Research Paper

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Emotional awareness and expression therapy, cognitive behavioral therapy, and education for fibromyalgia: a cluster-randomized controlled trial

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Abstract

Patients with fibromyalgia (FM) experience increased lifetime levels of psychosocial adversity, trauma, and emotional conflict. To address these risk factors, we developed emotion awareness and expression therapy (EAET) and tested its benefits against an active control condition, FM education, and the field's gold standard intervention for FM, cognitive behavioral therapy (CBT) for symptom management. Adults with FM (N = 230) formed 40 treatment groups, which were randomized to EAET, CBT, or education and given 8, 90-minute sessions. Patient-reported outcomes were assessed at baseline, posttreatment, and 6-month follow-up (primary end point). Retention of patients to follow-up was excellent (90.4%). Intent-to-treat analyses indicated that although EAET did not differ from FM education on pain severity (primary outcome), EAET had significantly better outcomes than FM education on overall symptoms, widespread pain, physical functioning, cognitive dysfunction, anxiety, depression, positive affect, and life satisfaction (between-condition *d*'s ranging from 0.29-0.45 SD) and the percentage of patients reporting being "very much/much" improved (34.8% vs 15.4%). Emotional awareness and expression therapy did not differ from CBT on the primary or most secondary outcomes, but compared to CBT, EAET led to significantly lower FM symptoms ($d = 0.35$) and widespread pain ($d = 0.37$) and a higher percentage of patients achieving 50% pain reduction (22.5% vs 8.3%). In summary, an intervention targeting emotional awareness and expression related to psychosocial adversity and conflict was well received, more effective than a basic educational intervention, and had some advantages over CBT on pain. We conclude that EAET should be considered as an additional treatment option for FM.

Keywords: Fibromyalgia, Emotional awareness, Emotional expression, Cognitive behavioral therapy, Education, Randomized clinical trial

1. Introduction

Fibromyalgia (FM) affects 2% to 4% of adults, particularly women, with widespread pain, fatigue, nonrestorative sleep, cognitive dysfunction, and mood disturbance.[62] It is a manifestation primarily of central nervous system (CNS) alterations stemming from a complex interplay of biological and psychosocial factors.[13,68] Medications for FM lack efficacy for many patients[15]; therefore, psychological interventions that help patients learn self-management skills to improve symptoms and functioning have been developed, particularly cognitive behavioral therapy (CBT). This intervention has been studied extensively[5,25,55,56,65,66]; it is considered the gold standard nonpharmacological FM treatment and is strongly recommended in practice guidelines.[2,27] Yet, the average benefits of CBT and other psychological therapies for FM are modest,[6,24] although sample means can obscure the fact that a minority of patients respond very well to such interventions.[43,44] Nonetheless, there is a need to develop and evaluate novel interventions that might have stronger effects or help more patients,[19] perhaps by targeting risk factors that are not directly addressed by current therapies.

Rates of lifetime psychosocial adversities, traumas, interpersonal difficulties, and emotional conflicts are substantially elevated in FM.[28,29,31,57,58,61] Although exact mechanisms linking adverse experiences and emotions to FM are still being investigated, the sensitization and augmentation of CNS circuits that modulate both emotions and pain are likely prominently involved.[40] Importantly, the failure to adaptively process and resolve conflicts and trauma appears to drive both somatic and psychological symptoms.[9,21,48,60]

Thus, an alternative model conceptualizes FM as a CNS-based condition that might be substantially improved and potentially reversed if patients engage in corrective emotional experiences.[1,50,52] Of note, various forms of psychotherapy successfully treat trauma and emotional conflicts, including experiential, psychodynamic, and cognitive behavioral (eg, prolonged exposure) therapies. All of these approaches use techniques that enhance patients' awareness, disclosure, experience, and often expression of avoided emotions, with the goal of trauma or

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conflict resolution and adaptive cognitive and interpersonal change. Yet rarely do treatments for FM purposely engage avoided emotions related to adversity or conflict. One small trial found that psychodynamic therapy led to some improvement but not more than a "high-standard" intervention involving health behavior advice and medication.[49] Another small trial of a group intervention found that emotional awareness and written expression techniques led to substantial pain reduction, compared to wait list controls.[30]

We integrated techniques from several trauma- and emotion-focused therapies and created a brief approach, which we call emotional awareness and expression therapy (EAET). It is designed to help patients attribute their pain and other symptoms to emotionally activated CNS mechanisms and become aware of, experience, and adaptively express their emotions stemming from adversity, trauma, or conflict. In a randomized controlled trial, we tested the superiority of EAET over FM education, which we conceptualized as a both an active control condition and a basic treatment, and compared EAET to the field's gold standard intervention, CBT. We examined changes in multiple patient-reported outcomes 6 months after treatment and also the feasibility, acceptability, and safety of providing EAET to patients with FM, given concerns that an emotion-activating approach might be poorly received by patients and potentially exacerbate symptoms.[7]

2. Methods

2.1. Participants and setting

The 2-site, 3-arm, cluster-randomized clinical trial recruited patients from the communities of both the Wayne State University and The University of Michigan. Recruitment for the "Pain and Stress Treatment for Fibromyalgia" ("PAST-FM") trial occurred via flyers sent to rheumatologists, advertisements in the community, announcements to FM patient associations, and informational workshops. Telephone screening was followed by in-person screening, at which the patient provided written informed consent, and a research staff member confirmed the presence of FM and assessed medical and psychosocial history. Included patients had FM as defined by the 1990 or 2011 criteria of the American College of Rheumatology.[67] We sought to generalize treatment effects to the full range of people with FM, so we did not limit recruitment to patients with certain risk factors, such as trauma. Exclusion criteria ensured that FM was the primary condition of concern, patients could appropriately engage in a group-based intervention, and there was adequate motivation to improve. Thus, exclusion criteria were as follows: (1) comorbid autoimmune disorders; (2) serious medical illness, cognitive impairment, psychosis, suicidality, or recent alcohol/drug dependence; (3) pending (or received within the past 2 years) FM-related litigation or disability; (4) non-English speaking; or (5) judged by principle investigator as inappropriate for group participation (based on interview and screen for borderline personality features). The institutional review boards at both universities approved the study, and the trial was registered prior to recruitment at clinicaltrials.gov (NCT01287481). Recruitment occurred from May 2011 through April 2014, and follow-up was completed in February 2015.

