

Running head: Pediatric Pain Screening Tool

Pediatric Pain Screening Tool (PPST): Rapid identification of risk in youth with pain complaints

Laura E. Simons, PhD^{1,2,3}, Allison Smith, PhD^{1,2}, Camila Ibagon, BA¹, Rachael Coakley, PhD^{1,2}, Deirdre E. Logan, PhD^{1,2}, Neil Schechter¹, MD, David Borsook, MD, PhD^{1,3}, Jonathan C Hill, PhD^{3,4}

¹Division of Pain Medicine, Department of Anesthesiology, Perioperative and Pain Medicine, Boston Children's Hospital, ²Department of Psychiatry, Harvard Medical School, ³P.A.I.N. Group, Boston Children's Hospital and Center for Pain and the Brain, ⁴Arthritis Research UK Primary Care Centre, Keele University, UK

Correspondence to: Laura E. Simons, Ph.D. Boston Children's Hospital 21 Autumn St. Boston, MA 02215 Tel: (617) 919-4677; Fax: (781) 216-1652. Email: Laura.Simons@childrens.harvard.edu

Disclosures: Dr. Simons, Dr. Smith, Camila Ibagon, Dr. Coakley, Dr. Logan, Dr. Schechter, Dr. Borsook, and Dr. Hill report no biomedical financial interests or potential conflicts of interest.

Pages: 24

Tables: 4

Figures: 2

Abstract

Moderate to severe chronic pain is a problem for 1.7 million children, costing \$19.5 billion annually in the United States alone. Risk-stratified care is known to improve outcomes in adults with chronic pain. However, no tool exists to stratify youth who present with pain complaints to appropriate interventions. The Pediatric Pain Screening Tool (PPST) presented here assesses prognostic factors associated with adverse outcomes among youth and defines risk groups to inform efficient treatment decision-making. Youth (n=321, ages 8-18, 90.0% Caucasian, 74.8% female) presenting for multidisciplinary pain clinic evaluation at a tertiary care center participated. Of these, 195 (61.1%) participated at 4-month follow-up. Participants completed the 9-item PPST in addition to measures of functional disability, pain catastrophizing, fear of pain, anxiety, and depressive symptoms. Sensitivity and specificity for the PPST ranged from adequate to excellent, with regard to significant disability (78%, 68%) and high emotional distress (81%, 63%). Participants were classified into low (11%), medium (32%), and high (57%) risk groups. Risk groups did not significantly differ by pain diagnosis, location, or duration. Only 2-7% of patients who met reference standard case status for disability and emotional distress at 4-month follow-up were classified as low-risk at baseline, whereas 71-79% of patients who met reference standard case status at follow-up were classified as high risk at baseline. A 9-item screening tool identifying factors associated with adverse outcomes among youth who present with pain complaints appears valid and provides risk stratification that can potentially guide effective pain treatment recommendations in the clinic setting.

Keywords: chronic pain, children, adolescents, stratified care, stepped care, questionnaire

There is now strong evidence that interventions such as cognitive behavioral therapy are an integral component of pain management for many patients[6,8]. However, access to care and engagement in services is hampered by factors such as a lack of available providers, scheduling conflicts, financial/insurance constraints, and insufficient knowledge of treatment efficacy[5,27]. Having a brief, validated tool to screen patients quickly for their risk of persistent symptoms and disability. It also allows providers to match treatment options more *efficiently* to patient presentation and more *effectively* address their needs, given that effect sizes for general cognitive behavioral treatments for pediatric chronic pain are modest[6].

In the clinical management of adults with low back pain, one approach to stratifying patients for targeted treatment is through use of the Keele STarT Back Screening Tool (SBST)[13]. SBST was designed to identify a patient's risk status (high, medium, or low) of poor clinical outcome using established biopsychosocial prognostic factors[12]. Allocation to the high-risk, more complex subgroup is primarily driven by the tool's psychosocial variables, highlighting the importance of psychological factors as prognostic indicators of clinical outcome[4,16,26]. Using a stratified care treatment approach based on the SBST[13] treatments can match the increasingly complex needs of patients. This approach is associated with incremental increases in quality of life years and reductions in healthcare costs related to back pain treatment compared to current best practice[14]. It also results in significant improvements in disability, particularly for high-risk patients [7]. Dissemination of the SBST has progressed rapidly and the tool is currently validated in several languages[2,10,20,22]. Related research has also found this measure to be predictive of treatment response[35] and disability outcomes six months after assessment[1] in adult patients with low back pain.

Although additional prognostic models and indicators have been identified in adult pain[21], no similar screening measures have been developed for youth with pain complaints. In the current investigation, we modified the musculoskeletal version of the SBST for pediatric patients and have

termed this the Pediatric Pain Screening Tool (PPST). The primary aims of the PPST are to 1) rapidly identify addressable treatment targets (e.g., sleep disruption, pain-related fear) and 2) derive cut-off scores for grouping patients into low risk (few negative prognostic indicators, responsive to analgesia, advice, and education), medium risk (moderately unfavorable prognosis, high level of physical/functional prognostic indicators, appropriate for physiotherapy), and high risk (very unfavorable prognosis, high levels of psychosocial prognostic indicators, appropriate for physical and cognitive-behavioral therapy) categories.

We hypothesized that items from the PPST would have adequate variability and test-retest reliability. Additionally we hypothesized that the PPST total score and psychosocial subscale would demonstrate acceptable discrimination of reference standard cases and non-cases (e.g., depressed vs. non-depressed) and we would be able to derive cutoff scores for subgrouping patients into one of three a priori risk groups (i.e., low, medium, high). Lastly, we hypothesized that patients who were classified as high risk at baseline would have the worst outcomes at 4-month follow-up, where as patients classified as low risk would have the most positive outcomes.

