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Convergent validity evidence for the Pain and Discomfort Scale (PADS) for pain assessment among adults with intellectual disability

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Abstract

Objectives—The main aim of the study was to generate initial convergent validity evidence for the Pain and Discomfort Scale (PADS) for use with non-verbal adults with intellectual disabilities (ID).

Methods—Forty-four adults with intellectual disability (mean age = 46, 52 % male) were evaluated using a standardized sham-controlled and blinded sensory testing protocol, from which FACS and PADS scores were tested for (1) sensitivity to an array of calibrated sensory stimuli, (2) specificity (active vs. sham trials), and (3) concordance.

Results—The primary findings were that participants were reliably coded using both FACS and PADS approaches as being reactive to the sensory stimuli (FACS: $F[2, 86] = 4.71$, $P < .05$, PADS: $F[2, 86] = 21.49$, $P < .05$) (sensitivity evidence), not reactive during the sham stimulus trials (FACS: $F[1, 43] = 3.77$, $p = .06$, PADS: $F[1, 43] = 5.87$, $p = .02$) (specificity evidence), and there were significant ($r = .41 – .51$, $p < .01$) correlations between PADS and FACS (convergent validity evidence).

Discussion—FACS is an objective coding platform for facial expression. It requires intensive training and resources for scoring. As such it may be limited for clinical application. PADS was designed for clinical application. PADS scores were comparable to FACS scores under controlled evaluation conditions providing partial convergent validity evidence for its use.

Keywords

Pain measurement; intellectual disability; PADS; FACS

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Introduction

Recent scientific attention has addressed the prevalence and incidence of pain in children and adults with intellectual and developmental disabilities (I/DD).[1,2,3,4,5] Pain appears to be common among individuals with cognitive and communication impairments often associated with I/DD, yet is not always appropriately assessed and treated.[1,6,7,8] Although the measurement of pain is essential for the study of pain mechanisms and for the evaluation of methods to control pain, there is no simple thermometer that can objectively record how much pain an individual experiences.[9] Traditional pain assessment and measurement tools (e.g. visual analog scales, numerical rating scales, anecdotal reports, and questionnaires) evaluate and determine presence/absence, intensity, and quality of pain by some form of self-report by respondents. As pain is a subjective experience, it is traditionally considered that self-report provides the best access to assess and measure pain. There are no guarantees, however, that self-report accurately reflects current or past pain experience.[10] Traditional pain assessment and measurement tools may not be appropriate for assessing and measuring pain for individuals with I/DD because they may not be capable of providing caregivers, healthcare personnel, educators or other related providers with reliable self-report because of communicative, cognitive, and/or motor system deficits.

An alternative measurement approach is to rely on nonverbal behavioral expression of pain[11] based on observational assessment of the behavioral features of an individual (e.g., guarding, withdrawn, etc.) and facial expression (e.g., wincing, grimacing, etc.) neither of which rely on the verbal skills of the individual but rather on the skills of the observer. Assessing nonverbal behavioral expression of pain among individuals with I/DD is a fairly recent application of facial coding and related behavioral measurement technology. Prkachin and Craig[12] described a model of pain expression with facial signals consisting of three stages involved with pain experience including (1) experience, (2) encoding, and (3) decoding of pain expression. In the first stage, the tissue stress caused by an acute or chronic problem contributes to pain through nociception, the process whereby information about injury is transmitted to the brain and transduced into psychological experience. In the second stage, changes in facial expression encode information about the experience. In the final stage, the facial changes are broadcast into the social world where they may be decoded by others. The usefulness of attending to others' facial displays is intuitively appealing as there is a powerful disposition to situate oneself so as to be able to attend to facial activity,[11] thus facial expressions have emerged as a viable pain measure.

Initial work investigating expression of pain among non-verbal individuals with I/DD has followed the logic of the nonverbal expression models outlined above including application of the Facial Action Coding System (FACS). FACS is one of the most studied assessment tools to detect presence/absence and intensity of pain expression. FACS consists of 45 well-defined, discrete facial action units (FAU) which can be coded by trained observers[13]. LaChapelle et al[6] studied the utility of nonverbal facial expressions using FACS to assess pain in persons with I/DD. In their study, forty adults with I/DD (35% were unable to provide valid self-report) were recruited, and their facial expressions were videotaped while undergoing a routine influenza vaccination. The results showed significant within-subjects effect for the intensity of facial activity across the baseline, swabbing, and injection

segments, suggesting that FACS was a valid tool to assess pain in persons with I/DD without relying on self-report.

A subsequent study by Defrin, Lotan, and Pick[14] raised the issue of how to select among available tools to assess pain among individuals with I/DD. In Defrin et al[14], FACS and the Non-Communicating Children's Pain Checklist (NCCPC-R) scores significantly increased during noxious stimulation in persons with mild to moderate I/DD and persons without I/DD (for FACS) and all groups (for NCCPC-R) compared to baseline. FACS scores did not significantly change following noxious stimulation for individuals with more severe and profound ID. This specific finding led Defrin et al to conclude that FACS may not be an appropriate tool for that subgroup of people. Overall, the Defrin et al results suggest that it may be necessary to tailor appropriate assessment tools based, in part, on levels of ID. This finding is important because it has consequences for resource allocation for a particularly vulnerable group of individuals.

