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DISSERTATION

Translation of the PROMIS item bank for sleep disturbances for application in Latvia

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List of Abbreviations

CAT	Computerized Adaptive Testing
CTT	Classic Test Theory
DSM	Diagnostic and Statistical Manual
EU	European Union
FACIT	Functional Assessment of Chronic Illness Therapy
FDA	Food and Drug Administration
HAL	Health Assessment Lab
HRQL	Health Related Quality of Life
ICSD	International Classification of Sleep Disorders
IRT	Item Response Theory
ICHOM	International Consortium for Health Outcomes Measurement
IQOLA	International Quality of Life Assessment

ISPOR	International Society For Pharmacoeconomics and Outcomes Research
ISOQOL	International Society of Quality of Life Research
MOT	Medical Outcome Trust
NIH	National Institutes of Health
PGP	Principles of Good Practice
PROMIS®	Patient-Reported Outcome Measurement Instrument System
PRO	Patient-Reported Outcomes
PROM	Patient Reported Outcome Measure
QoL-SIG	Quality of Life Special Interest group
RSU	Riga Stradins University
SEM	Standard Error Measurement
TCA	Translation and Cultural Adaption
US	United States
WHO	World Health Organisation

Zusammenfassung

Schlafstörungen sind ein weitverbreitetes Problem in allen sozialen Schichten der modernen industriellen Gesellschaft. Die subjektive Wahrnehmung von Schlafstörungen spielt in der Identifikation (Screening) und der Beurteilung des Therapieerfolges im Verlauf (Outcome) eine primäre Rolle. Die standardisierte Erfassung von Schlafstörungen, insbesondere in den Baltischen Staaten, ist bisher noch wenig etabliert. Daher besteht die Notwendigkeit für die Entwicklung eines standardisierten Instrumentes. Das 2004 gestartete Projekt Patient-Reported Outcomes Measurement Information System (PROMIS) ist ‚State of the Art' für die Entwicklung und Etablierung standardisierter Instrumente. Ziel der vorliegenden Arbeit war es, eine lettische Version der PROMIS Itembank v1.0 zu Schlafstörungen durch eine standardisierte Übersetzung und kulturelle Adaptation aus dem Englischen zu erstellen. Die 27 Items der englischen Original-Itembank wurden nach dem von PROMIS vorgegeben Standardverfahren übersetzt. Dieses schloss Vor- und Rückübersetzungen, deren Überprüfung sowie Schritte der kulturellen Harmonisierung mit ein. Die Mehrheit der übersetzten Items wurde im Übersetzungsprozess als mittelmäßig schwierig eingestuft. Übersetzungsschwierigkeiten entstanden durch einen kulturell leicht abweichenden Sprachinhalt oder durch sprachliche Unterschiede aufgrund einer im Lettischen umgangssprachlicheren Ausdrucksweise. Diese Probleme wurden in kognitiven Interviews untersucht. Die Ergebnisse der vorliegenden Arbeit zeigen auf, dass die sequenzielle Methodik zur Entwicklung neuer Befragungsinstrumente auf das Lettische anwendbar ist. Dies ermöglichte den Aufbau der PROMIS Itembank zu Schlafstörungen in lettischer Sprache. Die Itembank ist durch ein hohes Maß an begrifflicher Gleichwertigkeit gekennzeichnet und kann als Ausgangspunkt für weitere internationale Untersuchungen, die sich mit Selbstbeurteilungsfragen im Zusammenhang mit Schlafstörungen befassen, verwendet werden. In weiteren Schritten wird die Itembank in einer quantitativen Studie validiert, kalibriert und ihre psychometrischen Eigenschaften erhoben.

Abstract

Sleep disturbances constitute a widely distributed problem among all social classes of the modern industrial society. The subjective experience of sleep disturbances is a cornerstone in the identification (screening) of the problem and the assessment of clinical courses (outcome). A standardized assessment of sleep disturbances has not yet been established, especially in the Baltic States, which indicates the need for a standardized instrument. The Patient-Reported Outcomes Measurement System (PROMIS) project, established in 2004, represents the state of the art for the development and establishment of standardized instruments. The aim of this work is to provide a valid culturally adapted Latvian version of the PROMIS Bank v1.0 - Sleep Disturbance Item Bank. The 27 original English items were translated according to the PROMIS translation guidelines, including forward and backward translations, review, cultural harmonization and cognitive debriefing. The majority of the translated items were classified as of medium difficulty. Translation difficulties were caused by culturally slightly differing content and linguistic issues, due to the existence of more commonly used phrases in Latvian. This could be clarified using cognitive debriefing interviews. The results of this study indicate that the sequential method of instrument development is applicable to the Latvian language. This enabled us to develop the Latvian version of the PROMIS Sleep Disturbance item bank, which is characterized by a high degree of conceptual equivalence and can therefore be used as a basis for other international studies of patient-reported outcomes (PROs) related to sleep disturbance. In the future, a quantitative study will confirm and validate the translated item bank. The next steps include a survey of a large sample of Latvian people using the Latvian PROMIS Item Bank v1.0 - Sleep Disturbance. The data obtained will be used to calibrate national item parameters and to assess its psychometric performance.

1. Introduction

The introduction of this work describes sleep disturbances, the consequences of insomnia, and diagnostic classifications. After that, the theoretical background of self- reported instruments and modern test theories will be outlined. Next, different initiatives currently working to standardize patient-reported outcomes and the PROMIS Item Bank v1.0 - Sleep Disturbance will be presented. Finally, the importance of internationalizing PROs and the challenges which are faced specifically in Latvia will be described, and the aim of this study will be elucidated.

1.1 Sleep disturbance and sleep-related impairment

Sleep disturbances are a widely distributed problem among all social classes of modern industrial society and encompass a wide spectrum of sleep-related disorders and dysfunctions. In the US, a population-based study demonstrated that about 30% of the adult population suffers from insomnia (Ancoli-Israel and Roth, 1999). Furthermore, Ohayon et al. estimated that about 30-40% of the worldwide adult population complains about insomnia and 5-15% complains about excessive sleepiness (Ohayon, 2002, Ohayon, 2008). Linton et al. describe the main symptoms of sleep disturbances as difficulty initiating or maintaining sleep, waking up too early, and poor overall sleep quality (Linton et al., 2015). Abad and Guilleminault classify sleep disorders in four major categories: “dyssomnias; parasomnias; sleep disorders associated with mental, neurologic, or other medical disorders; and proposed sleep disorders.” Dyssomnias are further divided into: “intrinsic, extrinsic, and circadian rhythm sleep disorders” (Abad, 2003). Intrinsic factors originate or develop from the body, whereas extrinsic factors originate from the environment. Characteristics for dyssomnias are either inordinate sleepiness or trouble initiating or maintaining sleep; this group includes diseases such as inadequate sleep hygiene and jet lag syndrome. Parasomnias, such as sleep walking, are characterized by undesirable behavioral and physical phenomena that arise mainly during sleep. The third category of sleep disorders, those associated with mental, neurologic, or other medical disorders, manifests as a result of underlying medical conditions. These disorders are further subdivided into neurological, mental, or other medical conditions. Examples of disorders in this category include dementia, parkinsonism, fatal familial insomnia, panic disorder, and chronic obstructive pulmonary disease (American Academy of Sleep Medicine, 2000; Thorpy, 2000; Reite, Ruddy,

Nagel, 2002; Borbely, 1980; Zee P., Harsanyi, 2003; Silber, 2001; Elsenbruch et al., 2002; Moldofsky, 2002; Chokroverty, 2000; Neubauer, 1999).

In general, sleep researchers come to a common conclusion: everyone suffering from a sleep disturbance, either as a primary disease or as a symptom of another condition, suffers a measurable negative impact on quality of life. According to Roth, this decrease in quality of life manifests itself in many different health domains, such as “physical functioning, role limitation due to physical health problems, bodily pain, general health perception, vitality, social functioning, role limitations due to emotional health problems and mental health” (Roth, 2007).

Various studies have demonstrated that sleep duration, quality of sleep, and daytime sleepiness increase the risk of weight gain entailing obesity, increased blood pressure, metabolic syndrome, vulnerability to the common cold, psychiatric disorders, and all- cause moribundity (Breslau et al., 1996; Riemann and Voderholzer, 2003; Van Dongen et al., 2003; Cappuccio et al., 2007; Buysse et al., 2008; Cappuccio et al., 2008; Gangwisch et al., 2008; Hall et al., 2008; Cohen et al., 2009). Sleep deprivation is also connected with changes in alertness, psychomotor capacity, mood and affect regulation, memory, the following of moral rules, metabolic and appetite feedback control, and immune response (Van Dongen et al., 2003; Walker and Stickgold, 2004; Spiegel et al., 2005;Yoo et al., 2007; Buysse et al., 2010). Due to the complexity of sleep disturbances, lack of awareness of health care professionals including doctors, nurses, clinical psychologists, and the high cost of the application of instrumental examinations, several authors suggest that the actual number of people suffering from sleep disorders may be even higher than the reported numbers. (Stores and Crawford, 1998; Namen et al., 2001; Stores, 2007).

