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CROSS-CULTURAL ADAPTATION OF DISTRESS ASSESSMENT INSTRUMENT IN CHILDREN UNDERGOING PAINFUL PROCEDURES

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ABSTRACT
The study aimed to translate, back-translate to the Portuguese-Brazil language and cross-culturally adapt the content of OSBD scale for the evaluation of distress in painful contexts in children. In first step, two forward translations were made of the instrument from English to Portuguese. A consensus of these translations was obtained in second step. A native English speaker back-translated the preliminary version of the scale in Portuguese into the original English (Step 3). In step 4, an expert in the use of the OSBD reviewed the backtranslated version. Then, the Portuguese version of the OSBD was submitted to a committee of experts. The final step was the pretest. Pretesting showed that the scale was useful and comprehensible for the evaluation of pain-associated distress in Brazilian children.
Keywords: Distress; Pain; Measure; Cross-Cultural Adaptation.

RESUMO
O estudo teve como objetivo traduzir, retrotraduzir para o idioma Português-Brasil e adaptar culturalmente o conteúdo da escala OSBD para a avaliação do estresse em contextos de dor em crianças. Na primeira etapa, duas traduções do instrumento foram realizadas do Inglês para Português. Um consenso destas traduções foi obtido na segunda etapa. Um tradutor nativo retrotraduziu a versão preliminar da escala em Português para o original em Inglês (Etapa 3). Na etapa 4, um especialista no uso da OSBD reviu a versão retrotraduzida. Em seguida, a versão em Português do OSBD foi submetida a uma comissão de especialistas. O passo final foi um pré-teste. O pré-teste mostrou que a escala foi útil e compreensível para a avaliação do estresse associada a dor em crianças brasileiras.
Palavras-chave
Estresse; Dor; Instrumento; Adaptação Transcultural.

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ADAPTAÇÃO TRANSCULTURAL DO INSTRUMENTO DE AVALIAÇÃO DO DISTÚRBIO EM CRIANÇAS SUBMETIDAS A PROCEDIMENTOS DOLOROSOS

Pain is an adverse and stressful experience that can have a negative impact on development and quality of life of the child. Acute pain has been shown to be positively associated with distress (Howard, 2005). Painful procedures are the major source of distress in pediatric patients and may have long-term consequences on behavior (Howard, 2003), memory (Kennedy et al., 2008), pain perception (Noel et al., 2012), and developmental outcomes in children (Valeri et al., 2015). Therefore, the assessment of distress is relevant to prevent behavior and emotional problems in children.

Regarding observational behavior instruments for the evaluation of distress associated with medical procedures in children, the Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (PedIMMPACT) consensus rated the Observational Scale of Behavioral Distress (OSBD) as a well-established measure (Elliott, Jay & Woody, 1987; Jay et al., 1983). The OSBD is an observational coding measure that covers 13 behaviors indicating child distress during painful medical procedures. Each behavior is coded for its presence or absence over continuous intervals of 15 seconds. Because certain behaviors are indicative of higher levels of distress than others, each behavior is weighted based on intensity, ranging from 1 to 4 (with 4 indicating greater intensity). The weights were created and assigned based on the mean ratings of personnel familiar with specific painful procedure instruments used to code behavioral distress. The OSBD has been shown to be a valid and reliable behavior distress instrument for use with children (Elliott et al., 1987).

The understanding that pain in children can be undertreated due to its difficult assessment has increased awareness of the need to use scales for the objective measurement of pain and distress. In different cultures, instruments need to be translated into the language of the specific country, as well as being culturally adapted, with the aim of maintaining the content validity of the measure (Beaton et al., 2000). The present study aimed to translate, back-translate and cross-culturally adapt the Observational Scale of Behavioral Distress (OSBD) for distress assessment during painful events in Brazilian children undergoing clinical treatments.

Methods

Participants

The following professionals participated in the translation stage: three specialist psychology researchers who were fluent in the English and Portuguese languages and had experience in pediatric pain issues. The back-translation stage was performed by a native English speaker, fluent in both languages. The following professionals participated in the review process: two experts fluent in English that had experience with the OSBD in their practices. In the cross-cultural adaptation stage, two psychology researchers composed the committee of experts to analyze the semantic, idiomatic, and conceptual equivalences of the items of the scale. All the professionals involved in the process were requested to suggest changes and corrections in the final version.