Although FACS, to date, has the most validity evidence among the measurement protocols for nonverbal behavioral expression of pain, it requires time-consuming training to be certified as a FACS coder and includes micro-analytic coding procedures which may not fit or be too cumbersome for clinical use for pain assessment. It is critical for health care, educational, and rehabilitation personnel and caregivers to have access to a pain assessment tool which can be useful without time-consuming training. To begin to address the issue, the Pain and Discomfort Scale (PADS) was developed. PADS was created to assess pain and discomfort for individuals with I/DD in clinical and related contexts. While other established assessments for nonverbal behavioral expression of pain among individuals with I/DD (e.g. FACS) require long training and certification processes, PADS was originally designed to aid health care professionals to recognize and diagnose, and more effectively treat pain in patients with severe and profound communication difficulties[15] for useful purposes in clinical settings.

PADS includes a checklist based on items derived initially from the original Non-Communicating Children's Pain Checklist (NCCPC)[16]. The items derived from NCCPC were specifically selected for the identification of pain in people with I/DD and focused on nonverbal behaviors[17]. PADS was designed to be an objective and practical screening tool for the assessment of pain or discomfort in nonverbal adults[18]. PADS has been used to detect pain and discomfort in persons with I/DD during a dental scaling and polishing procedure[19]. The results showed significantly higher scores on the PADS during the scaling procedure than during other observations, which suggests that the PADS may be sensitive to painful procedures, but its specificity is unknown. Given the labor intensiveness of FACS and the potential clinical utility of PADS, further testing of the assessment performance and psychometric properties of PADS seemed warranted. A logical next step would be to evaluate the relation between PADS and an objective 'gold standard' facial coding approach (i.e., FACS). Convergent validity evidence for PADS would be generated by establishing whether PADS and FACS scores were correlated based on simultaneous application of each approach.

Purpose of the Study

The purpose of this study was to generate initial convergent validity evidence for PADS by comparing its performance in relation to the FACS during a standardized sham controlled blinded sensory testing (described below) to test (1) whether FACS and PADS were sensitive to calibrated sensory stimuli, (2) whether FACS and PADS were modality specific to different noxious and non-noxious (i.e., tactile) sensory stimuli, and (3) the degree of concordance between FACS and PADS as an initial test of the evidence for the convergent validity of PADS. We hypothesized that there would be significantly more facial action unit (FAU) activity for FACS and greater PADS item scores during the stimulus application segment versus baseline and recovery segments during active stimuli versus sham trials. We also hypothesized that there would be significantly more FAU activity for FACS and greater PADS item scores during noxious stimulus versus non-noxious stimuli. Finally, we hypothesized that FAU scores and PADS item scores would be correlated.

Materials and Methods

Sample

Following IRB approval and parental/guardian consent, a sample of 44 participants (23 males, 21 females) (41 Caucasians, 3 Non-Caucasians) with moderate to severe/profound I/DD (6 moderate I/DD, 3 severe I/DD, 35 profound I/DD) was recruited from a regional residential care facility in the United States. The mean age of the participants was 46 (Range 28–67, *SD* = 9.87). Eight were verbal, and 36 were non-verbal. Thirty-two were ambulatory, 8 were non-ambulatory, and 4 were partially ambulatory.

Sensory Testing Procedure

Each participant was seated on a chair in front of a medical examining screen located in a Movement Lab at the facility. A trained clinician applied five different modalities of sensory stimuli (i.e. pin-prick, heat, cold, deep pressure, and light touch) to the participants' back in random order through a small hole in the screen. To reduce order effects, the stimulus sequence was randomized and partially counterbalanced across participants (i.e., for any one participant the order in which the five stimuli were presented was randomly determined from a list consisting of 5 pre-specified sequences [counterbalanced] with the caveat that no participant's sequence could be the same as the prior participant). Each trial consisted of three time segments audibly signaled aloud by a tape recorder ("stimulus #," "now," and "record."). Each time segment was five seconds in duration and ran consecutively. Stimuli were applied immediately after the audible signal "now." Pin-prick was the only stimulus that was not applied for the full five seconds. It was applied immediately after the audible signal "now" and was in contact with the participant for approximately one second. To ensure coders were blind to the application of the stimulus, sham trials (i.e., no stimuli) were included while the clinician continued to signal each trial in a standardized audible way but no stimuli were applied. In total, there were ten trials (5 active, 5 sham) with trial order randomized.

A digital camera was set up to record the sensory testing sessions. The camera was orthogonal to the participant and was 2 meters away from the participant. The camera was

positioned and focused on the participant's head/face and upper body. Digital video was used and converted to DVD for subsequent coding using Pro-Coder for Digital Video (PCDV)[20]. PCDV is a software program designed to facilitate the collection and scoring of different forms of observational data from digital media files. Data files can be used to guide the coder in marking events for later quantification and analyses.

