Utility of the PROMIS Pediatric Pain Interference Scale in Juvenile Fibromyalgia

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Abstract

Objective The current study tested the utility of the PROMIS Pediatric Pain Interference (PPI) in relation to the widely-used Functional Disability Inventory (FDI) in a small-scale clinical trial.

Methods Forty youth with juvenile fibromyalgia (JFM) were randomized to either CBT only or a combined CBT and neuromuscular exercise group (i.e., FIT Teens). Participants completed the PPI and FDI at baseline, post-treatment, and three-month follow-up. **Results** The PPI and FDI were significantly correlated at baseline ($r = .51$) and post treatment ($r = .53$), and demonstrated similar improvements (d PPI = .87, d FDI = 1.22, $p < .05$) at post-treatment following FIT Teens. Following CBT only, neither the PPI nor the FDI improved significantly. **Conclusions** The PPI may be appropriate for use in non-pharmacologic interventions for pediatric pain.

Key words: fibromyalgia; functional impairment; pain interference; pediatric pain; PROMIS.

Introduction

Clinical trials for pediatric chronic pain, especially those using behavioral interventions, frequently emphasize teaching pain coping strategies with the primary goal to improve daily functioning. Measurement of functioning is therefore an important domain of assessment (in addition to pain, coping efficacy, and other outcomes) and recommended by the PedIMPACT consensus guidelines for pediatric chronic pain trials (McGrath et al., 2008). Functioning is a broad construct encompassing physical, emotional, and social aspects of daily life. To date, several measures exist to assess functional impairment in pediatric pain such as the Functional Disability Inventory (FDI, Walker & Greene, 1991), a widely used instrument in both clinical and research settings. This enables researchers to select self-report forms tailored to their specific population; however,

the lack of a uniform measure limits comparison across pediatric pain trials and different pain conditions. Use of a standardized instrument across studies may be valuable when conducting broader outcomes research in pediatric pain.

The Patient-Reported Outcomes Measurement Information System (PROMIS) suite of measures, developed by the National Institutes of Health (NIH), offers highly reliable, precise, and brief tools to measure patient health (DeWalt et al., 2015; Reeve et al., 2007). The PROMIS pediatric measures were developed to compare scores longitudinally across diverse pediatric groups (Hinds et al., 2013). The PROMIS Pediatric Pain Interference (PPI) scale assesses functional impairment in physical, psychological, and social functioning. It has received initial support for its psychometric properties (Varni et al., 2010) and demonstrated similar responsiveness to change relative to

the widely used FDI, following multidisciplinary outpatient and inpatient day treatment for pediatric chronic pain (Kashikar-Zuck, Carle, et al., 2016). Despite preliminary support for the PPI in a clinical pediatric pain population, additional research is needed to evaluate its utility in relation to the FDI in a comparative longitudinal trial with standardized treatment and clearly defined assessment time points.

The objective of the current study was to test the utility of the PPI relative to the FDI, in a small-scale trial comparing two nonpharmacologic interventions for juvenile fibromyalgia (JFM). The trial compared the effectiveness of an integrative neuromuscular exercise and cognitive-behavioral therapy (CBT) intervention for youth with fibromyalgia (i.e., Fibromyalgia Integrative Training program for Teens; FIT Teens) to pain-focused CBT alone. The FIT Teens intervention was significantly more effective in reducing functional disability (based on the FDI) than CBT only. We selected the FDI as the primary measure of functional impairment given its frequent use in clinical trials. The newer PROMIS PPI measure was administered as an additional measure of pain-related impairment with the intent of evaluating its performance against the FDI. In this secondary analysis paper, we first (Aim 1), assessed correlations between the PPI and FDI at each assessment time point (baseline, post-treatment, and 3-month follow-up). We predicted the PPI and FDI would be significantly correlated at each time point. Next (Aim 2), we evaluated reductions in impairment measured by the PPI and FDI following the two behavioral interventions (i.e., FIT Teens and CBT). We hypothesized the PPI and FDI would show significant reduction in impairment after treatment and the extent of change (effect size) in PPI scores would be similar to changes in FDI scores. Finally, as an exploratory aim (Aim 3), we examined associations between the PPI and other outcome measures of interest in the trial (i.e., pain intensity and depressive symptoms).