The pre-test stage was carried out with five children, aged 2-4 years, who were undergoing medical procedures in a Pediatric Intensive Care Unit (PICU) of a public teaching hospital in the southwest of Brazil (Clinical Hospital - HCFMRP-USP).

Ethical aspects

The study was approved by the Research Ethics Committee of the Clinical Hospital, Ribeirão Preto Medical School, University of São Paulo (Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo; HCFMRP-USP). All caregivers, who were the legal guardians of the children, signed the consent form prior to the initiation of the study.

Instrument

The OSBD is an observational coding measure that covers 13 behaviors (information seeking, verbal resistance, verbal fear, verbal pain, emotional support, cry, scream/yell, groan, rigidity, refusal position, restraint, flail, and nervous behavior) indicating child distress during painful medical procedures. Each behavior is coded for its presence or absence over continuous intervals of 15 seconds and is weighted based on intensity, ranging from 1 to 4 (higher scores indicating greater intensity). Overall distress scores were calculated by multiplying the total occurrence of each behavior by its

intensity weight, summing these weighted scores across all behaviors, and then dividing by the number of 15-second intervals. Distress scores for the specific phases of the procedure (anticipatory, procedural, and recovery) were calculated in a similar model using the total occurrence of behaviors in each phase and the number of intervals in each phase. This instrument has an evidence base of reliability and validity, and was designed in a pediatric context (Elliott et al., 1987).

Procedure

The study consisted of the following stages: translation, back-translation, cross-cultural adaptation of the OSBD and pre-test. The process consisted of five steps and was adapted from the methodology of Beaton et al. (2000). First, the original scale (coding form and coding manual) in English was translated into Brazilian Portuguese by two independent specialist psychology researchers who were fluent in both languages. These specialists were asked to use simple language with the purpose of capturing the meaning of the item rather than producing a literal translation. A third specialist psychology researcher created a consensus of these translations, obtaining the preliminary version (Step 2). This researcher had experience in pain studies and reconciled the discrepancies between the translations, designing a single document in Portuguese.

In the third step, a native English speaker, who was blinded to the original version, performed the back-translation of the preliminary version. The translator was also fluent in both languages and was unaware of the previous stages of the process. In step 4, an independent review was performed by two experts fluent in English that had experience with the OSBD in their practice. After being reviewed, the experts approved the backtranslated version. In step 5, the final Portuguese (Brazilian) version of the OSBD (EOEC - Escala de Observação de Estresse Comportamental) was submitted for appreciation by a committee of experts, composed of two other researchers that analyzed the semantic, idiomatic, and conceptual equivalences of the items of the scale. These researchers were informed about the objective of the study and its target population. They were asked to take into consideration the concepts of semantic equivalence, the referential meaning of the terms and the words used, as well as the general meaning of each behavior, the code options and the manual instructions.

After the cross-cultural adaptation process, a pre-test of the OSBD Portuguese (Brazilian) version was conducted. The pre-test was carried out with five pre-school age children, who were inpatients undergoing medical procedures in the Pediatric Intensive Care Unit. The OSBD was applied during needle procedures (acute pain event). The event was video recorded and subsequently coded by an expert and trained researcher.

Pre-test data analysis

The statistical descriptive analysis was performed using the Statistical Package for the Social Sciences (SPSS, version 23.0, Chicago, IL, USA) program.

Results

Cross-cultural adaptation process of the OSBD

Figure1. *S*ummarizes the steps of translation, back-translation and process of cross-cultural adaptation for Brazil.

Steps	Description
1st Step	Translations of the instrument were made from English to Portuguese (Brazilian) by two independent specialist psychology researchers.
2nd Step	Consensus of these translations was conducted by a third specialist psychology researcher, obtaining the preliminary version.
3rd Step	A native English speaker, who was blinded to the original version, performed the back-translation of the preliminary version.
4th Step	An expert in the use of the OSBD reviewed and approved the backtranslated version.
5th Step	The Portuguese (Brazilian) final version of the OSBD was submitted for the appreciation of a committee of experts, composed of two researchers that analyzed the semantic, idiomatic, and conceptual equivalences of the items of the scale.
Pre-test	The pre-test was carried out with five pre-school age children, who were inpatients undergoing medical procedures in the Pediatric Intensive Care Unit of a tertiary university hospital.

Note: OSBD = Observational Scale of Behavioral Distress/ EOEC = Escala de Observação de Estresse Comportamental.