1.2 Diagnostics of sleep disturbances and sleep-related impairment

Today, different methods exist to assess the sleep and sleep-related impairments of humans. The current gold standard to measure sleep-wake patterns and their disturbances is electrophysiological techniques such as electroencephalography, topographic mapping, actigraphy, and polysomnography. However, these methods require special equipment, educated personnel, and plentiful financial resources (Ancoli- Israel, 2005; Morgenthaler et al., 2007). An even more important point to consider when choosing a diagnostic tool is that the definition of insomnia according to the International Classification of Sleep Disorders (ICSD) and The American Psychiatric Association´s

Diagnostic and Statistical Manual (DSM) does not include polysomnographic criteria (Chesson et al., 2000). The ICSD defines mild insomnia as “an almost nightly complaint of an insufficient amount of sleep or not feeling rested after the habitual sleep episode” (American Academy of Sleep Medicine, 2005).

Whereas the DSM definition of primary insomnia reads as follows “ A complaint of difficulty initiating or maintaining sleep or of non-restorative sleep that lasts for at least a month, along with the presence of functional impairment or significant distress” (American Psychiatric Association, 1994). Moul et al. conclude in their work that the “two different definitions mirror the complexity of the syndrome and that insomnia is “a collection of symptoms and complaints rather than a collection of clinical signs” (Moul et al., 2004).

Therefore, standardized assessments of sleep disturbances as experienced by patients are cornerstones in their detection and determining the appropriate treatment for the patient (Deshpande et al., 2011). Thus, it is generally recommended that the method of choice for evaluating sleep disturbances and sleep related impairment are Patient Reported Outcome (PRO) measures (PROMs) (Buysse et al., 2010).

1.3 Theoretical background on self-report instruments

1.3.1 Patient-Reported Outcomes

PROs are the first choice in approaching sleep disturbances (Stores, 2007). But what are PROs and how do patients and medical staff benefit from them?

The Food and Drug Administration (FDA) defines a PRO as following:

“A PRO is any report of the status of a patient´s health condition that comes directly from the patient, without interpretation of the patient´s response by a clinician or anyone else. The outcome can be measured in absolute terms (e.g., severity of symptom, sign, or state of a disease) or as a change from a previous measure” (FDA, 2009).

As the definition describes, it is possible with PROs to have the patients’ voices and opinions on several aspects of care. This ranges from diagnostics, the patients` own perceptions of the influence of their condition, together with the therapy, on their lives. The approach to patients becomes more patient-centered and a more effective treatment tracking can be ensured. The use of PROs has established itself as an important tool for improving communication between patients and physicians, which itself can have a positive impact on the well-being of the patient (Kohlmann, 2010; Black 2013).

PROs offer the opportunity to transform `subjective experiences´ into `objective measures´ (Deshpande et al., 2011).

The conceptual model of Wilson and Cleary 1995 gives an opportunity to show the high impact of PROs in patient-centred medicine. The model (Fig.1.) integrates clinical and psychosocial approaches to health care by linking biological and physiological variables with subjective health constructs. Biological and Physiological Variables are describing the functioning of cells, organs and organ systems. These variables are usually measured by clinicians through physical examinations and by the application of the appropriate examination/investigation method such as blood analyses, or for example, MRI scans for diagnosing diseases. Symptom Status gives information about patients' perception of a disturbed physical, emotional or cognitive state. In mental diseases such as depression, patients´ symptoms are also a key for a diagnostic classification. The third domain, Functional Status, reflects the ability of patients to perform and execute tasks. It often summarises the outcome of a disease, but especially for rehabilitation doctors and physiotherapists it can also be a diagnostic measure. A subjective rating of the previously mentioned concepts is integrated into General Health Perceptions. The continuum is completed with Overall Quality of Life, which is influenced by non-medical factors such as patients´ financial situation or the country of residence. If you look more closely at the domains Symptom Status, Functional Status and General Health Perception, the question arises to what extent these are influenced by the environment, for example, how working conditions are adjusted to the complaints, and by characteristics of the individual, for example, the individual´s coping mechanisms. Wilson and Clark assume there is a causal pathway, but do not exclude reciprocal ways either. PROs provide a great chance to ascertain most of the domains, especially symptoms and the functional status. Whenever possible, it is recommended that the patient her-/himself assesses her/his own perceived health status. However in certain situations, for example in the case of small children or patients with dementia, proxy-ratings are also accepted. Clinicians can examine the functional status of a patient by performing different tests, but by applying PROs they can gather more information about patients' functionality from the patients themselves (Ojelabi et al., 2017; De Vet, 2011).

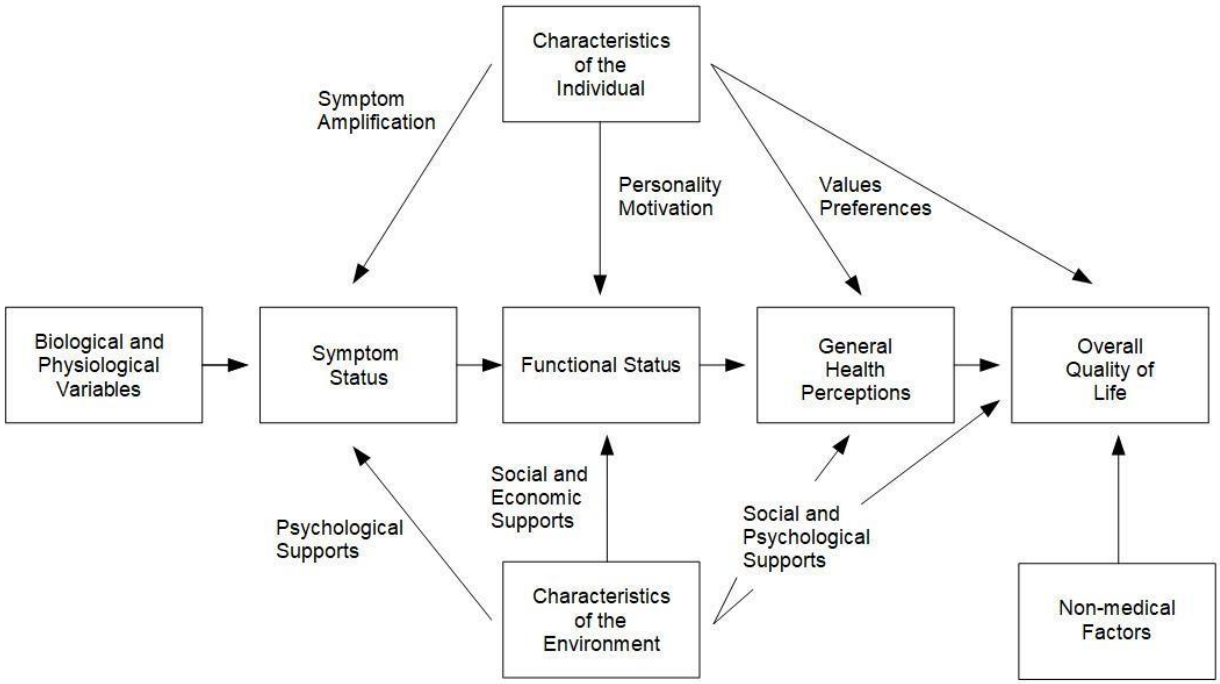

Figure 1: Relationship of PROs based on the conceptual model of Wilson and Cleary.

There are different categories of PROs and it is important to distinguish between them to ensure the usage of the right PROMs:

Generic PROs measure the well-being of all types of patients independent of their conditions. These PROs are useful not only in larger *clinical and research* challenges, but also provide information for health policy planning (*epidemiology),* cost-benefit calculation of prevention and rehabilitation measures (*health economics*) and for *quality assurance* in all areas (Redegeld, 2004; Radoschewski, 2000; Bullinger, 1997b; Ravens-Sieberer et al., 2001). The consistent use of generic PROs facilitates the comparison of local and international data and the comparison of patients' data with those of the general population.

Condition-specific PROs are the right tool to measure changes in a single patient over time. They are created to zero in on a specific disorder or condition and are more sensitive to detecting clinical changes. This makes these PROs particularly suitable for the assessment of clinical courses in groups or in an individual. The combination of condition-specific PROs makes an elicitation of different conditions possible, and there are some scales which allow a composite score of different PROs (Obbarius et al, 2018).

PROs have a wide range of complexity and areas of application and can measure a single health dimension such as “sleep disturbances” or “a combination of physical, mental and social aspects collectively known as health-related quality of life (HRQL)” (Kyte, 2015).

1.3.2 Methodical questions about PROs

There are many different PROMs available for assessing sleep disturbances. A literature review listed more than 100 questionnaires and overall 3000 items (Moul 2004). Many of them have not been validated or are designed either for different research purposes or for specific sleep disorders such as sleep apnea or narcolepsy. Another attempt to assess patients` sleep disturbances is by using sleep diaries. Diaries can be helpful on an individual level but allow no standardization (Buysee, 2010). Another disadvantage of so many different available PROMs with scores scaled on different metrics is the limitation of comparability across different interventions, patient groups, diseases, cultures, and countries (Rose, 2008). It is the researcher’s responsibility to distribute and apply PROMs which deliver only valid and reliable data. To accomplish this challenge, it is essential to develop and establish a standard for assessing sleep disturbances and all other self-reported health domains and to apply state-of-art psychometric methods. The advantages of working with standardized PRO measures which have the same significance as biomarkers and integrating them as parts of routine patient assessment are multidimensional. These can be, among others, high quality assessment of treatments, program effectiveness, improvement of comparative effectiveness research, and increase in data reliability (Nolte, 2015).

