MAIN TEXT

Introduction

Although survival from critical illness has significantly improved in the past years, continuing physical impairment after intensive care unit (ICU) discharge has become an increasing problem (Sukantarat et al. 2007; Van Der Schaaf et al. 2009). Muscle weakness acquired during critical illness, known as Intensive Care Unit-acquired weakness (ICU-AW) is present in approximately 50% of ICU admissions; the biggest risk factor for the development of ICU-AW is sepsis/multi-organ failure, and it is linked with prolonged mechanical ventilation (Stevens et al. 2007; Wieske et al. 2015). Research exploring early rehabilitation for patients in the ICU to prevent or minimize loss of muscle strength and physical function has shown promising results (Kayambu et al. 2013; Schaller et al. 2016). The use of measurement instruments to monitor and possibly minimise functional impairments after critical illness is of research interest in the ICU community worldwide (Connolly 2015; Parry et al. 2017). Monitoring and assessing impairments and changes in physical function during the ICU admission may enhance clinical reasoning and support decision-making in the individualised treatment for each patient (Connolly 2015; Reid et al. 2015). Thus, valid and reliable measurement tools are an important part of both clinical practice and research to assess physical function and to evaluate treatment effect. Currently, there are several measurement tools that can be used in the assessment of physical function in ICU patients, but there is no consensus on a 'gold standard' (Parry et al. 2015; Parry et al. 2017). The Chelsea Critical Care Physical Assessment Tool (CPAx) (Corner et al. 2013; Corner et al. 2014) has shown to be valid and has demonstrated strong clinimetric properties (Corner et al. 2015; Parry et al. 2015). The CPAx is a numerical and pictorial measurement tool consisting of 10 commonly assessed items of physical function graded on a 6-point Guttman-Scale from complete dependency to independence (0-5). An aggregate score

between 0 and 50 can be calculated, where 0 represents complete dependency and 50 is completely independent. However, no assessment tool has been translated and validated into Danish. A Danish measurement tool to assess physical function and evaluate treatment in the Danish ICUs is required.

The purpose of this study was therefore to translate the CPAx into Danish and carry out cross-cultural validation of the translated version.

Materials and methods

The design was a measurement property evaluation study, which was conducted in the Department of Physiotherapy and Occupational Therapy at Aarhus University Hospital, Denmark between October 2015 and June 2016. The study was approved by the Danish Data Protection Agency (reference number 615091). The local ethics committee was notified about the study, but according to Danish law, no further approval was needed. The study complies with the Helsinki declaration.

Translation, cross-cultural adaptation, pre-test

The translation of the original CPAx measurement tool (Corner et al. 2013) into Danish was completed with consent and assistance of the original author (EJC). Translation, cross-cultural adaptation and respondent validation were done by following and eight- step process in accordance with approved international guidelines (Beaton et al. 2000; Wild et al. 2005). Investigation of the clinimetric properties of the CPAx tool involved a pre-test and a focus group interview, the aim of which was to evaluate the applicability and respondent validation of the Danish version of CPAx in clinical practice. The steps of the study are described in Figure 1.

- **Insert Figure 1 approximately here –**

Forward translation (step 1)

Two independent bilingual authors (KAS, MGH) with Danish as their native language performed the forward translation of CPAx from English to Danish. One (KAS) was experienced within the field of critical illness and the other (MGH) was a certified English linguist unfamiliar with the clinical field. Both translators were asked to write down annotations about their rationale for translation, choices and linguistic considerations. These notes were used in the following reconciliation and synthesis procedure

Reconciliation and synthesis (step 2)

A meeting was established to discuss and synthesize the results of the translation from English to Danish. Disagreements between translators were resolved by discussion and consensus was achieved. If necessary a third author (AKP) resolved remaining differences in order to reach agreement on the synthesized Danish CPAx version. During the process the annotations from both translators about their rationale for translation, choices and linguistic considerations served as documentation in the final evaluation report to the author of the original CPAx (EJC).

