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Assessment of pain in children with cerebral palsy focused on translation and clinical feasibility of the revised FLACC score

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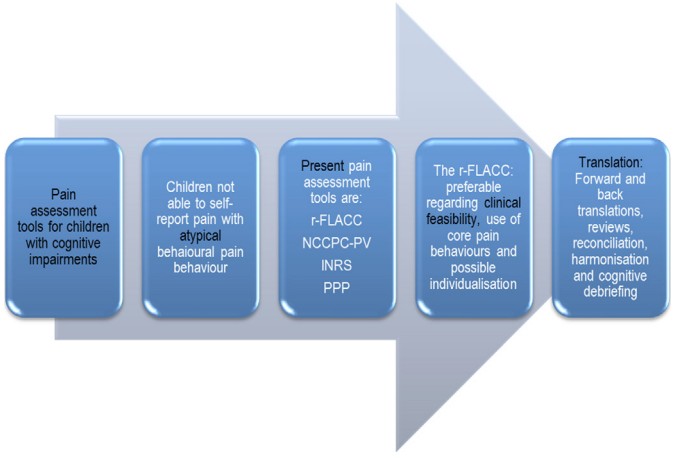
HIGHLIGHTS

- We evaluate pain assessment tools for children with cognitive impairments.
- Individualisation is essential in idiosyncratic atypical pain behaviour.
- r-FLACC is a valid, reliable and feasible behavioural pain score.
- We document the translation process of the r-FLACC.

GRAPHICAL ABSTRACT



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ABSTRACT

Background and aims: Assessment of pain in children with cognitive impairment (CI) including cerebral palsy (CP) is difficult. Several pain assessment tools have been developed and validated for use in children with CI. The revised Face, Legs, Activity, Cry and Consolability score (r-FLACC) includes core behaviours of children with CI and adds an open-ended descriptor for individualisation (5 items assigned 0–2 points, total range 0–10). Other pain assessment tools including individual pain behaviours are the Individualised Numeric Rating Scale (INRS) and the Paediatric Pain Profile (PPP). Both the Noncommunicating Childrens's Pain Checklist – Postoperative version (NCCPC-PV) and the Echelle Douleur Enfant San Salvador (DESS) are developed from core pain behaviours for children with CI but have no possibility for individualisation. For successful clinical application a pain assessment tool should not only be reliable and valid, but also clinically feasible. The aim of this study was to select the most valid and feasible pain assessment tool for children with CI and translate that tool into Danish.
Methods: A literature review on studies on pain, pain assessment tools, feasibility and CI was performed. Studies were evaluated with focus on children with CI not able to self-report pain and the r-FLACC was chosen for translation. A 10 step translation process guideline was used from the Translation and Cultural

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Adaptation Group, which describes preparation, forward translation, reconciliation, back translation, back translation review, harmonization, cognitive debriefing, review of cognitive debriefing, finalisation, proofreading, and final report.
Results: Studies show that the r-FLACC is superior regarding clinical feasibility. The r-FLACC is a useful tool for assessing pain in children with CI due to its ease to use in a clinical setting and its use of both core and individual pain behaviours. In the back translation review discrepancies of words between the original and the back-translated English versions were assessed and in three of nine discrepancies a word was changed. In the cognitive debriefing no issues were found regarding understandability, interpretation or cultural relevance of the translation. No other language translations of the r-FLACC score have been published; hence the harmonisation step with a comparison of the English back translations was not possible.
Conclusions: The r-FLACC is assessed to have the most preferable profile with use of core pain behaviours, flexibility regarding individualisation, good psychometric properties, and high clinical feasibility; hence suited for use in Danish children with CP. A Danish version of the r-FLACC score now exits and may be used in a clinical setting for the assessment of pain.
Implications: It is important for health-care professionals to be able to assess pain in hospitalized children with CP who are not able to self-report. The r-FLACC score is clinically feasible and has the potential for becoming the gold standard of pain assessments in children with CP. A standardised approach to pain assessment may lead to an increased focus on pain and help improve the treatment of pain in children with CP in Denmark.

