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Identifying Treatment Responders and Predictors of Improvement after Cognitive-Behavioral Therapy for Juvenile Fibromyalgia

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Abstract

The primary objective of this study was to estimate a clinically significant and quantifiable change in functional disability to identify treatment responders in a clinical trial of cognitive-behavioral therapy (CBT) for youth with juvenile fibromyalgia (JFM). The second objective was to examine whether baseline functional disability (Functional Disability Inventory), pain intensity, depressive symptoms (Children's Depression Inventory), coping self-efficacy (Pain Coping Questionnaire), and parental pain history predicted treatment response in disability at 6-month follow-up. Participants were 100 adolescents (11–18 years old) with JFM enrolled in a recently published clinical trial comparing CBT to a fibromyalgia education intervention (FE). Patients were

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identified as achieving a clinically significant change in disability (i.e., treatment responders) if they achieved both a reliable magnitude of change (estimated as a 7.8 point reduction on the FDI) using the Reliable Change Index (RCI), and a reduction in FDI disability grade based on established clinical reference points. Using this rigorous standard, 40% of patients who received CBT (n=20/50) were identified as treatment responders, compared to 28% in FE (n=14/50). For CBT, patients with greater initial disability and higher coping efficacy were significantly more likely to achieve a clinically significant improvement in functioning. Pain intensity, depressive symptoms, and parent pain history did not significantly predict treatment response. Estimating clinically significant change for outcome measures in behavioral trials sets a high bar but is a potentially valuable approach to improve the quality of clinical trials, enhance interpretability of treatment effects, and challenge researchers to develop more potent and tailored interventions.

Keywords

clinically meaningful change; clinical significance; cognitive-behavioral therapy; treatment responders; functional disability; pain coping efficacy

Cognitive-behavioral therapy (CBT) is an effective treatment for pediatric chronic pain conditions that significantly reduces functional disability [11, 35], with one study demonstrating maintenance of improvement in disability over 6 months for adolescents with Juvenile Fibromyalgia (JFM) [26]. Even with large and statistically significant overall treatment effects reported in clinical trials, there is variability in outcomes for individual patients and not all patients achieve functional improvements that are clinically meaningful [13]. Clinically meaningful or significant improvements are considered worthwhile to patients and involve a noticeable reduction in symptomatology [2, 7, 18]. To distinguish patients who achieve clinically significant improvements from those who do not, it is important to determine cut-off scores for outcome measures that represent clinically meaningful change. Such empirically-derived scores have the potential to significantly improve interpretability of treatment effects across trials and address the needs of clinicians who are seeking evidence to inform their practice [2, 9, 32, 48].

Functional disability, as measured by the Functional Disability Inventory (FDI) [47], is a key outcome measure in trials of behavioral interventions for pediatric chronic pain [30]. Although published clinical reference points have been established for the FDI [21], there are no clear established guidelines for determining whether statistically significant changes in the FDI are of clinical significance in randomized controlled trials. Unfortunately, the process of determining clinical significance remains a challenge, particularly among functional health outcomes (e.g., the FDI) [5, 16] due to varying methods of defining clinical significance [16, 48]. Estimating clinically meaningful differences has gained support as a new standard for determining clinical significance of treatment effectiveness [1, 7, 9, 41]. Thus, estimating clinically significant changes of functional disability following treatment can be a helpful tool to identify patients who respond to treatment and examine patient characteristics that predict treatment response.

A few studies in adults have identified patient characteristics that may predict positive response to treatment. In CBT studies of adults with chronic pain, predictors of positive

treatment response included older age, higher levels of distress, depression, or disability, greater coping efficacy, and less solicitous spouse behaviors at baseline [3, 43–45]. In children with chronic pain, parents play an integral role in the management of pain and functioning. Specifically, family history of chronic pain may be an additional factor to consider given its known association with patients' greater disability [29, 39, 40]. To date, little is known about predictors of treatment success in pediatric chronic pain.