Methods

Participants

Detailed information about the clinical trial study design, procedures, and results have been reported elsewhere (Kashikar-Zuck et al., 2018). Briefly, youth between the ages of 12 and 18 were recruited from pediatric rheumatology and pain clinics at a large Midwestern children's hospital in the United States. Eligibility criteria included diagnosis of JFM consistent with the 2010 American College of Rheumatology (ACR) criteria modified for pediatric use, moderate functional disability (i.e., FDI score ≥ 13), and moderate pain intensity (i.e., average pain in the past week ≥ 4 on visual analog scale). Participants with a comorbid rheumatic disease,

untreated major psychiatric diagnosis, developmental delay, a medical condition that precluded participation in physical activity (e.g., acute injury), and/or who were receiving pain-focused CBT or physical therapy were not eligible to participate.

A total of 40 youth (36 female; $M_{\text{age}} = 15.38$ years, $SD_{\text{age}} = 1.53$ years) were enrolled and randomized to either the FIT Teens or CBT condition. Participants identified as primarily non-Hispanic and Caucasian (93%, $n = 37$). Two participants were American Indian/Alaskan Native and one participant was biracial. Income ranged from $< \$25,000$ to $> \$150,000$, with the average parent-reported household income between \$75,000 and 100,000.

Procedure

A two-arm randomized controlled trial design with equal group allocation was used. Participants were randomized in groups of four to five youth to receive either the 8-week FIT Teens or CBT intervention. Participants completed self-report measures at baseline (T1), post-intervention (T2), and 3-month follow-up (T3). Retention at T2 and T3 was 90% ($n = 36$; FIT = 17; CBT = 19). All study procedures were approved by the Institutional Review Board.

Both interventions followed manualized treatment protocols (see Kashikar-Zuck, Tran, et al., 2016) and were delivered in a group format. Two sessions were held per week over 8 weeks, totally 16 sessions. Each session lasted approximately 90 min. All treatment sessions were facilitated by a pain psychologist and an exercise physiologist.

Measures

Demographic Information

Parents completed a self-report measure of participant's age, gender, race, ethnicity, and family income.

Functional Impairment

Youth completed two self-report measures of functional impairment, the PROMIS PPI and the FDI.

PROMIS Pain Interference-Short Form

The 8-item PROMIS PPI short form assessed pain interference over the past 7 days (refer to www.healthmeasures.net for additional information; Varni et al., 2010). Items are scored on a five-point Likert scale ranging from 1 (*never*) to 5 (*almost always*) and summed to create a total score ranging from 8 to 40, with higher scores suggesting greater interference by pain on daily activities. The PPI assesses interference in physical, psychological, and social domains. Internal consistency in the current sample was acceptable across all time points ($\alpha = .68-.83$).

Functional Disability Inventory

Difficulty completing physical activities across home, school, recreational, and social domains “in the past few days” was assessed using the 15-item FDI (Walker & Greene, 1991). Items are scored on a 5-point Likert scale ranging from 0 (*no trouble*) to 4 (*impossible*), and summed to create a total score ranging from 0 to 60, with higher scores suggesting greater pain-related disability. Internal consistency in the current sample was satisfactory ($\alpha \geq .79$) across all time points.

Pain Intensity

Average pain intensity over the previous 2 weeks was assessed using a 0–10 cm visual analog scale (VAS). The VAS was anchored with the terms *no pain* and *pain as bad as it can be*. The VAS is an extensively used and validated measure of pain intensity in children and adolescents (McGrath et al., 2008; Stinson, Kavanagh, Yamada, Gill, & Stevens, 2006; Von Baeyer, 2009).

