) [51]	CBT	Education on connection between stress and pain, automated thoughts, nuclear beliefs, coping, expressive writing, assertive communication, imagined exposure *(group) (8/8)*	16.5	None	No comparison condition	None	Pain (VAS) Depression (HADS[v]) Functional status (FIQ) Catastrophizing (PCS[w])	8
Rucco et al. (1995) [54]	Relaxation	Autogenic training *(group) (27/11)*	8	None	Control group consisted of psychological treatment	None	Pain (VAS) Sleep VAS sleep problems)	10
Sephton et al. (2007) [55]	Mindfulness-based treatment	Stress-reduction skills including sitting meditation and body scan *(group) (51/42)*	20	Hatha Yoga	Waitlist *(40/40)*	2	Depression (BDI)	12
Soares and Grossi (2002) [57]	Behavioral treatment	Applied relaxation, and pain management *(individual and group) (18/18)*	120	None	Waitlist *(17/17)*	6	Sleep (KSQ[x] Awakening) Functional status (FIQ) Catastrophizing (CSQ)	12
Soares and Grossi (2002) [57]	Education	Education, discussions about health-related topics, body awareness training *(individual and group) (18/18)*	102	None	Waitlist *(17/17)*	6	Sleep (KSQ Awakening) Functional status (FIQ) Catastrophizing (CSQ)	12
Thieme et al. (2003) [61]	Behavioral treatment	Time contingent intake and reduction of medication, training in assertive pain incompatible behaviour, education *(group) (40/38)*	75	None	Physical therapy *(21/21)*	15	Pain (MPI) Sleep (Hours of sleep diary) Depression (MPI subscale affective distress)	14
Thieme et al. (2006) [59]	CBT	Problem-solving, stress and pain coping strategies, relaxation *(group)* (*42/40*)	30	None	Attention placebo (*40/20*)	12	Pain (MPI) Depression (MPI affective distress) Functional status (FIQ) Catastrophizing (PRSS[y])	14
Thieme et al.	Behavioral	Changing observable pain behavioral by	30	None	Attention	12	Pain (MPI)	14

Table 2 (*continued*)

Study Year	Type of treatment	Description of psychological intervention (*N*/*N*[a]) (*group treatment /individual treatment*)	Total number of hours of psychological intervention	Type of cointervention (% of time spent on cointervention)	Control Condition (*N*/*N*)	Latest follow-up in months	Measures	Quality Score (x/20)[b]
(2006) [59]	treatment	applying positive reinforcement and punishment, structured time-contingent exercises, spouse training *(group) (43/40)*			placebo *(40/20)*		Depression (MPI affective distress) Functional status (FIQ) Catastrophizing (PRSS)	
van Santen et al. (2002) [67]	Relaxation	Biofeedback by tonometer using standard electrode placements on the forehead, visual feedback signal and progressive relaxation technique *(individual) (50/38)*	8	None	Active treatment *(50/44)*	None	Pain (VAS)	13
Vlaeyen et al. (1996) [69]	CBT	Modification of pain experience, imagery, applied relaxation, information about psychosocial factors influencing chronic pain *(group) (46/36)*	42	Physical exercise (30%)	Waitlist *(40/39)*	12	Pain (MPQ) Depression (BDI) Catastrophizing (PCL[z])	13
Vlaeyen et al. (1996) [69]	Education	Information about psychosocial factors influencing chronic pain, group discussions *(group) (39/30)*	42	Physical exercise (30%)	Waitlist *(40/39)*	12	Pain (MPQ) Depression (BDI) Catastrophizing (PCL)	13
Wigers et al. (1996) [70]	CBT	Cognitive-behavioral stress management including applied relaxation, introduction to cognitive therapy in coping with psychological problems (*group*) (*20/15*)	30	None	Aerobic exercise *(20/16)*	48	Pain (VAS) Depression (VAS) Sleep (VAS)	14