2.2. Randomization and masking

An independent statistician generated computer randomization sequences, separately for each site, in randomized blocks of 6 clusters (with the final cluster in each block rerandomized to prevent staff unblinding); assignments were placed in sealed, opaque envelopes. We formed and randomized clusters (groups) of patients, rather than individuals, to enhance recruitment and minimize nonattendance and attrition. That is, problems with attendance and retention can occur when patients are randomized individually and then instructed to join a treatment group that meets at a day, time, or location that is inconvenient or unmanageable. Therefore, the coordinator asked each enrolled patient for her or his availability and then formed groups of approximately 6 patients, all of whom could attend an assigned treatment at the same day, time, and location (of 4 locations throughout southeastern Michigan). Each patient then had a pretreatment assessment by a blinded research assistant. When the group of patients met for the first treatment session, the coordinator informed the group of their randomly assigned treatment. Thus, patient groups were blind to the treatment assignment until they were in attendance at the first treatment session.

2.3. Treatments and therapists

All 3 treatment conditions were designed to be equivalent on nonspecific factors (eg, credibility, format, duration, therapist contact), had comparable, face-valid labels, and were presented as treatments with legitimate rationales. For each treatment, a group of patients met with 1 therapist for 8, 90-minute, weekly sessions. Patients received weekly handouts, and patients who missed sessions were sent materials through e-mail. All patients continued their usual care.

The trial design controlled for allegiance effects potentially arising from any biases held by investigators, therapists, or data analysts, which can threaten internal validity in psychological intervention trials.[38] Each of the 3 treatments was developed by different investigators on the team who had expertise in the specific approach and who recruited, trained, and supervised therapists who were skilled in and committed to that approach. For each of the 3 treatments, a different set of 3 female therapists received treatment-specific, manual-based training before the trial, weekly supervision of audio-recorded sessions by the specific treatment experts during the trial, and retraining to ensure fidelity and competence at midtrial. To better reflect real-world practice and avoid threats to treatment fidelity, therapists conducted only the treatment in which they were trained and in which they had expertise. Therapists were not informed of the study hypotheses or the content of the other 2 treatments being tested. Given the proximity of the study sites, therapists were shared between sites within their arm of the trial.

2.3.1. Emotional awareness and expression therapy

Labeled "stress and emotions treatment" for patients, EAET borrows techniques from different therapies: experiential, intensive psychodynamic, prolonged exposure, expressive writing, and therapeutic rescripting. This version of EAET was modified from previous trials[10,23,30,41] and presented FM as an amplification of CNS pain and sensory processes due to stress or conflict that is followed by emotional avoidance. Becoming aware of and then experiencing and expressing more adaptive emotions, which is then ideally followed by more direct and honest interpersonal interactions, reduces CNS amplification and improves symptoms. In sessions, patients disclosed their stressors and were helped to identify and express avoided emotions by engaging in role-playing and empty chair techniques

while activating their bodies and voices to directly express avoided or missing feelings (eg, anger, guilt, love). Patients were encouraged to communicate honestly with significant people in their lives outside of sessions. Secondary topics were the expression of avoided forgiveness, gratitude, and sexuality and developing a new identity. Weekly homework included expressive writing, observing emotions, and communication patterns and engaging in emotionally activating daily activities. Therapists were 3 clinical psychologists holding doctorial degrees with experience in exposure-based or psychodynamic therapies.

2.3.2. Cognitive behavioral therapy

Labeled "thoughts and behaviors treatment," CBT was adapted from published, empirically supported protocols that focus on coping and skills training for pain and symptom management.[32,65,66] It is a gold standard treatment for chronic pain of all types.[20] Grounded in learning theory, operant principles, and cognitive change theory, it assumes that responses to pain can be influenced by social, environmental, attributional, and behavioral factors. Each session of the current protocol consisted of a topic-driven brief lecture, teaching and practicing of a skill, and homework applying skills to daily life. Skills included self-monitoring, time-based pacing to increase behavioral function, progressive muscle relaxation and guided imagery to reduce pain, behavioral strategies to improve sleep, pleasant activity scheduling and cognitive reframing for mood problems, memory and thinking skills for cognitive impairment, effective communication with providers to reduce stress, and goal setting for long-term functioning. Therapists were 3 clinical psychologists holding doctorial degrees with experience in and commitment to CBT pain management.

2.3.3. Fibromyalgia education

Labeled "brain and body treatment," this condition was adapted from a prior trial[42] and provided a basic treatment comparator while controlling for credibility, participation, group processes, and a committed therapist. The rationale of this treatment was that "knowledge about FM is empowering" and learning the latest information about FM enhances self-control by improving patient's communication with others about FM and reduces stress. Sessions covered the history and diagnosis of FM, assessment of pain, FM mechanisms including central sensitization, comorbid disorders, medications, evaluating FM research, and using the Internet for information on health care. The therapists were 3 experienced nurse educators.

2.4. Assessments

Patients had 3 assessments conducted by blinded research assistants: at pretreatment (2 weeks before randomization), posttreatment (2 weeks after session 8), and follow-up (6 months after session 8). Patient-reported outcomes were administered via computer in a supervised setting. Patients were paid for $100 for assessments, and treatments were provided at no charge.

