Translation and psychometric evaluation of a Swedish version of the parental stressor scale PSS: NICU.

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Translation and psychometric evaluation of a Swedish version of the parental stressor scale PSS: NICU

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ABSTRACT

Aim: The aim was to translate the Parental Stressor Scale: Neonatal Intensive Care Unit (PSS: NICU) into the Swedish language and to evaluate the psychometric properties of the Swedish version.

Method: The PSS: NICU was translated into Swedish using the process of forward-backward translation. Thereafter an internal panel of neonatal nurses (n=10) assessed face and content validity and a panel of parents (n=10) assessed content validity. A sample of 95 parents recruited from three different neonatal units completed the PSS: NICU and answered some open-ended questions in which they could comment on language and wording. There were eight new items in the PSS: NICU, compared to the very first version of the instrument. These had not been psychometrically tested previously. In this study the subscales and total scale were analysed both with and without the new items to determine whether or not to use them. Psychometric properties including internal consistency, Cronbach’s alpha (if item deleted) and corrected item total were evaluated.

Result: The result indicates that the Swedish version of PSS: NICU, both with and without the non-validated items, has acceptable psychometric properties and can be used in clinical practice in NICUs in Sweden.

Conclusion: In order to meet the psychological needs of parents, healthcare professionals need to identify risk factors in the Neonatal Intensive Care Unit that contribute to stress amongst parents. The Swedish version of the PSS: NICU can be used for this purpose.

Keywords: parental stress, Parental Stressor Scale: Neonatal Intensive Care Unit, psychometric evaluation.

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INTRODUCTION
It has been well established that the hospitalisation of a preterm born infant, in addition to the period after hospital discharge, is stressful for parents (1-3). The initial hospitalisation period might also affect the parents in a long-term perspective and earlier research has demonstrated an increased risk of post-traumatic stress disorders amongst parents caused by the initial hospitalisation of their infant (2, 4). Measuring parental stress will evaluate the effectiveness of nursing care and also help the professionals assess each parent’s progress in coping with their situation (5, 6). The Parental Stressor Scale: Neonatal Intensive Care Unit (PSS: NICU) is a well-documented instrument offering this possibility.

Parental Stressor Scale: Neonatal Intensive Care Unit was developed by M.S. Miles and colleagues (7) to measure parental perception of stressors that occur from the physical and psychosocial environment in the Neonatal Intensive Care Unit (NICU). The instrument includes three dimensions (subscales): Sights and Sounds of the unit, Infant Behaviour and Appearance, and Parental Role Alteration (7, 8).

These dimensions are known to be stressful for parents whose infant needs neonatal care (6, 9, 10). The PSS: NICU (7) was adapted from the Parental Stressor Scale: Pediatric Intensive Care Unit [PSS: PICU] (11) and aims to measure parental perception of stressors in the NICU. The instrument PSS:PICU was altered in order to reflect the stress that was associated with the appearance and behaviour of a preterm infant, changes in the parental role that differ for the parents of a preterm or new-born sick infant, and differences in the routines and environment in an NICU. Observations carried out in an NICU, interviews with parents, consulting with parents groups and previous literature formed the revision of the instrument. The acceptable alpha coefficients, ≥0.70 for all subscales as well as total scale showed that the PSS: NICU could serve as a reliable clinical instrument to evaluate the stressors experienced by parents in an NICU (7, 8).