Methods

Participants and procedure

Patients aged 8 to 18 and an accompanying parent who presented for a multidisciplinary pain clinic evaluation at the Chronic Pain Clinic at Boston Children's Hospital (BCH), Boston, USA (January 2012 to April 2014) were invited to participate. Patients and their parents were brought to a private room by a research assistant to obtain written informed consent/assent both to complete study-specific measures and to allow information from the clinical assessment to be used for research purposes. The PPST was completed specifically for this study, whereas all other measures are part of a standard clinic battery completed prior to their appointment on either paper (mailed to the family) or electronically (via

a link sent through email) at home. All participants were invited to participate in a 2-week and 4-month follow-up assessment via electronic data collection using REDCap software[11]. At the 2-week follow-up the PPST was administered exclusively the PPST while at the 4-month follow-up several additional measures were used to assess current functioning. The study was approved by the Institutional Review Board at BCH.

Chronic Pain Clinic Multidisciplinary Evaluation and Treatment

All patients participated in a multidisciplinary pain clinic evaluation, where the patient and parent(s) jointly met with a 1) physician and physical therapist and 2) clinical psychologist for two separate one-hour sessions. After these sessions, the treatment team met to review their assessments and recommendations for treatment. Following this meeting, the physician and clinical psychologist met together with each family to review all findings and provide recommendations. During this feedback session, each family received a completed Treatment Recommendation Form that outlined recommendations from medical, physical, and psychological disciplines. This specific form was designed to ensure the clarity of communicating recommended treatments from the treatment team and has become a standard of care in our service.

Chronic Pain Clinic outpatient treatment typically encompasses some combination of medical, physical, and psychological therapy. Within this sample for medical treatment, 69% were recommended a new medication or dosage change to the current medication. For physical therapy, 51% were recommended to initiate physical therapy and 28% were recommended to continue physical therapy. For psychology, 68% were recommended to initiate outpatient psychological treatment and 32% were recommended to continue with their current provider. Adherence to treatment recommendations across disciplines is described in the results.

Screening Tool

Pediatric Pain Screening Tool (PPST). This is a self-report pediatric adaptation of the 9-item STarT Musculoskeletal Screening Tool (SMST) that was based on the SBST (see [12] for a detailed description of the development of this tool). Consistent with the SBST, the PPST consists of two subscales: Physical and Psychosocial. For all items, patients are instructed, "Thinking about the **last 2 weeks** check your response to the following statements." Items 1-8 respondents check "yes" or "no." All "yes" responses are scored as 1. For item 9, patients check boxes with ratings from "not at all" to "a whole lot." The ratings "a lot" and "a whole lot" are scored as 1, whereas the lower ratings of "not at all", "a little", and "some" are scored as 0. Summing all items, PPST total scores range from 0 to 9. Psychosocial subscale scores range from 0 to 5 and 0 to 4 for the Physical subscale. The scoring format is identical to the adult screening tool to allow for rapid scoring and risk stratification in a busy clinical setting.

In consultation with the creator of the SBST (JH) and experts in pain treatment (RC, DL, NS, LS) seven of the items were reworded to be more appropriate for a pediatric sample, whereas two items from the physical subscale were replaced (getting dressed slowly, pain in the upper extremity) with difficulties attending school[19] and sleep[31]. Getting dressed slowly was considered less germane to pediatric pain and upper extremity pain too specific. The PPST physical subscale consists of four items assessing: 1) comorbid pain, 2) ambulating, 3) attending school and 4) sleep. The psychosocial subscale consists of five items assessing: 1) pain catastrophizing, 2) pain-related fear, 3) general anxiety, 4) depression, and 5) pain bothersomeness (see **Table 1** for specific items). We retained a 9-item format for the PPST to ensure that it remained brief, was consistent in scoring with the adult screening tool, and most importantly, the included items covered the salient domains.

Additional Measures

Pain intensity. Children were asked during the psychology interview to provide their average pain rating on a standard 11-point numeric rating scale[32] from 0 (no pain) to 10 (most pain possible).

Functional disability. The Functional Disability Inventory (FDI)[34] is a 15-item scale that assesses difficulty in physical and psychosocial functioning due to physical health. Higher total scores indicate greater disability. Scores of 13-29 reflect moderate disability and scores ≥ 30 reflect severe disability[15]. The internal consistency in this sample was .90.

Child fear of pain. The Fear of Pain Questionnaire for children [28] is a 24-item self-report inventory assessing pain-related fears. Total scores of 51 and higher are classified as high pain-related fear[28]. Internal consistency for the FOPQ was .91.

Pain catastrophizing. The Pain Catastrophizing Scale, Child report (PCS-C[3]) includes 13 items and assesses negative thinking associated with pain. The clinical reference point for high catastrophizing is 26 and greater[24]. Internal reliability for the current sample was .93 for the PCS-C.

Depressive Symptoms. The Children's Depression Inventory (CDI-2[18]) is a 28 item self-report measure assessing child depressive symptoms. T-scores of 65 or greater are defined as clinically significant[18]. Internal reliability for the current sample was .88.

General Anxiety. The Revised Children's Manifest Anxiety Scale[25] is a 45-item self-report measure assessing anxiety symptoms. All items (excluding the lie scale) are summed to obtain a total anxiety score. T-scores of 60 or greater are defined as clinically significant. Internal reliability for the current sample was .93.

Treatment Adherence. At 4-month follow-up assessment, parents were asked about each recommendation given at the CPC evaluation to treat their child's pain in the domains of medicine, physical therapy, and psychology and whether they completed the recommendation (answered dichotomously; 'yes'/'no'). Data were extracted on medication changes (increase/decrease dosage or add a new medication), physical therapy treatment (begin new treatment or continue current outpatient intervention), and psychology treatment (begin new psychological intervention or continue current outpatient intervention). The questions were modeled after the treatment recommendation

form that all patients receive at the end of the clinic evaluation[27,29].