Demographics and medical history were patient-reported using standardized assessment forms. Perceived *credibility* and *expectancy* of their assigned treatment was reported by patients on the Credibility/Expectancy Questionnaire[16] after session 1.

The authors made an a priori decision to first report patient-reported outcomes; thus, we present here the results of all patient-reported outcome measures that were assessed in this trial. Other variables assessed in this trial were experimental pain testing responses, heart rate variability, and daily actigraphy data, which may be reported later. We also assessed patient-report measures of proposed treatment mediators (eg, emotional awareness, emotional expression, catastrophizing, pain attitudes, and coping), but given our focus in this article is on trial outcomes rather than purported mechanisms, these additional measures are not reported here.

2.5. Primary outcome

The primary outcome measure was the pain severity index of the Brief Pain Inventory (BPI),[14] which is the mean of 4 items assessing current, worst, least, and average pain during the past week.

2.6. Secondary outcomes

To quantify pain responders, patients were classified as to whether they achieved *moderate (at least 30%)* and *substantial (at least 50%) pain reduction* from pretreatment.[15,18] Each patient's baseline pain severity index from the BPI was subtracted from her/his posttreatment and follow-up pain severity; the difference was divided by the baseline value and expressed as a percentage.

The modified 2011 American College of Rheumatology FM Survey Criteria (fibromyalgia symptom scale) assessed both the *spatial extent or widespreadedness* of pain (widespread pain index) and the frequency/severity of other FM symptoms.[67] We analyzed both the total of these indices—overall FM symptoms—and the widespread pain index subscale.

Other patient-reported secondary outcome measures were as follows: (1) the Pittsburgh Sleep Quality Index[11] to assess *sleep problems*; (2) the Multiple Ability Self-Report Questionnaire[51] to assess self-reported *cognitive dysfunction* (eg, memory, concentration, attention); (3) the Center for Epidemiological Studies-Depression Scale[46] to assess *depressive symptoms*; (4) the Generalized Anxiety Disorder-7[54] to assess *anxiety symptoms*; (5) the PROMIS Fatigue short form[12] to assess *fatigue*; (6) the 12-item Short-form Health Survey physical component score[63] to assess *physical functioning*; (7) the Positive Affect Negative Affect Schedule[64] to assess both *positive and negative affect*; (8) the Satisfaction with Life Scale[17] to assess *life satisfaction*, and (9) the number of times that the patient had "seen a physician or other health care professional for treatment of illness or symptoms" during the past 3 months," to assess *health care use*.

Finally, patients also rated *change in their overall health* since pretreatment using the Patient Global Impression of Change,[22] which has 7 categories ranging from "very much improved" to "very much worse." For outcome analyses, the rating was dichotomized into "very much/much improved" vs all other categories combined.

2.7. Adverse events and negative outcomes

Adverse events were recorded whenever patients made spontaneous reports to therapists during treatment or research assistants during assessments. Negative outcomes of each treatment were assessed as patients' reports of being "worse" or "very much worse" on the Patient Global Impression of Change scale.

2.8. Statistical analyses

The study was powered to test EAET compared to FM education on changes in mean pain severity. Based on studies of related

interventions for FM,[30,41] we estimated an effect size between 0.5 and 0.75 SD for this comparison and attrition at 15% at 6 months. We included the cluster effect, estimated as small (intraclass correlation coefficient = 0.1). Power analyses indicated the need to randomize at least 38 clusters of 6 patients (ie, 228 patients; 76 per treatment) for 80% power to detect an effect of $d = 0.61$ with a 2-tailed $\alpha = 0.05$.

Statistical analyses were conducted by an independent statistician who had no allegiance to any intervention in this trial. Preliminary analyses indicated no need for data transformations. Primary analyses examined individual patients (not clusters) and tested differences among treatments at the 6-month follow-up, which was the primary end point. (Analyses comparing posttreatment differences among treatments are also presented to inform readers of the speed and duration of effects.) Treatment was a 3-level categorical variable, and models included a random effect to control for each cluster nested within treatment. For continuous outcomes, linear mixed effects models (hierarchal linear models) were conducted. For dichotomous outcomes, mixed effects logistic regressions (hierarchical general linear models) were conducted. Planned comparisons focused primarily on EAET vs FM education and secondarily on EAET vs CBT. Although not the focus of this trial, data and analyses are presented in a table comparing CBT to FM education. Analyses were controlled for the baseline level of the outcome and 3 additional covariates that may affect FM treatment outcomes: age, body mass index, and baseline depression. (Note that we repeated primary analyses without the 3 additional covariates, and—as noted below—all but 2 of the statistically significant differences between treatments remained significant, which attests to the robustness of the findings to the inclusion of the covariates.) All analyses used a 2-tailed alpha of 0.05, and we calculated standardized effect sizes (*d*) between conditions; values of 0.2, 0.5, and 0.8 SD are considered "small," "medium," and "large," respectively.[47] For categorical outcomes, we calculated the number needed to treat (NNT), which is the inverse of the differences in absolute risk.