1.3.3 Item Response Theory and Computer Adaptive Testing

Modern measurement theories are the state-of-the-art in PROM development. These include item response theory which is defined as “a family of mathematical models that assumes that responses on a set of items or questions are related to an unmeasured “trait” and calibrate any numbers of items that are aimed to measure the same latent construct on a common metric” (Healthmeasures, 2018). IRT is based on the idea that each patient, according to his characteristics, has a given probability to choose one distinct answer to one specific item question. Therefore, each answer option of an item is described by a probability function, the item *response curve*.

The slope of the curve is called the *discrimination parameter*. The more the slope of the curve increases, the more discriminative the item. This means that the item discriminates between people with similar but not identical traits. The response curve of a highly discriminative item illustrates that a small change in trait levels results in large changes in probability. The more discriminative an item is, the higher its measurement precision.

Another parameter which affects the proband's answer is *item difficulty.* The median probability indicates where on the measured continuum of the trait the chance to answer "yes" is 0.5. The less of this trait is necessary to answer yes, or the more the curve is shifted to the left, the less discriminative an item is (Cook, 2014).

After PROMs have been calibrated using IRT, researchers and clinicians can create multiple instruments, including standard static instruments or short forms. They can use calibrated banks to choose items classified by specific content interests and originate a customized short or full-length PROM.

The use of a common metric allows items from different instruments to be calibrated on the same scale, which makes scores comparable across instruments and enables the transition from an instrument-based measurement of characteristics to a construct-based measurement (Rose et al., 2013). IRT measurement models enable the use of Computer Adaptive Testing (CAT), which allows the selection of the items and the total number of items to be adapted to the response behaviour of the patient (Cella, 2007). Based on patients' responses to previous questions, new items are selected and presented. Typically, CAT starts with an item in the middle range of characteristics. The answer allows an initial classification of the patient. The computer selects the items that follow based on the answers which were given to the preceding questions. The algorithm based on the IRT concept calculates the weighting of the answers. The result of CAT is that the patient answers only the items which are relevant to him. Therefore, CAT improves the precision and the range of measurement and reduces patient stress. The development of CAT is more elaborate than other methods, but it allows clear standardization of mental characteristics (Rose et al., 2013). Altogether, the use of standardized instruments and modern computer technology makes it possible to administer computerized adaptive tests and other patient-reported instruments which are collected with web-applications.

1.4 Initiatives for the standardization of PROs

As described above, there are a plethora of instruments available to assess hundreds of different health constructs. Thus, standardizing the assessment of PROs is a key challenge in increasing their acceptance in the medical field. There have been several efforts to achieve standardization, for example the ICHOM initiative. ICHOM suggests standard sets to measure what is most relevant for most of the patients suffering from a certain condition. Items are selected and combined from different questionnaires by a group of patient representatives, clinicians and measurement experts. So far no standard set for the assessment of sleep disturbances has been developed (ICHOM, 2017).

A more generic approach standardizing the assessment of PROs is the development of the Patient-Reported Outcome Measurement Information System (PROMIS). It was established in 2004 and cross-funded by the US National Institutes of Health. The aim of the PROMIS initiative is to establish an internet-based source for administering Computer Adaptive Testing, accumulate self-reported data, and supply instant health assessment reports (NIH, 2003). The NIH defines the aim of PROMIS as follows:

"The clinical outcomes research enterprise would be enhanced greatly by the availability of a psychometrically validated, dynamic system to measure PROs efficiently in study participants with a wide range of chronic diseases and demographic characteristics" (NIH, 2003).

In order to accomplish this goal, the NIH develops and validates item banks of modern test theories based on physical, social and mental health domains. The PROMIS tools were developed through the application of scientific standard criteria. Buysee et al. describe this process as: "scale development through an iterative procedure of literature searches, collecting and sorting items, expert content review, qualitative patient research and pilot testing" (Buysee et al. 2010). The routines of item bank development and validation are summarized in the PROMIS methodology and PROMIS maturity model (Cella et al., 2007; Cella et al., 2010).

Figure 2 gives an overview of the different domains for adults measured by PROMIS (Cella et al., 2007; Cella et al., 2010).

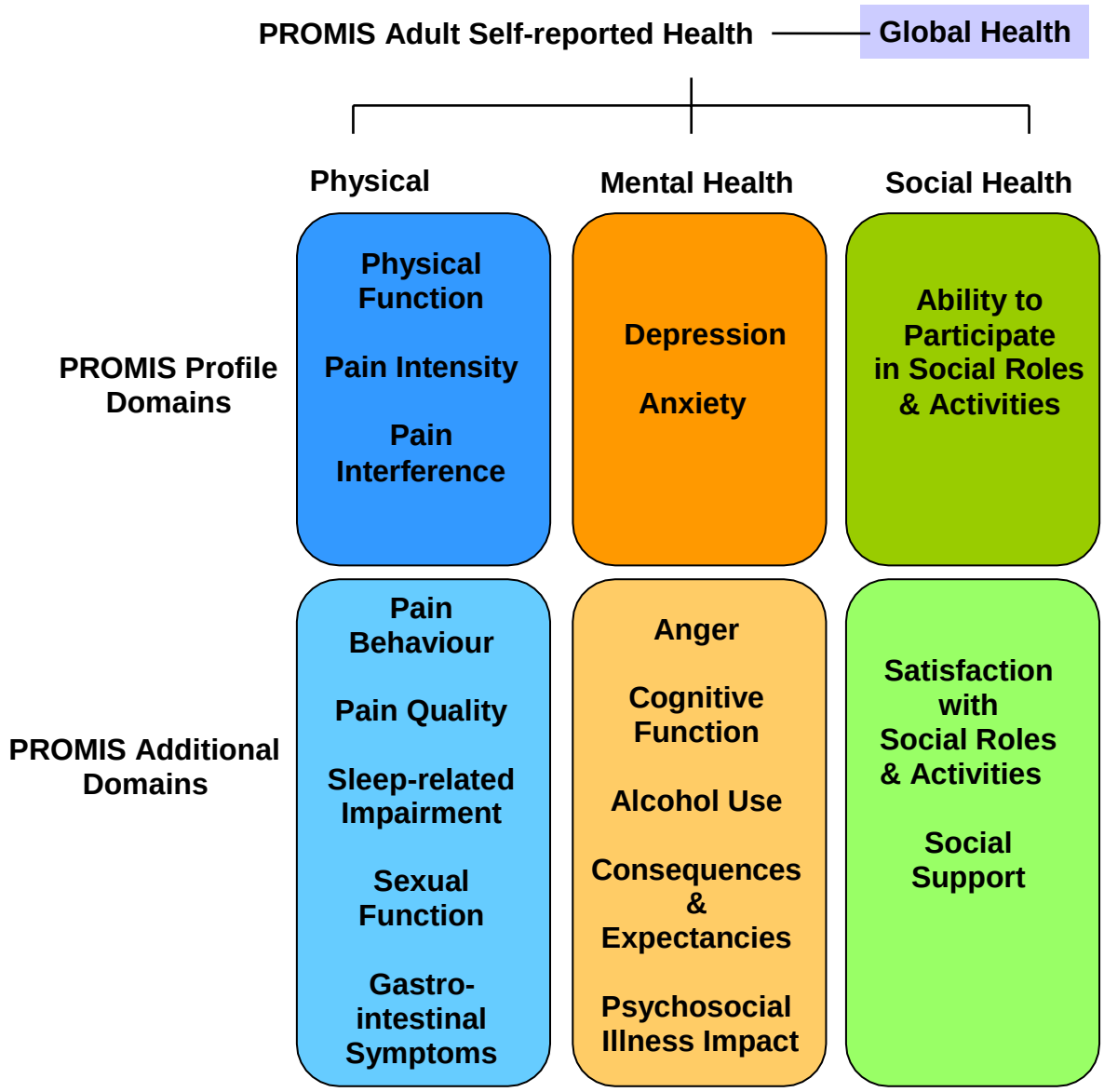

Figure 2: Overview of PROMIS domains according to NIH resources available on the PROMIS homepage (PROMIS, 2015).

1.5 The PROMIS Item Bank v1.0 - Sleep Disturbance

The Latvian translation was based on the existing US PROMIS Sleep Disturbance item bank; therefore, a brief overview of the characteristics of the PROMIS Item Bank v1.0 - Sleep Disturbance is presented. In the work of Buysee et al., Development of Short Forms from the PROMIS Sleep Disturbance and Sleep-Related Impairment item banks, item bank development is summarized and structured as “a rigorous and systematic methodology including literature reviews, qualitative item review, focus groups, cognitive interviewing and psychometric testing using methods from both classical test theory and item response theory” (Buysse et al., 2010).

Examination of sleep disturbances requires an initial definition of the terms *sleep* and *wakefulness*. With reference to the PROMIS Sleep Disturbance item bank, the following definition is used:

"Sleep and wakefulness are the two fundamental behavioural states of human beings. Sleep is a rapidly reversible, recurrent state of reduced (but not absent) awareness of an interaction with the environment. Wakefulness is a behavioural state of active engagement and interaction with the environment, including perception and processing of stimuli and the production of cognitive, emotional, and behavioural responses"

(Cella et al., 2010).

