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Adaptation and Cross-cultural Validation of Assessments: Illustrated With an Example from Occupational Therapy

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IMPRESSUM

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Zusammenfassung

Hintergrund: Der Ruf nach einer Evidenz-basierten Praxis im Gesundheitswesen hat u.a. dazu geführt, dass therapeutische Interventionen hinsichtlich ihrer Effektivität untersucht werden. Um die Wirksamkeit einer Intervention zu beweisen, muss das Ergebnis einer Intervention gemessen werden. Hierfür sind valide und reliable Instrumente notwendig. Wenn keine Instrumente in einer bestimmten Sprache existieren, kann entweder ein neues Instrument entwickelt oder ein bereits bestehendes In-strument übersetzt, transkulturell adaptiert und validiert werden.

Ziele der Präsentation: Darstellung des Vorgehens anhand eines Instruments aus der Geriatrie, dem Functional Autonomy Measurement System (SMAF). Sensibilisierung auf das Ausmass des Prozesses.

Inhalte: Bedeutung von validen und reliablen Instrumenten für eine Evidenz-basierte Praxis. Vor- und Nachteile der Übersetzung eines bereits bestehenden Instruments. Auswahl eines Instruments. Darstellung der einzelnen Phasen im Vorgehen. Übersetzung und Adaption eines Instruments. Phase der Validitäts- und Reliabilitätsüberprüfung. Standardisierung.

Abstract

In accordance with the professionalisation of health professions such as occupational therapy and the call for evidence-based practice the need for reliable and valid assessments

has risen. However, often such instruments lack in German. As many assessments have been developed in the US, i.e. in English one may consider translating and cross-culturally validating assessments for German. The aim of this contribution is to illustrate this procedure. Based on our experiences with adapting and validating the »Pediatric Evaluation of Disability Inventory« (PEDI) the process will be discussed and aspects to consider pointed out.

Schlagworte

- Ergotherapie
- pädiatrische Rehabilitation
- Assessment
- trans-kulturelle Adaption
- Pediatric Evaluation of Disability Inventory (PEDI)
- occupational therapy
- pediatric rehabilitation
- assessment
- cross-cultural adaptation
- Pediatric Evaluation of Disability Inventory (PEDI)

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1 Introduction

Current developments in the health sector have promoted the necessity of having valid and reliable assessments in practice in Switzerland: Firstly, as part of the professionalisation of members of a caring profession, such as occupational therapists the education has been institutionalised on a University -level. In Switzerland this development started in 2002 in the French-speaking part, whilst in the German speaking part this step was conducted in 2006. During their studies future occupational therapists learn to assess a client's situation with reliable instruments as a basis for planning intervention and identifying the most important aspect, where intervention is necessary. Secondly, the call for outcome-oriented and evidence-based medicine/practice has highlighted the necessity for valid assessments: Interventions are now being evaluated concerning their effectiveness and efficacy. One way of measuring the effect of a health care intervention is to compare health status before and after the intervention, i.e. to evaluate changes in functioning and/or ability to fulfil activities of daily living. For this, instruments are needed that fulfil the following criteria: i) they are scientifically proven to be valid and reliable; ii) they can discriminate between different health levels (e.g. healthy versus disabled); iii) are developed in the context of contemporary theories of the target construct and iv) finally, the practicability in practice is given (Boksch et al., 2007; Häussler, Streit, & Strassburg, 2002; Kothari, Haley, Gill-Body, & Dumas, 2003; Ostensjo, Bjorbaekmo, Carlsberg, & Vollestad, 2006; Streiner & Norman, 2005).

There is a lack of German assessments for paediatrics (Projektgruppe ergotherapeutische Befundinstrumente in der Pädiatrie, 2004). To obtain a German instrument an existing one can be adapted and validated instead of developing a new instrument. The advantages of translating an existing validated instrument include enhancing the international comparability of research results and saving of resources as the development of a new instrument is extremely resource extensive (Streiner & Norman, 2005).

The aim of this publication is to illustrate the extensive procedure of cross-culturally adapting assessments shown an example from occupational therapy and to point out, based on our experiences, aspects that need to be considered before and during tackling this task. After pointing out the growing importance of medical rehabilitation, an instrument helpful for health professionals in paediatrics, i.e. the PEDI, will be introduced. The steps for adapting and cross-culturally validating an assessment will be illustrated with regards to the PEDI.