1. Introduction

Assessment of pain in children with cognitive impairments (CI) represents a challenge. CI can be due to multiple causes, including cerebral palsy (CP). Self-report of pain is the gold standard but some children with CI may not have self-reporting ability; hence a valid, reliable and feasible behavioural pain assessment tool is necessary [1–3]. Pain behaviour in children with CI unable to self-report, is often atypical and confounded by baseline behaviour and physical disabilities leaving them particularly vulnerable to inaccurate pain assessment and management [4].

Several pain assessment tools have been developed for children with CI (Table 1) [4–11]. The revised Face, Legs, Activity, Cry and Consolability score (r-FLACC) was developed from the FLACC score by adding both core behaviours of children with CI (vocal, eating/sleeping, social/personality, facial expression, body/limbs and physiological) and an open-ended descriptor for individual pain behaviours and idiosyncratic atypical pain behaviour i.e. laughing, singing, clapping of hands, anger, self-injury [12,13]. Other scores including individual pain behaviours are the Individualised Numeric Rating Scale (INRS) and the Paediatric Pain Profile (PPP). In the INRS individual postoperative pain behaviour is stratified from 0 to 10 [10]. In the PPP everyday pain is assessed by 20 individualised behavioural items [9]. Both the Noncommunicating Childrens's Pain Checklist – Postoperative version (NCCPC-PV) and the Echelle Douleur Enfant San Salvador (DESS) are developed from core pain behaviours with no possibility for individualisation. The NCCPC-PV [8] is elaborate, acclaimed as being accurate but time-consuming. The DESS (10 items) is only validated for procedural pain [11]. The Multidimensional Assessment of Pain Scale (MAPS) includes behavioural and physiological pain variables and has good clinical feasibility though not validated for children with CI [14].

For successful clinical application a pain assessment tool should not only be reliable and valid, but also clinically feasible [14,15]. Studies have shown both better feasibility of the r-FLACC compared to the NCCPC-PV and that the NCCPC-PV was easier to use compared to the DESS [16]. Crosta et al. [4] concluded that the r-FLACC have better feasibility compared to both the NCCPC-PV, INRS and PPP. Chen-Lim et al. [17] found that 74% of nurses preferred the r-FLACC over the PPP with half reporting a completion time of 1 min or less for the r-FLACC compared to 3 min for the PPP.

Therefore, the r-FLACC appear to be the preferable tool for assessing pain in children with CI because of its clinical feasibility, use of core pain behaviours and individualisation [13]. Pain assessment tools are mostly developed in English and high quality translations are lacking. The Translation and Cultural Adaptation group (TCA Group) was initiated to review the literature and existing guidelines on translation and cultural adaptation and made a consensus on the methodology on translations of Patient-Reported Outcome Measures (PROM) requiring forward and back translations, reviews, reconciliation, harmonisation and cognitive debriefing of the translation [18].

The aim of this study was to select the most valid and feasible pain assessment tool for children with CI and document the translation of the r-FLACC into Danish.

2. Material and methods

2.1. r-FLACC score

A literature review on studies on pain, pain assessment tools, feasibility and CI was performed. Studies were evaluated with focus on children with CI not able to self-report pain, use of behavioural observations, assessments of the psychometric properties, possibility for individualisation, usefulness in a postoperative, procedural or everyday setting and clinical feasibility of the pain assessment tool. As a result the r-FLACC was chosen for translation.

The r-FLACC score is applicable for clinical pain assessments in children with CI and has the possibility of including the child's own characteristic and potentially atypical pain behaviours. Initially the child's individual pain behaviours have to be added to the r-FLACC score in an open-ended descriptor, whereupon the score is ready for individual pain assessment. An example of the parent-reported individual pain behaviours of a child with CP is presented in Fig. 1. When this is added to the r-FLACC score (Figs. 2 and 3) a more precise pain assessment can be made and assessments by primary caregivers, parents, physicians, physical therapists or nurses are possible. The r-FLACC score consists of 5 subgroups (Face, Legs, Activity, Cry and Consolability) in which the patient can be assigned 0, 1 or 2 points related to specific pain reactions, resulting in a total score between zero and ten, where 0 reflect no pain and 10 reflects the maximum level of pain.