The PROMIS Item Bank v1.0 - Sleep Disturbance covers the following sleep aspects:

- Self-reported perceptions of sleep quality
- Sleep depth
- Restoration associated with sleep
- Perceived difficulties and concerns with getting to sleep
- Perceived difficulties and concerns staying asleep
- Perceptions of the adequacy and satisfaction with sleep
  (Patient Reported Measurement Outcome System, 2013)

Based on the PROMIS Sleep Disturbance Item Bank v1.0, short forms were developed. For the development of post-hoc computerized adaptive tests, including item discrimination parameters, item definitions and clinical assessment were applied.

These short forms do not include:

- Symptoms of specific sleep disorders
- Self-reported estimation of sleep quantity, which includes the total amount of sleep, the timespan for falling asleep, and how long the person may have been awake during the night. (Yu et al., 2011).

The short forms are more general rather than disease-specific. They focus on the 7 preceding days and are available for people older than 18. Administering a short form requires instructing the patient to answer all the items. When questions are provided through CAT, the answer given by the patient guides the system's choice to subsequent items from the complete item bank. Even if the following questions differ between the

participants due to their preceding answers, the scores of the participants remain comparable.

If all participants should answer the same question to make a comparison over time easier manually delivered short forms are preferred. There are four different types of short forms (4, 6, 8a and 8b). For the selection of the short forms, 1000 participants have answered the items of the complete item bank. Experts reviewed the item ranking and reduced them into 8, 6 and 4 items. Patient-Reported Outcome Measures for Sleep Disturbance could be combined together with a short form from another domain, for example, physical functioning, depression, anxiety, pain interference, fatigue and satisfaction with participation in social roles. Professionals also had the chance to create their own short form by selecting items from the item bank. In table 1 the first items of the PROMIS Item Bank v1.0 - Sleep Disturbance are shown exemplarily (Yu et al., 2011, PROMIS, 2015). The numbering of the items follows the nomenclature in the initial database used by Buysse and his coworkers for the psychometric calibration and selection of the PROMIS Bank items (Buysse et al., 2010).

Table 1: Examples from the PROMIS Item Bank v1.0 - Sleep Disturbance concerning the statement **`In the past 7 days...´:**

Sleep105	**My sleep was restful.**	**Item score**
	o Not at all	5
	o A little bit	4
	o Somewhat	3
	o Quite a bit	2
	o Very much	1
Sleep106	**My sleep was light.**	
	o Not at all	1
	o A little bit	2
	o Somewhat	3
	o Quite a bit	4
	o Very much	5
Sleep107	**My sleep was deep.**	
	o Not at all	5
	o A little bit	4
	o Somewhat	3
	o Quite a bit	2
	o Very much	1

Each question has five response options ranging from 5 (“not at all”) to 1 (“very much”); depending on the specific item, one out of three possible answer tables is used. Each set of answers is ranked with score values from 1–5.

The first block of questions can be evaluated on an *intensity scale* as illustrated above:

(5) Not at all, (4) A little bit, (3) Somewhat, (2) Quite a bit (1) Very much.

The second group of questions can be answered with a *frequency scale*:

(5) Never, (4) Rarely, (3) Sometimes, (2) Often, (1) Always.

Only one item (S109), assessing *overall sleep quality*, uses the following scale:

(5) Very poor, (4) Poor, (3) Fair, (2) Good, (1) Very Good.

For a valid evaluation of the answers, at least 50% of the questions must be answered (Correia, 2012). The complete item bank was translated in this study, containing a total of 27 questions, with the results listed in Table 7.

1.6 Significance of international investigations

It is crucial to compare the assessed data not only across interventions, patient groups, and diseases but also across countries and cultures. To aggregate data in different countries and cultural groups and therefore make a comparison possible, valid translated and culturally adapted PROMs are needed (Epstein, 2015). Therefore, a standard for translation and adaption which is culturally adapted and understandable and which maintains the meaning and function of the items in the original version must be employed (Sperber, 2004). In the past, different translation methods, different terminology, guidelines created by instrument developers, and poorly translated instruments resulted in inconsistencies and a lack of comparability of data sets, which threatened the robustness of research findings in general (Wild et al., 2005). Different organisations have devised various means of overcoming the linguistic and cultural challenges that researchers must face when using PROMs in different countries or in different populations of the same country.

- The Health Assessment Lab (HAL), a non-profit organization supporting the science of outcome measurement, is dedicated to improving health and health care. For example, HAL researchers have collaborated in the International Quality of Life Assessment (IQOLA) Project. The aim of this project was to create and adapt 200 translations of the SF-36®, SF-12® and SF-8™ Health for use in more than 70 countries (Aaronson et al., 1992). Since 2000, the Medical Outcome Trust has also been a part of HAL with the aim to enhance health care services by

establishing the universal adoption of health outcome assessment in health care. HAL is also involved in the PROMIS initiative (HAL, 2017).

- MAPI is a patient-centered research company. Their network of over 1,000 PRO linguistic experts in over 100 countries has already translated 2,500 PRO instruments into over 170 languages (MAPI, 2017).
- FACIT (Functional Assessment of Chronic Illness Therapy) is an organization affiliated with an outcome research group under the direction of Dr. David Cella. FACIT has translated over 50 FACIT questionnaires and more than 75 non-FACIT questionnaires into up to 60 languages. The translated questionnaires cover a broad range of different disease areas such as malignancies, HIV/AIDS, multiple sclerosis, and general chronic illness. FACIT is member of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and ISOQOL (International Society of Quality of Life Research). FACIT serves as a translation source for various NIH projects, including PROMIS (FACIT, 2017). In 1999, ISPOR formed the Quality of Life Special Interest group (Qol-SIG) and the Translation and Cultural Adaptation group (TCA) and created guidelines and standards for the translation and cultural adaption of PROMs. A detailed review of current practice, literature, and existing guidelines including standards from FACIT, IQOLA and MOT was conducted to overcome problems such as lack of consistency in terminology and methodology. This work resulted in “Translation and Cultural Adaptation of Patient Reported Outcomes Measures–Principles of Good Practice”. These principles take into consideration issues facing the pharmaceutical industry, regulatory institutions, and the broader research community. They also consider key actors and components of the analysis and the possible advantages and risks related to the different approaches. (Wild et al., 2005). These principles are consistent with the updated FACIT translation methodology and are the basis for the PROMIS translation standard and cultural adaptations (Eremenco et al., 2005; Correia, 2012).

1.7 Challenges of data collection and implementing PROs in Latvia

Today Latvia is a country, made up of very different ethnic groups living alongside on another. In 2014 there were about 61.14 % Latvians, 26.21% Russians, 3.47 % Belarusians, 2.29 % Ukrainians, 2.20 % Poles, 1.27 % Lithuanians, 0.28 % Jews, 0.29 %

Roma, 0.14 % Germans, 0.11 % Tatars, 0.10 % Armenians, 0.10% Estonians and 2.4 % other groups (The Latvian Institute, 2014).

The different spoken languages of the various ethnic groups affect not only the relationship of the people within Latvian society, but also the relationship of physicians to their patients and vice versa. This may also be influenced by the fact that over a long period of their history Latvians had to deal with the crucial factors of survival, rather than enjoy the quality of life. This had emotional, physical, social, political, economic and geographic reasons, but had social and medical consequences (Ancane, 2014). Broad segments of the population felt a sense of helplessness when faced with the difficult social conditions, and this created a kind of self-directed anger. Such phenomena led to a broad spectrum of medical conditions: clinical depression, panic attacks with typical psychosomatic characteristics, sleep disturbances and a few chronic, mostly somatic diseases (Ancane, 2014).

For historical reasons, but also due to the dramatic social upheavals of the last decades, the social-economic situation in Latvia is stressful for the population. Many Latvians have to work in more than one work place (Circenis and Millere, 2011). The *Standard Eurobarometer* shows that 28 % of the Latvians in comparison to 16 % of the population of other European Union member countries declare health and social security as the two most important issues their country is currently facing. Satisfaction with life in general at 63 % is one of the lowest in the European Union (EU) and shows that there is a strong difference between the satisfaction in Latvia and that in other countries, which counts 80 % (Eurobarometer, 2007). These findings are intertwined with a high prevalence of sleep disturbances. (Upmane and Sebre, 2010).

1.8 Study aim

There are no completed studies evaluating sleep disturbances in Latvia nor is there a valid instrument to investigate sleep disturbance in the Latvian population or to compare the results with those of other countries. The existing significant numbers and facts from the Eurobarometer require an instrument, which rapidly and precisely evaluates sleep disturbances and sleep-related impairment. The aim of this work is to fulfill a step of the development of an applicable and comparable instrument which measures sleep disturbance in the Latvian population by creating a valid culturally adapted Latvian translation of the PROMIS Bank v1.0 - Sleep Disturbance Item Bank based on the PROMIS Instrument Maturity Model. By following the PROMIS Instrument Maturity Model

which describes “the stages of instrument scientific development from conceptualization through evidence of psychometric properties in multiple diverse populations”, a basis can be provided to calibrate the questionnaire and to assess its psychometric performance (Healthmeasures, 2018). This fulfils an important methodological requirement and thus provides a contribution to the future studies of sleep disturbance in Latvia and clinical daily routine.