Depressive Symptoms

Youth completed the 28-item Children’s Depression Inventory-Second Edition (CDI2; Kovacs & Staff, 2003) to assess depressive symptoms over the previous 2 weeks. Youth endorsed one of three statements (e.g., *I like myself*, *I do not like myself*, and *I hate myself*) which are scored from 0 to 2. The CDI2 is summed to create a total score ranging from 0 to 56 with higher scores indicating greater symptom severity. The CDI is a widely used self-report measure of depression in youth with pain (Conte, Walco, & Kimura, 2003; Kashikar-Zuck, Vaught, Goldschneider, Graham, & Miller, 2002) and demonstrates acceptable internal and test–retest reliability (Smucker, Craighead, Craighead, & Green, 1986). Internal consistency in the current sample was good ($\alpha \geq .83$) across all time points.

Data Analytic Plan

Descriptive statistics were conducted to test the distribution of scores and check for outliers. All self-report variables were normally distributed (skew and kurtosis < 2) and within the expected range. Means, standard deviations, and T1 correlations are summarized in Table I. Bivariate correlations using the full sample were conducted to test the association between the PPI and FDI at each time point (Aim 1). Paired samples *t*-tests were conducted to assess changes in PPI and FDI scores following intervention (T2) and at 3-month follow-up (T3; Aim 2). Effect sizes (Cohen’s *d*) were calculated to compare the extent of improvement in functioning. Bivariate correlations were conducted to test associations among PPI scores and self-reported pain intensity and depressive symptoms (exploratory Aim 3).

Table I. T1 Means, Standard Deviations, and Intercorrelations Between PROMIS Pain Interference and Core Pediatric Pain Outcomes ($n = 40$)

	1	2	3	4
1. PROMIS Pediatric Pain Interference	–			
2. Functional Disability Inventory	0.51**	–		
3. VAS pain intensity	0.47**	0.37*	–	
4. CDI depressive symptoms	0.46**	0.43**	0.28	–
Mean	30.20	25.58	6.48	14.93
Standard deviation	4.76	7.78	1.40	6.50
Observed range	17–39	13–42	4.0–9.9	2–28
Possible range	8–40	0–60	0–10	0–56

Note. CDI = Children’s Depression Inventory; PROMIS = patient-reported outcomes measurement information system; VAS = visual analog scale.

* $p < .05$; ** $p < .01$.

Results

Associations Between PPI and FDI at Baseline, Post-Treatment, and Follow-Up

Using the full sample (T1, $n = 40$; T2 and T3, $n = 36$), the PPI and FDI were moderately and significantly correlated at baseline and post-treatment (T1 $r = .51$, T2 $r = .53$; $p < .05$). At follow-up (T3), the PPI and FDI were marginally related ($r = .32$, $p = .058$).

Changes in PPI and FDI at Post-Treatment and at 3-Month Follow-Up

Post-Treatment

Results are summarized in Table II. At post-treatment, the FIT Teens group showed significant reduction in impairment as measured by both the PPI ($t = 2.61$, $p < .05$, Cohen’s $d = .87$) and FDI ($t = 3.04$, $p < .01$, Cohen’s $d = 1.22$). Following CBT, neither PPI scores nor FDI scores improved significantly; however, PPI scores showed marginal improvement in the expected direction ($t = 2.04$, $p = .056$, Cohen’s $d = .39$).

Three-Month Follow-Up

At T3, the FIT Teens group maintained their improvement based on FDI scores ($t = -2.60$, $p < .05$, Cohen’s $d = .87$). Improvement based on PPI scores at T3, also appeared to be maintained based on descriptive data but did not reach statistical significance ($t = -1.80$, $p = .09$, Cohen’s $d = .65$). Similar to post-treatment results, the CBT group did not show statistically significant changes on either the PPI ($t = -2.06$, $p = .054$, Cohen’s $d = .45$) or the FDI ($t = -1.42$, $p = .17$, Cohen’s $d = .18$).