[a] N/N = Number of subjects, who began and completed the treatment (began/completed).
[b] Range [0–20] with a lower value indicating poorer quality of study.
[c] MOS SF-36 = Medical Outcome Study (MOS) short form 36-item questionnaire (SF-36).
[d] BDI = Beck Depression Inventory.
[e] FIQ = Fibromyalgia Impact Questionnaire.
[f] CBT = Cognitive-behavioral therapy.
[g] VAS = Visual Analogue Scale.
[h] RAND = The RAND 36-item health survey 1.0.
[i] CSQ = Coping Strategies Questionnaire.
[j] BPI = Brief Pain Inventory.
[k] ISQ = Insomnia Symptom Questionnaire.
[l] SCL 90R = Symptom Check List 90R.
[m] CES-D = Center for Epidemiological Studies Depression Scale.
[n] EMDR = Eye Movement Desensitization and Reprocessing.
[o] SUD = Subjective Units of Discomfort Ratings.
[p] If the comparison condition consisted of a psychological treatment, we considered the comparison condition separately for purposes of the analyses.
[q] BDI-II = Beck Depression Inventory-II.
[r] PSQI = Pittsburgh Sleep Quality Index.
[s] Follow-up *n* was missing and therefore, effect size was not calculable.
[t] MPQ = McGill Pain Questionnaire.
[u] MPI = Multidimensional Pain Inventory.
[v] HADS = Hospital Anxiety and Depression.
[w] PCS = Pain Catastrophizing Scale.
[x] KSQ = Karolinska Sleep Questionnaire.
[y] PRSS = Pain-Related Self-Statement Scale.
[z] PCL = Pain Cognition List.

corresponded to a fail-safe *N* of 194 studies (z = 9.843). According to the Trim and Fill method, the number of missing studies that would be needed to make the plot symmetric was $n = 0$ studies, indicating that the results are robust. For this analysis, study quality again moderated the effect with studies receiving lower validity scores reporting higher effect sizes ($B = -0.049$, $SE = 0.022$, $p = 0.03$). Treatment dose did not moderate the effect ($B = -0.003$, $SE = 0.006$, $p = .63$).

For all psychological treatments excluding CBT ($n = 18$ treatment conditions), the average pre–post effect size for pain intensity reduction (Hedges's *g*) was 0.27 (95% *CI*: 0.17–0.37, $z = 5.361$, $p < .001$). This effect size corresponded to a fail-safe *N* of 270 ($z = 7.83$). The number of missing studies that would need to fall to the left of the mean effect size in order to make the plot symmetric was $n = 7$ studies. Assuming a random-effects model, the new effect size was Hedges's $g = 0.14$ (95% CI: 0.03–0.26).

For this analysis, neither the quality of studies ($B = -0.009$, $SE = 0.019$, $p = .64$) nor the type of treatment ($B = 0.049$, $SE = 0.034$, $p = .151$) moderated the effect, indicating that combining these different treatment types was justified. In this analysis, treatment dose was a significant moderator ($B = 0.005$, $SE = 0.002$, $p = 0.007$) with higher treatment doses leading to greater effects.

The confidence intervals for the effect size for CBT and the effect size for all other psychological treatments did not overlap, indicating that CBT was significantly better than the other psychological treatments in improving fibromyalgia pain intensity.

3.7.2. Sleep problems

Type of psychological treatment was also a significant moderator of treatment efficacy concerning sleep. We hypothesised that CBT and relaxation techniques would prove to be more effective treatments for sleep problems associated with fibromyalgia than other psychological treatments [13,47,49]. We performed two separate analyses, one including CBT and relaxation treatments and another including all other types of treatment.

Table 3
Effect sizes for all outcome measures for any psychological treatment and subgroups of treatments.