Sensory Stimuli

The five sensory modalities included pin-prick, heat, cold, deep pressure, and light touch. Pin-prick was applied with a neuropen with a sterile neurotip (Owen Mumford). Heat was applied with a test tube filled with warm water (39 degrees Centigrade). Cold was applied with a tip therm device (metal end) controlled below 22.78 degrees Centigrade. Deep pressure (4 grams of force) was applied with an Algometer (Wagner model FDK). Light touch was applied with a monofilament instrument VF-1 (purple - 2.0 grams force). Because of the range and degree of cognitive and communicative impairments in this sample, great care was taken during the sensory testing. Unlike conventional quantitative sensory testing in which stimuli are repeatedly presented and participants indicate when the stimuli are perceived, stimulus trials were modified to be time limited and of short duration (≤ 5 sec.) and only conducted once per participant. It is relevant here to mention our approach to informed consent. Informed consent for procedures for this vulnerable population is always an issue (and among the myriad reasons that such individuals are likely not included in very much pain research). We took great care in describing and discussing procedures with parents/guardians. In addition, if an individual participant was not cooperative in terms of sitting through the procedure (after the 2nd instance of standing, moving away from area [if possible], resistant to evaluation) then the protocol required their exclusion/termination from the study. No participant was excluded or dropped based on the sensory testing protocol.

Measurement

Facial Action Coding System (FACS)—FACS is an anatomically based measurement system in which trained coders identify the presence or absence, intensity and temporal features of 45 well-defined, discrete facial action units (FAU). Each action unit represents the movement of a single facial muscle or in a few cases a group of muscle strands that move as a unit[11]. Prior to this study, three coders were trained independently to become FACS certified coders[21]. The final exam for FACS certification required 70 % accuracy in coding FAUs. Coders were trained to apply specific operational criteria to determine which actions have taken place and to identify their onset, offset, and intensity over specified time intervals[11].

Prior work has shown that there are specific FAUs in FACS that provide reliable information about pain expression[6,13]. Sixteen FAUs were selected for this study. The FAUs selected were AU4 (brow lowerer), AU5 (upper lid raise), AU6 (cheek raiser), AU7 (eye lid tightener), AU9 (nose wrinkler), AU10 (upper lip raiser), AU17 (chin raiser), AU18 (lip pucker), AU25 (lips part), AU26 (jaw drop), AU27 (mouth stretch), AU43 (eyes closed), and AU50 (vocalization). AU4, AU6, AU7, AU9, AU10, AU17, AU25, AU26, AU27, and AU43 were selected based on Defrin, et al[14] and LaChapelle et al[6] in their work on pain and I/DD. The other FAUs were selected based on preliminary observation. FAU frequencies

were coded based on presence (coded as 1) and absence (coded as 0) of occurrence of each specific FAU during an observation period. FAU frequencies were summed and for subsequent data analysis (described below). The three FACS certified coders independently coded the videos of participants during the sensory testing procedure to avoid dependency among the coders. The FACS coders were blinded to stimulus modality and active vs. sham procedures.

Operationally Defined Gross Motor Behaviors—In addition to the FAUs from FACS, four gross-motor head/face behaviors were coded based, in part, on the results of a study by Defrin et al[14]. The four pain behaviors included 'head turn,' 'head down,' 'head back,' and 'freeze.' 'Head turn' was coded when the orientation of the head was right or left on a vertical axis as defined in the manual of the FACS. 'Head turn' did not include head tilt and eye movement. 'Head down' was coded when the chin was pressed down as in the FACS manual. 'Head back' was scored when the chin was lifted up as defined in Defrin et al[14]. The operational definition of 'freeze' was no facial and body movement during the entire time segment (5 consecutive seconds) based on Defrin et al[14].

Pain and Discomfort Scale (PADS)—The Pain and Discomfort Scale (PADS) is a pain assessment tool for nonverbal behavioral pain expression and was developed for individuals with I/DD. PADS includes a checklist based on items derived from Non-Communicating Children's Pain Checklist (NCCPC)[16] and a 4-point behavioral rating scale for intensity. The items derived from NCCPC were specifically selected for the identification of pain in people with I/DD and focus on nonverbal behaviors[18]. The PADS was designed to be an objective and practical screening tool for the assessment of pain or discomfort in nonverbal adults[17]. PADS is comprised of the five domains: vocal, mood/interaction, facial expression, body and limbs, and physiological. The five domains consist of 18 items with the intensity scale. Ten of the 18 items were selected for this study to correspond with the pain and discomfort signs from the face and head (PADS items not related to facial expression/head movement were not used in this study). The specific PADS items selected were grimace, furrowed brow, change in eyes, mouth open, lips pucker tight/pout/quiver, clenches teeth, protects, and flinches (Table 1). Two PADS coders were trained to an 85% agreement criteria on the PADS domains prior to the study.