The PSS: NICU has been translated into several languages and tested in several countries; however, no Swedish version has been available. Frank et al. (2005) established the instruments psychometric properties in a British sample and compared the scores with a reference sample from the United States. The PSS: NICU scores were similar in Britain and the United States samples. Cronbach’s alpha coefficients for the subscales varied between 0.77 and 0.96, which indicated good internal consistency (9). Another British study by Reid and Bramwell investigated the stress occurrence of mothers of moderate preterm infants. However, they also carried out a psychometric test and Cronbach’s alpha coefficient varied between 0.81 and 0.85 for the different subscales (12). The instrument was also translated into Turkish and a study was conducted, showing that the Cronbach’s alpha coefficient for all subscales was within acceptable limits, ranging between 0.78 and 0.88. For the two different scoring methods, described as Metric 1 and Metric 2, the alpha coefficients for the total scale were 0.89 and 0.90 respectively (6). In an Italian study Montiroso et al. (10) measured maternal stress and support in 25 NICUs and found that PSS: NICU has appropriate psychometric properties when tested on a large population (n=156), the Cronbach’s alpha coefficient varied between 0.79 and 0.89 for the different subscales. In a cross-cultural study between New Zealand and Japan, the translated Japanese version was tested for internal consistency and indicated good levels in Cronbach’s alpha coefficient for Metric 2, ranging
from 0.77 to 0.94. Metric 1 was not tested in this study. Internal consistency of the PSS: NICU in the New Zealand population indicated a good level in Metric 2, with Cronbach’s alpha coefficient ranging from 0.79 to 0.95, except for one subscale (sights and sounds), which was calculated as 0.56 (13).

Health care professionals play an important role in helping parents to adjust to different stressors in the NICU. By identifying the factors contributing to parents’ stress, they can assist parenting adaptation and thereby promote parent-infant relationship (14). The aim of this study was to translate the PSS: NICU into the Swedish language and to establish the content and construct validity and the reliability of the instrument.

METHODS
Design and setting
The study was divided in two steps. The first was translation of the PSS: NICU from the original version into a Swedish. The second step was to evaluate the psychometric properties. The study was conducted at three NICUs in southern Sweden.

Instrument
The instrument includes three subscales: Sights and Sounds of the unit (6 items), Infant Behaviour and Appearance (17 items) and Parental Role Alteration (11 items) (7, 8). In the Infant Behaviour and Appearance and Parental Role Alteration subscales, the final four items have been added since the first version and are not psychometrically tested [Appendix 1]. These items were added by Miles to reflect the changes in neonatal care and the increased survival of extremely preterm infants. Therefore, in the present study, the subscales and total scale have been analysed both with and without the new items in order to determine whether or not they should be used.

Parents first indicate whether they have experienced the item listed and then rate the level of stress caused by the experience on a 5 point Likert scale ranging from 1 “not at all stressful” to 5 “extremely stressful”. If the parents have not experienced something listed, they are able to indicate this by choosing Not Applicable [NA]. Finally, an additional item asks parents to rate the overall stress of their experience of having an infant in an NICU.

The PSS: NICU provides two possible scoring methods: the stress occurrence level (Metric 1) and the overall stress (Metric 2) (7, 8). Metric 1 is the level of stress experienced by the parents when a situation occurs. Only those who have had the experience receive a score on the item. NA is coded as missing. Scale scores for each subscale as well as total scale are calculated by averaging the stress responses for the items experienced. The denominator is the number of items answered by the parents on each respective subscale. Metric 2 calculate the overall level of stress from the environment. It calculates the stress score using all the items, giving a rating of 1 (not at all stressful) for those items not experienced by the parents. According to this scoring method, NA will thus be changed to 1. Scale scores in Metric 2 are determined by calculating a mean value for the stress responses in the different subscales and the denominator is the total number of items on each subscale (7, 8). In this study, internal consistency is calculated for both Metric 1 and Metric 2, whilst the other analyses are related to scoring method 1.
Translation procedure
The translation of the instrument PSS: NICU was conducted according to guidelines set by Streiner and Norman (15) which are in line with the developing process by Miles et al. (7). These guidelines by Streiner and Norman (15) recommend a translation from the original language to the target language and then a back translation by two bilingual translators. First a native Swedish speaker translated the instrument from the original English version into a Swedish version. Then a back-translation from Swedish to English by a native English speaker was conducted. Neither of the translators was familiar with the purpose of the instrument. During the translation process the first and last authors compared the Swedish version with the original version, discussed the differences and possible cultural differences to confirm good content validity, and discussed language uncertainties with the translators.

The translated version was then reviewed by a group of neonatal nurses (n=10) at a level III NICU to modify the wording in accordance with cultural aspects and to establish face and content validity. Furthermore, the translated instrument was reviewed for content validity by a group of parents (n=10) who have had an infant in the NICU. The charge nurse selected the group of parents according to the inclusion criterion – parents that understand and spoke Swedish. The parents who participated in the content validity process were contacted by letter and given an information sheet explaining the study. All parents gave written consent to participate. The parents completed the instrument and evaluated the language and the wording in accordance with cultural aspects. Minor adjustments were made after the review of the instrument by the nurses and by the parents.