Outcome	Type of effect	n[a]	g	95% CI[b]	z	p	Fail-safe N
Any psychological treatment							
Pain intensity	Pre–post[c]	26	.37	.27–.48	7.14	.00	946
Pain intensity	Pre-follow-up[d]	15	.47	.30–.65	5.31	.00	486
Pain intensity	TAU[e]/WLC[f] controlled	5	.34	.05–.64	2.27	.02	7
Pain intensity	Active group controlled[g]	10	.5	.14–.86	2.69	.01	65
Sleep problems	Pre–post	17	.46	.28–.64	5	.00	466
Sleep problems	Pre-follow-up	12	.41	.14–.68	2.95	.00	146
Sleep problems	TAU/WLC controlled	3	.23	.−61–.57	1.58	NS[h]	–
Sleep problems	Active group controlled	6	.36	.−02–.73	1.85	NS	–
Depression	Pre-post	20	.33	.20–.45	5.11	.00	479
Depression	Pre-follow-up	16	.34	.22–.46	5.49	.00	391
Depression	TAU/WLC controlled	12	.44	.21–.66	3.84	.00	12
Depression	Active group controlled	8	.56	.19–.93	2.99	.00	54
Functional status	Pre–post	14	.42	.25–.58	5.03	.00	367
Functional status	Pre-follow-up	11	.52	.29–75	4.48	.00	361
Functionals status	TAU/WLC controlled	2	.24	−.22–.70	1.01	NS	–
Functional status	Active group controlled	6	.52	−.09–1.13	1.68	NS	–
Catastrophizing	Pre-post	8	.33	.17–.49	3.94	.00	78
Catastrophizing	Pre-follow-up	7	.40	.22–.59	4.34	.00	97
Catastrophizing	TAU/WLC controlled	4	.11	−.15–.37	0.81	NS	-
Catastrophizing	Active group controlled	2	.47	.11–.82	2.59	.01	Not applicable
Cognitive-behavioral treatment (CBT[i]) only[j]							
Pain intensity	Pre-post	8	.6	.43–.76	7.03	.00	194
Cognitive-behavioral treatment (CBT) and relaxation treatment only							
Sleep problems	Pre-post	.11	.68	.39–.97	4.64	.00	294
Any psychological treatment excluding CBT							
Pain intensity	Pre-post	17	.27	.17–.37	5.36	.00	270
Any psychological treatment excluding CBT and relaxation							
Sleep problems	Pre-post	6	.21	.07–.35	2.99	.00	16

[a] n = number of treatment conditions in the analysis.
[b] CI = confidence interval.
[c] Pre–post: effect size was computed for the difference of means between pre-treatment and post-treatment (short-term efficacy).
[d] Pre-follow-up: Effect size was computed for the difference of means between pre-treatment and the longest available follow-up (long-term efficacy).
[e] TAU = Treatment as usual.
[f] WLC = Wait control list.
[g] TAU/WLC or active group controlled: Effect size was computed taking the available control group into account (short-term efficacy).
[h] NS = not significant.
[i] CBT = cognitive-behavioral treatment.
[j] Analyses with subgroups of psychological treatments with respect to different outcome measures were only performed in case of significant moderator "type of treatment".