Statistical Analyses

Data were entered and analyzed using SPSS version 21.0 (SPSS IBM, New York, USA).

Scale variability and repeatability. Floor and ceiling effects were considered present if > 15% of respondents achieved the highest/lowest possible tool scores. To investigate test-retest reliability, 2-weeks after evaluation a subset of patients received and completed the PPST (n=221). We examined intra-class correlation coefficients (ICC) using a two-way random effects ANOVA model (participant x time-point). Given the dichotomous (yes/no) response format, we employed measures of absolute agreement, wherein systematic differences between time-points are considered relevant. ICC values ≥ 0.70 reflect adequate test-retest reliability. To examine scale variability by pain diagnosis and location, one-way ANOVAs were conducted. Pearson Product Moment correlations were conducted to examine the association between PPST scores and duration of pain.

Discriminant validity. Using receiver operating characteristic (ROC) curves and by calculating the area under the curve (AUC) for the overall PPST score and the psychosocial subscale, we compared scores against 'cases' on relevant reference standards. Reference standard multi-item measures were dichotomized to provide 'cases' and 'non-cases' using established cut-offs. We examined scores in relation to functional disability for baseline and 4-month follow-up (cases defined as FDI score of ≥ 13 [15]). For the psychosocial measures, reference standard cases were as follows: FOPQ ≥ 51 [28], PCS-C ≥ 26 [24], CDI-2 T-score ≥ 65 [18], RCMAS-2 T-score ≥ 60 [25]. Psychosocial distress cases were identified for patients who were elevated on ≥ 2 psychosocial measures. Strength of discrimination was classified according to the following descriptors: 0.7- <0.8 acceptable discrimination, 0.8- <0.9 excellent discrimination [36].

Deriving PPST cut-off scores. The primary goal of creating the PPST was to provide clinically meaningful subgroups to inform treatment decision-making. To define risk groups, we examined ROC

curves for PPST total and psychosocial subscale scores against reference standard cases of disability and psychosocial distress. As a screening tool, sensitivity was weighed as more important than specificity.

Predictive validity. We examined the predictive ability of PPST risk groups defined at baseline on disability, fear, catastrophizing, depression, and anxiety outcomes at 4-month follow-up. We used chi-square and one-way ANOVAs to examine differences across the groups based on frequency of reference standard cases and continuous scores at 4-month follow-up.

Treatment by risk group. We examined treatment recommendations given by risk group using chi-square analysis and adherence at 4-month follow-up by baseline risk group using one-way ANOVAs.

Treatment response. To examine treatment response, we calculated change scores for the total PPST scale score and each outcome of interest between baseline and 4-month follow-up: disability, fear, catastrophizing, depression, and anxiety. We then conducted Pearson Product Moment bivariate correlations between PPST change scores and each outcome. We also calculated minimal clinically important difference (MCID) scores for the PPST and FDI using the half standard deviation approach[23]. For the FDI, MCID was 6 (SD=11.4 in large cross-validation study of FDI with 1300 youth [15]). We used chi-square analyses to examine the frequency of patients who reported MCIDs for the PPST and FDI as an additional indicator of treatment response.

Results

Participants

Of the 452 patients eligible for the study, 321 enrolled (71% recruitment rate). The primary reason for not enrolling was research recruitment conflicting with clinic schedule (e.g., patient arrived late, evaluation lengthy). Patients self-identified predominantly as Caucasian (90%) and female (74.8%). Mean age was 13.73 (SD=2.47). Primary pain diagnosis included: musculoskeletal pain (43.2%), complex regional pain syndrome (CRPS; 18.6%), neuropathic (not CRPS; 7.3%), functional abdominal pain (6.6%),

headache (including chronic daily, tension, migraine, and combined headaches; 6.0%), endometriosis (3.5%), and other diagnoses (juvenile rheumatoid arthritis, inflammatory bowel disease, Ehlers-Danlos Syndrome/joint hypermobility, gynecological pain, genitourinary pain, postural orthostatic tachycardic syndrome, conversion disorder; 14.8%). The primary pain locations included: lower extremity (37.1%), upper extremity (11.3%), back/neck (19.2%), abdomen (including flank and chest, 14.2%), head (including jaw and face, 8.5%), hip/pelvis (5.7%), and diffuse body pain (4.1%). The duration of pain ranged from less than one month to over 15 years with a median duration of 13 months and 8.8% reported pain duration of less than 3 months. The parents were predominantly mothers (92%) and the majority of the parents were married (67%). The parents were generally well-educated; 64% of mothers completed college (42%) or a graduate degree (22%) and 60% of fathers completed college (34%) or a graduate degree (27%).

For 4-month follow-up, 61% of enrolled patients participated. There were no significant differences for PPST scores, functional disability, pain catastrophizing, fear of pain, general anxiety, and depression at the time of evaluation between the group of individuals who completed 4-month follow-up measures (n=195) and those who did not complete 4-month follow-up measures (n=126). The relative frequency of recommendations did not significantly differ for medical, physical therapy, or psychological treatments between those who completed follow-up and those who did not.

Scale variability and repeatability. Among the nine items on the PPST, “pain being problematic” (79.2%) was the most frequently endorsed item, whereas “worry about the pain not getting better” (36.6%) was least frequently endorsed. Frequency of endorsement for each item is detailed in **Table 1**. With regards to total scores on the PPST, 2.2% of respondents scored 0 and 5.3% scored 9, thus there was no evidence of floor/ceiling effects. Using one-way ANOVAs PPST total scores did not significantly differ by pain diagnosis, $f(6, 310)=1.09$, *ns*, or pain location, $f(6, 311)=1.15$, *ns*, and scores were not associated with pain duration based on bivariate correlation analyses ($r=-0.02$, *ns*). The total PPST score

(ICC = 0.75) and psychosocial subscale (ICC = 0.70) demonstrated acceptable 2-week test-retest reliability.