2 Growing importance of rehabilitation and activities of daily living

The concept of medical rehabilitation has received more and more attention in contemporary medicine. Rehabilitation aims to achieve optimal functioning within the constraints set by a disabling condition. In the past, paediatric rehabilitation was characterised by adapting adult interventions to children, which were delivered by adult patients-oriented professionals. However, theories on childhood development and focus of interventions have influenced this approach and changed paediatric rehabilitation into a specialised professional activity. In addition, the focus of interventions has shifted from impairments

to function and from the child to its environment (family, community) (Helders et al., 2003; Helders, Engelbert, Gulmans, & Van-Der-Net, 2001). Supporting and improving activities of daily living have become often more important outcomes of rehabilitation than promoting optimal functioning. These developments are strongly influenced by and based on the International Classification of Functioning, Disability and Health (ICF) from the WHO (World Health Organization, 2001). The ICF is a universal classification of human functioning that can be used to document functional status associated with health conditions. Functioning is described from three perspectives: body systems, execution of tasks and actions (activities), and involvement in life situations (participation). Personal and environmental factors belong to contextual factors both are added to represent the background of an individual life and could mediate a person-environment interaction.

As members of a caring profession, occupational therapists are concerned with the integration of people with disabilities into community living and the promotion of their full participation in society. More specifically, the focus of the occupational therapist is the person's ability to perform those daily life tasks that they need and/or want to perform. An assessment that can help occupational therapists (and other health professionals) plan and evaluate their therapy with children is the PEDI, which is described in the following paragraph.

3 The Instrument PEDI

The PEDI is designed for three purposes: to describe a child's functional status; for program evaluation of inpatient, outpatient, and school-based programs; and to monitor change in children with functional disabilities. It was designed to be used for children between 6 months and 7.5 years (or older if their functional development is significantly delayed. It can be used with many diagnostic groups (Feldman, Haley, & Coryell, 1990; Haley, Coster, Ludlow, Haltiwanger, & Andrellos, 1992).

The instrument is organised into three measurement dimensions: functional skills, caregiver assistance, and modifications. Each of these is organised into self-care, mobility, and social function. The functional skill measure is organised hierarchically based on the order in which skills are typically achieved by children. Each item is scored on a capable / not capable dichotomous scale. There t3 self-care, 59 mobility, and 6r social functi9on items. The caregiver assistance scale explores the öamount of assistance the child requires in task areas that are more general than the specific items in the functional skills area. Each item is rated on a six-item scale from total assistance to independence. The modifications scale allows consideration of the frequency that modifications (either typical modifications used by children, or specific modifications used by children with disabilities) are used. The care giver assistance and modifications measures each have eight self-care, seven mobility and five social function items.

The instrument can be administered in different ways. Either parents or professionals can complete the instrument. If parents are responding, they can typically be given the functional skills component to fill in independently, as long as someone familiar with the PEDI reviews it with them afterwards. The caregiver assistance and modifications scales are more demanding to understand an may best be completed with structured interview

with parents. There is a computer programme available to assist with scoring, but it can also be scored manually. Raw scores, normative standard scores, or scaled scores can be used.

Depending on the type of administration, it can take 45 to 60 minutes to complete the instrument by interviewing parents, or 20 to 30 minutes if a professional is completing it based on observations of the child. The PEDI can be used by occupational and physical therapists, nurses or psychologists.

4 The way to a cross-culturally adapted and validated assessment

Different phases can be distinguished in the long way of adapting and calibrating an assessment.

- Selection of assessment to be adapted
- Translation and adaptation of selected assessment
- Evaluation of psychometrics of the translated PEDI
- Development of normative values
- Standardisation of assessment

These steps will be illustrated in the following including our experiences and/or experiences of other research groups with the process.

4.1 Selection of assessment

After a need for an assessment in a special area has been identified and one has decided to adapt an existing instrument instead of developing a new one, the following aspects need to be considered:

- *Which assessment is suitable?*
  Paediatric rehabilitation research mainly in the US has brought many instruments within the last decade. Instruments suitable for adaptation need to be valid, reliable, and able to discriminate in the culture where they were developed. According to Katelaars et al.'s (1998) overview over paediatric instruments most measures were developed and validated for discriminative purposes and only two functional assessment measures for children with cerebral palsy meet psychometric criteria to fulfil the criteria of reliability and validity: the Gross Motor Function Measure (GMFM) and the Paediatric Evaluation of Disability Inventory (PEDI). The two instruments differ from and complement one another: GMFM is used by the clinician to observe behaviour, while PEDI consists of an interview held with the parents of the children. The GMFM has already been translated and validated in German (Russel, Rosenbaum, Avery, & Lane, 2006). Other studies have shown that the PEDI captures activities of daily living better than the Functional Independent Index for children

does (Gall, Denniston, Hookway, & Galvin, 2004; Kothari et al., 2003; Ottenbacher et al., 1999; Ziviani et al., 2001). Ostensjo et al. (2006) indicate that the ICF could serve as a conceptual framework to clarify the measurement construct of the PEDI scales, and the classification of the functional skills scales shows that the PEDI is primarily is a measure of activities and participation. For paediatric rehabilitation this means focusing on age-specific capability and performance of child in his/her environment as well as activity and participation concepts according to the ICF (World Health Organization, 2005). Due to this analysis of our literature review we decided to validate the PEDI in German.

- *Validity and reliability:* Does the assessment answer to the respective criteria (see above)?
  Several studies have shown that the instrument is valid and reliable as well as sensitive to change (for overview see (Law, Baum, & Dunn, 2001).

- *Copyright:* The original developers of PEDI have the copyright on the instrument. Often – when the instrument is published, the rights may lie with a publisher. In the case of PEDI however the rights stayed with the developers. We negotiated with them whether they agree with the planned process and how they want to be included in the process.

- *Other research group:* The developers confirmed that we were the only research group planning to adapt PEDI TO German.

- *Literature review: What experiences have other researcher groups in other countries made with adapting the respective instrument?*
  Our literature review identified several project groups, who have tackled the task in the past (Marie Berg, Fräslie, & Hussain, 2003; Erkin, Elhan, Aybay, Sirzai, & Ozel, 2007; Gannotti & Cruz, 2001; Nordmark, Orban, Hägglund, & Jarnlo, 1999; Tsai, Yang, Chan, Huang, & Wong, 2002). Our closest contact is with a representative of the Dutch research group (Wassenberg-Severijnen, 2005).

- *»Science to market«: How will the assessment be made available to practice: Through a regular, official publisher or through private publishing venture?*
  We decided to look for a publisher who may be interested in publishing the German version. Here one needs to clarify what royalties need to be taken account of (e.g. for the developers and/or for the research group doing calibration). Especially between the North America and Europe there are differences between extent of royalties developers or authors receive from a publisher: in North America these can be about 25%, whilst in Europe 15% is the maximum. This for us has turned out to be quite a challenge as long as the developers of PEDI did not understand this difference.

- *Project partners*: If we adapt an assessment for the German culture it is necessary to include representatives of Germany and Austria, too as linguistic intricacies may differ between the three countries. The aim is to have an assessment that is usable in

all three countries. We have found practice partners in all three countries that are interested in participating in this project.

4.2 Translation and adaptation of selected assessment

Guillemin et al. (1993) propose a sequence of steps for cross-cultural adaptation of health-related quality of life instruments in order to maintain the sensibility of the tool in the target culture. Based on these reflections, Beaton et al. (2002) put down recommendations for the cross-cultural adaptation of Health Status Measures, which are reported in the following and will be used as a basis for our procedure (see figure 1).

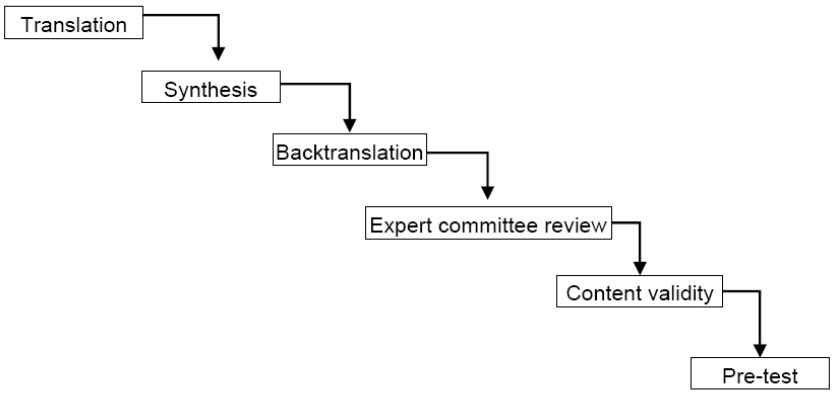

Figure 1: Process of cross-cultural adaptation (adapted from Beaton, D. et al. (2002))

Translation
Following Beaton et al.'s (Beaton et al., 2002) recommendations two translators with different backgrounds should be selected to ensure the best possible translation: One translator should be knowledgeable about the concept the instrument addresses and will thereby ensure producing a translation taking account of the more clinical perspective. The other translator should not be aware or informed about the concept and should not have a clinical background. This translator will ensure best possible equivalence from the linguistic side reflecting a language used by the common population (T1). A qualified translator, whose mother tongue is German, will do another translation (T2). First adaptations will result during this step, e.g. changing inches to centimetres.