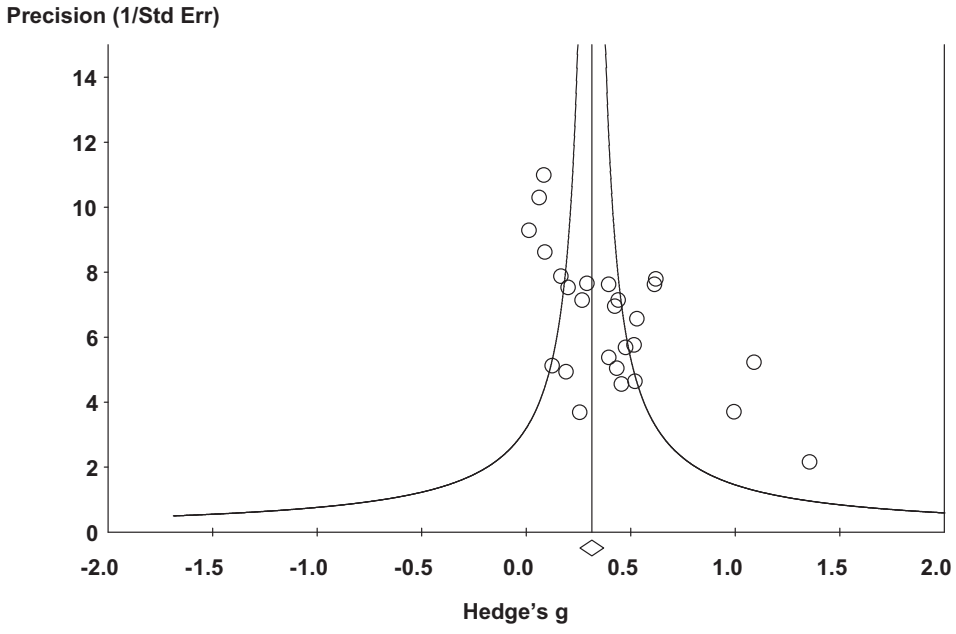

Fig. 2. Funnel plot of precision by Hedges's g for pre–post pain intensity measures for any psychological treatment.

The average pre–post effect size for CBT and relaxation treatments combined for sleep problem reduction (based on 11 treatment conditions; 4 CBT, 7 relaxation) was Hedges's $g = 0.68$ (95% *CI*: 0.39–0.97, $z = 4.624$, $p < .001$). This effect size corresponded to a fail-safe *N* of 294 studies ($z = 10.261$), indicating that publication bias can be ruled out. Treatment dose ($B = -0.006$, $SE = 0.006$, $p = 0.28$), quality of studies ($B = 0.002$, $SE = 0.016$, $p = .91$) and type of treatment ($B = -0.026$, $SE = 0.112$, $p = .81$) did not moderate the effect. Because type of treatment was not a significant moderator, combining CBT and relaxation was justified.

For other psychological treatments combined ($n = 6$ treatment conditions), the average pre–post effect size for sleep problem reduction was Hedges's $g = 0.21$ (95% *CI*: 0.07–0.35, $z = 2.99$, $p = .003$). This effect size corresponded to a fail-safe *N* of 16 ($z = 3.677$). Using Trim and Fill the number of missing studies that would be needed to make the plot symmetric was $n = 0$ studies, so all values remain unchanged. The fail-safe *N* indicates that this effect size is unreliable and should be considered preliminary. Neither treatment dose ($B = 0.0001$, $SE = 0.001$, $p = .92$) nor type of treatment ($B = -0.02$, $SE = 0.111$, $p = .86$) moderated the effect. Quality of studies was a significant moderator ($B = 0.08$, $SE = 0.034$, $p = .02$) with studies of higher validity scores reporting greater effect sizes.

The confidence interval for the effect size for CBT combined with relaxation treatments did not overlap with the confidence interval for the effect size for all other psychological treatments, indicating that CBT and relaxation treatments were superior to all other psychological treatments in reducing sleep problems in fibromyalgia patients.

3.8. Description of conditions with effect sizes identified as outliers

Before computing pooled effect sizes, 4 unusually high effect sizes were excluded. The studies that reported these effect sizes are described below.

The Ferraccioli et al. study [19] was excluded completely because it contained only one condition of interest (see Fig. 1) and the pre–post effect size for pain was an outlier (Hedges's $g = 3.15$, 95% *CI*: 1.67–4.63). In this study, 6 patients were trained in progressive muscle relaxation (PMR) while listening to their own pulse through a loudspeaker for a total of 5 h. This condition was called "Electromyography Biofeedback (EMG-BFB)". The authors do not offer an explanation for this unusually high effect size stating that they "have no data to interpret how EMG-BFB works in fibromyalgia".