Analyses were intent-to-treat and conducted on all 230 randomized patients. To replace any missing values, especially at posttreatment and follow-up assessments (due to attrition), we used multiple imputation, which is a missing data technique in which multiple data sets of plausible values for missing data are created from model-based predictive distributions and estimates, and standard errors are obtained using multiple imputation combination rules.[37] Data are assumed to be missing at random for this technique to be valid, which means that other variables on which we have information account for differences in the distribution of missing variables for observed and missing cases. Other commonly used data replacement methods, such as last or baseline observation carried forward methods, assume that data are missing *completely* at random; that is, the missing data are unrelated to any study variables, which is an unlikely scenario. Multiple imputation better reflects the variance in estimating the missing variables than these other methods, which underestimate the variance, leading to narrower confidence intervals, a less conservative estimate of the treatment effect, and possibly finding significant effects when they are not present. Much literature supports the use of multiple imputation as the most appropriate approach for missing data replacement.[4,33,36]

We conducted multiple imputation by chained equations using R 3.1.2 package mice (version 2.22) with a fixed but randomly selected seed of 110. A total of 20 imputations with 5 within-imputation iterations were computed. All variables in the current data set (ie, patients' baseline values and posttreatment and follow-up values for all outcome measures, treatment condition, cluster, and all sociodemographic and medical history variables)

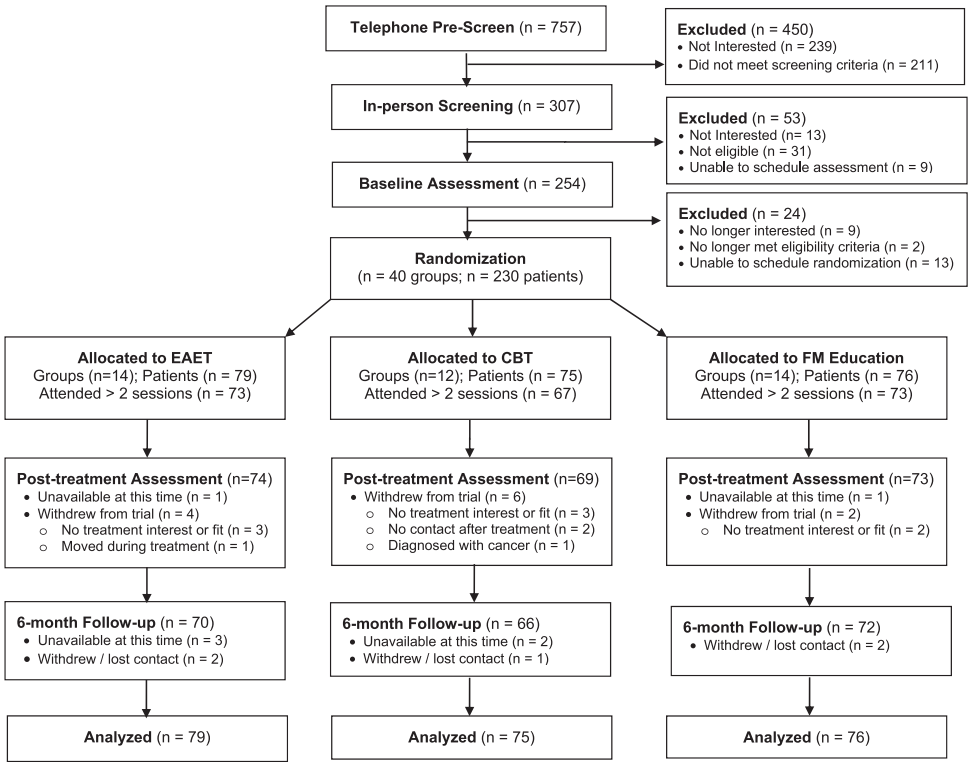

Figure 1. Flow of participants through the clinical trial.

were entered into the multiple imputation and used to estimate the missing values. We also conducted a sensitivity analysis by repeating the linear mixed models on only those cases for which we had complete data, given that mixed models can themselves account for data missing at random. The multiple imputations further improved our analyses by also imputing any missing baseline covariates. We obtained very similar results from the models using the multiple imputed data and the complete cases, suggesting that our data were likely missing at random, and the data were handled well by both the multiple imputations and the linear mixed models.

3. Results

3.1. Sample recruitment and characteristics

Figure 1 depicts patient flow: 757 people had telephone screening, 307 had in-person screening, 252 met study criteria, and 230 (30.4% of original contacts) were formed into 40 treatment groups, averaging 5.75 patients each, and randomized. There were 12 to 14 groups—75 to 79 patients total—per treatment. **Table 1** presents demographics, medical history, and medication use for the full sample and each condition.

3.2. Credibility, engagement, and attrition

Ratings of treatment credibility and expectancy did not differ among the treatments after session 1 (**Table 1**). Early attrition was very low: only 17 patients (7.4% of the randomized sample) attended fewer than 3 sessions (EAET, 7.6%; CBT, 10.7%; education, 3.9%), whereas 73.9% of the patients completed at least 6 sessions (EAET, 77.2%, CBT, 64.0%, education, 80.3%). Treatments did not differ significantly on these measures. Fully 216 patients (93.9%) had the posttreatment assessment, and 208 patients (90.4%) had the 6-month follow-up assessment; attrition did not differ among the treatments. Follow-up noncompleters did not differ from completers on demographics or baseline levels of outcomes. Reasons for noncompletion of the treatments or posttreatment and follow-up assessments were obtained from patients when possible and are presented in **Figure 1**. More than one-third of the patients missing follow-up assessment (n = 8 of 22 patients; 3 EAET, 3 CBT, 2 FM education) had dropped out of the trial early during their respective treatments due to a lack of fit with or interest in the assigned treatment. The remaining 14 patients actively withdrew during follow-up, were temporarily unavailable for the assessment, or were lost to contact during the follow-up period.

3.3. Therapist adherence and fidelity to treatments

We created a rating form of topics and activities from all 3 treatment manuals, and raters listened to audio-recordings of 25% of all sessions (randomly selected and stratified by site, treatment, and session number). Therapist adherence and treatment fidelity were high: all topics occurred in their assigned treatments, as intended, and almost all topics occurred only in the intended treatment and not in either of the other 2 treatments. Only 2 of 48 topics showed any treatment overlap: the EAET topic, "shared personal, private stories about stressful experiences in their current lives," occurred rarely in both CBT and FM education, and the FM education topic, "discussed FM symptoms," occurred regularly in CBT, as might be expected.