Discriminant validity. We generated receiver operating characteristic curves to derive the area under the curve (AUC) for the overall PPST score and psychosocial subscale against reference standard cases to examine how well the screening tool could discriminate cases from non-cases. The area under the curve (AUC) for the overall PPST score ranged from .68 (for pain catastrophizing) to 0.80 (functional disability), reflecting adequate to excellent discrimination (**Table 2**). For the PPST psychosocial subscale, the AUC was adequate to acceptable (0.68-0.76).

Deriving PPST cutoff scores. Based on the approach used for the SBST[13] we examined ROC curves to derive cutoff scores for the PPST. The ROC curves for disability and psychosocial distress are depicted in **Figure 1**. A PPST total score of 5 or greater was the best concurrent predictor of a reference standard case of moderate to severe functional disability. For the PPST psychosocial subscale, a score of 3 or greater was the best concurrent predictor of a reference standard psychosocial distress case. Given these two cut-off scores, the low-risk group was defined as a PPST total score of 0-2 (PPST total cutoff for disability minus the PPST psychosocial subscale cutoff for psychosocial distress). For the high-risk group, given that it is driven by psychosocial factors, a score of 3 or greater for the PPST psychosocial subscale was defined as high-risk and lastly, a total PPST score ≥ 3 and psychosocial subscale 0-2 was defined as medium risk (see **Figure 2** for scoring rubric). Within this tertiary care sample, 11% were classified as low risk, 32% as medium risk, and 57% as high risk. Importantly, PPST risk group did not significantly differ by pain diagnosis, pain location, or duration of pain.

Predictive validity by risk group. **Table 3** details the frequency of cases at follow-up by baseline risk group. Among patients at the 4-month follow-up, a very small percentage (2-7%) of reference standard case status at 4-month follow-up (e.g., clinically significant depression at 4-month follow-up) were classified as low-risk at baseline. At follow-up a very high percentage (71-79%) of patients who

met reference standard case status for disability, catastrophizing, fear, anxiety, and depression at follow-up were classified as high risk at baseline (**Table 3**). With regards to continuous outcome values, the omnibus ANOVAs were significant for each outcome (see **Table 4**). Specifically, the baseline low risk group had significantly lower disability at follow-up compared to the two other risk groups, while the baseline high-risk group had significantly higher pain catastrophizing, fear of pain, anxiety, and depressive symptoms compared to the other two risk groups.

Treatment by risk group. There was no significant difference by PPST risk group status on whether or not patients received treatment recommendations for medication changes, physical therapy, or psychological treatment. We examined adherence to treatment recommendations by baseline risk status. Overall patients were quite adherent to medical medication recommendations (94%) and physical therapy recommendations (92%), while relatively less adherent to psychology treatment recommendations (73%). Patients who were classified as high risk at baseline were significantly less likely to be adherent to psychology treatment recommendations (35%) compared to low risk (17%) and medium risk (18%) patients, $\chi^2(2)=6.69$, $p<0.05$. No differences by risk status emerged for medical or physical therapy treatment adherence.

Treatment response. We examined the association between changes in PPST scores from evaluation to 4-month follow-up and changes in disability, catastrophizing, fear, anxiety, and depression from evaluation to 4-month follow-up. We observed robust associations between decreases in PPST scores at 4-month follow-up and decreases in functional disability ($r=0.70$, $p<0.01$), pain catastrophizing ($r=0.52$, $p<0.01$), pain-related fear ($r=0.46$, $p<0.01$), and depression ($r=0.46$, $p<0.01$), with moderate effects for changes in general anxiety ($r=0.29$, $p<0.01$).

The PPST at baseline had a mean of 5.31 and standard deviation of 2.17, thus a minimal clinically important difference (MCID) was defined as a 1-point decrease on this measure. Among the patients who reported a MCID on the functional disability inventory (6-point or greater decrease at 4-month

follow-up) 85% also reported a MCID on the PPST and conversely, 69% of patients who reported a MCID on the PPST reported a MCID on the FDI, $X^2(2)=54.2$, $p<0.01$.

Discussion

This study introduces a valid screening tool to identify prognostic factors associated with adverse outcomes among youth who present with pain complaints and defines risk groups that can efficiently inform treatment decision-making. The treatment of chronic pain is a challenge. Early identification of patients who present with impairing pain-related comorbidities (e.g., sleep disruption, depressed mood) has the potential to significantly improve the rate of recovery.

Validity of PPST

A key objective for this study was to derive PPST cutoff scores for grouping patients into risk groups. Such groups would aid clinician decision-making for providing conservative treatment through education and advice (low risk), referrals for physiotherapy (medium risk), or additional referrals for psychological evaluation/support (high risk). Using receiver operating curves and examining the area under the curve, the 9-item PPST was able to discriminate reference standard cases of disability, pain catastrophizing, fear of pain, anxiety, and depressive symptoms. Most importantly, baseline risk groups robustly predicted outcomes four months later. A very small percentage (2-7%) of patients who met reference standard case status (e.g., clinically elevated anxiety) at 4-month follow-up were classified as low risk at baseline, whereas an overwhelming percentage (71-79%) of patients who met reference standard case status for disability, catastrophizing, fear, anxiety, and depression at follow-up were classified as high risk at baseline. These results provide strong support for the utility of PPST in the clinic setting.