Back-translation (step 3)

Two independent bilingual translators with English as their native language translated the synthesized Danish CPAx version back into English. Both translators were health professionals and experienced in professional translation. However, they were unfamiliar with and blinded to the original CPAx version. Both translators were asked to write down annotations about their rationale for translation, choices and linguistic considerations. These notes were used in the following reconciliation and synthesis procedure and served as documentation in the final evaluation report to the author of the original CPAx (EJC).

Review of back-translation (step 4)

A meeting was established between the English back translators and two of the authors (KAS, AKP). The back-translations were discussed and compared to the original version. Any discrepancies between the two translations were discussed and consensus was obtained in order to reach agreement on a final synthesized back-translated English version. During the process the annotations from both translators about their rationale for translation, choices and linguistic considerations served as documentation in the final evaluation report to the author of the original CPAx (EJC).

Harmonisation (step 5)

The synthesized back-translated English version and the original CPAx tool were discussed in a committee consisting of selected health professionals with expertise in the ICU area and the authors, including the original author (EJC).

Pre-test (step 6)

As recommended by Beaton et al. (Beaton et al. 2000), the pre-test sample included 30 patients from the target population. Three physiotherapists with experience in treating ICU patients, not involved in the translation process, were selected for the pre-test and the following evaluation. The purposive sample of three local physiotherapists were selected based on their clinical experience as well as their in-depth knowledge to the ICU patients and setting. The demographics of physiotherapist and patients are presented in Table 1 A and 1 B.

- **Insert Table 1 A and 1B approximately here**

The physiotherapists pre-tested the synthesized the preliminary Danish CPAx version in the ICU setting. Prior to the pre-test the physiotherapists were certified in the CPAx assessment using the

English e-learning program (Chelsea and Westminster Hospital NHS Foundation Trust 2013). The physiotherapists were asked to write down annotations from the pre-test concerning the actual test session and their experiences with the CPAx tool. The annotations were then gathered in themes associated with the individual items and levels.

Focus group interview (step 7)

After the pre-test a focus group interview was conducted to discuss and evaluate cultural adaptation and the applicability of the CPAx tool in the clinical practice. Participants of the focus group were the three physiotherapists involved in the pre-test, as well as the research team where one acted as moderator (AKP) and one as chairman and supervisor (KAS). The focus group was conducted in a meeting room at Aarhus University Hospital and lasted three hours. The focus group was based on the themes and annotations made by the physiotherapists from the pre-test. This acted as a topic guide. Each of the ten items was individually discussed level by level, and various suggestions to modifications considered by the physiotherapists and the research group. Consensus on the final modifications and adjustments was established and recorded in the evaluation report by the research group moderator. The focus group was performed according to approved recommendations (Fayers and Machin 2007).

Evaluation report (step 8)

A report including all comments and rationale for changes and adjustments during the entire translation process was sent to the original author (EJC).

Results

Translation process

During the translation process some words were rephrased or adjusted, due to linguistic, grammatical, terminological and cultural differences between the English and Danish. Changes

from the original CPAx version to the synthesized back-translated English version were discussed with and accepted by the original author (step 9). The changes are presented in Table 2 (second column).

- **Insert Table 2 approximately here**

Pre-test and focus group interview

The outcome from the pre-test and evaluation of the Danish CPAx tool concluded that the tool was appropriate and applicable in the clinical setting of the Danish ICU. However, in the focus group the participants agreed that some items and levels needed further clarifications and adjustments to avoid uncertainties during assessment to maximise the reliability of the tool in practice. All the adjustments and modifications as a result of the focus group are presented in Table 2 (column three).

Final version

During the entire process including the translation, pre-test and evaluation, all changes (rephrasing, adjustments and modifications) were presented, discussed and approved by the original author of the CPAx (EJC). In the entire process it was agreed to avoid extensive changes in the Danish version that could affect the content and the construct of the original CPAx tool. The final version of CPAx presented as the final synthesized English version is presented in Figure 2.