2. Methods

This chapter is built up by listening of the methodically key steps of this work. This is followed by a graphically demonstration of the procedure and closed by detailed descriptions and explanations of the single steps.

2.1 Key steps in the translation procedure

The translation and cultural adaptation process of this work is based on the principles which were developed by the “Task Force for Translation and Cultural Adaption” led by Diane Wild in 2005 and which are equivalent to the FACIT guidelines. Thirteen steps were developed, and they are seen as the gold standard for the translation of the PROMIS Questionnaires and referenced in their official Instrument and Validation Scientific Standards Version 2.0 documentation. They are:

1. Preparation; 2. Forward translation; 3. Reconciliation; 4. Back translation; 5. Back translation review; 6. Expert reviews; 7. Prefinalization review; 8. Finalization; 9. Harmonization and quality assurance; 10. Formatting, typesetting and proofreading; 11.Cognitive debriefing; 12. Review of cognitive debriefing results and finalization; and 13. Proofreading. In the last step, a final report is prepared. A flow chart of the key translation steps is shown in the Figure 3.

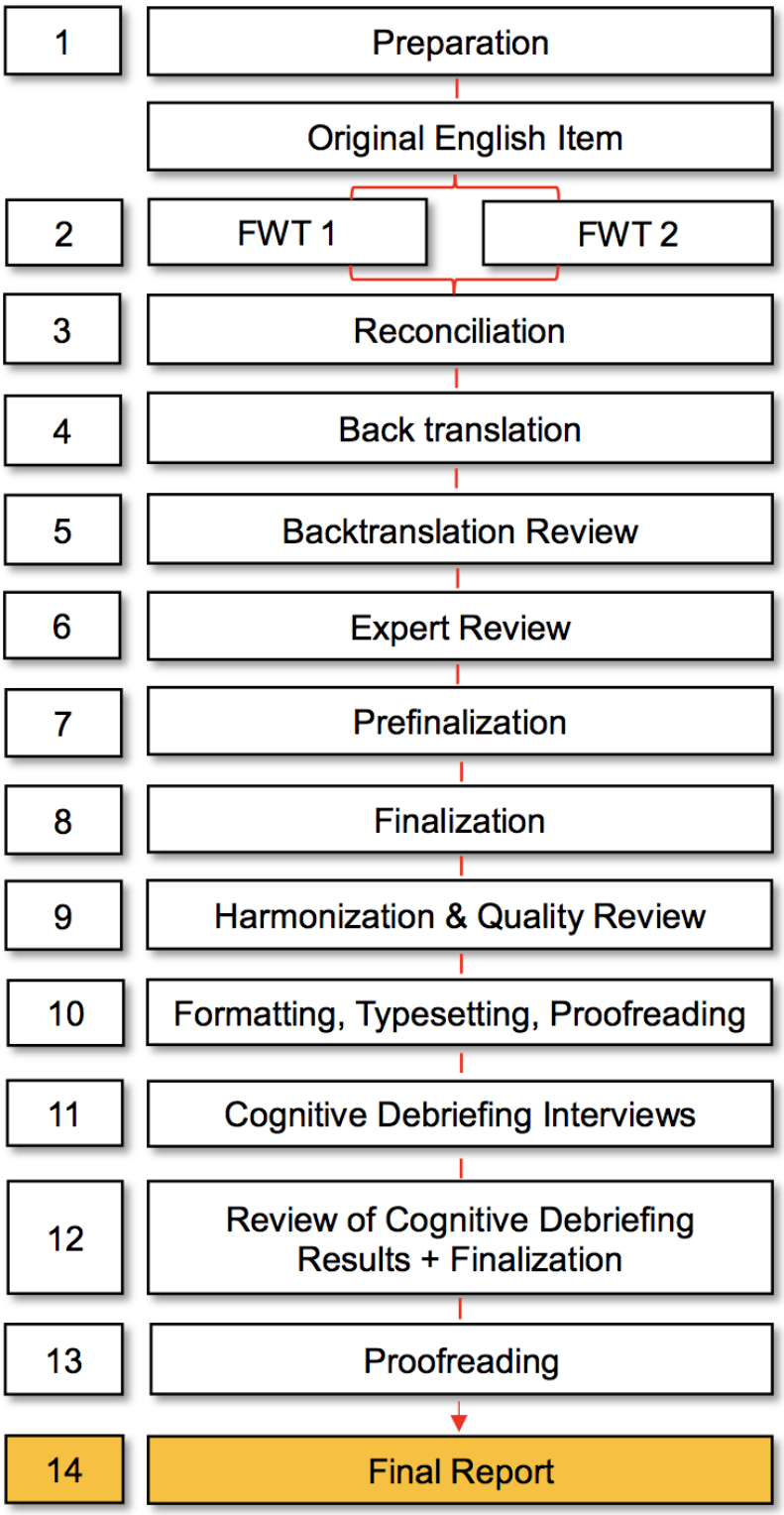

Figure 3: The key translation steps. The numbers refer to the text section below where the single steps are explained in detail.

Each of these steps is explained in detail below as it pertains to the current project.

1. Preparation

The preparation phase included obtaining permission for the project from the PROMIS Health Organization (PHO), becoming acquainted with the definition and translation guidelines of PROMIS, nominating the different team members and assigning their tasks. The team consisted of seven persons: a project manager, who was the PROMIS translation director and coordinated and oversaw the different steps of the translation process, two forward translators, one independent translator for the reconciliation of the final provisional translation, one back translator, the in-country consultant and a proof- reader.

2. Forward translation

In this step the aim was to create two simultaneous forward translations.

Two translators who spoke Latvian as their native language and were fluent in English carried out the translations independently of each other. The translators were provided with a clear explanation of the basic concept. Instead of a literal translation of the items, it was more important to capture the conceptual meaning of the item keeping in mind that the questionnaire would be provided to patients.

3. Reconciliation

For the reconciliation the project manager, the two forward translators and one independent translator met with the aim of developing one reconciled forward translation. The independent translator spoke Latvian as his native language and had not seen the items before the meeting. His task was to choose the most appropriate forward translation, recommend alterations or offer new translations and give reasons and explanations why his choices for the reconciled version would convey the meaning of the original item in the best possible way.

4. Back translation

A person speaking English as a native language and fluent in Latvia performed the back translation. This person had only seen the reconciled version and none of the forward translations or the original items in English. The task for the back translator was to use clear, simple language and to make a more literal than conceptual translation. The back translator had no medical training and had not previously seen the original English source or item definitions.

5. Back translation review

In this step a comparison between the source and the back-translated English version was carried out to detect discrepancies and to determine to what extent these two versions harmonised with each other.

6. Expert reviews

A group of Latvian native-speaking linguists and health care professionals investigated the preceding steps and selected the most applicable variant or offered an alternative translation.

7. Pre-finalization review

The objective of the pre-finalization review was to evaluate the expert reviewers´ comments and detect potential problems that could result from their recommended translations. Questions and comments were selected to be used as guidance for the following step, as guidance. In this step, we compared our results with the translation results of Mapi and harmonized the two translations with each other. This was done because Mapi, one of the leading companies working with patient-centred research, linguistic validation and translation had already translated a subset of items for a commercial company (Mapi, 2015).

8. Finalization

A Latvian native speaker who was taking the preceding steps in consideration performed the finalization of the translation. The decisions for the final version were based on the explanations and justifications provided by the Latvian native speaker.

9 Harmonization and quality assurance

The final translation was compared with the source as well as with other languages if applicable and the items with each other. Then the quality review was performed by the PROMIS Statistical Center to check its consistency with previous translation attempts.

10. Formatting, typesetting and proofreading

The final questionnaire was formatted, typeset and reconciled by two independent proofreaders.

11. Cognitive debriefing

The Latvian questionnaire was pretested by six participants in cognitive debriefing interviews with the “think aloud method”. This method gives participants the chance to verify that the meaning of the original item is conveyed identically to that of the translated item by saying aloud what they are thinking about the question. We studied the way the participants understood, mentally processed, and responded to the items (Ericsson and Simon, 1980; Willis, 2006). The cognitive debriefing interviews took place in rooms in the Riga Stradins University building and at the Psychosomatic Institute Riga in February 2015. Before the participants were interviewed, they were informed about the project. The information highlighted that the interviews were conducted only to validate the questionnaire and not to analyse the participants´ sleep quality and that their data would be stored reliably and anonymously. All participants signed an informed consent. Written notes were made and digital recordings were taken during the interviews.

After the participants were informed, the “think aloud method” was explained and we asked practice questions.

“How many windows are in your house? Whilst you are counting please say what you are seeing and thinking about?” (Willis, 2006) During this time, the participants had the possibility to ask comprehension questions. In the cases of detectable ambiguities, further practice questions (usually up to three) were asked. The items were read out loud and accompanied by guiding questions as:

“Whilst you were answering the question, what were you thinking about? What crossed your mind before you gave your answer?”

We preselected some items and words where we suspected some understanding difficulties to further investigate them using the probing technique. The probing technique was implemented by asking more specific questions for the preselected items (see Table 2).