Associations Among PPI, Pain Intensity, and Depressive Symptoms at Baseline

At baseline, PPI scores were moderately and significantly correlated with pain intensity ($r = .47$) and

Table II. Differences in PROMIS Pediatric Pain Interference and Functional Disability Inventory Scores Across Time

	T1: baseline M (SD)	T2: post-treatment M (SD)	T3: 3-month follow-up M (SD)		<i>t</i> (df)	<i>p</i>	<i>d</i>
FIT teens intervention (<i>n</i> = 17)							
PROMIS Pediatric Pain Interference	31.00 ^a (3.92)	27.29 ^b (4.65)	27.94 ^{a,b} (5.40)	T1 vs. T2	2.61 (16)	.019	0.866
				T1 vs. T3	-1.80 (16)	.09	0.649
FDI	26.24 ^a (7.75)	18.71 ^b (4.61)	19.76 ^b (5.55)	T1 vs. T2	3.04 (16)	.008	1.218
				T1 vs. T3	-2.60 (16)	.019	0.874
Cognitive behavioral intervention (<i>n</i> = 19)							
PROMIS Pediatric Pain Interference	29.32 ^a (5.29)	27.00 ^a (6.74)	26.95 ^a (5.23)	T1 vs. T2	2.04 (18)	.056	0.386
				T1 vs. T3	-2.06 (18)	.054	0.451
FDI	24.21 ^a (8.44)	23.95 ^a (11.04)	22.68 ^a (9.01)	T1 vs. T2	0.18 (18)	.863	0.026
				T1 vs. T3	-1.42 (18)	.17	0.175

Note. Letters in superscript indicate significant differences across time. FDI = Functional Disability Inventory; FIT teens = fibromyalgia integrative training program for teens; PROMIS = patient-reported outcomes measurement information system. Values in bold indicate $p < .05$.

depressive symptoms ($r = .46$) using the full sample. Functional Disability Inventory scores were similarly associated with increased pain intensity ($r = .37$) and depressive symptoms ($r = .43$).

Discussion

PROMIS measures were designed by NIH to enable researchers and clinicians to make longitudinal comparisons across studies and chronic illness conditions. The PROMIS measures are appealing due to availability, psychometric rigor, and brief length. Despite preliminary support for the utility of PROMIS measures (DeWalt et al., 2015; Hinds et al., 2013), their usefulness in comparative clinical trials is yet to be determined. The current study tested the utility of the PROMIS PPI measure relative to the widely used FDI in a secondary analysis of a completed pilot trial of nonpharmacologic treatments for JFM. Overall, results suggested that both the PPI ($\alpha \geq .68$) and FDI ($\alpha \geq .79$) were reliable in the context of a clinical trial for pediatric pain and the two measures performed similarly following both treatment conditions.

As predicted, the PPI and FDI were significantly correlated at T1 and T2. Correlations were moderate (approximately 26–28% shared variance), suggesting the PPI may assess a related but somewhat distinct construct compared with the FDI. Contrary to hypotheses, PPI and FDI scores were not statistically significantly correlated at T3. This result is unexpected, given that previous research has found significant correlations between other self-report measures of functional impairment (Hainsworth, Davies, Khan, & Weisman, 2007), as did our own findings at the first two time points. However, T3 findings are consistent with work from Karayannis, Sturgeon, Chih-Kao, Cooley, and Mackey (2017) who found significant cross-sectional relations between PROMIS pain interference and physical functioning in a sample of adults with noncancer pain, though poor associations

longitudinally, suggesting improvements in pain interference may not correspond with improvements in physical functioning over time. Importantly, the PPI and FDI were still moderately and positively related at T3 ($r = .32$); however, this value was not statistically significant. Small sample size and item-level differences between the PPI and FDI may partially explain the modest (as opposed to strong) correlations. Specifically, the FDI primarily consists of questions assessing interference in physical activities and daily routines (e.g., walking upstairs, doing chores, eating meals); whereas, the PPI evaluates pain-related impairment in mood (e.g., feeling angry), social functioning (e.g., difficulty having fun), cognitive impairment (e.g., hard to pay attention), as well as physical activity (e.g., hard to run). Moreover, the FDI assesses impairment when youth are “sick or not feeling well” whereas the PPI assesses impairment specific to pain. Given that youth with JFM often experience multiple somatic symptoms (e.g., fatigue, dizziness), answers on the FDI may reflect disability from overall JFM symptoms rather than solely from pain. Although the FDI has been extensively validated in the context of pediatric pain, this semantic difference may have affected youth responses and further contributed to the moderate correlations between the PPI and FDI, particularly at T3. Notably, both the PPI and FDI were significantly correlated with pain intensity and depressive symptoms.