Sample and data collection
Of 189 parents in total, 95 completed the instrument during an 18-month period, and 19 participants represented the same family. The parents were recruited from two level II NICUs, at two different hospitals– where obstetrics and paediatric departments were present (n=27, n=55), and one tertiary NICU – with full resources for obstetric and neonatal intensive care, n=13 (16). All parents of infants admitted to the NICUs were eligible for participation. Exclusion criteria were parents of infants who had been transferred from another hospital and parents who neither understood nor spoke Swedish. Both parents were offered the opportunity to complete the instrument.

A registered nurse, who was not involved in the direct care of the infant, informed the parents of the study and invited them to participate between the third and the fifth day after the infant’s admission to the NICU – if the parents had previously visited their infant at least once. The study was conducted in accordance with the Helsinki Declaration (2013). All parents received written and verbal information about the study; the right to withdraw without giving any reason; the guarantee of confidentiality and that no findings would be associated with specific persons. They gave their written consent to participate. The Ethics Committee at the University of Lund (LU 173-2006) approved the study. In 2009 permission to translate and psychometric test the PSS: NICU was obtained from the original author of the instrument (Miles, M. S.).

Parents provided information via a form to collect standard infant demographic and clinical characteristics such as age, diagnosis received and mechanical ventilation as well as parent characteristics such as age, education and neonatal experience. Parents completed the
questionnaire PSS: NICU and answered some open-ended questions which they could comment on language and wording.

**Statistical analysis**
The data analysis was conducted using IBM SPSS Statistics (version 22: IBM Corporation, Armonk; NY, USA). Descriptive statistics (mean, SD) were calculated for Metric 1 with and without the new non-validated items. Internal consistency was calculated for both Metric 1 and Metric 2 using Cronbach’s alpha coefficient (17) and a coefficient ≥0.70 was interpreted as acceptable. Cronbach’s alpha if item deleted and corrected item total were calculated for the subscales and the total scale for Metric 1. Alpha if item deleted represents the scale’s Cronbach’s alpha coefficient for internal consistency if an individual item was removed from the scale. The alpha if item deleted was compared with the final alpha value and if item deleted was lower than the final alpha it was assessed that the item fits into the scale. Corrected item total indicates the degree to which each item correlates with the total score when the single item is removed from the total score. When analysing corrected item total, the item should correlate with the total score above 0.20 (15). Construct validity was investigated by analysing the correlation between the PSS: NICU’s subscales and total scale using Spearman rank-order correlation (15). To determine the instruments ability to detect differences floor-ceiling effects (i.e., the percentage scoring the lowest and highest score) were examined. A proportion of < 15 % is considered a low and acceptable floor-ceiling effect (18).

**RESULT**
The overall response rate was 50.3 %. The instrument was fully completed by the parents; however there was an option to answer NA for each item and the total amount of NA corresponds to 31.1 % with the highest value for item 6 in the subscale sights and sound “having a machine breathe for my baby”. In total 87 % scored this item “not applicable”. However, of those who had experienced this item, 6.5 % found it to be stressful on some level.

Most of the parents answered the open-ended questions about the language and wording, and they described the language in the instrument as easy to understand and read.

**Parent and infant characteristics**
Over an 18-month period, 95 parents completed the instrument during their NICU stay; parent characteristics are shown in Table 1. Among the infants (n=108) seven were twins and two were triplets. The average birth weight was 2399 g and varied between 430 to 4390 g. The gestational age at birth (gestational week and days), mostly determined by ultrasound measurement during the second trimester, ranged between 23+6/7 and 42+0/7 (Mean 34+6/6). An Apgar score between 7 to10 was the most common value (50 %). About 13 % of the infants had mechanical ventilation, 21 % had nCPAP and 30 % was cared for in an incubator. The most common diagnoses were preterm (50 %), SGA (17 %) and respiratory disorder (11%).
Table 1 Parent characteristics