PADS was developed as follows. As mentioned above, the initial 31 NCPC items were used as test pool items on the preliminary version of the PADS. A 4 point behavioral severity rating scale for use in scoring the severity/intensity of each item was then added. This preliminary version was used to screen a sample of 304 adolescents and adults with moderate, severe, or profound intellectual disability. Forty-five cases from this sample were retested 1–2 weeks after initial testing to provide data for test-retest reliability analyses. Our intent with this initial dataset was to identify those test items which met or exceeded specific, a priori psychometric criteria. Items were retained if (a) the item was endorsed as present for at least 5% of the sample, (b) reliability for the item was > 0.60, and (c) the item-total correlation for the item was > 0.60. Based on analyses for this initial sample, 3 items were dropped because they were not directly observable in an examination context (eating less, increased sleep, decreased sleep), and 11 items were dropped because they did not meet

one or more of the psychometric criteria (a specific word or sound for pain, seeking comfort, not moving/less active, agitated/fidgety, floppy, stiff/tense/rigid, gesturing to body part that hurts, moving body in specific way to show pain, shivering, change in color, sweating). This left a revised item pool of 17 items. Based on consultation with published pain research using the Facial Action Coding System to identify specific nonverbal signs of pain in children and in persons with developmental disabilities[6, 22, 23], we included 1 new item that focused on specific facial actions (mouth open/lips separated). This left a final revised pool of 18 items for the PADS.

Following this item selection phase, PADS was further revised by changing the behavioral scoring scheme for item scoring from a generic 4 point severity rating to a more specific 5 point scale that provided specific anchors based on ease of detection and frequency of occurrence. On a previous sample (N = 65) of individuals with severe to profound I/DD, reliability of PADS was examined. The mean inter-rater reliability of the PADS across four raters was 0.82, ranging from 0.64 to 0.93[17], indicating excellent reliability for clinical screening. The content validity of the PADS is also excellent as the items were derived directly from the NCCPC. The PADS' sensitivity was independently tested on a sample with I/DD (N = 28) during a dental scaling and polishing procedure[19]. The results showed significantly higher scores on the PADS during the scaling procedure than during other observations, suggesting that PADS was sensitive to a painful procedure.

Inter-rater agreement

The inter-rater agreement (Agreement/Agreement + Disagreements × 100) for the frequencies of FAUs from 30% of the data randomly selected was 73% (Range 38–96%) among the three FACS coders. The final passing 'gold standard' score to be certified as a FACS coder is 70%[24]. Thus, our overall mean agreement value exceeded the FACS 'gold standard'. We investigated the lower bound of agreement and found that it was accounted for by one subject for whom the two coders made initial different decisions about the baseline status of one of the AUs. These differences were resolved through consensus. The inter-rater agreement on the frequencies of operationally defined gross motor behaviors of 30% of the data randomly selected was 90% (Range 81–98.3%) among the three coders. The overall mean inter-rater agreement on the PADS scores from 30% of the data randomly selected was 93% (Range 85–100%) between the two PADS coders.

Data Analyses

The data were analyzed with SPSS 14.0 software. To test for the sensitivity and specificity of our sensory testing protocol, the inference model was based on a 2 (active vs. sham trial) X 3 (time-segment) repeated measures ANOVA with sensitivity indexed by the time effect and specificity by the interaction. The variables compared (i.e. dependent variables) were frequencies of FAUs for FACS, frequencies of operationally defined gross motor behaviors, and PADS scores. The factors (i.e. independent variables) were three time segments consisting of 'baseline,' 'stimulus,' and 'recovery,' (i.e. "stimulus," "now," and "record" audibly signaled respectively) and modality of stimuli provided (i.e. pin-prick, heat, cold, deep pressure, light touch, and sham). Stimulus modalities were grouped into tactile (light touch, deep pressure) and noxious (pin-prick, heat, cold). For the convergent validity

hypotheses testing (i.e. concordance between PADS and FACS), the correlation between the frequencies of FAUs for FACS and PADS scores during active versus sham sensory stimulation and during noxious stimulus versus non-noxious stimulus was evaluated.

Results

FACS: Sensitivity & Specificity Evidence

The FAU frequencies of the five sham trials were compared across participants and tested by two-way repeated measures ANOVA to examine whether there were any significant differences among the five sham trials. The factors were three time segments (i.e. 'baseline,' 'stimulus,' and 'recovery') and five sham trials. There were no differences in FAU frequencies for the five sham trials. Accordingly, the mean FAU frequency from the five sham trials from each participant was then calculated and pooled to compare active stimulation versus sham (i.e., no stimulation). There was a significant difference in within-subjects effects for FAU frequencies across the three time segments ($F[2, 86] = 4.71$, $P < .05$). Post-hoc analysis showed that there was a significant increase between baseline and stimulus segment ($t[43] = -3.55$, $p < .01$) and significant decrease between stimulus and recovery segment ($t[43] = 3.69$, $p < .01$) during active stimulation. This finding provides support for the sensitivity of FACS. There were no significant differences among the five different modalities of stimulation (i.e., pin-prick, heat, cold, deep pressure, and light touch).