In the current study, secondary analyses of data from our published randomized controlled trial of CBT for JFM [26] were used as an exemplar to begin the process of evaluating clinical significance for the FDI (the primary outcome) in pediatric trials of chronic pain. The objectives were to: 1) estimate clinically significant changes in functional disability to identify treatment responders versus non-responders, and 2) test whether patient characteristics at baseline (functional disability, pain intensity, depressive symptoms, coping efficacy, parent pain history) predicted clinically significant treatment response in functional disability.

Methods

Patients

Participants were 100 children and adolescents aged 11 to 18 years with JFM who were recruited from four pediatric rheumatology centers and completed a randomized clinical trial comparing CBT to an educational intervention (Fibromyalgia Education; FE) [26]. Children and adolescents were eligible to participate if they met the following inclusion criteria: 1) met Yunus and Masi's [49] JFM classification, 2) were on stable medications for 8 weeks, 3) reported average pain intensity ≥ 4 on a 0–10 cm Visual Analog Scale based on one week of daily pain diaries, and 4) reported at least mild disruption in daily activities due to JFM symptoms (i.e., score >7 on the Functional Disability Inventory). Exclusion criteria included: 1) diagnosis of any other chronic rheumatic disease, 2) documented developmental delay, 3) current symptoms of bipolar disorder, major depressive disorder, panic disorder, or psychosis, or 4) active use of opioid medications.

Institutional Review Board approval was obtained at each site. Parents of the participants provided written informed consent and children and adolescents provided written assent.

Study Procedures

After completing a comprehensive medical and psychosocial baseline assessment which included a battery of questionnaires, eligible participants were randomized to receive either CBT or FE. In each treatment arm, participants met individually with a trained, doctoral level therapist for 8 weekly treatment sessions in which the interventions were delivered using manualized protocols. CBT focused on training in active and adaptive behavioral and cognitive coping strategies in pain management. FE was designed to provide educational information about fibromyalgia, its treatment, and healthy lifestyle habits with no active training or instruction for behavior change. Sessions were well attended and the study had a high retention rate (88%) without any differential drop out in the two treatment arms. See

Kashikar-Zuck's [26] published trial for further details on the study treatments, study procedure, and primary outcomes.

Measures

The following measures were administered as part of the comprehensive baseline assessment. Functional disability, pain intensity, depressive symptoms, coping self-efficacy, and parent pain history were selected for the analyses based on evidence of their prediction of treatment response in studies of adults with various chronic pain conditions. Additional factors of potential interest (e.g., age, medication use, duration since pain onset) were considered, but not included in analyses due to inconsistent predictive value based on the adult pain literature as well as limited statistical power [3, 43–45].

Functional Disability – Primary Outcome—The Functional Disability Inventory (FDI) is a well-validated 15-item self-report instrument that assesses children and adolescents' perceived difficulty to perform daily activities in home, school, recreational, and social settings due to their pain symptoms [47]. This measure was the primary outcome used in our trial, defined as change in FDI from baseline to end of study (6-month follow-up), and was used to assess clinically significant changes in functional disability outcomes in this secondary analysis [26]. Baseline FDI scores also were used as a predictor of achieving clinically important changes in functioning. Participants rated how much difficulty they have performing each of the activities on a 5-point Likert scale (0 = no trouble to 4 = impossible). Total scores on the FDI ranged from 0 to 60, with higher scores indicating greater disability. For children with chronic pain, the clinical reference points include: 0–12 = No/Minimal disability, 13–29 = Moderate disability, and 30–60 = Severe disability. These clinical cut-offs were based on a published study of the validity of the FDI in a large (n=1300) multicenter clinical sample of youth with chronic pain [21]. The FDI has been found to have high internal consistency, moderate to high test-retest reliability, moderate cross-informant (parent-child) reliability, and good predictive validity [4, 47].

Average Pain Intensity—Participants rated their average pain intensity on a 0–10 cm Visual Analog Scale (0 “No pain” to 10 “Pain as bad as you can imagine”) daily for one week. Average ratings were calculated for one week at baseline and used for analyses.