<table>
<thead>
<tr>
<th></th>
<th>Mothers (n= 61)</th>
<th>Fathers (n= 34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Year (Mean, SD)</td>
<td>31 (SD =4.81)</td>
<td>33 (SD = 5.38)</td>
</tr>
<tr>
<td>Educational qualification, (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary</td>
<td>33.8</td>
<td>44.1</td>
</tr>
<tr>
<td>University degree</td>
<td>67.2</td>
<td>55.9</td>
</tr>
<tr>
<td>Earlier experience of neonatal care, (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9.8</td>
<td>8.8</td>
</tr>
<tr>
<td>No</td>
<td>90.2</td>
<td>91.2</td>
</tr>
<tr>
<td>NICU visit in total when completed the instrument, (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-5</td>
<td>9.8</td>
<td>5.9</td>
</tr>
<tr>
<td>5-10</td>
<td>11.5</td>
<td>26.5</td>
</tr>
<tr>
<td>&gt;10</td>
<td>75.4</td>
<td>61.8</td>
</tr>
</tbody>
</table>

PSS: NICU characteristics
Descriptive statistics for the PSS: NICU, Metric 1 (stress occurrence) with and without the added items are shown in Table 2. The mean values are concentrated to the lower part of the scale, ranging from 1.47 to 1.62 with nonvalidated items included, and 1.62 to 1.78 when these items were excluded. The standard deviations were modest. The floor and ceiling effect was within the recommend range, <15% of the respondents received the highest or the lowest value.

Table 2 Descriptive statistics for Parent Stressor Scale: Neonatal Intensive Care Unit (PSS: NICU)

<table>
<thead>
<tr>
<th>PSS:NICU Scales</th>
<th>Sights and Sounds</th>
<th>Infant Behaviour and Appearance</th>
<th>Parental Role Alteration</th>
<th>Total score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metric 1</td>
<td>Mean</td>
<td>1.47</td>
<td>1.41</td>
<td>1.48</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>1.33</td>
<td>0.80</td>
<td>0.92</td>
</tr>
<tr>
<td>Metric 1*</td>
<td>Mean</td>
<td>1.62</td>
<td>1.78</td>
<td>1.62</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>0.88</td>
<td>1.12</td>
<td>0.77</td>
</tr>
</tbody>
</table>

*The new non-validated items is excluded

Internal consistency
Cronbach’s alpha coefficients for the Swedish version of the PSS: NICU indicated acceptable internal consistency for each subscale as well as the entire scale (Table 3). When analysing the two subscales with the new added items (Infant Behaviour and Appearance and Parental Role Alteration) Cronbach’s alpha coefficient remained acceptable (Table 3). Cronbach’s
alpha if item deleted varied between 0.843 and 0.870 for the total scale, corresponding values for the subscales were as follows: Sights and Sounds 0.644 to 0.811, Infant Behaviour and Appearance 0.665 to 0.745 and Parental Role Alteration 0.811 to 0.838. Cronbach’s alpha, if item deleted when the new nonvalidated items were excluded, varied between 0.810 and 0.851 for the total scale and for the subscales Infant Behaviour and Appearance 0.582 and 0.690 and Parental Role Alteration 0.787 and 0.815.

**Construct validity**
Corrected item total correlation varied between 0.140 – 0.659 for the total scale; and for the subscales, correlation varied between; Sights and Sounds 0.118 and 0.768, Infant Behaviour and Appearance 0.113 and 0.625 and for Parental Role Alteration 0.312 and 0.643. Corrected item total when the non-validated items were excluded varied between 0.140 and 0.657 for the total scale, and for the subscales between: Infant Behaviour and Appearance 0.110 and 0.598 and Parental Role Alteration 0.464 and 0.626. The item “Having a machine (respirator) breathe for my baby” in the subscale Sights and Sounds was below 0.20 when the subscale was calculated. However, as a part of the total scale it was over 0.20. The items “The unusual colour of my baby (for example looking pale or yellow jaundiced)” and “The small size of my baby” in the subscale Infant Behaviour and Appearance was below 0.20 when the subscale was calculated, as well as in the total scale. The relationship between PSS: NICU subscales and total scale was investigated using Spearman’s rank order correlation to describe the strength (and direction) of the relationship between two variables, see Tables 4 and 5.