It is currently estimated that moderate to severe chronic pain is a problem for 1.7 million children costing 19.5 billion dollars per year. That places pediatric chronic pain on par with the most expensive pediatric health conditions, namely ADHD and asthma[9]. Unfortunately, it is often very difficult for providers to know what interventions are necessary for treatment. One research study found that pediatricians could not agree on the cause of a chronic pain presentation in 57% of patients. Moreover physicians could not agree on a diagnostic approach to treating the symptoms for over one-third of these patients[17]. This lack of consensus conveys how challenging it is to decipher the various clinical and psychological correlates of chronic pain, and highlights exactly how hard it can be to know exactly how to treat the pain problem. With emerging research now documenting that untreated or persistent chronic pain in childhood can predispose the development of adult chronic pain[33], effective screening tools such as the PPST are needed to more effectively identify necessary treatments.

Use of PPST

Providing targeted treatment early is of utmost importance for optimal clinical care. The current investigation puts forth a brief and clinically meaningful tool to screen patients who present with pain complaints. The PPST identifies modifiable targets for primary (e.g., sleep hygiene), secondary (e.g., addressing anxiety/depression), and tertiary care interventions (e.g., interdisciplinary treatment with psychology and PT for elevated pain-related fear). This measure may fill a currently unmet need for providers (e.g., pediatricians, gastroenterologists, orthopedists, neurologists) who see pediatric patients with pain in their practice, as it represents the first screening tool in pediatric pain and is quick to complete and score (1-2 minutes). Once administered, the cutoff scores clearly identifying a patient's level of risk are immediately accessible, thus allowing providers to effectively integrate this information into a tailored treatment plan. PPST scores appear to be invariant by pain diagnosis and pain location, supporting the generalizability of this measure across pain complaints.

In the current study clinicians did not have access to PPST scores and we did not find any association between risk status and treatment recommendations given at the CPC evaluation. It will be important to examine in future studies if PPST risk-stratified treatment recommendations results in better treatment matching, higher adherence to psychological treatment recommendations, greater healthcare savings, and improved outcomes.

To extend the potential clinical utility of the measure, we also examined potential treatment responsiveness of the PPST. Decreases in PPST scores were robustly associated with improvements in distress and functioning. Additionally, 85% of patients who reported a minimally clinically important difference (MCID) in functional disability at 4-month follow-up also reported a MCID on the PPST, suggesting that this brief tool has the potential to measure patient progress and treatment response, echoing recent results in adult back pain [35].

Limitations and future directions

The items for the PPST were thoughtfully selected based on the SMST and clinical expertise of the study team. However, due to the focus on maintaining a brief (9-item) tool, the PPST items may not include all dimensions associated with heightened risk. As a departure from the adult tool, we did incorporate items on sleep and school functioning, which the clinical experts on the study team believed to be key issues among pediatric pain patients and is reflected in the literature. This is reinforced by the high frequency of endorsement of these two items in our chronic pain clinic sample. Although the dichotomous scoring format of the PPST allows for ease of scoring in a busy clinical setting, it does truncate score distribution and range. The lack of ceiling and floor effects for the PPST in this sample as well as evidence of treatment sensitivity does temper this concern. Additionally, the PPST was validated in a tertiary care clinic and may operate differently in a primary care setting. For example, only 11% of patients in this study were classified as low risk whereas the low risk group in the adult primary care

study ranged from 40-47% [13]. We believe that this discrepancy accurately reflects the level of impairment among patients who present to a specialized chronic pain clinic and is further underscored by the high number of patients who were recommended for psychological treatment within this sample. It will be important to further validate the PPST in specialty (e.g., gastroenterology) and primary care settings. Although the large number of reference standard cases observed at baseline and at 4-month follow-up afforded us the opportunity to robustly test predictions with the PPST, the results need to be replicated in a less clinically complex sample.

This tool is poised to be the cornerstone of a stratified care trial implemented in primary and secondary (e.g., gastroenterology) clinics, wherein the PPST is administered and patients are either randomized to received current best practice or stratified cared based on PPST risk categorization (e.g., medium risk = referral for PT evaluation). A stratified care trial will enable us to evaluate if using this measure to inform treatment decisions will result in more targeted care that results in potentially less chronicity and health care savings. Additionally, it would likely be quite beneficial to create a screening tool for parent risk of poor outcomes (e.g., parent's own distress and behaviors).

Conclusions

As we make inroads toward our understanding of how to most effectively manage persistent pain in youth, more attention to matching treatment to the patient is warranted [30]. The PPST allows providers to quickly and effectively identify the medium to high-risk youth who will benefit from access to more comprehensive treatments. Targeting the more entrenched biological and psychological factors that may maintain chronic pain *early* in the diagnostic process may ultimately improve recovery rates and alter maladaptive long-term trajectories.

Acknowledgements

This study were supported by an NIH grant (K23 HD067202) awarded to LS, an NINDS grant (K24NS064050) awarded to DB, the Sara Page Mayo Endowment for Pediatric Pain Research and Treatment, and the Department of Anesthesiology, Perioperative and Pain Medicine at Boston Children's Hospital. Research coordinator support was provided through the Harvard Catalyst Clinical and Translational Research Center (NCATS grant #8ULTR000170). The authors wish to thank the research assistants and student interns who worked on this study (Molly Basch, Elizabeth Carpino, Maya Hernandez, Connie Hsu, Christina Iversen, Molly McDonald, Melissa Pielech, Margaret Ryan, Kelly Smith).