Note: Although in the recommendations a strong focus is set on linguistic equivalence we have decided a clinical background is just as important as a respective translator knows the clinical setting.

Synthesis
This stage aims to produce a synthesis of the two translations. A moderator will work with the two translators on discussing translation differences and producing a synthesis of the two translations (T12). This process will be documented in a report.

Back-translation
Two qualified translators, who were not involved in the process so far and who are naïve to the outcome measurement, will translate the synthesis (T12) back from German into English independently from each other. The moderator mentioned in the synthesis process will produce an overview over the differences between the two back-translations (BT1, BT2).

Note: This step often is questioned by publishers (personal communication, from several representatives of publishers, e.g. Ralf Horn, Pearson Assessment, 26.01.2008; experts in translation processes (Marueen Ehrensberger-Dow, Institute of translation, 16.08.2008). We have not definetly decided on this aspect. It may be helpful thouth to have a least one back-translation to show the original developers of what has come out of the translation process.

Expert committee review
A multidisciplinary review committee will be constituted to compare source translation and back-translations. It will consist of two professionals in paediatric rehabilitation, a developmental psychologist, two of the translators involved so far (one with a clinical background and one qualified translator) as well as a methodologist with special knowledge in constructing questionnaires. The committee's aim will be to produce a pre-final version of the questionnaire for field-testing by reviewing all translated versions (T1, T2, T12, BT1, BT2) as well as the original instrument (= 6 questionnaires).

We will organise a one-day workshop that will be prepared and conducted by the moderator mentioned above. The experts will receive copies of the original instrument, all translations, the synthesis, the back-translations as well as the reports of the process and decisions taken so far in advance for their preparation. The moderator will lead the discussion in a structured way aiming to facilitate finding a consensus. This discussion will be documented and a respective report produced highlighting adaptations made and the motivation for these adaptations.

The developers of the PEDI will be involved during this process as follows: Unresolved questions from this workshop will be discussed with the authors. On this basis the PEDI project group will propose solutions to the expert committee and aim to find a consensus by e-mail. Again, this process will be documented carefully.

In the Netherlands this step resulted in adding an answer option with regard to using eating cutlery, i.e. child is able to use knife and fork together. This reflects a cultural difference: While in the US also adults often first cut up all their food, put down the knife, change fork to other hand and eat with their fork only. In Europe, however one usually as of a certain age is expected to keep knife and fork in the respective hands, then cutting a piece of food and putting it directly into one's mouth without changing fork to the other hand. Further in the PEDI developed for the US only the bathtub was mentioned. In Europe however showers are just as common if not more important than bathtubs are. A respective adjustment was made (Wassenberg-Severijnen, 2005).

Content validity and clinical feasibility

Aim: To review the content validity due to adaptations made and to receive feedback on lacking or mistakable items. In addition, the clinical feasibility of the instrument will be assessed. Possible adaptations may follow from this step.

Procedure: A validity questionnaire will be sent to allied health professionals familiar with functional status of infants and young children. We are planning to translate the questionnaire from the Dutch research group as a mean of building on their experience. The questionnaire addresses the following areas:

- accuracy of the content,
- clinical feasibility,
- discriminative- and evaluative power per domain,
- length of questionnaire,
- accuracy per item and should any items be added or deleted,
- specific feedback on any items can be given.

Participants: The professionals will not have been involved in the previous adaptation process (aim: 20 answers). The following professional groups should be represented: paediatric occupational therapists and physiotherapists, special needs teachers, paediatricians, neuropaediatricians, scientific co-workers in paediatric rehabilitation facilities and speech and language therapists.

Recruitment: The professionals will be recruited through the professional networks of the representatives of practice.