- **Insert Figure 2 approximately here**

Discussion

The original English CPAx measurement tool was translated into Danish and a cross-cultural validation of the translated CPAx was carried out. Results from the pre-test and focus group

evaluation resulted in some but limited modifications and adjustments to preserve comparability between the original CPAx version and the Danish translation. The applicability and relevance of the Danish version were evaluated as high by the physiotherapists who tested the tool in the clinical setting. All changes and adjustments from the original English version were discussed and approved by the original author (EJC). This appears to be the first English-language publication to report all steps of the translation and cross-cultural adaptation process of the original CPAx version into another language, including evaluation of applicability and comparability after pre-test of the translated Danish version in the ICU setting. From a clinical and research perspective, this provides an appropriate measurement tool that can be used in Denmark and be further evaluated and validated in the Danish population. Methodologically, this study is also of value, as it highlights the practical application of a thorough translational validation process. The process of this study can be utilised by other non-English speaking countries to adapt the CPAx, to suit their local clinical context.

A strength of this study is the involvement of original author (EJC) throughout the entire process, including discussion of modifications and approval of the ongoing adjustments. The close collaborative work between the local research group and EJC ensured that the English and the Danish versions are comparable. With the CPAx being translated and validated into multiple languages it provides the opportunity of data comparison in future studies.
Another strength in our study was the choice of the translators, which was done according to the approved recommendations (Beaton et al. 2000). In the forward translation this meant including one translator aware of the ICU setting as well as the measurement tool, and one translator not being aware of concepts and without clinical background. Involving translators with different

profiles and backgrounds provides both a clinical perspective and perspective more focused on the translation and the language. The same was achieved in the back-translation where two authorized translators both unfamiliar with the ICU setting and the CPAx tool were involved as recommended (Beaton et al. 2000). This contributed to avoiding risk of information bias.
A final strength of the study was the involvement of three specialised ICU physiotherapists in the focus group and pre-test. This added more quality into the discussion and evaluation of the cross-cultural adaptation, and applicability of the Danish CPAx tool.

Limitations of the study

Translations can be affected by the translator's subjective choice of wording. However, by following the international guidelines and conducting consensus meetings between the translators and the researchers during the process, ensured that the translations were thoroughly and objectively evaluated. Same considerations regarding subjectivity apply to the focus group evaluation, where three selected physiotherapists were chosen to evaluate the CPAx together with the research group to determine the cross-cultural adaptation and applicability. The adjustments during the focus group interview were constantly considered in comparison to the original CPAx version to ensure high comparability, and only adjustments that were found inevitable, were added. During evaluation it was emphasized that the CPAx was kept as simple and close to the original version, as possible. To support our subjective focus group evaluation of cross-cultural adaptation and applicability, we could have created a quantitative evaluation score for the Danish CPAx tool by making a questionnaire, which could have been distributed to physiotherapists nationally. However, it was decided more appropriate to only include a smaller

specialised group of physiotherapists familiar with the CPAx so they had a good understanding of the tool.

Finally, the translated version of the CPAx tool was pre-tested and evaluated in three different ICUs within the same university hospital in Denmark. Involving ICUs from other hospitals could have made the evaluation more comprehensive, but the research group decided that feedback from physiotherapists working in three independent ICUs within the same institution was sufficient.

Regarding future applications, this study describes the first step towards a standardised and validated CPAx tool for assessment of physical function in Danish ICU patients. The next step will be to further examine the clinimetric properties of the Danish CPAx tool in order to meet scientific standards. This will be conducted in a following study with investigation of the inter-tester reliability and responsiveness of the Danish version of the CPAx tool.

Conclusion

The Danish version of the CPAx tool was successfully translated into Danish by following the international approved guidelines for translation and cultural adaptations of outcome measurements. The tool was pre-tested in the ICU setting and was evaluated as an appropriate clinimetric tool for assessment of physical function in ICU patients.

The translated and validated version of the Danish CPAx will be available on the Danish Physiotherapy Association´s website.

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