**Table 3** Alpha Coefficients (Cronbach’s alpha) for PSS: NICU Scales using Metric1 (Stress Occurrence Level) and Metric 2 (Overall Stress Level)*

<table>
<thead>
<tr>
<th>SCALE</th>
<th>METRIC 1</th>
<th>METRIC 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sights and Sounds</td>
<td>0.756</td>
<td>0.763</td>
</tr>
<tr>
<td>Infant Behaviour and Appearance</td>
<td>0.727</td>
<td>0.856</td>
</tr>
<tr>
<td>Infant Behaviour and Appearanceb</td>
<td>0.642</td>
<td>0.842</td>
</tr>
<tr>
<td>Parental Role Alteration</td>
<td>0.852</td>
<td>0.864</td>
</tr>
<tr>
<td>Parental Role Alterationb</td>
<td>0.821</td>
<td>0.842</td>
</tr>
<tr>
<td>Total Scale</td>
<td>0.865</td>
<td>0.921</td>
</tr>
<tr>
<td>Total Scaleb</td>
<td>0.828</td>
<td>0.911</td>
</tr>
</tbody>
</table>

*In Metric1, Stress Occurrence Level, an individual not experiencing an item does not receive a score for the item. In Metric 2, Overall Stress level, individuals not experiencing an item receive a score of 1, indicating no stress was experienced. Averaging available items for the individual creates scale scores

bThe new non-validated items is excluded
**Table 4** Inter-scale correlation between PSS: NICU subscales and total scale.

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Total scale</th>
<th>Sights and Sounds</th>
<th>Infant Behaviour and Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sights and Sounds</td>
<td>0.685*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant behaviour and appearance</td>
<td>0.835*</td>
<td>0.448</td>
<td></td>
</tr>
<tr>
<td>Parental role alteration</td>
<td>0.835*</td>
<td>0.472</td>
<td>0.528</td>
</tr>
</tbody>
</table>

Spearman rank order correlation with the non-validated items.
* Correlation is significant at the 0.01 level (2-tailed).

**Table 5** Inter-scale correlation between PSS: NICU subscales and total scale.

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Total scale</th>
<th>Sights and Sounds</th>
<th>Infant Behaviour and Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sights and Sounds</td>
<td>0.685</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant Behaviour and Appearance</td>
<td>0.883</td>
<td>0.493*</td>
<td></td>
</tr>
<tr>
<td>Parental Role Alteration</td>
<td>0.826</td>
<td>0.493*</td>
<td>0.535*</td>
</tr>
</tbody>
</table>

Spearman rank order correlation, the new non-validated items are excluded.
* Correlation is significant at the 0.01 level (2-tailed).

**DISCUSSION**

The validity and reliability of the Swedish version of PSS: NICU was examined, based on a sample of 95 parents from three different NICUs in Sweden. The PSS: NICU provides important information for clinical practice and research regarding how stressful parents experience particular NICU situations and the level of stress they experience from various aspects of the NICU environment (6, 9). The answer rate was low, approximately 50%. One reason for the low answer rate may be that parents experiencing high levels of stress due to their infant being in a critical condition declined to participate. This could also be the reason why many parents answered NA to items that concern advanced care, for example the item “Having a machine (respirator) breathe for my baby” in the subscale Sight and Sounds. Only 13% of the parents answered that their infant had had mechanical ventilation.

The result in the present study indicates that PSS: NICU is a valid and reliable instrument with good content and construct validity, as well as satisfactory internal consistency and the result is consistent with previous research (7, 9, 10). Translation is a critical part in cultural
adjustments of instruments, as the significance can be changed during the translation procedure (19). It is therefore essential that the translation procedure follows a systematic process to ensure validity of the translated instrument – which was taken into consideration by the forward-backward translation process (15, 19). No major differences were encountered between the two translators, which may strengthen the validity of the Swedish version of the instrument. In our study the translated version was reviewed by a group of parents with earlier experiences of having an infant at an NICU. This is in line with the guidelines by Streiner and Norman (2008) who state that a translated questionnaire should be checked by a group of people who are similar in characteristics to the target population (15). The parents had an opportunity to answer open-ended questions about the language and wording, and all parents found the language in the instrument easily understood, indicating that the instrument is user-friendly.