Depressive symptoms—The Children's Depression Inventory (CDI) is a 27-item self-report measure used to assess baseline levels of depressive symptoms. It has been well-validated for use in children and adolescents [27]. The CDI has strong psychometric properties and is frequently used in pediatric pain research [6, 10, 22]. Participants select one of three statements for each item, and total scores range from 0 to 54. In this study, the total raw score was used as an overall indicator of severity of depressive symptoms at baseline.

Coping Self-Efficacy—The coping efficacy subscale of the Pain Coping Questionnaire (PCQ) [37] assessed overall pain coping efficacy at baseline, which is one's perceived ability to manage and cope with pain. The coping efficacy subscale is comprised of 3 items (e.g., “When you are hurt or in pain for a few hours or a few days, how often do you think

you can do something to change it?”), and is part of a 39-item self-report questionnaire that assesses pain coping strategies in children and adolescents. Scores on the pain coping efficacy items range from 1 to 5. A total score was calculated ranging from 3 to 15, such that higher scores indicate greater initial pain coping efficacy. The PCQ has demonstrated good internal consistency ($\alpha = 0.79\text{--}0.89$) in samples of children and adolescents [37] as well as good content, construct, and concurrent validity [36]. The coping efficacy subscale also has been shown to be sensitive to treatment effects in a prior CBT study of adolescents with JFM [24, 25].

Parent Pain History—The Parent Pain History Questionnaire assessed parental history of a variety of pain conditions. Parents indicate whether or not they have experienced 12 pain conditions (e.g., fibromyalgia, migraines headaches, low back pain, shoulder/neck pain) and whether or not they had sought medical treatment for each. The total number of pain conditions experienced as reported at baseline was used in this study as an indicator of maternal pain history. Similar parent pain history questionnaires have been used in previous studies of adolescents with JFM [23, 28, 40].

Statistical Analysis Plan

Two general approaches have been used to determine clinically important or meaningful differences in prior studies. Anchor-based approaches compare changes in outcome to another measure of change, often an anchor or external criterion, whereas distribution-based approaches compare changes in outcome to a measure of variability (see Copay [7] and Wyrwich & Wolinsky [48] for a detailed review). In this study, clinically meaningful changes were calculated using Jacobson and colleagues' [19] framework that combines both anchor- and distribution-based approaches to estimate clinically significant change, which includes the following: 1) achieving a magnitude of change that is statistically reliable, and 2) demonstrating movement from a dysfunctional to more functional range over the course of treatment.

For the first criterion in estimating clinical significance, a statistically reliable change in functional disability was established using the distribution-based Reliable Change Index (RCI) approach [19, 20]. The RCI is beneficial because it uses the standard error of difference (SE_{diff}) to determine whether a change in score from pre- to post-treatment is due to real change and not measurement error. The following equation was used to calculate RCI:

$$RCI = \frac{X_1 - X_2}{SE_{diff}}$$

where SE_{diff} is computed directly from the standard error of measurement, which is derived from the standard deviation at baseline and the scale reliability estimate. RCI values for individual patient changes in disability were calculated, and values that exceeded 1.96 were unlikely to occur by chance and reflected an actual reliable change in scores with 95% confidence [20].

The second criterion in estimating clinical significance calls for movement in the outcome of interest from a dysfunctional to more functional range based on established clinical criteria. This criterion is further supported by Crosby and colleagues (2003) who note that distribution-based methods are greatly enhanced by comparing the estimated threshold value to other clinical measures to enhance interpretability. Therefore, the established FDI clinical reference points for pediatric pain patients (0–12 = No/Minimal disability, 13–29 = Moderate disability, and 30–60 = Severe disability) [21] were used to identify patients who demonstrated an improvement in the level of disability on their FDI scores from baseline to follow-up (e.g., moving from the severe disability level to the moderate and/or minimal disability level; moving from the moderate disability level to the minimal disability level).