Table 2: Items which were preselected for the probing technique (2.3, Step 11)

Item Number	Original	Latvian Translation
Sleep125	I felt lousy when I woke up	Es jutos draņķīgi, kad pamodos
Sleep105	My sleep was restful	Es jutos atpūties pēc miega
Sleep116	My sleep was refreshing	Mans miegs bija atspirdzinošs
Sleep90	I had trouble sleeping	Man bija traucēts miegs

After the interview the participants' demographic data were recorded (gender, age, occupation).

The evaluation of the cognitive debriefing was classified into

a) Error-free

b) Containing one or more errors

c) A "struggle", i.e. the participant clearly had difficulties answering the question, but eventually reached an appropriate answer (Al-Janabi et al., 2013).

We further classified the errors into the following categories: comprehension, retrieval, and judgement or response errors.

The cognitive debriefing interviews had the aim to validate and check the comprehension of the questionnaire so the data were edited by a selective transcription. Transcription is the process in which auditory material is modelled into written form. The selective form makes it possible to focus on the comprehension of the item and to disregard excesses which are not relevant (Hussy et al., 2013).

12. Review of Cognitive Debriefing Results and Finalization

The participants´ comments were collected and summarized into issues. Translation solutions were proposed and verified.

13. Proofreading

The Latvian items were sent to a proofreader, who checked the spelling of the items.

14. Final report

This work included the final report. The item history of all the items used in this study was documented in an Excel file. The development process of selected items is shown in the Results section.

3. Results

The following section presents a transparent protocol of the translation process of PROMIS Item Bank v1.0 - Sleep Disturbance and an outline of the difficulties the investigator had. In subpoints 3.1-3.2 the results of the translations steps and of the answer options and time memory span will be outlined. Subpoint 3.3 “Key steps in the translation process of the sleep disturbance items” is a tabular display of the single steps of the item translation process, categorized by degree of difficulty.

In 3.3.1.and 3.3.2 a more detailed description of the single steps, classified into simple or medium difficult items, can be read. Subpoint 3.4 focuses on the cognitive debriefing results, followed by subpoint 3.5 which deals with the results of the probing technique. At the end of this chapter in subpoint 3.6 the final Latvian Version of PROMIS Item Bank v1.0 – Sleep Disturbance is shown against to the original English version of the items.

3.1 Establishing of the Latvian PROMIS Item Bank v1.0 - Sleep Disturbance

On the 5th of October, 2014 authorization to translate the PROMIS Sleep Disturbance item bank into Latvian was received and the team members were nominated as described in the Methods section (2.3, Step 1).

3.1.1 Translation process from forward translation to finalization

The translation was carried out as described in 2.3 (Step 2-Step 8).

We classified the items according to the level of difficulty of the translation process into easy, medium and difficult items. Easy items were items which only produced one or two Latvian versions during the whole translation process, medium items produced three to four versions, while difficult items produced five to six different versions during the translation process (Wahl et al., 2011).

The difficulty level of the majority of the items was medium. 11 of the 27 items were considered item easy to translate, while 16 sleep disturbance items were medium. Items

classified as difficult according to the definition above were not encountered during the whole translation process.

In the following sections the translation results of some selected items are shown exemplarily.

3.2 Translation of answer options and time memory span

The first block of response options (“In the past 7 days / not at all / a little bit / somewhat / quite a bit / very much”) showed different level of difficulty (see Methods 2.2). The RSU team translated the time memory span “In the past 7 days” during all translation steps with “Pēdējo 7 dienu laikā” [During the last 7 days]. The Latvian version of Mapi was “Pēdējās 7 dienās” [In the last 7 days]. In the team we discussed both versions. After reconciliation with the translation director from PROMIS we decided on “Pēdējās 7 dienās” [In the last 7 days]. For “Not at all” only one translation was offered: “nemaz”. “A little bit” was translated by one forward translator with “mazliet” [a little bit, somewhat], by the other with “reti” [rarely]. In the team we decided for “reti” [rarely], and in the later steps we compared “reti” with the translation offered by Mapi “mazdrusciņ” [rarely].Together with the PROMIS translation director we decided for “mazdrusciņ”, which has the same meaning as “reti” but it is more typical everyday language (Correia, 2015; personal communication). The same process was repeated with the answer option “somewhat”. The RSU team chose one of the answer options of the forward translator “dažreiz" [sometimes]. The back translation resulted into “nedaudz” [not much]. We nominated “nedaudz” for a better answer option because it is more common. The Mapi translation was “vidēji" [middle]. We discussed that Mapi´s version is more suitable in the context of the other answer options. “Quite a bit” was translated with a combination of the two forward translators. “Diezgan daudz” [quite much] and “bieži” [often] became “diezgan bieži” [quite often]. The Mapi translation was the same as that of the first forward translator “diezgan daudz”. Together with the PROMIS translation director, “diezgan daudz” was chosen. The same was the case for the last option “very much”. Our answer option after reconciling came from the second forward translator “Ļoti bieži” [very often]. The first forward translator translated it into “ļoti daudz” [very much]. The difference between “Ļoti bieži” and “ļoti daudz” is that the first option gives the opportunity to answer as “frequency” and the second as “amount”. After harmonization with the Mapi translation, we changed our translation to “ļoti daudz”, an adjustment process as a

consequence of changes in the earlier answer options. These changes led to an adaptation of all the answer options to measure qualitative aspects of sleep.

The other answer option blocks revealed only one Latvian option in the whole translation process. The answer block (“Never / rarely / sometimes / often / always”) corresponds to (“nekad / reti / dažreiz / bieži / vienmēr”) and the answers (“very poor / poor / fair / good / very good) have the Latvian translation (“loti slikta / slikta / vidēja / laba / loti laba”).

3.3 Key steps in the translation process of the sleep disturbance items

The following table shows the single steps of the item translation process categorized by degree of difficulty to illustrate the methodology**.**

Table 3: Translation history of sleep disturbance items

Item Number	Original/Back Translation	Latvian Translation	Translation Steps
	SIMPLE ITEMS		
Sleep42	It was easy for me to fall asleep	Man bija viegli aizmigt Es aizmiegu bez problēmām	Forward translation1 Forward translation2
		Man bija viegli aizmigt	Review and first reconciled version of the two FTs
	I found it easy to go to sleep		← Back translation
		Man bija viegli aizmiegt	Second reconciled version after BT
		Man bija viegli aizmiegt	Reviewed by PROMIS Statistical Center
		Man bija viegli aizmiegt	Cognitive debriefing
		Man bija viegli aizmiegt	Final version
Sleep50	I woke up too early and could not fall back asleep	Es pamodos par agru un vairs nevarēju aizmigt Es pamodos agrāk un nevarēju iemigt	Forward translation1 Forward translation2
		Es pamodos par agru un vairs nevarēju aizmigt	Review and first reconciled version of the two FTs
	I woke up too early and couldn't get to sleep again		← Back translation
		Es pamodos par agru un vairs nevarēju aizmigt	Second reconciled version after BT
		Es pamodos par agru un vairs nevarēju aizmigt	Reviewed by PROMIS Statistical Center
		Es pamodos par agru un vairs nevarēju aizmigt	Cognitive debriefing
		Es pamodos par agru un vairs nevarēju aizmigt	Final version

Table 3: Translation history of sleep disturbance items (continued)

Sleep67	I worried about not being able to fall asleep	Es uztraucos par to, ka nevarēšu aizmigt	Forward translation1
		Es uztraucos par to, ka nevarēšu aizmigt	Forward translation2
		Es uztraucos par to, ka nevarēšu aizmigt	Review and first reconciled version of the two FTs
	I worried that I won't be able to fall asleep		← Back translation
		Es uztraucos par to, ka nevarēšu aizmigt	Second reconciled version after BT
		Es uztraucos par to, ka nevarēšu aizmigt	Reviewed by PROMIS Statistical Center
		Es uztraucos par to, ka nevarēšu aizmigt	Cognitive debriefing
		Es uztraucos par to, ka nevarēšu aizmigt	Final version
Sleep70	I felt sad at bedtime	Es jutu skumjas pirms gulētiešanas	Forward translation1
		Es jutu skumjas pirms gulētiešanas	Forward translation2
		Es jutos skumji, ejot gulēt	Review and first reconciled version of the two FTs
	I felt sad as I went to sleep		← Back translation
		Es jutos skumji, ejot gulēt	Second reconciled version after BT
		Es jutos skumji, ejot gulēt	Reviewed by PROMIS Statistical Center
		Es jutos skumji, ejot gulēt	Cognitive debriefing
		Es jutos skumji, ejot gulēt	Final version
Sleep71	I had trouble getting into a comfortable position to sleep	Man bija grūtības atrast ērtu pozīciju kurā aizmigt	Forward translation1
		Man bija grūtības atrast ērtu gulēšanas stāvokli	Forward translation2
		Man bija grūti atrast ērtu pozīciju, kurā aizmigt	Review and first reconciled version of the two FTs
	I found it hard to get into a comfortable position for sleep		← Back translation
		Man bija grūti atrast ērtu pozīciju, kurā aizmigt	Second reconciled version after BT
		Man bija grūti atrast ērtu pozīciju, kurā aizmigt	Reviewed by PROMIS Statistical Center
		Man bija grūti atrast ērtu pozīciju, kurā aizmigt	Cognitive debriefing
		Man bija grūti atrast ērtu pozīciju, kurā aizmigt	Final version

Table 3: Translation history of sleep disturbance items (continued)