2.2. Translation of the r-FLACC score

The translation process of the r-FLACC was initiated in 2010. In general the translation complies with the international

Table 1
List of pain assessment tools for children with CI and their characteristics. DESS: Echelle Douleur Enfant San Salvador, INRS: Individualised Numeric Rating Scale MAPS: Multidimensional Assessment of Pain Scale, NCCPC-PV: Noncommunicating Childrens's Pain Checklist–Postoperative version, PPP: Paediatric Pain Profile, r-FLACC: Revised Face, Legs, Activity, Cry, Consolability, VAS-OBS: Visual Analogue Scale Observer.

Pain score	Target description	Score description	Pros	Cons
DESS	Age 6–33, CI. Validated for procedural pain ($n = 50$).	10 items scored 0–4. Total range 0–40.	Items developed to include anxiety, direct signs of pain and unusual psychic or motor troubles.	Requires familiarity with the child. Low clinical feasibility. Only validated for procedural pain. Not including individual pain behaviour.
INRS	Age 6–18, CI Validated for postoperative pain ($n = 50$).	Parents recall past pain behaviours rating them from 0 to 10.	Created uniquely for each patients individual pain behaviour	Only based on parents' or caregivers' interpretations. Low evidence on clinical feasibility.
MAPS	Age 0–31 mo, not CI. Validated for postoperative pain ($n = 19$).	Similar to r-FLACC with 5 items scored 0–2.	High clinical feasibility, physiological parameters. Similar to r-FLACC	Not validated for CI or everyday pain. Low evidence on clinical feasibility. Not including individual pain behaviour.
NCCPC-PV	Age 3–19, CI. Validated for postoperative pain ($n = 25$).	27 items, 6 categories scored 0–3. Total range 0–81.	Acclaimed for accuracy	High complexity, low clinical feasibility. Elaborate and time-consuming. Not including individual pain behaviour.
PPP	Age 1–18, CI. Validated for everyday pain ($n = 140$).	20 items scored 0–3, including required pain history, baseline, ongoing assessments, interventions and outcomes. Total range 0–60 points.	Variable time frame, individualised by interviews with both parents and health care professionals.	Requires familiarity with the child. Not validated for clinical postoperative use. Elaborate and time-consuming. Low clinical feasibility. Designed only for use by parents.
r-FLACC	Age 4–21, CI. Validated for postoperative pain ($n = 52$).	5 items scored 0–2 points. Total range 0–10. Open-ended descriptor for possible individual pain behaviour.	High clinical feasibility, includes individual pain behaviour.	Validation study included both self-reporting and non-self-reporting children with CI.

guideline set up by the Translation and Cultural Adaptation Group. This guideline consists of 10 steps which are defined as the framework in the translation process [18]. The study was approved by the local ethics committee (M-20100189) and the Danish Data protection Agency (1-16-02-97-10).

In the first step, preparation, the original developer of the r-FLACC pain score was contacted and permission for beginning the translation process was obtained. Furthermore, the original developer was invited to be involved in the translation process but declined. The second step is the forward translation from English into Danish and this was performed independently by two different medical doctors (LKP, LN) who both were native speakers of the target language (Danish), residing in the target country (Denmark) and fluent in the source language (English). Step three is reconciliation, in which a translation panel consisting of the two forward translators, a nurse specially trained in pain monitoring and a native person (Danish) with an education in the source language (English) reconciled the Danish forward translation. First, the two forward translators compared their translations

Fig. 1. Example of individual pain behaviours of a child with CP. These behaviours are to be added to the r-FLACC score in the open-ended descriptors in each of the five categories.