To determine the characteristics that predicted a clinically significant improvement on the FDI, participants' FDI change scores from baseline to 6-month follow-up were first categorized as “reliably improved” ($RCI \geq 1.96$), “reliably declined” ($RCI \leq -1.96$), or “stable” ($-1.96 < RCI < 1.96$). Similarly, the change in the severity of participants' FDI scores from baseline to follow-up also were categorized as “improved” (e.g., FDI score moved from severe (30–60) to moderate (13–29) or from severe or moderate to minimal (0–12) level), “declined” (FDI score moved into higher severity level), or “stable” (FDI score remained in same level). Participants who achieved a clinically significant difference in functioning were classified as treatment responders if they achieved a reliably improved FDI change score **and** improved the disability level of their FDI score from baseline to follow-up. Treatment non-responders included those who achieved a reliably improved FDI score but whose severity category remained stable or declined, or those whose FDI scores were stable regardless of change in level of severity. Frequencies of treatment responders' and non-responders' FDI severity at the end of the study (i.e., no/minimal, moderate, or severe disability) were explored to further support the clinical significance of change in functional disability. Binary logistic regression analyses were conducted to examine whether baseline disability, average pain intensity, depressive symptoms, coping efficacy, and parental pain history predicted treatment response. Given that both treatment arms were active interventions, analyses were conducted separately for CBT and FE groups in order to identify predictors that were relevant within each active intervention. In particular, separate group analyses allowed for a clearer determination of which patients were likely to positively respond to CBT and evaluate whether the prediction of treatment success differed for patients who only received fibromyalgia education.

Results

Sample Characteristics

The final sample of 100 patients (50 in each arm) were 15.02 years on average ($SD = 1.75$). A majority of the sample were Caucasian (90%), female (93%), and attended regular school (86%). There were no significant differences between participants in the CBT and FE conditions with regard to age, gender, race, socioeconomic status, duration since pain onset, average pain intensity, functional disability, depressive symptoms, school absences, or type of schooling at baseline.

Estimating Clinically Significant Change

The standard deviation of the FDI at baseline was 8.419 ($M = 19.82$), and the internal consistency of the FDI for the sample was excellent (Cronbach's $\alpha = 0.887$). A baseline to follow-up FDI change score of at least 7.8 was needed in order to exceed the RCI cut-off value of 1.96, and corresponded to an average 40% reduction in disability. To establish a statistically reliable change with the RCI method, patients were classified as reliably improved, stable, or declined in their functional disability from baseline to 6-month follow-up (Table 1). Specifically, in the CBT group, 44% of patients achieved statistically reliable change in disability compared to 32% of patients in FE. The number of patients who remained stable in their FDI was comparable across both groups (52–54%). Notably, 14% of patients in the FE condition experienced a statistically reliable decline in functional disability relative to only 4% in the CBT group. A large effect size suggests that patients in CBT were more likely to improve (versus decline) in their FDI scores compared to FE (OR = 4.81, 95% CI = 0.88–26.3, $p = 0.06$).

To examine patients' change on a clinical criterion, patients also were classified as improved, stable, or declined in their FDI severity from baseline to 6-month follow-up (Table 1). In the CBT group, 48% of patients achieved an improvement in disability level (e.g., moved from the severe or moderate level at baseline to the moderate or mild level at follow-up) compared to 40% of patients in FE. A comparable proportion of patients across both groups remained stable within their FDI severity level (40–44%). Lastly, 20% of patients in FE demonstrated movement into a more dysfunctional FDI level (e.g., from mild to moderate disability) relative to only 8% in CBT.

Identifying Treatment Responders vs. Non-Responders

Taken together, 40% of patients in the CBT group were identified as treatment responders given that they achieved a statistically reliable change in disability **and** also achieved an improvement in disability level from baseline to follow-up, compared to 28% of patients in the FE group (Table 2). Additionally, treatment responders in the CBT group demonstrated individual changes in FDI scores ranging from approximately 43–91% ($M = 66.73$, $SD = 17.06$). In contrast, 72% of patients who received FE were treatment non-responders in that they did not meet both criteria of demonstrating a statistically reliable change in disability and reduction in their FDI severity compared to 60% of patients in CBT. A majority of treatment responders across both groups ended treatment with an FDI score in the minimal range as opposed to over half of treatment non-responders in the FE group who ended treatment with an FDI score that remained within the moderate or severe range of disability (FDI > 13) (Table 3).