The mean FAU frequency during active stimulation was greater than during sham (Table 2) with a modest significant difference in within-subjects effects of FAU frequencies between sham ($M = 1.52$, $SD = 1.46$) and active ($M = 1.78$, $SD = 1.43$) (Table 1) stimulation during the stimulus segment ($F[1, 43]= 3.77$, $p = .06$). There was a significant interaction effect for active vs. sham and the three time segments ($F[2, 86] = 3.88$, $p < .01$) (Table 2). The results indicate that the mean FAU frequency during the 'stimulus' segment during the active stimulation ($M = 1.78$ [$SD = 1.43$]) was significantly greater than during the 'stimulus' segment during the sham trials ($M = 1.52$, $SD = 1.46$) (Table 2). This finding provides partial support for the specificity of FACS.

PADS: Sensitivity & Specificity Evidence

Identical analyses were performed for the PADS data (two-way repeated measures ANOVA with three time segments [i.e. 'baseline,' 'stimulus,' and 'recovery'] as factors. First, total PADS scores from the five sham trials from each participant were tested to examine whether there were any significant differences among the five sham trials. There were no differences in PADS scores across the five sham trials indicated no or low PADS scores during all sham trials compared to the active trials. Second, PADS score means from the five sham trials from each participant were calculated to use for a comparison between active and sham sensory. There was a significant difference in within-subjects effects of PADS scores across three time segments ($F[2, 86] = 21.49$, $P < .01$). Post-hoc analysis showed that there was a significant increase between baseline and stimulus segment ($t[43] = -5.22$, $p < .01$) and significant decrease between stimulus and recovery segment ($t[43] = 5.16$, $p < .01$) during active stimulation. Post hoc analysis also showed that there was a significant decrease between stimulus and recovery segment ($t[43] = 3.51$, $p < .01$) during sham trials. The

finding shows that changes in PADS scores are sensitive to presence/absence of active stimulation which provides support for the sensitivity of PADS.

Total PADS item scores during active stimulation were higher than those during sham (Table 3). There was a significant difference in within-subjects effects of PADS scores between sham trials (M = 4.8, SD = 2.69) and active stimulation (M = 5.86, SD = 3.11) during the stimulus segment (F[1, 43] = 5.87, p = .02) (Table 3). There was a significant interaction effect of active vs. sham and three time segments (F[2, 86] = 6.61, p < .01). The results indicate that the mean PADS score during the 'stimulus' segment during the active stimulation (M = 5.86 [SD = 3.11]) was significantly greater than that during the 'stimulus' segment during the sham trials (M = 4.8, SD = 2.69) (Table 3). This finding provides support for the specificity of PADS.

PADS & FACS Convergent Validity Evidence

Pearson correlation coefficients were calculated to examine concordance between the total FAU frequencies and total PADS scores. Correlations for FACS FAU frequency and PADS' item scores during sham vs. active stimulation procedures and noxious vs. tactile stimulation procedures, respectively, were examined. There was a moderate correlation between the total AU frequencies in FACS and total PADS scores during sham (r = .44, p < .01). The correlation between the total FAU frequencies in FACS and total PADS scores during active stimulation was .47 (p < .01). There was a moderate correlation between the total AU frequencies in FACS and total PADS scores during noxious stimulation (r = .51, p < .01). The correlation between the total AU frequencies in FACS and total PADS scores during tactile stimulation was .41 (p < .01).

Analysis of Gross Motor Behaviors

Four gross motor behaviors (i.e. head turn, head down, head back, and freeze) were coded by FACS coders based, in part, on the results of a study by Defrin et al[14]. Total frequencies of head movement (i.e. head turn, head down, and head back) and freeze were analyzed. First, frequencies of head movement and freeze from the five sham trials from each participant were tested by two-way repeated measures ANOVA with two factors, three time segments and five sham trials to examine whether there were any significant differences among the five sham trials. There were no differences in head movement across the five sham trials but there was a significant difference in freeze across the five sham trails (F[2, 43] = 3.72, p = .05). Post hoc analysis showed that there were significant increases in 'freeze' between baseline (M = .03, SD = .11) and stimulus (M = .05, SD = .16) and decreases in 'freeze' between stimulus (M = .05, SD = .16) and recovery (M = .01, SD = .07) segments during sham trials. Second, total head movement and freeze means from the five sham trials from each participant were calculated to use for a comparison between active and sham sensory.

There were no significant differences in within-subjects effects of head movement across three time segments. There was a significant difference in within-subjects effects of total head movement between sham trials (M = 1.25, SE = .09) and active stimulation (M = 1.19,

SE = .09) (*F*[1, 43] = 4.27, *p* = .045). Head movement during sham trials was significantly higher than those during active stimulation across the three time segments.

There were no significant differences in within-subjects effects of freeze across the three time segments. There were no differences in freeze between sham trials and active stimulation. Freeze during sham trials was higher than those during stimulus and recovery segments during active stimulation. Frequency of 'freeze' (*M* = .03, *SD* = .1) was minimal compared to occurrence of head movement (*M* = 1.22, *SD* = .65) across three segments during sham and active sensory. There were no interaction effects of stimulation (sham v. active) X segments in head movement and in freeze.