ACCEPTED

References

- [1] Beneciuk JM, Bishop MD, Fritz JM, Robinson ME, Asal NR, Nisenzon AN, George SZ. The STarT back screening tool and individual psychological measures: evaluation of prognostic capabilities for low back pain clinical outcomes in outpatient physical therapy settings. *Physical therapy* 2013;93:321-333.
- [2] Bruyere O, Demoulin M, Beudart C, Hill JC, Maquet D, Genevay S, Mahieu G, Reginster JY, Crielaard JM, Demoulin C. Validity and reliability of the French version of the STarT Back screening tool for patients with low back pain. *Spine* 2014;39:E123-128.
- [3] Crombez G, Bijttebier P, Eccleston C, Mascagni T, Mertens G, Goubert L, Verstraeten K. The child version of the pain catastrophizing scale (PCS-C): a preliminary validation. *Pain* 2003;104:639-646.
- [4] Eccleston C, Crombez G, Scotford A, Clinch J, Connell H. Adolescent chronic pain: patterns and predictors of emotional distress in adolescents with chronic pain and their parents. *Pain* 2004;108:221-229.
- [5] Eccleston C, Morley S, Williams A, Yorke L, Mastroyannopoulou K. Systematic review of randomised controlled trials of psychological therapy for chronic pain in children and adolescents, with a subset meta-analysis of pain relief. *Pain* 2002;99:157-165.
- [6] Eccleston C, Palermo TM, Williams AC, Lewandowski Holley A, Morley S, Fisher E, Law E. Psychological therapies for the management of chronic and recurrent pain in children and adolescents. *The Cochrane database of systematic reviews* 2014;5:CD003968.
- [7] Foster NE, Mullis R, Hill JC, Lewis M, Whitehurst DG, Doyle C, Konstantinou K, Main C, Somerville S, Sowden G, Wathall S, Young J, Hay EM, team IMBS. Effect of stratified care for low back pain in family practice (IMPACT Back): a prospective population-based sequential comparison. *Annals of family medicine* 2014;12:102-111.
- [8] Gatchel RJ, McGeary DD, McGeary CA, Lippe B. Interdisciplinary chronic pain management: past, present, and future. *The American psychologist* 2014;69:119-130.
- [9] Groenewald CB, Essner BS, Wright D, Fesinmeyer MD, Palermo TM. The Economic Costs of Chronic Pain Among a Cohort of Treatment-Seeking Adolescents in the United States. *The Journal of Pain* 2014;15:925-933.
- [10] Gusi N, del Pozo-Cruz B, Olivares PR, Hernandez-Mocholi M, Hill JC. The Spanish version of the "STarT Back Screening Tool" (SBST) in different subgroups. *Atencion primaria / Sociedad Espanola de Medicina de Familia y Comunitaria* 2011;43:356-361.
- [11] Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)- A metadata- driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics* 2009;42:377-381.
- [12] Hay EM, Dunn KM, Hill JC, Lewis M, Mason EE, Konstantinou K, Sowden G, Somerville S, Vohora K, Whitehurst D, Main CJ. A randomised clinical trial of subgrouping and targeted treatment for low back pain compared with best current care. The STarT Back Trial Study Protocol. *BMC Musculoskelet Disord* 2008;9:58.
- [13] Hill JC, Dunn KM, Lewis M, Mullis R, Main CJ, Foster NE, Hay EM. A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Rheum* 2008;59:632-641.
- [14] Hill JC, Whitehurst DG, Lewis M, Bryan S, Dunn KM, Foster NE, Konstantinou K, Main CJ, Mason E, Somerville S, Sowden G, Vohora K, Hay EM. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *Lancet* 2011;378:1560-1571.
- [15] Kashikar-Zuck S, Flowers SR, Claar RL, Guite JW, Logan DE, Lynch-Jordan AM, Palermo TM,

- Wilson AC. Clinical utility and validity of the Functional Disability Inventory among a multicenter sample of youth with chronic pain. *Pain* 2011;152:1600-1607.
- [16] Kashikar-Zuck S, Goldschneider KR, Powers SW, Vaught MH, Hershey AD. Depression and functional disability in chronic pediatric pain. *Clin J Pain* 2001;17:341-349.
- [17] Konijnenberg AY, de Graeff-Meeder ER, Kimpen JL, van der Hoeven J, Buitelaar ER, Uiterwaal CSPM. Children with unexplained pain: Do pediatricians agree regarding the diagnostic approach and presumed primary cause? *Pediatrics* 2004;114:1220-1226.
- [18] Kovacs M. The Children's Depression Inventory (CDI). *Psychopharmacology bulletin* 1985;21:995-998.
- [19] Logan DE, Simons LE, Stein MJ, Chastain L. School impairment in adolescents with chronic pain. *The journal of pain : official journal of the American Pain Society* 2008;9:407-416.
- [20] Luan S, Min Y, Li G, Lin C, Li X, Wu S, Ma C, Hill JC. Cross-cultural adaptation, reliability, and validity of the Chinese version of the STarT Back Screening Tool in patients with low back pain. *Spine* 2014;39:E974-979.
- [21] Mallen CD, Thomas E, Belcher J, Rathod T, Croft P, Peat G. Point-of-care prognosis for common musculoskeletal pain in older adults. *JAMA internal medicine* 2013;173:1119-1125.
- [22] Morso L, Kent P, Albert HB, Hill JC, Kongsted A, Manniche C. The predictive and external validity of the STarT Back Tool in Danish primary care. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* 2013;22:1859-1867.
- [23] Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. *Medical care* 2003;41:582-592.
- [24] Pielech M, Ryan M, Logan D, Kaczynski K, White MT, Simons LE. Pain catastrophizing in children with chronic pain and their parents: Proposed clinical reference points and reexamination of the PCS measure. *Pain* 2014.
- [25] Reynolds CR, Richmond BO. Revised Children's Manifest Anxiety Scale, Second Edition (RCMAS-2), Manual, 2008.
- [26] Simons LE, Kaczynski KJ. The Fear Avoidance model of chronic pain: examination for pediatric application. *The journal of pain : official journal of the American Pain Society* 2012;13:827-835.
- [27] Simons LE, Logan DE, Chastain L, Cerullo M. Engagement in multidisciplinary interventions for pediatric chronic pain: parental expectations, barriers, and child outcomes. *Clin J Pain* 2010;26:291-299.
- [28] Simons LE, Sieberg CB, Carpino E, Logan D, Berde C. The Fear of Pain Questionnaire (FOPQ): assessment of pain-related fear among children and adolescents with chronic pain. *The journal of pain : official journal of the American Pain Society* 2011;12:677-686.
- [29] Simons LE, Sieberg CB, Pielech M, Conroy C, Logan DE. What does it take? Comparing intensive rehabilitation to outpatient treatment for children with significant pain-related disability. *Journal of pediatric psychology* 2013;38:213-223.
- [30] Turk DC. The potential of treatment matching for subgroups of patients with chronic pain: lumping versus splitting. *Clin J Pain* 2005;21:44-55; discussion 69-72.
- [31] Valrie CR, Bromberg MH, Palermo T, Schanberg LE. A systematic review of sleep in pediatric pain populations. *Journal of developmental and behavioral pediatrics : JDBP* 2013;34:120-128.
- [32] von Baeyer CL, Spagrud LJ, McCormick JC, Choo E, Neville K, Connelly MA. Three new datasets supporting use of the Numerical Rating Scale (NRS-11) for children's self-reports of pain intensity. *Pain* 2009;143:223-227.
- [33] Walker LS, Dengler-Crish CM, Rippel S, Bruehl S. Functional abdominal pain in childhood and adolescence increases risk for chronic pain in adulthood. *Pain* 2010;150:568-572.
- [34] Walker LS, Greene JW. The functional disability inventory: measuring a neglected dimension of