The Edinger et al. study [18] showed a pre–post effect size of Hedges's $g = 6.21$ (95% *CI*: 4.55–7.86) for the outcome variable "sleep" in the condition "sleep hygiene". Seventeen patients were treated with a short (approximately 3 h) treatment that included listening to an audiocassette that provided sleep education and following verbal and written instructions by the therapist. The authors comment that the effect sizes for the sleep hygiene treatment exceeded expectations on measures of mental well-being and pain. In their opinion, these high effect sizes were not surprising because the sleep hygiene therapy condition included encouragement to exercise, an intervention with proven efficacy in fibromyalgia management. Post hoc tests showed that the improvements associated with the sleep hygiene therapy were attributable to a "subset of sleep hygiene therapy recipients who elected to implement the key CBT strategy by standardizing their sleep schedules".

The Rucco et al. study [54] showed a pre–post effect size of Hedges's $g = 5.64$ (95% *CI*: 4.37–6.91) for the outcome variable "pain" and Hedges's $g = 4.00$ (95% *CI*: 3.07–4.92) for the outcome variable "sleep". In the "Erickson's technique" condition of this study, 17 patients learned verbal techniques (such as analogous language and structured communication) with the aim of changing their state of consciousness and using problem solving skills and neurolinguistic programming to reduce inner tension. No description of treatment duration was provided. The authors commented on the effectiveness of the treatment by emphasizing the unique combination of treatment techniques.

4. Discussion

4.1. Summary of the results

To examine the short-term and long-term efficacies of psychological treatments for fibromyalgia, we examined 23 studies that included 30 psychological treatment conditions and 1396 patients. The pooled effect sizes for short-term and long-term efficacies concerning all outcomes were small, but robust. Although other treatments proved effective, CBT outperformed other psychological treatments in short-term fibromyalgia pain intensity reduction, reaching a medium effect size. Additionally, CBT and relaxation/biofeedback were significantly more effective than other psychological treatments in reducing sleep problems associated with fibromyalgia. The results indicate that all psychological treatments were equally effective in decreasing depression.

For pain intensity and depression, the results also indicate that psychological treatments were more effective than control conditions, with small to medium effect sizes. However, due to the small number of studies that included control conditions these results should be regarded as preliminary.

Moderator analyses revealed that for reducing pain intensity and depression with psychological interventions, higher treatment doses lead to greater effect sizes. The quality of studies moderated the effects of four analyses.

4.2. Strengths of the current study and comparison with previous reviews

To enhance the validity of this analysis we focused on studies that administered psychological interventions for at least 60% of the total treatment time. Additionally, in order to keep the patient sample as homogenous as possible, we focused on adult patients meeting the American College of Rheumatology criteria for a diagnosis of fibromyalgia. Because we believe that psychological treatment should involve contact with a trained professional, we excluded non-interactive interventions. Since we expected the study sample to be rather small, we decided a priori to include uncontrolled studies. These criteria, combined with the fact that some studies did not report statistics necessary to conduct necessary analyses, resulted in our study sample overlapping only partially with those of previous reviews. Specifically, only 15 studies overlapped with the Thieme and Gracely [60] review. The remaining 17 studies included in the Thieme and Gracely review were excluded for the following reasons: contained non-interactive interventions ($n = 4$ studies), interventions consisted of less than 60% psychological treatment ($n = 3$ studies), patients had had mixed first diagnoses or were younger than 18 years ($n = 3$ studies), or provided insufficient data or irrelevant outcome measures ($n = 6$ studies). We identified and included 8 studies not included in the Thieme and Gracely review.

Despite differences in study samples and methods, our results are in line with those of Thieme and Gracely [60]. Interestingly, our moderator analyses revealed positive effects of higher treatment dose on decreasing pain intensity, one of the major findings of the Thieme and Gracely review. Thieme and Gracely expressed surprise that relaxation and biofeedback, effective treatments for other pain disorders, did not prove helpful in reducing

fibromyalgia pain intensity in their review. By considering not only pain intensity but also sleep problems, we showed that relaxation and biofeedback were effective in reducing sleep disturbances associated with fibromyalgia and therefore are effective treatments.