Discussion

This study was conducted to generate initial convergent validity evidence for the Pain and Discomfort Scale (PADS), a behavioral pain rating scale, by comparing its scores with those generated by the Facial Action Coding System (FACS), an anatomically-based micro-analytic measurement approach for facial movement and expression, during a standardized evaluation. A modified quantitative sensory testing procedure with five different modalities of active sensory stimuli and a sham control was used with a sample of adults with I/DD. The quantitative sensory testing was modified in the sense that calibrated stimuli were applied but only once therefore it is important to note that this study is not a sensory or pain threshold study. The primary findings were that individuals were reliably coded using both approaches as being reactive to the sensory stimuli (evidence for sensitivity of the two measurement approaches), not reactive during the sham stimulus trials (specificity evidence), and there were significant correlations between PADS and FACS (convergent validity evidence). Several points can be made based on these initial results.

First, our FACS results are consistent with the finding from LaChapelle et al[6] that determined FACS was suitable for assessing pain in individuals with I/DD. In LaChapelle et al[6], intensity of overall facial activity was significantly greater during an injection (i.e. noxious stimulus) segment than during the other segments. Although there were no comparisons to sham in LaChapelle et al, the results from the current study provide further evidence of the sensitivity of FACS to a range of tactile stimulation. Importantly, for the purpose of the current study, the FACS results provided evidence that the protocol worked as intended (i.e., reactivity as indexed by facial expression time locked to stimulus application).

Second, the results indicated that the PADS scores were more sensitive to active versus sham conditions. This suggests that PADS was a sensitive measure. The results are consistent with Phan et al[19] who found significant increase in PADS scores during periods when noxious stimuli were applied (dental scaling) compared with pre-post observational periods, supporting the sensitivity of PADS. The current results did not provide any evidence to support the specificity of PADS with respect to noxious vs. tactile stimuli. PADS may be appropriate for detecting pain among individuals with I/DD but may not discriminate among the types or sources of pain.

Third, there were moderate correlations between total FACS and PADS scores during both active and sham trials providing initial convergent validity evidence for the PADS, specifically in regard to its face/head relevant items. This finding is consistent with the correlations between FACS and NCCPC-R by Defrin et al[14]. As PADS items were derived from NCCPC-R, the consistency in correlations reported on between the two studies provides additional evidence for the content and construct validity evidence of PADS. It should be noted, though, the correlations were significant but moderate. It is likely that procedural/method differences (a behavioral checklist vs. second-by-second scoring of muscle movements) could attenuate such correlations as they are measuring different albeit related features of sensory experience. It may also be that although the FAUs used were documented to reflect pain expression in prior studies, not every AU nor necessarily the same AU was active for every participant. Thus, there may have been diminished FACS sensitivity because non-pain-related AUs were lumped into the analysis with pain-related AUs. This diminished sensitivity would also attenuate correlations between FACS and PADS.

It may be worth noting, given the paucity of the literature in the area of pain and I/DD, that our FACS results differed somewhat from Defrin et al,[14] however, who suggested detailed facial expression might not be suitable to measure acute pain in individuals with severe-profound IDD. In Defrin et al,[14] FACS scores increased significantly during vaccination relative to baseline only in individuals with mild to moderate I/DD and control individuals without I/DD. The majority of the sample in the current study consisted of individuals with severe to profound I/DD, and the results reported here suggest some degree of FACS sensitivity. Differences between the two studies include stimulus modalities (needle injection vs. an array of noxious/non-noxious calibrated stimuli) which may account for the differences in outcomes. Indeed, in the current study, it is worth pointing out that FACS did not appear to be specific to any one of the five different modalities (i.e. pin-prick, heat, cold, light touch, or deep pressure) although all five modalities increased in FAU frequency during stimulus segments and decreased during recovery. Contrary to conventional quantitative sensory testing (QST) procedures, stimulus intensities were constant in the current study (as mentioned above). To date, there have been few pain assessment studies with individuals with I/DD that have investigated systematically different stimulus modalities.

The gross motor behavior results are somewhat puzzling. Contrary to the results of sensitivity testing for FACS and PADS, total head movements (i.e. ‘head turn,’ ‘head down,’ and ‘head back’) during sham were significantly higher than those during active stimulations. This finding is also contrary to the results from Defrin et al[14] who reported increased frequency of gross-motor/head. ‘Freeze’ occurred very infrequently across all time segments during both sham and active sensory compared to head movement. A few different interpretations are possible to account for the discrepancy in results between this study and Defrin et al.[14] First, the definitions of gross motor behaviors in this study may have differed from those in Defrin et al.[14] In their study, gross motor behaviors were not operationally defined or, at least were not reported, and so they may not be comparable. Second, the procedural difference in these two studies may account for the discrepancy in frequency of head movement. In Defrin et al,[14] head movement was reported to be directed toward the

stimuli (i.e. injection) (e.g. participants moved heads either toward or away from the injection) while participants in this study were blind to source of stimuli and none of the stimuli were comparable to a needle injection.