Sleep72	I tried hard to get to sleep	Es ļoti centos aizmigt Es ar grūtībām aizmigu Es ļoti centos aizmigt	Forward translation1 Forward translation2 Review and first reconciled version of the two FTs
	I tried very hard to get to sleep		← Back translation
		Es ļoti centos aizmigt	Second reconciled version after BT
		Es ļoti centos aizmigt	Reviewed by PROMIS Statistical Center
		Es ļoti centos aizmigt	Cognitive debriefing
		Es ļoti centos aizmigt	Final version
Sleep86	I tossed and turned at night	Vārtījos visu nakti pa gultu Es naktī grozījos Es naktī daudz grozījos pa gultu	Forward translation1 Forward translation2 Review and first reconciled version of the two FTs
	I turned a lot in bed during the night		← Back translation
		Es naktī daudz grozījos pa gultu	Second reconciled version after BT
		Es naktī daudz grozījos pa gultu	Reviewed by PROMIS Statistical Center
		Es naktī daudz grozījos pa gultu	Cognitive debriefing
		Es naktī daudz grozījos pa gultu	Final version

Table 3: Translation history of sleep disturbance items (continued)

Sleep 92	I woke up and had trouble falling back to sleep I woke and found it hard to go to sleep again	Es pamodos un man bija grūtības atkal aizmigt Es pamodos un man bija grūtības atkal iemigt Es pamodos un man bija grūti atkal aizmigt Es pamodos un man bija grūti atkal aizmigt Es pamodos un man bija grūti atkal aizmigt Es pamodos un man bija grūti atkal aizmigt Es pamodos un man bija grūti atkal aizmigt	Forward translation1 Forward translation2 Review and first reconciled version of the two FTs ← Back translation Second reconciled version after BT Reviewed by PROMIS Statistical Center Cognitive debriefing Final version
Sleep93	I was afraid I would not get back to sleep after waking up I worried that I wouldn't be able to go to sleep again after waking up	Baidījos, ka pēc pamošanās vairs neaizmigšu Es baidījos, ka nepiecelšos pēc pamošanās Es baidījos, ka vairs nespēšu aizmigt pēc pamošanās Es baidījos, ka vairs nespēšu iemigt pēc pamošanās Es baidījos, ka vairs nespēšu iemigt pēc pamošanās Es baidījos, ka vairs nespēšu iemigt pēc pamošanās Es baidījos, ka vairs nespēšu iemigt pēc pamošanās	Forward translation1 Forward translation2 Review and first reconciled version of the two FTs ← Back translation Second reconciled version after BT Reviewed by PROMIS Statistical Center Cognitive debriefing Final version

Table 3: Translation history of sleep disturbance items (continued)

Sleep105	My sleep was restful	Mans miegs bija mierīgs	Forward translation1
		Mans miegs bija mierīgs	Forward translation2
		Es jutos atpūties (-usies)[1] pēc miega	Review and first reconciled version of the two FTs
	I felt rested after sleep		← Back translation
		Es jutos atpūties (-usies) pēc miega	Second reconciled version after BT
		Es jutos atpūties (-usies) pēc miega	Reviewed by PROMIS Statistical Center
		Es jutos atpūties (-usies) pēc miega	Cognitive debriefing
		Es jutos atpūties (-usies) pēc miega	Final version
Sleep106	My sleep was light	Mans miegs bija trausls	Forward translation1
		Mans miegs bija viegls, patīkams	Forward translation2
		Mans miegs bija trausls	Review and first reconciled version of the two FTs
	My sleep was light		← Back translation
		Mans miegs bija trausls	Second reconciled version after BT
		Mans miegs bija trausls	Reviewed by PROMIS Statistical Center
		Mans miegs bija trausls	Cognitive debriefing
		Mans miegs bija trausls	Final version
Sleep107	My sleep was deep	Mans miegs bija dziļš	Forward translation1
		Mans miegs bija dziļš	Forward translation2
		Mans miegs bija dziļš	Review and first reconciled version of the two FTs
	My sleep was deep		← Back translation
		Mans miegs bija dziļš	Second reconciled version after BT
		Mans miegs bija dziļš	Reviewed by PROMIS Statistical Center
		Mans miegs bija dziļš	Cognitive debriefing
		Mans miegs bija dziļš	Final version

Table 3: Translation history of sleep disturbance items (continued)

Sleep109	My sleep quality was…	Mana miega kvalitāte bija…	Forward translation1
		Mana miega kvalitāte bija…	Forward translation2
		Mana miega kvalitāte bija…	Review and first reconciled version of the two FTs
	My sleep quality was…		← Back translation
		Mana miega kvalitāte bija…	Second reconciled version after BT
		Mana miega kvalitāte bija…	Reviewed by PROMIS Statistical Center
		Mana miega kvalitāte bija…	Cognitive debriefing
		Mana miega kvalitāte bija…	Final version
Sleep115	I was satisfied with my sleep	Es biju apmierināts ar savu miegu	Forward translation1
		Esmu apmierināta ar sava miega kvalitāti	Forward translation2
		Es biju apmierināts ar savu miegu	Review and first reconciled version of the two FTs
	I felt satisfied with my sleep		← Back translation
		Es biju apmierināts ar savu miegu	Second reconciled version after BT
		Es biju apmierināts (-a) ar savu miegu	Reviewed by PROMIS Statistical Center
		Es biju apmierināts (-a) ar savu miegu	Cognitive debriefing
		Es biju apmierināts (-a) ar savu miegu	Final version
Sleep116	My sleep was refreshing	Mans miegs bija atsvaidzinošs	Forward translation1
		Mans miegs bija atjaunojošs	Forward translation2
		Mans miegs bija atsvaidzinošs	Review and first reconciled version of the two FTs
	My sleep was refreshing		← Back translation
		Mans miegs bija atsvaidzinošs	Second reconciled version after BT
		Mans miegs bija atspirdzinošs	Reviewed by PROMIS Statistical Center
		Mans miegs bija atspirdzinošs	Cognitive debriefing
		Mans miegs bija atspirdzinošs	Final version

Table 3: Translation history of sleep disturbance items (continued)

Item Number	Original/Back Translation	Latvian Translation	Translation Steps
	MEDIUM ITEMS		
Sleep20	I had a problem with my sleep	Man bija kāda problēma ar manu miegu	Forward translation1
		Man ir problēmas ar miegu	Forward translation2
		Man bija problēmas ar miegu	Review and first reconciled version of the two FTs
	I had problems with my sleep		← Back translation
		Man bija problēmas ar miegu	Second reconciled version after BT
		Man bija problēmas ar miegu	Reviewed by PROMIS Statistical Center
		Man bija problēmas ar miegu	Cognitive debriefing
		Man bija problēmas ar miegu	Final version
Sleep44	I had difficulty falling asleep	Man bija grūti iemigt	Forward translation1
		Man ir grūtības aizmigt	Forward translation2
		Man bija grūti aizmigt	Review and first reconciled version of the two FTs
	I found it hard to get to sleep		← Backtranslation
		Man bija grūti aizmigt	Second reconciled version after BT
		Man bija grūti aizmigt	Reviewed by PROMIS Statistical Center
		Man bija grūti aizmigt	Cognitive debriefing
		Man bija grūti aizmigt	Final version

Table 3: Translation history of sleep disturbance items (continued)

Sleep45	I laid in bed for hours waiting to fall asleep	Es stundām gulēju gultā pirms aizmigu	Forward translation1
		Es gulēju gultā stundām gaidot, kad aizmigšu	Forward translation2
		Es pavadīju vairākas stundas, gaidot, kamēr iemigšu	Review and first reconciled version of the two FTs
	I spent a number of hours trying to go to sleep		← Back translation
		Es pavadīju vairākas stundas, gaidot, kamēr iemigšu	Second reconciled version after BT
		Es pavadīju vairākas stundas, guļot gultā un gaidot, kamēr aizmigšu	Reviewed by PROMIS Statistical Center
		Es pavadīju vairākas stundas, guļot gultā un gaidot, kamēr aizmigšu	Cognitive debriefing
		Es pavadīju vairākas stundas, guļot gultā un gaidot, kamēr aizmigšu	Final version
Sleep93	I was afraid I would not get back to sleep after waking up	Baidījos, ka pēc pamošanās vairs neaizmigšu	Forward translation1
		Es baidījos, ka nepiecelšos pēc pamošanās	Forward translation2
		Es baidījos, ka vairs nespēšu aizmigt pēc pamošanās	Review and first reconciled version of the two FTs
	I worried that I wouldn't be able to go to sleep again after waking up		← Back translation
		Es baidījos, ka vairs nespēšu iemigt pēc pamošanās	Second reconciled version after BT
		Es baidījos, ka vairs nespēšu iemigt pēc pamošanās	Reviewed by PROMIS Statistical Center
		Es baidījos, ka vairs nespēšu iemigt pēc pamošanās	Cognitive debriefing
		Es baidījos, ka vairs nespēšu iemigt pēc pamošanās	Final version

Table 3: Translation history of sleep disturbance items (continued)