The non-validated items in subscales Infant Behaviour and Appearance and Parental Role Alteration (Appendix 1) are analysed for Cronbach’s alpha in this study in order to determine whether or not to use the items. These items are important to reflect the increased care and survival of extremely preterm infants (20). Parental Role Alteration showed a good alpha value, both with and without the nonvalidated items. However, the subscale Infant Behaviour and Appearance when the non-validated items were excluded showed a lower Cronbach’s alpha <0.70 compared to when the nonvalidated items were included. One reason this subscale shows a lower Cronbach’s alpha coefficient compared with the other subscale might be that this subscale seems to measure not only parental stress, it also seems to focus on medical aspects. These aspects may be difficult for parents to relate to. The values for alpha if item deleted were compared with the values for the final alpha. As the values for alpha when item deleted were lower than the final alpha, there was no need to remove any items from the instrument.

According to Miles (7, 8) the scoring method Metric 2 implies giving a rating of 1 (not at all stressful) for those items not experienced by the parents. This scoring method might affect the validation especially if the amount of NA is high on any item in one of the subscales. In the present study we decided to calculate all statistics for Metric 1 but only Cronbach’s alpha coefficient for Metric 2. This was a deliberate choice because it seems more appropriate to calculate the stress response experienced by the parents rather than give them a value for items not experienced.

Construct validity examined by corrected item total correlation showed some items in the subscales, respectively, that were lower than the recommended 0.20 and this may indicate that some items may be removed or that the factor structure needs to be further evaluated. The item “Having a machine (respirator) breathe for my baby”, in the subscale Sights and Sounds was below 0.20 when the subscale was calculated. However, as a part of the total scale it was over 0.20. This item was scored not applicable by 87 % of the participants and the low response rate might have affected the outcome. The choice to omit or not these items with varying degree of alpha can probably be done based on the care situation (i.e. if the care includes mechanical ventilation or not). It is to be noted that this item was moved from the subscale Infant Behaviour and Appearance to subscale Sights and Sounds by Miles during the developing process of PSS: NICU, as it loaded more strongly in the subscale Sight and Sounds (7, 8). As this item showed a low value (<0.20) in our study it was calculated in both
subscales, yet since the values were almost the same for the item regardless the subscale, the item was finally calculated in the subscale Sights and Sounds. In subscale Infant Behaviour and Appearance, there were two items that showed a value below 0.20; “The unusual colour of my baby (for example looking pale or yellow jaundiced)” and “The small size of my baby”. In this subscale the parents compared the appearance of their child with what is considered normality and this comparison may be difficult for some parents due to lack of knowledge about healthy full-term infant appearance. If parents have little experience of newborn infants it may be difficult to assess what a normal colour is for a baby and perception of the size of their baby may vary.

Inter-scale correlations were calculated for each of the subscales on the PSS: NICU as well for the total scale. The subscales correlated moderately to each other but correlated highly with the total scale, ranging from 0.7 to 0.8 including the non-validated items and 0.6 to 0.8 when these items were excluded. The subscale Sights and Sounds correlated lower to the total scale compared to the other two subscales. This could indicate that item six “Having a machine breathe for my baby” in subscale Sights and Sounds does not match this subscale. This item also showed a lower value on corrected item total.

CONCLUSION
Identification of parental stress in NICUs is essential to determine strategies to support parents at an NICU. Our findings indicate that the Swedish version PSS: NICU, both with and without the nonvalidated items, has acceptable psychometric properties and can be a useful tool in clinical practice in NICUs in Sweden.

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AUTHOR CONTRIBUTION
All of the authors have contributed to the design, interpretation of the result and the drafting of the manuscript. C Månsson performed the data collection and statistical analyses. All the authors read and approved the final manuscript.

ETHICAL APPROVAL
The study was approved by the Ethics Committee at the University of Lund (Ref.no. LU 173-2006)

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