and agreed on a single final version. This version was reviewed by the last two persons in the panel in order to correct any cultural, medical or linguistic problems. In the fourth step a back translation into English was performed by a professional certified native (Danish) translator educated in translating English medical texts. This translation was primarily literal and a conceptual review was undertaken in the back translation review. Step five is a back translation review, where a comprehensive review of the English back translation against the original English version was conducted in order to make revisions eliminating discrepancies. As a result of this several words in the r-FLACC score were discussed with a source language (English) specialist. Harmonisation, step six, includes a literature search to identify English back translations of multiple language versions in order to perform comparisons to the English back translation of the Danish version. Step seven is a cognitive debriefing, in which the Danish version of the r-FLACC and questionnaire was reviewed and used in a small clinical setting on patients and parents in order to check understandability, interpretation and cultural relevance of the translation. Step eight and nine includes a review of cognitive debriefing results and finalisation where no discrepancies were found and no amendments were required and a proofreading of the r-FLACC score in order to correct any typographic, grammatical or other errors. The last step is presenting the final report of the translation process and present description is the final report on the translation of the r-FLACC score (Figs. 2 and 3).

3. Results

Current literature suggests that the r-FLACC score is preferable for pain assessments in children with CI, hence the r-FLACC was chosen for translation. The Danish version of the r-FLACC pain score is the end result of this part of the study (Fig. 3). In the back translation review all discrepancies were assessed and listed in Table 2. The changes made in the back translation into English completed the translation process but caused no change in the forward translation and final Danish version of the r-FLACC. In six instances of discrepancies no changes were made, since the basic meaning of the words were identical. In three instances of discrepancies in the back translation review, a change of a word/phrase in the forward translation was made. The word "splinting respiration" was

r-FLACC score for pain assessment in children with cerebral palsy.

Face:
0 point: No particular expression or smile
1 point: Occasional grimace/frown; withdrawn or disinterested; *appears sad or worried*
2 point: Consistent grimace or frown; frequent/constant quivering chin, clenched jaw; *distressed-looking face; expression of fright or panic*
Individualized behavior:

Legs:
0 point: Normal position or relaxed; *usual tone & motion to limbs*
1 point: Uneasy, restless, tense; *occasional tremors*
2 point: Kicking, or legs drawn up; *marked increase in spasticity, constant tremors or jerking*
Individualized behavior:

Activity:
0 point: Lying quietly, normal position, moves easily; *Regular, rhytmic respirations*
1 point: Squirming, shifting back and forth, *tense or guarded movements; mildly agitated (e.g. head back and forth, agression); shallow, splinting respirations, intermittent sighs.*
2 point: Arched, rigid or jerking; *severe agitation; head banging; shivering (not rigors); breath holding, gasping or sharp intake of breaths, severe splinting*
Individualized behavior:

Cry:
0 point: No cry/verbalization
1 point: Moans or whimpers; occasional complaint; *occasional verbal outburst or grunt*
2 point: Crying steadily, screams or sobs, frequent complaints; *repeated outbursts, constant grunting*
Individualized behavior:

Consolability:
0 point: Content and relaxed
1 point: Reassured by occational touching, hugging or being talked to. Distractible.
2 point: Difficult to console or comfort; *pushing away caregiver, resisting care or comfort measures*
Individualized behavior:

Fig. 2. The r-FLACC score for pain assessment in children with cerebral palsy. Revisions from the original FLACC score to this r-FLACC score are noted in italics.

r-FLACC score til bestemmelse af smerter hos børn med cerebral parese

Face / Ansigt:
0 point: Neutralt udtryk eller smil
1 point: Lejlighedsvis grimassering/panderynken; tilbagetrukket el. uinteresseret; *virker ked af det eller bekymret*
2 point: Vedvarende grimassering eller panderynken; hyppig/konstant dirrende hage, sammenbidte tænder; *stresset ansigtsudtryk; udtrykker frygt eller panik*
Individuel adfærd:

Legs / Ben:
0 point: Normal eller afslappet stilling; *normal muskelspænding & bevægelse af ben*
1 point: Urolige, rastløse, anspændte; *lejlighedsvise rystelser*
2 point: Sparkende, eller benene trukket op; *markant øget spasticitet, konstante rystelser eller spjæt*
Individuel adfærd:

Activity / Aktivitet:
0 point: Ligger stille, normal stilling, bevæger sig frit; *regelmæssig rytmisk, vejrtrækning*
1 point: Vrider sig, flytter sig frem og tilbage, *anspændte el. forsigtige bevægelser; let agiteret (f. eks bevæger hovedet frem og tilbage, aggression); overfladisk, indtrækninger, lejlighedsvise suk.*
2 point: Kroppen spændt som en bue, stiv eller spjættende; *svær agitation; slår med hovedet; skælven (ikke kulderystelser); holder vejret, gisper el. skarpe vejrtrækninger, svære indtrækninger*
Individuel adfærd:

Cry / Gråd:
0 point: Ingen gråd/ udtrykker sig ikke i ord om smerte.
1 point: Støn el. klynk; lejlighedsvis klagen; *lejlighedsvise verbale udbrud eller stønnen*
2 point: Græder vedholdende, skriger eller snøfter, hyppige klager; *gentagne udbrud, konstant stønnen*
Individuel adfærd:

Consolability / Trøstbarhed:
0 point: Veltilpas og afslappet
1 point: Beroliget ved lejlighedsvis berøring, knus el. ved at blive talt til. Kan afledes.
2 point: Svær at trøste eller få til at føle sig tilpas; *skubber plejepersonale og pårørende væk, modsætter sig omsorg el. tiltag for at opnå veltilpashed*
Individuel adfærd:

Fig. 3. The Danish version of the r-FLACC score for pain assessment in children with cerebral palsy. Revisions from the original FLACC score to this r-FLACC score are noted in italics.

Table 2
List of the discrepancies of words found in the back translation review and the subsequent changes.

Original version *(English)*	Forward translation *(Danish)*	Back translation *(English)*	Remark
Sad	"Ked af det"	Upset	Changed to feel unhappy, no change in forward translation
Clenched jaw	"Sammenbidte tænder"	Clenched teeth	No change. Difference due to literal translation and not conceptual
Fright or panic	"Frygt eller panik"	Fear or panic	No change
Marked	"Markant"	Significant	No change
Quietly	"Stille"	Still	No change
Moves easily	"Bevæger sig frit"	Moves freely	No change
Guarded movements	"Forsigtige bevægelser"	Careful movements	No change
Mildly agitated	"Let agiteret"	Slightly agitated	No change
Aggression	"Vrede"	Anger	Changed to "aggression" in forward translation
Head banging	"Slår med hovedet"	Head shaking	Changed to "slår hovedet imod noget" in forward translation
Sharp intake of breaths	"Hiver efter vejret"	Fighting for breath	Changed to "skarpe vejrtrækninger" in forward translation

discussed with a source language person (United States) due to the lack of a conceptual similar word in the target language.

In the cognitive debriefing the Danish version of the r-FLACC score was used for postoperative pain assessment in children with CP by the parents and the primary investigator. No issues were found regarding understandability, interpretation or cultural relevance of the translation.

In the harmonisation step a literature search was performed. Since no other language translations of the r-FLACC score have been published, a comparison of the English back translation to multiple language versions could not be performed.

4. Discussion

This study evaluated the pain assessment tools available for children with CI and found the r-FLACC valid, reliable and clinically feasible. Hence, a translation process into Danish using back and forward translations in accordance with the international guidelines set up by the Translation and Cultural Adaptation Group was performed. The translation of the r-FLACC pain score through approved techniques gives a clinically useful high quality Danish version, which is feasible in daily practice.

Several factors are to be considered in the choice of a pain assessment tool for children with CI. Is the score based on self-report, behavioural observations or physiological measurements? Does it require assessment only by parents or health-care professionals or both? Have the psychometric properties of the score been assessed (validity, reliability and responsiveness)? Is it validated for use in a postoperative, procedural or everyday setting? Can individual pain behaviour be incorporated in the assessment of pain? Is the score clinically feasible?