Table 2 presents the baseline, posttreatment, and follow-up data for all continuous measures, along with effect sizes and significance of each treatment comparison. **Figure 2** presents frequency data for several of the dichotomous outcomes at follow-up.

Table 1

Baseline demographic and clinical characteristics of the total sample and each of the 3 treatment conditions.

Characteristic	Total sample (N = 230)	EAET (n = 79)	CBT (n = 75)	FM education (n = 76)
Age (y)	49.13 (12.22)	48.98 (11.70)	48.13 (12.54)	50.28 (12.48)
Sex: female, n (%)	216 (93.9)	73 (92.4)	68 (90.7)	75 (98.7)
Race, n (%)				
White	179 (77.8)	68 (86.1)	57 (76.0)	54 (71.1)
Black	41 (17.8)	8 (10.1)	15 (20.0)	18 (23.7)
Other	10 (4.3)	3 (3.8)	3 (4.0)	4 (5.3)
Married/Partnered, n (%)	139 (60.4)	50 (63.3)	42 (56.0)	47 (61.8)
Education (y)	14.89 (2.31)	15.15 (2.42)	14.81 (2.38)	14.68 (2.12)
BMI (kg/m^2)	30.25 (6.96)	29.16 (6.64)	30.16 (7.71)	31.46 (6.37)
FM onset (y)	13.61 (10.52)	13.57 (10.81)	13.79 (10.22)	13.48 (10.64)
FM diagnosis (y)	8.35 (7.97)	8.86 (8.08)	8.84 (7.62)	7.36 (8.19)
Disability, n (%)	57 (24.8)	22 (27.9)	21 (28)	14 (18.4)
Opioids, n (%)	94 (40.9)	31 (39.2)	29 (38.7)	34 (44.7)
Antidepressants, n (%)	125 (54.3)	45 (57.0)	40 (53.3)	40 (52.6)
Anticonvulsants, n (%)	67 (29.1)	25 (31.6)	23 (30.7)	19 (25)
2 or more medicines, n (%)	92 (40.0)	34 (43.0)	30 (40.0)	28 (36.8)
Treatment credibility*	0.00 (0.86)	−0.11 (0.93)	0.14 (0.82)	−0.03 (0.82)
Treatment expectancy*	0.00 (0.91)	0.00 (0.91)	0.11 (0.92)	−0.11 (0.90)

Data are mean (SD) unless indicated as n (%).

* Scale has M = 0.0 (SD = 1.0) because items were converted to *z*-scores before averaging.

BMI, body mass index.

Table 2

Means and SD of baseline, posttreatment, and 6-month follow-up data for each outcome for the 3 treatment conditions and comparisons between treatments (N = 230).

Outcome measure, time point	EAET (n = 79), M (SD)	CBT (n = 75), M (SD)	FM education (n = 76), M (SD)	Omnibus, *P*	EAET vs education, *d*	EAET vs CBT, *d*	CBT vs education, *d*
Mean pain severity (BPI)							
Baseline	5.34 (1.55)	5.35 (1.62)	5.47 (1.74)				
Posttreatment	4.48 (1.99)	4.69 (1.65)	5.20 (1.68)	0.019	−0.39**	−0.17	−0.23
6-month follow-up	4.40 (2.13)	4.82 (1.70)	4.94 (1.96)	0.50	−0.15	−0.18	0.02
FM symptom scale							
Baseline	19.84 (5.79)	17.75 (5.95)	18.66 (5.03)				
Posttreatment	15.13 (6.47)	15.20 (5.48)	17.09 (5.82)	0.009	−0.41**	−0.19	−0.22
6-month follow-up	13.18 (6.76)	14.95 (6.01)	16.04 (6.25)	0.002	−0.45**	−0.35*	−0.10
Widespread pain index							
Baseline	11.24 (4.39)	9.88 (4.60)	10.68 (3.87)				
Posttreatment	7.82 (5.25)	8.81 (3.91)	9.62 (4.48)	0.006	−0.43**	−0.30*	−0.15
6-month follow-up	7.24 (4.67)	8.40 (4.12)	9.14 (4.78)	0.011	−0.40**	−0.37*	−0.04
Sleep problems (PSQI)							
Baseline	12.13 (4.36)	12.36 (4.06)	12.53 (4.35)				
Posttreatment	10.33 (4.70)	10.09 (4.27)	12.50 (4.40)	0.0001	−0.54***	−0.04	−0.53***
6-month follow-up	9.75 (4.47)	10.13 (4.18)	10.74 (4.29)	0.16	−0.29†	−0.22	−0.09
Cognitive difficulties (MASQ)							
Baseline	100.63 (18.89)	94.23 (19.52)	96.01 (18.72)				
Posttreatment	94.06 (21.12)	94.87 (21.16)	98.72 (20.61)	0.0005	−0.57***	−0.39*	−0.20
6-month follow-up	94.49 (20.58)	92.60 (18.89)	96.86 (19.65)	0.012	−0.44**	−0.26†	−0.18
Depression (CES-D)							
Baseline	25.96 (11.99)	20.20 (11.88)	18.30 (11.69)				
Posttreatment	19.62 (12.10)	16.35 (11.44)	18.22 (11.21)	0.048	−0.29*	0.00	−0.30*
6-month follow-up	19.25 (11.39)	17.33 (11.90)	18.46 (12.07)	0.062	−0.34*	−0.12	−0.23
Anxiety (GAD-7)							
Baseline	9.14 (5.48)	7.57 (5.56)	6.51 (5.21)				
Posttreatment	7.18 (5.16)	6.23 (5.19)	6.53 (5.14)	0.23	−0.18	0.05	−0.23
6-month follow-up	7.24 (4.91)	5.82 (5.03)	7.12 (5.20)	0.007	−0.33*	0.11	−0.45**
Fatigue							
Baseline	60.94 (6.50)	60.51 (5.71)	59.89 (6.38)				
Posttreatment	59.31 (7.97)	57.95 (6.08)	59.46 (5.46)	0.22	−0.16	0.09	−0.25†
6-month follow-up	58.18 (7.25)	58.40 (5.76)	59.02 (5.52)	0.32	−0.22	−0.11	−0.12
Physical functioning (SF-12)							
Baseline	35.22 (7.96)	35.51 (9.24)	34.86 (8.84)				
Posttreatment	38.88 (9.95)	37.50 (10.14)	36.63 (8.52)	0.28	0.22	0.17	0.05
6-month follow-up	39.37 (9.85)	39.08 (9.88)	36.91 (9.48)	0.12	0.31*	0.16	0.16
Negative affect							
Baseline	22.81 (7.69)	19.53 (7.94)	18.92 (7.22)				
Posttreatment	20.58 (7.65)	18.36 (7.91)	18.26 (7.67)	0.84	−0.07	0.01	−0.08
6-month follow-up	20.03 (7.25)	18.63 (7.86)	19.41 (7.42)	0.31	−0.22	−0.06	−0.17
Positive affect							
Baseline	24.56 (7.71)	28.20 (7.76)	27.62 (8.22)				
Posttreatment	27.90 (8.60)	30.83 (7.65)	28.12 (8.43)	0.09	0.23	−0.07	0.30*
6-month follow-up	28.52 (8.82)	30.07 (8.67)	27.55 (8.41)	0.062	0.38*	0.17	0.23
Satisfaction with life							
Baseline	15.72 (7.33)	18.28 (7.83)	18.21 (7.39)				
Posttreatment	18.06 (8.29)	19.23 (8.07)	19.15 (7.64)	0.73	0.10	0.09	0.01
6-month follow-up	18.89 (8.43)	19.64 (7.81)	18.58 (7.72)	0.11	0.29*	0.08	0.21
Health care use (past 3 months)							
Baseline	5.80 (8.10)	4.32 (5.82)	4.12 (4.89)				
Posttreatment	5.56 (8.99)	3.73 (4.68)	4.54 (5.73)	0.21	−0.25†	−0.08	−0.17
6-month follow-up	4.10 (5.73)	3.39 (4.13)	4.80 (6.13)	0.28	−0.22	−0.05	−0.16