Data analysis: Most of the data will be able to be analysed in a descriptive manner, i.e. in the form of frequencies and percentages of a given answer. The question on specific feedback will be an open question, thus a qualitative approach will be taken, i.e. a content analysis will be conducted to categorise the answers

Note: One needs to balance the gain of this step against possibly barriers. It is to be expected that new inputs for further items will be received, whilst at the same time the assessment will often be judged as too long. On the other hand one might receive helpful input from experts in practice, e.g. in the Dutch research project this step identified the necessity of adding an item on ability to ride a bike (Wassenberg-Severijnen, 2005).

Pre-testing

Aim: A field test of the new instrument uses the pre-final version with subjects from the target setting to check for equivalence in source and final versions. Mistakable items can still be revised at this stage.

Procedure: Guillemin et al. (1993) suggest the probing technique in accordance with Schuman (Schuman, 1966) for pre-testing. Subjects from the target audience are asked to first complete the new questionnaire and are then interviewed to probe, what they thought was meant by each item and their response (E.g. »Why did you selected that answer?« »Please describe what you mean with you answer?«). The participants are encouraged to

elucidate their understanding of the item in an open-ended manner. The interviews will be audio-taped. From the total of 217 questions[1] 75 (average) questions per person will randomly be selected and discussed with parents. We will thus obtain 8 answers for each of the 217 questions.

Participants: 25 main carers of children with and without disabilities in the ages between 6 and 90 months.

Recruitment: The parents of handicapped children will be recruited at the participating hospitals and clinics in Austria, Germany and Switzerland. Approval of the respective ethics committees will be needed. Those parents of children without known disabilities will be approached via personal networks of the project group (a variation of social backgrounds and age of the parents will be looked for). The parents will be asked to sign an informed consent.

Analysis: The interviews will be transcribed. The answers given by the parents will be discussed in the project group and with a further paediatric professional so as to evaluate the questionnaire's comprehensibility by the parents. A report on the results and discussion will be prepared for the authors of the PEDI.

Authorisation by authors

The pre-test is the final stage of the adaptation process. At this point the authors of the original PEDI will be asked for authorisation of this translation. As a basis for this decision the German versions plus the back translated versions and a list of the adaptations including the motivations for making these adaptations will be sent to the authors. This decision is the prerequisite for the next steps in the validation of the German translation, i.e. evaluation of the psychometrics. After the authorisation of this translation the participating hospitals will be allowed to use the translation internally for a reduced price during the rest of the project.

4.3 Evaluation of psychometrics of the translated PEDI

After the authorisation of the translated version by the original authors the psychometrics of the translated instrument need to be re-evaluated as one can assume that the changes made will also affect these measures of the instrument. These analyses may result in further minor adaptations in the translation. The following steps are based on the usual steps for validating an instrument, also if newly developed and have no relevance for cross-cultural adaptation. They are summarised here for the sake of completeness. Further information can be found in any methodological book on test statistics (Streiner & Norman, 2005).

Reliability

Aim: The following investigations will be designed to establish the psychometric properties of the German PEDI: inter-interviewer reliability, test-retest reliability, and the internal consistency. Although in this phase ideally the adaptation process should be considered finished it is possible that the following analysis will identify aspects that require further adaptations of the translation.

[1] 197 questions (dichotomous scores: positive or negative score possible), and 20 questions with 6 rank-ordered response choices (range: from 0 =totally dependent to 5 =independent)

Participants: Parents of children with disabilities (n=60) and without known disabilities (n=60) (see table 1).

Ethics: Approval by the respective ethics committees will be asked for.

Recruitment: Parents of children with disabilities will be recruited through the participating hospitals. They will be approached by the paediatric professional treating their children and informed about the study. If they agree to participate they will be asked to sign an informed consent. While recruiting the parents the possibility to audiotape interview and/or (partially) redo the interview within a few weeks will be checked. Parents of children without known disabilities will be contacted through respective paediatric doctors and day care centres in the three countries. The ages of the children will be between 6 and 90 months.

Data collection: Six interviewers (2 in each country) will be trained in the aim and use of PEDI according to the PEDI manual. They will conduct the interviews with the parents either in the hospital or at a quiet place of the carers' convenience. For further details see table 1.

Table 1: Data analysis reliability studies

Psychometric properties	**Data collection**	**Analysis**
Inter-interviewer reliability	60 audio-taped interviews with parents of disabled and 60 non disabled children: one interviewer scores "live" during interview; one according to audio-tape	Proportion of identical answers in every item (or, depending on variance in answers: Cohen's kappa); Intra-class correlation coefficients (ICC)
Test-retest reliability	Same parent of same 120 children interviewed a second time after 2 weeks	Ditto
Internal consistency	Non-disabled children only (n=60); from data pool collected for investigating inter-interviewer reliability and rest-retest reliability	Cronbach's alpha

Discriminative validity

The *aim* of this step is to review whether the instrument can discriminate between healthy children and children with disabilities.