In contrast to Bennett and Nelson [4] who questioned the efficacy of CBT on decreasing fibromyalgia pain intensity and van Koulil et al. [66] who doubted the long-term efficacy and benefits of CBT in comparison with other interventions, our results demonstrate that psychological treatments provide sustained pain relief for fibromyalgia patients, also in comparison with active control groups. These divergent conclusions are likely the result of employing different methods (i.e., qualitative vs. quantitative analyses) and different inclusion and exclusion criteria for treatment conditions and study participants. Bennett and Nelson [4] aimed to investigate interventions using CBT alone or in combination with other treatments. Their review was based on 13 studies, of which only 5 were included in our meta-analysis. The remaining studies were not eligible for our meta-analysis because they included juvenile patient samples or interventions in which less than 60% of the treatment was devoted to psychological intervention. Additionally, our study sample is different and larger than that included in the van Koulil et al. review [66], which included CBT-based interventions, exercise, and multimodal interventions.

4.3. Limitations

One limitation of our study is that the results rely on meta-analytic techniques and are therefore strongly dependent on factors such as the study selection criteria, the quality of the included studies, expectancy effects, and statistical assumptions about true values [36,50].

We used liberal study inclusion criteria in order to achieve a sufficient study sample and to investigate potential moderators. We quantified the quality of the included studies using a detailed modified Jaded criteria [38] validity rating scale that also served as a moderator. The liberal inclusion criteria resulted in a heterogeneous study sample including some studies with unsatisfactory validity. As Hunter and Schmidt [37] noticed, methodological weaknesses of included studies are not necessarily a problem in that they lead to more conservative effect size estimates. Nevertheless, one of the most important findings of our meta-analysis is that there are relatively few studies on psychological treatments for fibromyalgia, and many of these are of low methodological quality. As expected, most of the available studies were uncontrolled. With the exception of the active group controlled effect size for pain intensity, all results on controlled effect sizes are too preliminary to draw any firm conclusions. Another potential limitation could be the fact that we pooled various psychological treatments together to arrive at one effect size. We addressed this problem by considering "treatment type" as a moderator. Finally, sixteen studies met the inclusion criteria but did not provide sufficient data and authors could either not be successfully contacted or were unable to provide requested results.

In order to limit possible biases, we adopted a rather conservative approach. Our pooled effect size estimates are conservative excluding outliers (i.e., unusually large effect sizes) and including ITT data instead of completer data when possible. Following the recommendations by Moses et al. [44] we analyzed the effect sizes using a random-effects model. We ruled out the potential publication bias in two different sensitivity analyses, both providing surprisingly good results in most analyses. Therefore, despite the limitations, we conclude that the presented results are unbiased and reliable for the pre–post and pre-follow-up effects.

4.4. Clinical and scientific implications

The results of this study suggest that adult fibromyalgia patients, who suffer from a variety of symptoms, such as pain, sleep problems, poor functional status, and depressed mood, should be treated with high-dose CBT accompanied by relaxation/biofeedback. CBT consisting of cognitive, respondent and behavioral components proved most effective for pain reduction – therefore, we recommend employing all three intervention types. Clinicians treating fibromyalgia patients with psychological methods should keep in mind that they can successfully work with their patients on several goals, such as reducing pain, sleep problems and catastrophizing and elevating mood and daily functioning. However, both clinicians and patients should also be aware that the effects will likely be rather small and require a high number of sessions to occur. Fibromyalgia is a heterogeneous disease and there is evidence that some drugs [31] or exercise [25] is moderately effective for treating the disorder. Multicomponent therapies have been shown to be effective, although only in the short-term [29]. Thus, based on the results of this study, we suggest treating fibromyalgia patients with a combination of methods that include psychological interventions as a major component.