†$P < 0.10$; *$P < 0.05$, **$P < 0.01$, ***$P < 0.001$ (2 tailed).

Mean and SD values at posttreatment and 6-month follow-up include imputed values for missing patients, thus reflecting the full randomized sample at all 3 time points. Omnibus *P* reflects a simultaneous comparison among all 3 treatments; however, a priori, planned comparisons focused on EAET vs FM education and EAET vs CBT. A negative *d* value means that the first treatment listed decreased more in that outcome measure than the second treatment listed. For physical functioning (SF-12), positive affect, and satisfaction with life, higher scores indicate better functioning. All other measures, lower scores indicate better health status.

BPI, Brief Pain Inventory; CES-D, Center for Epidemiological Studies-Depression Scale; GAD-7, Generalized Anxiety Disorder-7; MASQ, Multiple Ability Self-Report Questionnaire; PSQI, Pittsburgh Sleep Quality Index; SF-12, 12-item Short-form Health Survey.

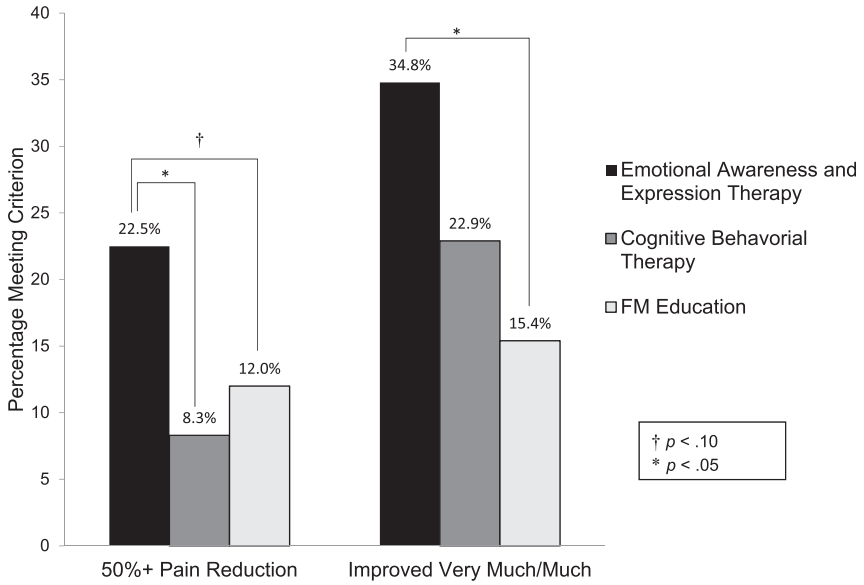

Figure 2. The percentage of patients in each treatment at 6-month follow-up reporting at least 50% pain reduction (left columns) and very much/much improvement (right columns).

3.4. Emotional awareness and expression therapy vs Fibromyalgia education

Emotional awareness and expression therapy had lower pain intensity than FM education only at posttreatment but not at 6-month follow-up. However, EAET was significantly superior to FM education on multiple secondary outcomes at follow-up. Compared to FM education, EAET resulted in significantly lower FM symptoms, widespread pain, cognitive difficulties, depression, and anxiety and significantly higher physical functioning, positive affect, and life satisfaction. Similarly, the prevalence of being "very much" or "much improved" was significantly greater in EAET than FM education at both posttreatment (32.7% vs 5.1%; $P = 0.0006$) and follow-up (34.8% vs 15.4%; $P = 0.015$) (**Figure 2**) (Note that the effect for physical functioning fell to $P = 0.057$, and for life satisfaction, it fell to $P = 0.15$ when the 3 additional covariates were excluded from the model.).