Figure 1. Steps of the cross-cultural adaptation process of OSBD/ EOEC to the Portuguese (Brazilian) language.

All professionals involved in the process were requested to suggest changes and corrections in the version under analysis. The cross-cultural adaptation and the content assessment of the scale were carried out using the evaluation of two experts and the administration of a pre-test with the target populations that would benefit from this assessment in the future. The content assessment necessarily involved an examination to check whether the items of the scale were representative of what was intended to be measured (Cronbach & Meehl, 1955).

During the process, a few terms of the OSBD were changed with the purpose of making them as understandable as possible. Regarding the final version, all the professionals involved (100%) reported they could understand the scale and the psychologists who performed the pre-test verified their comprehension of the scale. Figure 2 presents the final version of the OSBD in the Portuguese (Brazilian) language.

Behavior category	Definition	Examples	No examples
Busca por informações	*Qualquer questão a respeito do procedimento médico.*	*Quando você vai parar?* *A agulha está dentro?*	*Eu vou receber um brinquedo?*
Resistência Verbal	*Qualquer expressão de atraso, término ou resistência.*	*Pare.* *Eu não quero isso.* *Não me machuque.*	*Eu te odeio.* *Isso é horrível.*
Verbalização de Medo	*Afirmação de estar apreensivo ou com medo do procedimento atual.*	*Estou com medo.* *Estou assustado.* *Estou nervoso.*	*Isso vai doer?*
Verbalização de Dor	*Afirmação de dor, dano, ou machucado.*	*Isso dói.* *Isso arde.*	*Isso vai doer?* *Isso é frio.*
Suporte Emocional	*Solicitação verbal ou não verbal de abraços, aperto de mão, conforto físico ou verbal pela criança.*	*Segure-me.* *Ajude-me.* *Mamãe, por favor.*	*Mamãe é utilizado como um nome.* *Mamãe me tira daqui.*
Chorar	*Sons de choro e/ou aparecimento de lágrimas*	*Soluçando.* *Contorcendo o rosto com aparecimento de lágrimas.*	*Fungando.* *Respiração pesada.*
Gritar	*Expressão vocal de dor ou angústia em tom alto/intensidade*	*Fortes, estridentes, altos tons.* *Gritos agudos.*	*Gritando com expressão de raiva.*
Resmungar	*Tom baixo, geralmente com maior duração.*	*Som de gemido.*	*Quando a afirmação verbal é expressa para fora.*
Rigidez	*Tensão muscular clara.*	*Punhos cerrados ou articulação rígida.* *Dentes apertados.* *Encolhido.*	*Debater-se.*
Comportamento de Recusa	*Não está de acordo com as instruções a respeito do posicionamento, após 2 solicitações.*	*Cobrir as pernas com as mãos quando a enfermeira está pronta para dar a injeção.*	*Antes de começar ou depois que os procedimentos são realizados.*
Contenção	*Criança deve ser contida fisicamente para baixo com pressão perceptível (pelo menos 2 mãos nas pernas ou no corpo).*	*Força puxando criança para a posição enquanto a criança resiste.*	*Procedimentos habituais dos enfermeiros necessários para manter criança em posição para o procedimento.*
Debater-se	*Movimentos aleatórios amplos dos braços e pernas ou do corpo inteiro, sem intenção de fazer contato agressivo.*	*Chutar com as pernas repetidamente e de forma aleatória.* *Jogando os braços para cima várias vezes e de forma aleatória.*	*Leve movimento da perna durante procedimento.* *Mudança de posição*
Comportamento nervosa	*Quaisquer sinais físicos de ansiedade.*	*Roer as unhas.* *Morder os lábios.* *Dedo ou pés inquietos, inquietação no corpo.*	*Não codifique respostas aleatórias (deve ser mantido por 3 segundos).*

Note: OSBD = Observational Scale of Behavioral Distress/ EOEC = Escala de Observação de Estresse Comportamental.

Figure 2. The OSBD/ EOEC Portuguese (Brazil) version: 13 behaviors categories.

Pre-test step

Table 1 presents the OSBD behaviors described in English and Portuguese and the respective scores obtained from the five children observed. The pre-test sample was composed of five inpatient pre-school age children, four boys and one girl, with a mean age of 3 years (± 1), who were submitted to needle procedures in the pediatric intensive care unit according to clinical requirements.