Baseline Predictors of Treatment Response

Logistic regression analyses resulted in an overall significant model for CBT, $\chi^2 = 15.84$, $p < 0.01$ (Table 4). Patients participating in CBT who had greater initial functional disability were significantly more likely to achieve a clinically significant treatment response (OR = 1.13, $p < 0.01$). Additionally, for patients who received CBT, those with higher coping efficacy at baseline were 1.56 times more likely to achieve a clinically significant improvement in disability. Average pain intensity, depressive symptoms, and parent pain

history were not significant predictors of treatment response in CBT. There were no significant baseline predictors of treatment response for patients in FE (non-significant overall model, $\chi^2 = 6.67$, $p = 0.25$).

Discussion

The lack of clear established guidelines for estimating individual changes in functional outcomes in clinical trials of behavioral treatment for pediatric chronic pain, particularly in terms of clinical significance of study findings, has contributed to the difficulty of interpreting clinical trial results and translating these into clinical practice. To our knowledge, this is the first study to explore the clinical significance of individual patient improvements in functional disability in a well-controlled randomized clinical trial of CBT for pediatric chronic pain. Estimation of clinically meaningful difference values for commonly used treatment outcome measures, such as the FDI, is one of the first and essential steps needed to establish a higher standard for determining clinical significance in pediatric pain trials. In this study, a clinically significant improvement in functional disability for patients with JFM comprised an approximate 8-point reduction in FDI scores following behavioral treatment coupled with a reduction in disability level by the end of treatment. The cut-off value of approximately 8 points also represents an average 40% reduction in functional disability, which is greater than the 30% reduction in pain intensity that is considered a clinically significant improvement for average pain intensity [14, 31]. Although there is no direct comparison for clinically meaningful differences on the FDI, integrating a statistically reliable change and change on a clinical criterion is, by far, more conservative and clearly sets a higher bar for defining “improvement” compared to traditional group mean differences. In fact, group mean differences often result in large and statistically significant treatment effects in behavioral trials, including Kashikar-Zuck’s [26] primary trial finding, often with moderate sample sizes (n ’s typically ranging from 30–80) [35]. With the more conservative approach of examining clinical significance, the results from the current study continue to support the primary trial findings that CBT is beneficial in the treatment of JFM, however the effects are less robust due to power limitations. In order to advance the evidence-base for behavioral interventions for pediatric chronic pain, it is critical for researchers to consider clinical significance rather than statistical significance as a primary outcome. By doing so, clinical trials that are powered based on clinical significance will be able to more fully capture meaningful changes in patients’ functional outcomes.

Estimating clinically meaningful change is a novel approach that has been used to establish clinically significant changes in pain intensity in a few studies of adults with chronic pain [13–15, 31, 38], and is just starting to generalize to other pain-related health outcomes in adults [33, 41, 46]. Comparing CBT to an educational intervention (FE) that provided support and education (as opposed to a wait-list or standard care control typically used in clinical trials of CBT for chronic pain) further contributed to the more rigorous and conservative method of estimating clinical significance in this study. Forty percent of patients who received CBT were treatment responders and a majority achieved a clinically significant improvement in functional disability that resulted in no/minimal disability. Notably, this is a similar response rate compared to studies in adults with fibromyalgia who