Participants: Children with different kinds of disabilities (n=200) and without known disabilities (n=60)

Ethics and recruitment: Same procedure as in reliability study.

Data collection: Four experienced clinicians will interview the parents (primary carers). The clinicians will be chosen according to their expertise in the relevant patient groups and will receive a training program according to the guidelines of the PEDI manual. After an interviewer has completed at least 20 face-to-face interviews (at the hospital or at home of child) s/he can conduct the interview by telephone.

Data analysis: First, reliability and item-test correlations of each of the outcome scales need to be established. Discriminant analysis by canonical discriminant functions will be conducted so as to predict a child's group membership. As the sample sizes are too small

to conduct discriminant analysis with the children of the same age, we will first need to compute age-corrected scale scores based on an analysis of covariance.

4.4 Development of normative values

If normative values are to be useful, this needs to be adapted to the culture in the country they are going to be used in. PEDI has been translated into many languages (Berg et al., 2003; Erkin et al., 2007; Gannotti & Cruz, 2001; Nordmark et al., 1999; Tsai et al., 2002; Wassenberg-Severijnen, 2005). These studies of cross-cultural validation in different cultures provide evidence of variability related to age norms and the relevance of items in the specific culture. Slovenian, Turkish and Dutch children without disabilities scored significantly differently from American normative values in several functional skills and the caregiver assistance scales. A qualitative and quantitative data analysis confirmed socio-cultural influences and differences of performance of functional skills between the US norms and children in Puerto Rico.

Therefore, after the translation, validation and reliability studies have been completed a decision will be taken with the original authors and the publisher, whether so many changes were made to the instrument that new normative standard scores for the German PEDI need to be developed. The probability is quite high that this step will be necessary as experiences of other research groups show.

The *aim* of this step is to develop normative standard scores for the German PEDI.

Participants: A sample of parents of approximately 1200 children (i.e. 75 non-handicapped children per 14 age groups) (Bridges & Holler, 2007) representative for the population of children aged between 6 months and 90 months with normal development in Austria, Germany and Switzerland. We will look to have a sample with an equal age distribution across the age span of 6 to 90 months, equal representation of girls and boys, proportional representation of parent educational levels and appropriate distribution of community size. These were the aspects taken account of defining the US PEDI norms.

Sampling process: To be defined with national offices of statistics in the three countries.

Recruitment: Parents of selected children will receive a letter asking for participation in this study. Parents will have different possibilities to answer the request: i) by a card and a pre-addressed envelope to the research centres in Switzerland, Austria and Germany ii) by Internet iii) by mail iv) by telephone to the research centres.

Data collection: 50 Students (from the disciplines of occupational therapy, physical therapy, nursing, social sciences) will be trained according the PEDI manual guidelines. They will need to take at least 20 interviews face to face before being able to interview by telephone.

Data analysis: To test scales and structure of the data: factor analysis and multilevel analysis due to nested structure of interviewers. To compute standard scores: Rasch analysis.

4.5 Standardisation of translated assessment

The manual for the PEDI should be available in German. Its aim is to ensure that practitioners know how to use the assessment if no training is required. These manuals can be very extensive including the development of the original instrument and respective research on psychometrics. The German manual will need to be updated with the research on the adaptation and transcultural validation. A decision will be needed on how big the manual and the work to for translating the manual shall be to balance the need informing on the scientific basics of the instrument with the information most practitioners nee, i.e. what is the assessment needed for, for which clients and how the assessment is administered. Another possibility to ensure that the PEDI is used in a standardised fashion is to offer training for professionals.

5 Conclusion

The necessity for valid and reliable assessments for health professionals is undoubted. The process of adapting an existing assessment is less resource intensive than developing a new one. All the same, the process is a long one and it is worth carefully selecting the assessment to be adapted. In addition, the formal aspects of being in contact with the developers of the assessment and/or publishers and negotiating the general conditions of such a project is an important step to avoid investing a lot of time and effort in a research project that is not supported. Finally one needs to keep in mind, what this is all about. In the end we want to improve practice and health interventions in the interest of our clients.

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