- child health status. *Journal of pediatric psychology* 1991;16:39-58.
- [35] Wideman TH, Hill JC, Main CJ, Lewis M, Sullivan MJ, Hay EM. Comparing the responsiveness of a brief, multidimensional risk screening tool for back pain to its unidimensional reference standards: the whole is greater than the sum of its parts. *Pain* 2012;153:2182-2191.
- [36] Youngstrom EA. A primer on receiver operating characteristic analysis and diagnostic efficiency statistics for pediatric psychology: we are ready to ROC. *Journal of pediatric psychology* 2014;39:204-221.

ACCEPTED

Figure Legends.

Figure 1. Scoring cut-offs for subgroup allocation. Receiver operating characteristic (ROC) curves for overall tool score and psychosocial subscale score against reference standard cases for A) Disability (total), B) Psychosocial distress defined using catastrophizing, fear, depression, anxiety (psychosocial subscale). Boxed numbers indicate sensitivity and specificity values. The green line signifies the null.

Figure 2. PPST Scoring Rubric.

ACCEPTED

Table 1. Frequency of PPST item endorsement.

PPST items	Agree	Disagree
Physical Subscale		
My pain is in more than one body part.	69.4%	30.6%
I can only walk a short distance because of my pain.	56.8%	43.2%
It is difficult for me to be at school all day.	73.1%	26.9%
It is difficult for me to fall asleep and stay asleep at night.	63.6%	36.5%
Psychosocial Subscale		
It's not really safe for me to be physically active.	45.9%	54.1%
I worry about my pain a lot.	48.3%	51.7%
I feel that my pain is terrible and it's never going to get any better.	36.6%	63.4%
In general, I don't have as much fun as I used to.	61.7%	38.3%
Overall, how much has pain been a problem in the last 2 weeks?*	79.2%	20.8%

Note. For this item, patients respond “not at all”, “a little”, “some”, “a lot”, and “a whole lot.” Responses of “a lot” and “a whole lot” are in the Agree column and coded as endorsement of bothersomeness for the total scale.

Table 2: Discriminate validity: area under the receiver operating characteristic curve (AUC) for screening tool overall scores and psychosocial subscale scores against reference standard cases.

Reference Standards	Case Definition	Overall tool scores, AUC (95% CI)	Psychosocial subscale scores, AUC (95% CI)
Disability	FDI \geq 13	.80 (.75-.86)	
Disability (4 months later)	FDI \geq 13	.72 (.65-.79)	
Catastrophizing	PCS-C \geq 26	.68 (.62-.74)	.68 (.62-.74)
Fear	FOPQ \geq 51	.80 (.74-.85)	.76 (.71-.82)
Depression	CDI \geq 65	.78 (.72-.84)	.75 (.69-.82)
Anxiety	RCMAS T-score \geq 60	.74 (.67-.81)	.72 (.65-.80)
Psych Index	Case on 2 or more psych variables*	.79 (.73-.84)	.76 (.70-.81)

Note. 95% CI = 95% confidence interval; *Psych variables include catastrophizing, fear, depression, anxiety.

ACCEPTED

Table 3. Baseline risk group and disability, pain catastrophizing, fear, anxiety, and depression cases at follow-up.

	Baseline Risk Group			Chi-square value
	Low	Medium	High	
Follow-up Functioning				
Moderate to Severe Disability	2% (n=2)	26% (n=24)	71% (n=65)	20.2**
High Pain Catastrophizing	6% (n=4)	16% (n=11)	78% (n=54)	17.1**
High Fear of Pain	4% (n=2)	18% (n=9)	78% (n=40)	11.6**
Clinically Anxious	7% (n=2)	14% (n=4)	79% (n=23)	5.84*
Clinically Depressed	2% (n=1)	20% (n=9)	78% (n=36)	6.11*

Note. Bold values are proportions significantly different at the .05 level; *p < .05; **p < .01.