positively responded to CBT (38%) [44] and somewhat higher compared to adult patients with chronic pain who achieved clinically significant improvements in disability following Acceptance and Commitment Therapy (ACT) (25%) [46]. In contrast, only 28% of patients in FE positively responded to treatment and 20% actually declined in their functioning. This decline may reflect the natural course of change over 6 months that occurs when patients receive no direct training in coping skills to manage pain. Additionally, approximately 35% of patients in both groups demonstrated stable FDI scores that remained within the same severity level over time. Minor fluctuations in FDI scores that do not meet the threshold value and do not cross severity levels may reflect less willingness or openness by patients to participate in treatment and indicate the need for additional or more intensive education regarding the goals and benefits of behavioral intervention. These individual patterns of change often are not evident in clinical trial findings that focus on evaluating group mean differences, but provide meaningful information about patients' response to behavioral interventions. Information about the likelihood of an individual patient's response to an intervention can guide clinicians with clinical decision-making and potentially lead to improved patient care. Although the estimation of clinical significance has not yet been fully explored in the pediatric chronic pain literature, this study provides preliminary evidence and a rationale to support the use of this approach as a method of evaluating clinical significance and improving interpretability of treatment effects across pediatric pain trials.

Our second objective was to use the results to better understand individual patient characteristics that predicted clinically significant treatment response in functional disability following behavioral treatment. The findings suggest that patients with greater functional disability at baseline were more likely to achieve a clinically significant change in disability, which may reflect more opportunity to improve their functioning with treatment. Additionally, patients with initial high levels of coping efficacy were 1.6 times more likely to respond positively to CBT. A high initial coping self-efficacy may represent a protective factor that helps patients be receptive to and harness more adaptive coping strategies in response to pain. In contrast, those with lower coping efficacy before starting treatment may be in an early stage of readiness to change their behavior and coping. Consequently, they may not adopt or utilize the coping strategies taught during treatment as regularly or effectively to manage pain, or may require a longer duration of psychological intervention before meaningful changes are noted. As such, patients with lower coping efficacy may benefit from tailored treatments that better match their needs. For example, these patients may benefit from CBT that is modified to include a motivational interviewing approach to enhance patients' willingness to engage in behavior change before the onset of teaching adaptive coping skills to manage pain. Moving forward, understanding patients' cognitive appraisals of pain (e.g., catastrophic thinking) as well as their pain beliefs may also be important to assess [24, 42] to guide the development of tailored interventions that enhance coping efficacy and improve daily functioning.

In contrast, baseline levels of pain intensity, depressive symptoms, and parent pain history were not predictive of a clinically significant treatment response, despite their evidence in the adult chronic pain literature [3, 43]. This may suggest that youth's response to treatment may be influenced by a more complex interaction of factors that incorporates the context of the family and parental responses to pain [34], such as marked catastrophic thinking coupled

with parental overprotection [17]. Additional research is warranted in this area to examine how the interaction of child, parent, and family responses to pain influences youth's treatment response.

The interpretation of study findings should be considered within the context of a few limitations. First, clinically meaningful change was calculated using Jacobson's framework for defining and estimating clinical significance, which includes establishing a statistically reliable change in the outcome of interest and movement of the outcome from a dysfunctional to more functional level [19]. A variety of well-supported approaches to estimating clinically meaningful differences are available and have been commonly utilized in past studies [1, 7, 8, 12]. Future studies might use alternative approaches to establish clinical significance, and it will be important to examine whether similar estimates are found. Additionally, it is not clear whether these findings will be generalizable to other pain conditions. Lastly, the number of constructs examined in predicting improvement in functional disability was limited due to the sample size of each treatment group. It is likely that with a larger sample and greater statistical power, additional predictors might have emerged as significant predictors of treatment response. Future examination of additional variables, such as adolescent and parental pain beliefs, catastrophic thinking, readiness and motivation to change, and acceptance is warranted to understand their potential in predicting treatment response.