Table 1.
Pre-test results: OSBD/ EOEC Scores obtained with five children observed during painful procedures

Original Version (OSBD)	**Portuguese (Brazil) Version (EOEC)**	**Median**	**Minimum**	**Maximum**
Rigidity	*Rigidez*	27.5	7.5	35.0
Cry	*Chorar*	13.5	6.0	25.5
Nervous Behavior	*Comportamento nervoso*	7.0	0	20.0
Verbal Pain	*Verbalização de Dor*	0	0	32.5
Scream/ Yell	*Gritar*	0	0	24.0
Flail	*Debater-se*	0	0	24.0
Emotional Support	*Suporte Emocional*	0	0	18.0
Verbal Resistance	*Resistência Verbal*	0	0	10
Restraint	*Contenção*	0	0	8.0
Verbal Fear	*Verbalização de Medo*	0	0	7.5
Groan	*Resmungar*	0	0	7.5
Refusal Position	*Comportamento de Recusa*	0	0	4.0
Information Seeking	*Busca por informações*	0	0	0
Overall Score	*Escore Total*	4.3	2.0	6.2

Note: OSBD = Observational Scale of Behavioral Distress/ EOEC = Escala de Observação de Estresse Comportamental.

As can be seen in Table 1, the most frequent behaviors of the children were the following: cry, rigidity, and nervous behavior. Of these, rigidity was the behavior that indicated greater intensity (2.5). The only behavior that was not observed in this sample was information seeking. This specific behavior refers to any doubt regarding the medical procedures.

Discussion

Previous studies on pain issues have shown that pain continues to be under-assessed and under-treated in pediatric patients (Birnie et al., 2014; Taylor et al., 2008). The lack of an appropriate assessment of the pain of the child and its associated negative affects (e.g. distress) results in pain and its consequences remaining unrecognized, which leads to inappropriate management by the health professionals (Birnie et al., 2014; Taylor et al., 2008). The assessment of children during pain experiences is a challenge, as younger children or those with developmental delays require observational measures to identify indicators of pain and other associated negative affects (Cohen et al., 2008).

The majority of observational scales used in pain contexts include items that could be interpreted as indicators of pain or other negative emotions such as fear, anxiety, and distress. Some authors have recognized the difficulty in discriminating pain intensity from pain unpleasantness and from other emotions such as distress (von Baeyer & Spagrud, 2007). Scales that can differentiate pain intensity from its affective aspect or from other negative emotions are necessarily to prevent developmental behavior problems in children. In different countries these instruments need to be culturally adapted prior to their use in clinical practice. The aim of the present study was to translate to the Portuguese language, back-translate and cross-culturally adapt the OSBD Scale for the evaluation of distress associated with painful contexts in Brazilian children.

The choice of the OSBD instrument was mainly due to the fact that this scale has an evidence base for reliability and validity, and was designed in a pediatric context (Elliott, Jay & Woody, 1987; Pretzlik & Sylva, 1999). The OSBD instrument was classified as a "well-established" measure by the *Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials* - PedIMMPACT consensus (Dworkin et al., 2005; McGrath et al., 2008). This consensus establishes criteria regarding the quality of instruments, classifying them as "well-established", "approaching well-established", and "promising", based on the validity, reliability, and measurement detailing parameters. The classification of "well established" is given when the measure achieves the following criteria: validity, reliability, measurement accuracy that allows replication and publication by different groups of researchers in peer-reviewed journals.

The OSBD instrument is convenient to use, and useful in the practice and research. Recently, researchers have used this instrument to measure distress as an outcome to demonstrate the efficacy of non-pharmacological interventions, reflecting the sensitivity of this tool to changes in child distress behaviors in research and clinical settings (Sil, Dahlquist & Burns, 2013; Wohlheiter & Dahlquist, 2013).

It is important to note that when measures are to be used across cultures, the items must not only be translated well linguistically, but also must be culturally adapted to maintain the content validity of the instrument (Beaton et al., 2000). This study was concerned with the cultural adaption of both the behavior coding form and the coding manual, checking whether all the items of the scale were representative of what was intended to be measured and making them as understandable as possible with regard to the Brazilian culture.

In conclusion, the Brazilian version of the OSBD was shown to be easily comprehensible for the evaluation of acute pain-associated distress. The version showed content validity. This instrument will be applied with Brazilians samples, and may contribute to a better assessment of distress in children undergoing painful procedures. Future studies could evaluate the other psychometric properties of the Portuguese (Brazilian) version of the OSBD and apply this scale in different populations and settings in Brazil.

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