Sleep problems were significantly lower after EAET than FM education at posttreatment only but not follow-up. Similarly, the prevalence of moderate (at least 30%) pain reduction was greater for EAET than for FM education at posttreatment only (30.5% vs 16.6%; $P = 0.047$) but not follow-up (30.3% vs 25.7%, $P = 0.43$). Finally, fatigue, negative affect, and health care use did not differ significantly between EAET and FM education at either time point, nor did the prevalence of substantial (at least 50%) pain reduction (EAET and FM Education, posttreatment: 16.8% vs 7.5%; $P = 0.11$; follow-up: 22.5% vs 12.0%; $P = 0.07$).

3.5. Emotional awareness and expression therapy vs cognitive behavioral therapy

Emotional awareness and expression therapy did not differ significantly from CBT in mean pain severity or on most secondary outcomes, including the prevalence of moderate (at least 30%) pain reduction (CBT posttreatment and follow-up: 19.6% and 22.0%, respectively, vs EAET posttreatment and follow-up: 30.5% and 30.3%) or being very much/much improved (CBT: 19.5% and 22.9% at posttreatment and follow-up; EAET 32.7% and 34.8%).

In contrast, EAET was significantly superior to CBT on 3 secondary outcomes at follow-up; compared to CBT, EAET had significantly lower FM symptoms and widespread pain (**Table 2**) and significantly greater prevalence of substantial (at least 50%) pain reduction (**Fig. 2**; follow-up EAET = 22.5% vs CBT = 8.3%; $P = 0.020$; posttreatment EAET = 16.8% vs CBT = 6.4%; $P = 0.057$). Emotional awareness and expression therapy also showed significant improvements over CBT on cognitive difficulties at posttest only, but this did not persist through follow-up.

The NNT with EAET to obtain at least 50% pain reduction at follow-up was 5 (compared with no intervention, assuming no change), 10 (compared with FM education), and 7 (compared with CBT). The NNT with EAET to obtain very much/much improvement at follow-up was 3 (compared with no intervention/no change), 5 (compared with FM education), and 9 (compared with CBT).

3.6. Adverse events and negative outcomes

No adverse events were reported for CBT or FM education. During EAET, brief symptom exacerbation (eg, increased pain or sleep problems) was occasionally reported; however, in only 1 case did it last longer than a few days. Also, 1 EAET patient reported at follow-up both substantial symptom reduction and "anger" that she no longer knew how to relate to others. Note that EAET had very low reported rates (and the lowest numerically of all 3 treatments) of "very much worse/worse" global impression of change at both posttreatment (EAET: 2.8%; CBT: 3.5%; FM education: 8.2%) and follow-up (EAET: 4.9%; CBT: 10.7%; FM education: 10.1%).

4. Discussion

This trial tested a relatively novel psychological intervention for FM. The EAET approach seeks to reduce pain and other symptoms by (1) framing FM as a CNS-based process that is strongly influenced by avoided or unexpressed emotions related to trauma, adversity, or conflict and (2) encouraging the awareness and expression of these emotions, including in

relationships. We found that EAET was viewed as credible, had high participation rates, and had as few negative outcomes as both FM education and the field's standard psychological treatment for FM, CBT. More importantly, although treatments did not differ significantly on the BPI mean pain intensity at 6-month follow-up, EAET was superior to FM education on most other outcome measures. This trial also found that EAET did not differ from CBT on most outcomes, but it had stronger benefits than CBT on several secondary pain-related outcomes.

At 6-month follow-up, compared to FM education, EAET led to greater reductions in FM symptoms, widespread pain, depression, anxiety, and cognitive difficulties and also greater improvements in physical functioning, positive affect, and satisfaction with life. These effects were reflected in a higher prevalence of EAET patients reporting being very much/much improved overall. Given that FM education controlled for many nonspecific factors (eg, credibility, support, rationale, committed therapist), these findings suggest that there is unique value of giving patients a new conceptual framework and directly targeting their avoided emotional experiences.

The rationale for EAET is that FM can be rooted in, exacerbated, or maintained by unresolved stressful, traumatic, or conflictual emotional experiences.[40] Rather than viewing FM as a chronic disease for which one can only manage symptoms, as CBT does, EAET attributes symptoms of FM to affectively modulated brain pathways.[3,35] These pathways can be modified and potentially reversed by creating new, corrective experiences, especially by encouraging patients to approach and experience rather than inhibit or avoid important emotions and interpersonal interactions. This perspective is consistent with the "stress intolerance and pain hypersensitivity syndrome model" of FM,[59] and the "promoted or purposeful quiescence" theory, which suggests that FM reflects recuperative and avoidance behaviors that protect a person from psychological threat.[26] The current trial adds to other studies that attest to the value of therapies that directly target avoided emotional processes in people with pain and other somatic disorders,[1,34] including written emotional disclosure,[8,23] emotional processing of trauma,[41] and enhanced emotional awareness[30] for FM. Similarly, EAET for general musculoskeletal pain[10] and anger awareness and expression training for headaches[53] also have shown efficacy.