Malviya et al. [13] stated that the original FLACC score developed for cognitively healthy children had low reliability in the "legs and activity" items when used for assessment of pain in children with CI, reflecting the presence of baseline motor impairment. After revision, the r-FLACC showed excellent agreement in all five items. The INRS, the NCCPC-PV and the r-FLACC are validated for postoperative pain assessments in children with CI. The r-FLACC has the advantage of the possibility of individualisation, which the NCCPC-PV lacks and the standardisation that the INRS omits. The discussion on standardisation versus individualisation of a pain assessment tool continues in a review by Crosta et al. [4], who conclude that incorporating elements of both is ideal and a score that solely relies on parent or caregivers input is not a dependable pain measure method for all situations. The PPP and the DESS are primarily validated for everyday pain assessments and procedural pain, respectively, and comparisons to a clinical postoperative setting should only be made with cautions. Since the validation of the PPP was focused on everyday pain it included a low number of patients with high PPP scores and might therefore be best for assessment of mild to moderate pain [9].

The translation from research to clinical use is highly dependent on the clinical feasibility of the pain assessment tool. Recently a number of feasibility studies have been published [4,15,16,19]. Voepel-Lewis suggests that although the psychometric properties are necessary to ensure accurate pain assessment, the ability to implement these tools into busy daily routines may depend largely on their pragmatic qualities defined as complexity, compatibility and relative advantage. The PPP and NCCPC-PV may have good psychometric properties, but high complexity with many items and a high total score makes them time-consuming with low clinical feasibility. In a review by Crosta et al. [4] the r-FLACC was the preferred pain assessment tool of the majority of nurses because of its ease of use in a variety of inpatients settings, its inclusion of parent report, its low time to complete and score the instrument and its flexibility of being used with or without parental input.

By using the international translation guidelines a thorough analysis of the cultural and linguistic differences between the original language and target language has been accomplished hence establishing cross-cultural validity. Each step in the translation process is discussed by Wild et al. [18] after a review of 12 sets of guidelines available for translation and cultural adaptation. This study adheres to these steps, hence increasing the quality of the translation, although some points of discussion can be made. Permission for translation was obtained from the developers of r-FLACC respecting copyright, but the developers declined to be involved in the translation process, which poses a risk of misinterpretation of items or conceptual equivalence of the forward translation. The reconciliation of the forward translation was done by both the forward translators and an independent native speaker of the target language in order to avoid both misinterpretations in addition to avoiding a biased translation that is written in one person's own personal style or speech habit. Opposite to the agreement of Wild et al. [18] the present translation uses a native translator

of the target language and not of the original language. Since the translator has a special education in translating English medical texts the authors are convinced that the psychometric performance is maintained from the original version to the back translated version and that no conceptual differences exists. This is in accordance with the fact that the back translation review only suggested a change in 3 words in the forward translation. The TCA group [18] states that harmonisation is a key objective of the translation and cultural adaptation process but this step has been omitted from the majority of guidelines. The harmonisation of all new translations with each other and the source version is a quality control step and ensures that data from global trials can be safely aggregated. To the best of our knowledge translation of the r-FLACC score into other languages has not been published, hence harmonisation was impossible. The last step is publicising the final report, which might be flawed due to difficulties in getting reports on translation processes into non-English languages accepted for publication in internationally indexed journals.

5. Conclusions

When determining the most appropriate pain assessment tool many factors need to be considered. After reviewing the literature, the r-FLACC was assessed to have the most preferable profile with use of core pain behaviours, flexibility regarding individualisation, good psychometric properties, and high clinical feasibility; hence suited for use in Danish children with CP. A Danish version of the r-FLACC score now exits and may be used in a clinical setting for the assessment of pain. The process of translation used increases the quality of the score.

6. Implications

It is of critical importance for health-care professionals to have the ability to assess pain in hospitalized children with CP who are not able to self-report. The r-FLACC score is a clinically feasible tool for recognizing and assessing pain in children with CP and has the potential for becoming the gold standard of pain assessments in children with CI, e.g. CP. A more uniform and standardised approach to pain assessment may lead to an increased awareness of pain in children with CP and increased focus may help to improve the treatment of pain and as a consequence the quality of life of children with CP in Denmark.

Conflicts of interest

The authors have no conflict of interest.

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