There are a number of external and internal validity issues in this study that should be noted. First, this was a non-random convenience sample therefore additional study with randomly selected samples would be warranted to further establish the generality of the study findings. Second, the results may also be limited to residential populations, but may not represent more community-based populations of individuals with I/DD. Third, the majority of the sample was Caucasian, which may or may not be relevant with respect to cultural variables in relation to pain expression. This is unlikely as culture effects are usually found when studying groups of individuals within their home cultures. Fourth, the sample size was relatively small thus there were likely power issues related to effect detection, but, conversely, it was a relatively homogeneous sample in terms of ID severity. Fifth, the PADS items were limited to those relevant to face/head, therefore the convergent validity evidence generated in the study does not reflect the full PADS. Sixth, given the audible signal for coding, there could have been a conditioning effect operating and confounding reactivity (i.e., participant was reacting to audible signal not tactile sensory stimulus). This is unlikely given that the same audible signaling procedure was used across active and sham trials and facial expression during sham trials at the time of the audible signal (i.e., when coders coded) was low to non-existent. Last, in typical QST procedure, a sensory/tactile threshold is established and a pain threshold is also established by repeated stimulus application at increasing intensities. The individual indicates (most often verbally) when they feel/perceive the stimulus and when it is felt/perceived as painful. In this study, single stimulus trials were used and so sensory/pain threshold are unknown. Part of the issue, here, was an ethical concern in which we had recruited a sample of individuals not capable of quickly reporting verbally when they were feeling pain, when they were not, and trying to establish a threshold value; thus our approach of applying each stimulus once and relatively briefly.

In summary, using a blinded, sham-controlled procedure, further evidence for the sensitivity of PADS and FACS to detect changes in behavior during sensory testing was generated among a sample of individuals with I/DD. Coders/observers in almost all cases of previous studies using FACS[6,14] or PADS[19] were aware of stimulus sources and timing. In the current study sham trials were built in to the procedure to further guard against rater bias as a further test of the measurement protocols and their performance. The correlation between FACS and PADS was moderate and significant. FACS and PADS scores both increased in relation to stimulus application. Because FACS requires intensive training and certification procedure to become a coder, PADS may be a more promising tool with an easier coding system for use in clinical settings. The overriding issue remains, however, that pain is a subjective and multidimensional phenomenon. Because of this pain assessment tools need to be studied from a variety of perspectives including physiological, behavioral, social, cognitive, and developmental. Individuals with I/DD, especially those with severe to profound I/DD with limited verbal communication, tend to rely on caregivers' ability to detect pain and advocate for treatment. It is critical that the research community continue to test and validate pain assessment tools that may be useful for caregivers but also can be used reliably for different types of pain (e.g. acute, procedural, chronic).

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References

1. Stallard P, Williams L, Lenton S, Velleman R. Pain in cognitively impaired, non-communicating children. Arch Dis Child. 2001; 85:460–462. [PubMed: 11719327]
2. Breau LM, Camfield CS, McGrath P, Finley GA. The incidence of pain in children with severe cognitive impairments. Arch Pediatr Adolesc Med. 2003; 157:1219–1226. [PubMed: 14662579]
3. Breau LM, Camfield CS, McGrath P, Finley GA. Risk factors for pain in children with severe cognitive impairments. Dev Med Child Neurol. 2004; 46:364–371. [PubMed: 15174527]
4. Bottos, S.; Chambers, CT. The epidemiology of pain in developmental disabilities. In: Oberlander, TF.; Symons, FJ., editors. Pain in children & adults with developmental disabilities. Baltimore: Paul H. Brookes Publishing Co; 2006. p. 67-87.
5. Oberlander, TF.; Symons, F. Pain in children & adults with developmental disabilities. Baltimore: Paul H. Brookes Publishing Co; 2006.
6. LaChapelle DL, Hadjistavropoulos T, Craig KD. Pain measurement in persons with intellectual disabilities. Clin J Pain. 1999; 15:13–23. [PubMed: 10206563]
7. Breau LM, MacLaren J, McGrath PJ, Camfield CS, Finley GA. Caregivers' beliefs regarding pain in children with cognitive impairment: relation between pain sensation and reaction increases with severity of impairment. Clin J Pain. 2003; 19:335–344. [PubMed: 14600533]
8. Oberlander TF, Symons F, van Dongen K, Abu-Saad HH. Pain in individuals with developmental disabilities: challenges for the future. Prog Pain Res Manage. 2003; 24:705–723.
9. Turk, DC.; Melzack, R. The measurement of pain and the assessment of people experiencing pain. In: Turk, DC.; Melzack, R., editors. Handbook of assessment of pain. 2. New York: The Guilford Press; 2001. p. 3-11.
10. Jensen, MP.; Karoly, P. Self-report scales and procedures for assessing pain in adults. In: Turk, DC.; Melzack, R., editors. Handbook of assessment of pain. 2. New York: The Guilford Press; 2001. p. 15-34.
11. Craig, KD.; Prkachin, KM.; Grunau, RE. The facial expression of pain. In: Turk, DC.; Melzack, R., editors. Handbook of assessment of pain. 2. New York: The Guilford Press; 2001. p. 153-169.
12. Prkachin KM, Craig KD. Expressing pain: the communication and interpretation of facial pain signals. J Nonverbal Behav. 1995; 19:191–205.
13. Prkachin KM. The consistency of facial expressions of pain: a comparison across modalities. Pain. 1992; 51:297–306. [PubMed: 1491857]
14. Defrin R, Lotan M, Pick CG. The evaluation of acute pain in individuals with cognitive impairment: A differential effect of the level of impairment. Pain. 2006; 124:312–320. [PubMed: 16781070]
15. Phan A, Edwards CL, Robinson EL. The assessment of pain and discomfort in individuals with mental retardation. Res Dev Disabil. 2005; 26:433–439. [PubMed: 16039095]
16. McGrath PJ, Rosmus C, Camfield C, Campbell MA, Hennigar A. Behaviours caregivers use to determine pain in non-verbal, cognitively impaired people. Dev Med Child Neurol. 1998; 40:340–343. [PubMed: 9630262]
17. Bodfish, JW.; Harper, VN.; Deacon, JR.; Symons, FJ. Western Carolina Center Research Report. 2001. Identifying and measuring pain in persons with developmental disabilities: A manual for the Pain and Discomfort Scale (PADS).
18. Bodfish, JW.; Harper, VN.; Deacon, JM.; Deacon, JR.; Symons, FJ. Issues in pain assessment for adults with severe to profound mental retardation. In: Oberlander, TF.; Symons, FJ., editors. Pain in children & adults with developmental disabilities. Baltimore: Paul H. Brookes Publishing Co; 2006. p. 173-192.