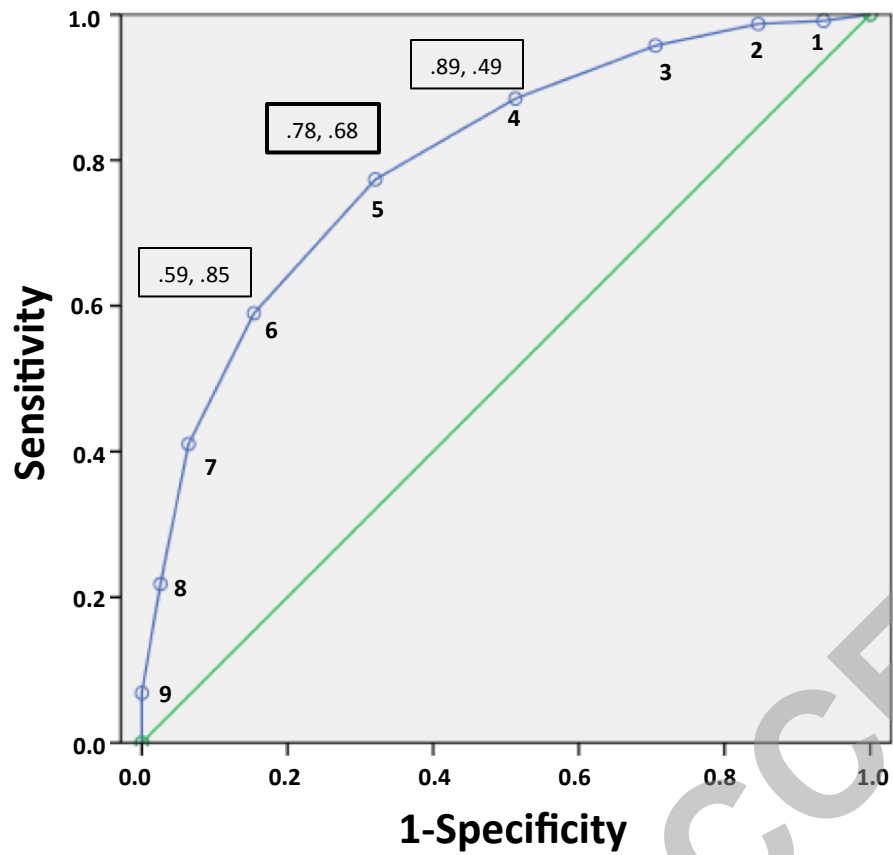
ACCEPTED

Table 4. Baseline risk group and disability, pain catastrophizing, fear, and depression scores at follow-up.

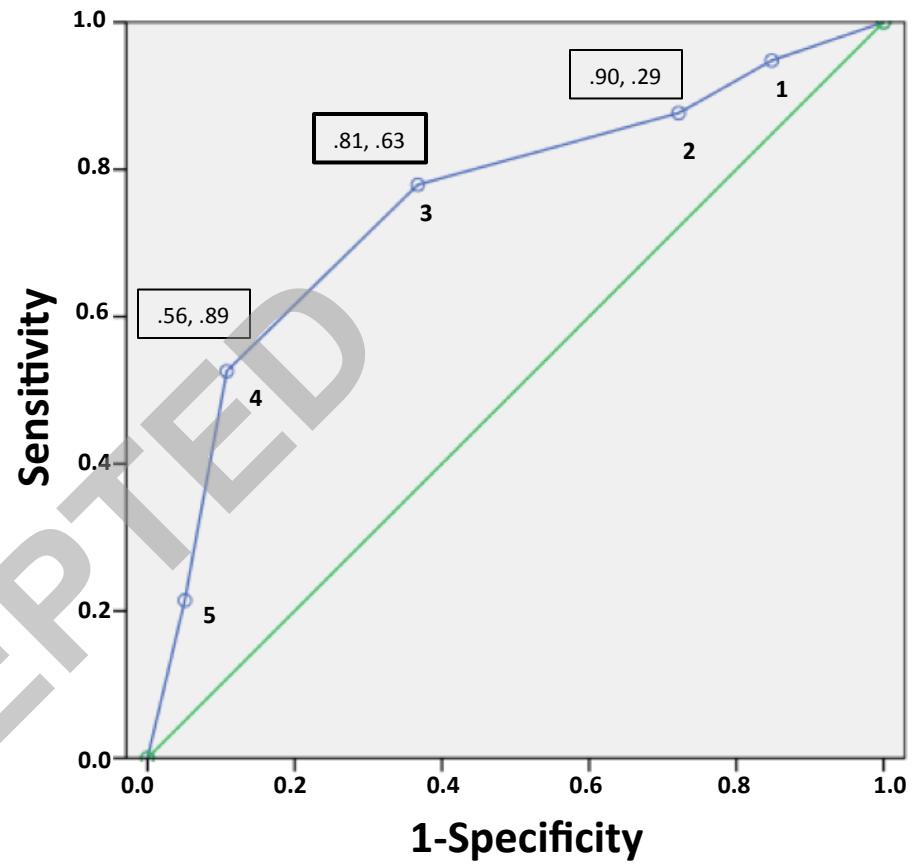
	Baseline Risk Group			F
	Low	Medium	High	
	M (SD)	M (SD)	M (SD)	
Follow-up Functioning				
Functional Disability	4.22 (5.62) ^a	12.8 (11.0) ^b	15.9 (11.3) ^b	11.4**
Pain Catastrophizing	13.5 (10.9) ^a	16.5 (10.5) ^a	25.7 (13.4) ^b	15.5**
Fear of Pain	17.1 (17.8) ^a	27.8 (19.9) ^a	40.5 (22.4) ^b	14.4**
Anxiety	41.7 (10.1) ^a	42.4 (10.7) ^a	49.3 (12.0) ^b	8.58**
Depression	47.2 (8.87) ^a	50.9 (10.7) ^a	56.1 (11.5) ^b	8.00**

Note. *p < .05; **p < .01.

ACCEPTED



A



B