These limitations notwithstanding, the estimation of clinical significance for functional disability for youth with fibromyalgia begins the process of establishing an important reference point for clinicians and researchers interested in interpreting treatment effects using a common metric for measuring patients' functional disability. Future studies may consider establishing clinical significance for outcome measures, such as disability or pain intensity, for pediatric chronic pain patients in real-world clinical settings to clarify whether these clinically meaningful changes translate into clinical practice. Researchers evaluating the use of CBT may also need to consider how to make treatment effects more powerful by adding new components to treatment or using more tailored approaches based on patient needs (e.g., motivational interviewing for those who show more reluctance to incorporate behavioral changes, or combining physical exercise training/behavioral activation for those who are very sedentary). Lastly, future clinical trials can build on this approach to establish clearer standards for estimating clinical significance, improve interpretability of treatment outcomes across pediatric pain trials, and guide the development of more powerful tailored interventions to match patient needs and result in greater patient improvements.

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Summary

A clinically significant change in functional disability for adolescents with fibromyalgia comprised an approximate 8-point reduction in disability scores and a reduction in disability grade following cognitive-behavioral treatment (CBT).

Table 1

Frequency (and percentage) of patients who improved, remained stable, or declined in their FDI change scores (using RCI) and FDI severity level from baseline to follow-up.

	FE n (%)	CBT n (%)	χ^2
Reliable FDI Change			3.77
Improved	16 (32)	22 (44)	
Stable FDI	27 (54)	26 (52)	
Declined	7 (14)	2 (4)	
Total n	50	50	
FDI Severity Change			3.03
Improved	20 (40)	24 (48)	
Stable	20 (40)	22 (44)	
Declined	10 (20)	4 (8)	
Total n	50	50	

Note: FDI = Functional Disability Inventory; RCI = Reliable Change Index

Table 2

Frequency (and percentage) of patients who met criteria for treatment response vs. treatment non-response based on reliable (RCI) change in FDI and change in FDI severity.

	FE n (%)	CBT n (%)
Treatment Responders	14 (28)	20 (40)
FDI Reliably Improved & Severity Improved		
Treatment Non-Responders	36 (72)	30 (60)
FDI Reliably Improved & Severity Stable	2 (4)	2 (4)
FDI Stable & Severity Improved	6 (12)	6 (12)
FDI Stable & Severity Stable	17 (34)	18 (36)
FDI Stable & Severity Declined	4 (8)	2 (4)
FDI Reliably Declined & Severity Declined	7 (14)	2 (4)

Note: FDI = Functional Disability Inventory; RCI = Reliable Change Index

Table 3

Frequency (and percentage) of treatment responders' and non-responders' functional disability severity category at follow-up by treatment group.

Treatment Group	Treatment Responders n (%)	Treatment Non- Responders n (%)	Total n
FE	14 (28)	36 (72)	50
No/Minimal Disability	12 (24)	9 (18)	
Moderate Disability	2 (4)	17 (34)	
Severe Disability	0 (0)	10 (20)	
CBT	20 (40)	30 (60)	50
No/Minimal Disability	15 (30)	12 (24)	
Moderate Disability	5 (10)	13 (26)	
Severe Disability	0 (0)	5 (10)	

Note: FDI = Functional Disability Inventory; No/Minimal Disability range (FDI = 1–12); Moderate Disability range (FDI = 13–29); Severe Disability range (FDI = 30).

Table 4

Logistic regression analyses to identify baseline predictors of clinically significant treatment response.

Baseline Predictor	Fibromyalgia Education			Cognitive-Behavioral Therapy		
	β	OR (95% CI)	Wald χ^2	β	OR (95% CI)	Wald χ^2
Functional Disability (FDI)	0.10	1.10 (0.99–1.22)	3.40	0.12	1.13 (1.03–1.23)	7.05**
Average Pain Intensity (VAS)	–0.40	0.67 (0.38–1.16)	2.03	–0.25	1.29 (0.77–2.16)	0.91
Depressive Symptoms (CDI)	0.05	1.05 (0.93–1.18)	0.65	–0.01	1.01 (0.91–1.13)	0.06
Coping Efficacy (PCQ)	0.31	1.37 (0.88–2.13)	1.92	0.45	1.56 (1.01–2.43)	3.97*
Parent Pain History	0.17	1.19 (0.88–1.61)	1.20	–0.03	1.03 (0.85–1.25)	0.09

* $p < 0.05$