Following both the FIT Teens and CBT intervention, the PPI and FDI performed similarly. In this comparative trial, the FIT Teens treatment showed superiority over the CBT treatment. Both measures improved significantly following FIT Teens resulting in large effect sizes for both the PPI and FDI at post-treatment (Cohen's $d = 0.87$ and 1.22 , respectively) and moderate and large effect sizes for the PPI and FDI at T3 (Cohen's $d = 0.65$ and 0.87 , respectively). Following CBT, neither PPI nor FDI scores improved significantly at either time point. Decreases in PPI

scores were observed but not significant at T2 and T3 (Cohen's $d=0.39$ and 0.45 , respectively). Overall, these findings suggest that the PPI performed similarly to the FDI following both treatment conditions.

The current study provides preliminary support for the PPI in the context of clinical trials for pediatric pain, though findings are limited by a small sample size. Additionally, consistent with prevalence rates of pediatric chronic pain (Zapata, Moraes, Leone, Doria-Filho, & Silva, 2006), results are limited by participants being primarily Caucasian females which affects generalizability. Despite these limitations, our results add to the growing research supporting the use of PROMIS measures as brief, reliable, and easily accessible (Varni et al., 2010) and directly expands on work from Kashikar-Zuck, Carle, et al. (2016) examining sensitivity to change in both the PPI and FDI. Overall, the PPI appears to be a well-established assessment measure consistent with guidelines outlined by Cohen and colleagues (2008).

Although preliminary, results suggest the PPI performs similar to the FDI following behavioral intervention, supporting the usefulness of the PPI as a tool for capturing improvements in pain interference. As a brief 8-item self-report form, busy medical clinics may consider incorporating the PPI into clinic procedures to monitor patient progress. Importantly, additional work is needed to assess the differential responsiveness of the PPI compared with the FDI and other impairment measures to guide providers and researchers in their selection of functional impairment outcome measures. Specifically, future work should incorporate the PPI and FDI in larger comparative clinical trials, with multiple points of measurement (i.e., baseline, throughout active treatment, post-treatment, and follow-up) to identify how different mechanisms of treatment change correspond to specific changes in outcome measures. For example, if researchers hypothesize changes in cognitive or emotional factors during treatment are instrumental in affecting functional outcomes, then the PPI may demonstrate greater change given that it has specific items related to attention and mood. Conversely, if the proposed mechanism for functional improvement is reversing deconditioning and physical decline via exercise or exercise adherence, then a more physically based outcome measure, such as the FDI, may be warranted. Moreover, research is needed to determine minimally important differences in a pediatric chronic pain sample. The PPI raw scores can be converted into T-scores (with a raw score ≥ 27 corresponding to T-score ≥ 65), though how this value applies to specific clinical presentations remains unknown. Future work should assess reliable cut off values for the PPI, similar to cutoff values established for the FDI (i.e., 0–12 minimal disability, 13–29 moderate disability, 30+ severe

disability; Kashikar-Zuck et al. 2011). Finally, research is needed to test the predictive validity of the PPI using larger longitudinal designs to evaluate its usefulness in assessing long-term functioning.

In conclusion, the PPI shows promise as a reliable and useful tool to measure pain-related impairment, and performed similarly to the FDI in the context of this small-scale study. Additional work is needed to replicate findings in larger clinical trials and further understand the nuances of these two instruments and their sensitivity to different forms of intervention.

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Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

Conflicts of interest: None declared.

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