19. Phan A, Edwards CL, Robinson EL. The assessment of pain and discomfort in individuals with mental retardation. Res Dev Disabil. 2005; 26:433–439. [PubMed: 16039095]

20. Tapp, J. Procoder for digital video user manual. Nashville: The John F. Kennedy Center at Vanderbilt University; 2003.

21. Ekman, P.; Friesen, WV.; Hager, JC. Facial action coding system: the manual. Salt Lake City: Research Nexus Division of Network Information Research Corporation; 2002.

22. Oberlander TF, Gilbert CA, Chambers CT, O'Donnell ME, Craig KD. Biobehavioral responses to acute pain in adolescents with a significant neurologic impairment. Clin J Pain. 1999; 15:201–209. [PubMed: 10524473]

23. Craig KD, Hadjistavropoulos HD, Grunau RV, Whitfield MF. A comparison of two measures of facial activity during pain in the newborn child. J Pediatr Psychol. 1994; 19:305–18. [PubMed: 8071797]

24. Sayette MA, Cohn JF, Wertz JM, Perrott MA, Parrott DJ. A psychometric evaluation of the Facial Action Coding System for assessing spontaneous expression. J Nonverbal Behav. 2001; 25:167–185.

Table 1

Pain and Discomfort Scale (PADS) items used

Circle one score (0, 1, 2, 3, 4, or NA for each of the items listed)						
0 = Not present						
1 = Difficult to detect or only occurs once or twice during assessment						
2 = Occurs infrequently during assessment and is easy to detect						
3 = Occurs frequently during assessment and is easy to detect						
4 = Occurs almost continuously during assessment and is easy to detect						
NA = Not assessed						
Facial Expression						
Grimace	0	1	2	3	4	NA
Furrowed brow	0	1	2	3	4	NA
Change in eyes (eyes closed tight)	0	1	2	3	4	NA
Mouth open	0	1	2	3	4	NA
Lips pucker tight	0	1	2	3	4	NA
Pout	0	1	2	3	4	NA
Quiver	0	1	2	3	4	NA
Clenches teeth	0	1	2	3	4	NA
Body and Limbs						
Protects	0	1	2	3	4	NA
Flinches	0	1	2	3	4	NA

Table 2

Mean AU frequencies with standard deviations in parentheses in FACS during sham and active stimuli across time segments

	Stimulus Condition	
	Sham	**Active**
Segment 1 (baseline)	1.53 (1.44)	1.53 (1.35)
Segment 2 (stimulus)	1.52 (1.46)	1.78 (1.43)*
Segment 3 (recovery)	1.47 (1.27)	1.49 (1.34)

* $p < .05$

FACS possible range (0–13; 13 FAUs with each unit scored 0/1)

Table 3

Mean PADS scores with standard deviations in parentheses during sham and active stimuli across time segments

	Stimulus Condition	
	Sham	**Active**
Segment 1 (baseline)	4.45 (2.74)	4.44 (2.78)
Segment 2 (stimulus)	4.80 (2.69)	5.86 (3.11)*
Segment 3 (recovery)	4.22 (2.50)	4.24 (2.76)

* $p < .05$

PADS possible range (0–40; ten 4 point items); note: given that 4 of 5 stimuli were likely sub-threshold nociceptive it would be unlikely to observe PADS scores in the extremely high range; it was also likely there was a de facto range restriction given that most of the scoring for PADS was derived from facial change thus limiting the number of items and restricting range.