The direct scientific implication of this study is that more RCTs on the efficacy of psychological treatments for fibromyalgia are needed. These RCTs should comply with current methodological standards [9] (e.g., using multiple measures to assess treatment success [16]). Since our knowledge of the moderators and mediators of treatments for fibromyalgia is still limited, future research should focus on process measures. Keeping the heterogeneity of fibromyalgia in mind, instruments assessing pre-treatment levels of psychological distress or pain coping strategies [39] should be developed and used to identify subgroups of fibromyalgia patients who might differentially benefit from specific psychological interventions. For example, Thieme and Gracely [60] suggest that patients with high pain-related interference and catastrophizing may benefit from purely behavioral interventions, while patients with higher levels of affective distress may benefit from additional cognitive interventions. This hypothesis needs to be further investigated. Mechanisms of action of psychological treatments for fibromyalgia are also unknown and should be addressed in future studies.

4.5. Conclusions

This study is the first to use meta-analytic techniques to assess the efficacy of psychological interventions for fibromyalgia across five different outcomes: pain, sleep, depression, catastrophizing, and functional status. In sum, our analyses suggest that psychological treatments for fibromyalgia are promising interventions and are comparable to the short-term effects of drug treatment for fibromyalgia [30,31] and to other treatments for pain (e.g., CBT for low back pain [35]). The stable long-term effects of psychological interventions for fibromyalgia indicate that these treatments may be favorable in comparison to other non-psychological treatments [20,32] that provide only short-term effects.

Conflicts of interest

The authors report no conflicts of interest.

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Appendix A. Improving the quality of reports of meta-analyses of randomized controlled trails: the QUOROM statement checklist

Heading	Subheading	Descriptor	Reported? (Y/N)	
Title		Identify the report as a meta-analysis [or systematic review] of RCTs	Yes	
Abstract		Use a structured format[27]	Yes	
		Describe		
	Objectives	The clinical question explicitly	Yes	
	Data Sources	The databases (ie, list) and other information sources	Yes	
	Review methods	The selection criteria (ie, population, intervention, outcome, and study design); methods for validity assessment, data abstraction, and study characteristics, and quantitative data synthesis in sufficient detail to permit replication	Yes	
	Results	Characteristics of the RCTs included and excluded; qualitative and quantitative findings (ie, point estimates and confidence intervals); and subgroup analyses	Yes	
	Conclusion	The main results	Yes	
		Describe		
Introduction		The explicit clinical problem, biological rationale for the intervention, and rationale for review	Yes	
Methods	Searching	The information sources, in detail[28] (e.g., databases, registers, personal files, expert informants, agencies, hand-searching), and any restrictions (years considered, publication status,[29] language of publication[30,31])	Yes	
	Selection	The inclusion and exclusion criteria (defining population, intervention, principal outcomes, and study design[32])	Yes	
	Validity assessment	The criteria and process used (e.g., masked conditions, quality assessment, and their findings[33–36])	Yes	
	Data abstraction	The process or processes used (e.g., completed independently, in duplicate)[35,36]	Yes	
	Study characteristics	The type of study design, participants' characteristics, details of intervention, outcome definitions, &c,[37] and how clinical heterogeneity was assessed	Yes	
	Quantitative data synthesis	The principal measures of effect (e.g., relative risk), method of combining results (statistical testing and confidence intervals), handling of missing data; how statistical heterogeneity was assessed;[38] a rationale for any a-priori sensitivity and subgroup analyses; and any assessment of publication bias[39]	Yes	
Results	Trial flow	Provide a meta-analysis profile summarising trial flow (see figure)	Yes	
	Study characteristics	Present descriptive data for each trial (e.g., age, sample size, intervention, dose, duration, follow-up period)	Yes	
	Quantitative data synthesis	Report agreement on the selection and validity assessment; present simple summary results (for each treatment group in each trial, for each primary outcome); present data needed to calculate effect sizes and confidence intervals in intention-to-treat analyses (eg 2x2 tables of counts, means and SDs, proportions)	Yes	
Discussion		Summarise key findings; discuss clinical inferences based on internal and external validity; interpret the results in light of the totality of available evidence; describe potential biases in the review process (e.g., publication bias); and suggest a future research agenda	Yes	Yes
Quality of reporting of meta-analyses				

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