This trial was not powered to detect differences between EAET and CBT, which would be expected to be small or negligible, given that trials rarely demonstrate superiority of one psychological treatment over a bonafide comparator.[39] Moreover, trials that do demonstrate such superiority are often biased by allegiance effects, in which investigators or therapists favor one treatment over another.[38] The current trial controlled for allegiance effects and found that EAET did not differ from CBT on the primary outcome—pain severity—or on most secondary outcomes. However, EAET had better outcomes than CBT on some pain-related secondary measures: FM symptoms—particularly widespread pain—and the frequency of 50% pain reduction. Fidelity checks on the treatments indicated that the CBT content was presented as intended and provided according to the protocol by experienced, committed, CBT pain psychologists. The findings on CBT from this study are consistent with those of a meta-analysis that concluded that CBT has modest benefits on FM pain, functioning, and mood when compared to no treatment[24] and a Cochrane review that concluded that CBT may reduce FM pain, negative mood, and disability "slightly" after 6 months when compared to all controls combined but had no significant effect on these outcomes when compared with active controls.[6] However, it should be noted that this trial's CBT, which was matched in length to the other 2 treatment arms and lasted for only 8, 90-minute sessions, was on the briefer end of the spectrum of CBT trials demonstrating efficacy for FM and chronic pain.

Our use of FM education as a basic comparator/active control condition yielded a very stringent test of both EAET and CBT. Fibromyalgia education was viewed by participants as being as credible as the other 2 treatments and was well received and attended. Moreover, FM education may have provided patients a new way to understand and explain the CNS nature of FM. Indeed, studies of the "explaining pain" model have shown that giving patients a brain-based explanation leads to reduced pain and symptoms.[45] Thus, our FM education condition was certainly more than an attention-placebo condition; it could be considered a basic treatment in its own right. Patients receiving FM education likely benefited from the content and group process, as revealed by the observed improvements in pain and sleep at follow-up. Such improvements attenuated the comparative benefits of both EAET and CBT.

Substantial improvement in FM from any intervention—psychological or pharmacological—is rare. In the current trial, the mean improvement in pain severity for all EAET patients was less than 1 point on a 0 to 10 scale, indicating that EAET, overall, had limited benefits. The average change, however, obscures the fact that EAET was quite helpful to a considerable minority of patients: almost one-third of EAET patients had moderate pain reduction, and 22.5% had substantial pain reduction. These outcomes of EAET compare favorably with the pain effects of medications used to treat FM; for example, compared to improvement rates on placebo, pregabalin led to only 11% more FM patients improving moderately (30% pain reduction) and only 9% more FM patients improving substantially (50% pain reduction).[15] Unlike medication, however, benefits of EAET lasted at least 6 months after the termination of treatment.

Both the heterogeneity of FM and aspects of EAET as conducted in this trial likely limited the benefit of EAET. Although unresolved trauma or psychosocial adversity are common in FM, some patients do not have these risk factors,[28] and including such patients probably underestimated the effects of EAET. Targeting EAET to appropriate patients would likely yield larger effects. Furthermore, some patients appeared reluctant to engage in EAET, and enhancing patient motivation or teaching skills to help patients regulate their newly experienced emotions prior to EAET may increase its effectiveness. Many patients reported that EAET started an important change process but that more sessions were needed to address long-standing issues. Lengthening EAET's duration or providing booster sessions may improve response rates. Finally, in service of rigorously testing whether this new approach had merit, we developed a "refined" version of EAET that was devoid of most cognitive behavioral components (eg, engaging in pain-eliciting behavior to extinguish fear). In practice, EAET and CBT likely complement each other and hold benefit for patients when offered in tandem.

There are several other limitations. First, generalizability of the findings is limited not only because we excluded some patients, but more importantly, patients self-selected into this trial. It is likely that participants were more open to the role of stress in FM—and may have had more stress to address—than unselected patients with FM. Second, we did not conduct psychiatric interviews to determine rates of posttraumatic stress disorder or screen for unresolved trauma or conflict. Such information would have shed light on the representativeness of this sample and guided analyses of subgroups of patients. Third, we nested therapists within treatments rather than crossed therapists among treatments, which leaves therapist effects uncontrolled. However, our

approach better reflects real-life practice and ensured that each treatment was provided with expertise and unbiased commitment. Finally, several measures have limitations. The Center for Epidemiological Studies-Depression Scale is not an optimal measure of depression in FM because it assesses other common FM symptoms (eg, sleep and concentration problems), and the limited improvement in physical functioning, particularly in CBT, may have stemmed from the limited sensitivity to change of the SF-12.

In conclusion, this trial has demonstrated that a treatment that provides patients a new conceptual model of FM and facilitates their awareness and expression of avoided emotions related to psychosocial adversity or conflict is both feasible and efficacious. Emotional awareness and expression therapy was well accepted by patients and did not lead to treatment rejection or patient deterioration. It surpassed an active education condition on most secondary outcomes. Although not different from CBT on most outcomes, EAET surpassed CBT on several pain-related measures. Yet EAET, as currently conducted, likely helps only some patients with FM, and research needs to identify which patients are most likely to be aided by this approach and which patients will benefit most by CBT or other therapies. Nonetheless, we encourage clinicians to consider EAET when other therapies have not been helpful or for patients with histories of trauma or psychosocial adversity. We also encourage researchers to test EAET on other populations with centralized pain conditions and to explore ways to integrate components of both EAET and CBT into a potentially more effective therapy than either one alone.

Conflict of interest statement

S. E. Harte has received personal fees from Cerephex, Forest Laboratories, Eli Lilly, Merck, and Aptinyx; serves or has served as a consultant for Pfizer, Regeneron, Analgesic Solutions, Aptinyx, Longitude Capital Management, and deCode Genetics; is a member of Arbor Medical Innovations, LLC; and has received nonfinancial support from Coy Labs. D. J. Clauw has received personal fees from Abbott Pharmaceutical, Aptinyx, Astellas Pharmaceutical, Cerephex, Daiichi Sankyo, Pfizer, Samumed, Theravance, Tonix, Williams & Connolly LLP, and Zynerba and has received research support from Aptinyx, Cerephex, and Pfizer. D. A. Williams serves as a consultant to Community Health Focus Inc and is an honorarium recipient from Pfizer as grant reviewer through the American Pain Society. He is the President of the American Pain Society. The remaining authors have no conflict of interest to declare.

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