Sleep65	I felt physically tense at bedtime	Pirms gulētiešanas jutos fiziski sasprindzis	Forward translation1
		Es jūtos saspringta dodoties gulēt	Forward translation2
		Dodoties gulēt, jutos fiziski sasprindzis	Review and first reconciled version of the two FTs
	I felt physically tense as I went to sleep		← Back translation
		Dodoties gulēt, jutos fiziski sasprindzis	Second reconciled version after BT
		Dodoties gulēt, jutos fiziski sasprindzis	Reviewed by PROMIS Statistical Center
		Dodoties gulēt, jutos fiziski sasprindzis	Cognitive debriefing
		Dodoties gulēt, jutos fiziski sasprindzis	Final version
Sleep68	I felt worried at bedtime	Jutos satraukts pirms gulētiešanas	Forward translation1
		Es jūtos noraizējusies ejot gulēt	Forward translation2
		Jutos satraukts pirms gulētiešanas	Review and first reconciled version of the two FTs
	I felt jumpy as I went to sleep		← Back translation
		Jutos satraukts, dodoties gulēt	Second reconciled version after BT
		Jutos uztraukts (-a), dodoties gulēt	Reviewed by PROMIS Statistical Center
		Jutos uztraukts (-a), dodoties gulēt	Cognitive debriefing
		Jutos uztraukts (-a), dodoties gulēt	Final version

Table 3: Translation history of sleep disturbance items (continued)

Sleep69	I had trouble stopping my thoughts at bedtime	Man bija grūtības apturēt savas domas pirms gulētiešanas	Forward translation1
		Man ir grūti apturēt savas domas ejot gulēt	Forward translation2
		Man bija grūti apturēt savas domas, ejot gulēt	Review and first reconciled version of the two FTs
	I found it hard to stop thinking as I went to sleep		← Back translation
		Man bija grūti apturēt savas domas, ejot gulēt	Second reconciled version after BT
		Man bija grūti apturēt savas domas, ejot gulēt	Reviewed by PROMIS Statistical Center
		Man bija grūti apturēt savas domas, ejot gulēt	Cognitive debriefing
		Man bija grūti apturēt savas domas, ejot gulēt	Final version
Sleep78	Stress disturbed my sleep	Stress iztraucēja manu miegu	Forward translation1
		Stress traucēja manu miegu	Forward translation2
		Stress traucēja manu miegu	Review and first reconciled version of the two FTs
	Stress disturbed my sleep		← Back translation
		Stress traucēja manu miegu	Second reconciled version after BT
		Stress traucēja manu miegu	Reviewed by PROMIS Statistical Center
		Stress traucēja man aizmigt	Cognitive debriefing
		Stress traucēja man aizmigt	Final version

Table 3: Translation history of sleep disturbance items (continued)

Sleep87	I had trouble staying asleep	Man bija grūtības nogulēt visu nakti	Forward translation1
		Man ir problēmas aizmigt	Forward translation2
		Man bija grūtības nogulēt visu nakti	Review and first reconciled version of the two FTs
	I found it hard to sleep all night long		← Back translation
		Man bija grūtības nogulēt visu nakti	Second reconciled version after BT
		Man bija grūti palikt aizmigušam(-ai)	Reviewed by PROMIS Statistical Center
		Man bija grūti nogulēt visu nakti nepamostoties	Cognitive debriefing
		Man bija grūti nogulēt visu nakti nepamostoties	Final version
Sleep90	I had trouble sleeping	Man bija grūtības gulēt	Forward translation1
		Man ir problēmas gulēt	Forward translation2
		Man bija grūtības gulēt	Review and first reconciled version of the two FTs
	I had difficulties sleeping		← Back translation
		Man bija grūtības gulēt	Second reconciled version after BT
		Man bija traucēts miegs	Reviewed by PROMIS Statistical Center
		Man bija traucēts miegs	Cognitive debriefing
		Man bija traucēts miegs	Final version
Sleep108	My sleep was restless	Mans miegs bija nemierīgs	Forward translation1
		Mans miegs bija nemierīgs	Forward translation2
		Es nejutos atpūties pēc miega	Review and first reconciled version of the two FTs
	I did not feel rested after sleep		← Back translation
		Mans miegs bija nemierīgs	Second reconciled version after BT
		Man bija nemierīgs miegs	Reviewed by PROMIS Statistical Center
		Man bija nemierīgs miegs	Cognitive debriefing
		Man bija nemierīgs miegs	Final version

Table 3: Translation history of sleep disturbance items (continued)

Sleep110	I got enough sleep	Es pietiekami ilgi gulēju	Forward translation1
		Es gulēju pietiekami daudz	Forward translation2
		Es gulēju pietiekami daudz	Review and first reconciled version of the two FTs
	I had sufficient sleep		← Back translation
		Es gulēju pietiekami daudz	Second reconciled version after BT
		Es pietiekami izgulējos	Reviewed by PROMIS Statistical Center
		Es pietiekami izgulējos	Cognitive debriefing
		Es pietiekami izgulējos	Final version
Sleep125	I felt lousy when I woke up	Nejutos labi, kad pamodos	Forward translation1
		Es jutos slikti, kad pamodos	Forward translation2
		Es nejutos izgulējies, kad pamodos	Review and first reconciled version of the two FTs
	I felt horrible when I woke up		←Back translation
		Es jutos draņķīgi, kad pamodos	Second reconciled version after BT
		Es jutos draņķīgi, kad pamodos	Reviewed by PROMIS Statistical Center
		Es jutos draņķīgi, kad pamodos	Cognitive debriefing
		Es jutos draņķīgi, kad pamodos	Final version

[1]Terms in brackets refer to grammatical gender (masculine/feminine)

3.3.1 Items which were classified as simple to translate

Item 67 “In the past 7 days I worried about not being able to fall asleep” was one of the items which during the whole translation process resulted in one version: “Pēdējo 7 dienu laikā es uztraucos par to, ka nevarēšu aizmigt”. Another example is Item 106 “…my sleep was light”; during the whole translation process two variants were offered. Forward translator 1 translated this item into “…mans miegs bija trausls” whereas forward translator 2 “…mans miegs bija viegls, patīkams”. During the reconciliation meeting we discussed that forward translator 2 understood the meaning of “light” in a positive way, as “care-free”. We decided on the version with “trausls”, which describes the opposite of “deep”.

3.3.2 Items which were classified as medium difficult to translate

An example of an item which was medium difficult to translate was Item 78 “In the past 7 days stress disturbed my sleep”. During the forward translation two variants arose. The first variant was “Stress iztraucēja manu miegu“[Stress disturbed my sleep]. The second forward translator used the verb “traucēja”. The prefix “iz-“ transforms the verb “traucēja” [to disturb] into a one-time event. Our first reconciled version was “Stress traucēja manu miegu”, which also became the Latvian version for the cognitive debriefing interviews. During the interviews half of the participants had difficulties understanding the item. This item was challenging because it was unclear how something could be evaluated while sleeping.

Another example is item 108 “In the past 7 days my sleep was restless”. Both forward translators translated this into “Mans miegs bija nemierīgs”. In the reconciliation meeting it was preferred to translate this item into the negation of item 105 “My sleep was restful”, which is “Es nejutos atpūties pēc miega”. After the back translation, which resulted in “I did not feel rested after sleep”, our discussion concluded that the version offered by our forward translators “Mans miegs bija nemierīgs” was the more precise option for item 108. After the review by Helena Correia North Western, our version “Mans miegs bija nemierīgs” [My sleep was restless] had to be compared with “Man bija nemierīgs miegs” [I had restless sleep]. Our final version became “Man bija nemierīgs miegs” [I had restless sleep]. In Latvian as in other languages, for example Spanish, it is more natural to say “I had restless sleep” than “My sleep was restless”. For item 87 “In the past 7 days I had trouble staying asleep“, we came to the definite conclusion after the first reconciliation meeting that version 1 “Man bija grūtības nogulēt visu nakti” Latvian translation is the correct translation. The second version “Man ir problēmas aizmigt [I had problems to sleep] was too unprecise. The back translation resulted in “I found it hard to sleep all night long”. The PROMIS review opened a discussion between “Man bija grūti palikt aizmigušam(-ai)” [I had many difficulties remaining sleeping] and our version “Man bija grūtības nogulēt visu nakti”. We decided that “Man bija grūti palikt aizmigušam(-ai)” was more suitable and a more concrete version for the item bank.

3.4 Results of cognitive debriefing

The following table lists the participants that were selected to attend the cognitive debriefing part of the translation process. The group consisted of six persons. Within the group, the gender distribution was equal (three women / three men) and the average age was 44.6 years. The occupations of the participants were chosen intentionally to cover a wide social stratum.

Table 4: Participants in the cognitive debriefing

Participant	Gender	Age	Occupation
1	female	27	Administration worker
2	female	34	PhD in political science
3	female	59	Lower educational level
4	male	70	Lower educational level
5	male	58	Engineer
6	male	20	Student
		Ø 44.6	

The cognitive debriefing process is summarized in Table 5. The items which were challenging in comprehensibility for the participants are listed. The column “error” shows the number of participants who had difficulties understanding the specific item. In the column “code” the questions are classified into subgroups with regard to the content of the problem. During the cognitive debriefing interview five out of six participants had problems understanding item 87. Therefore we established “Man bija grūti nogulēt visu nakti nepamostoties” [It was hard for me to sleep through the night without waking up]. This is clearer and does not change the meaning of the item (see also Table 3).

Table 5: Results of cognitive debriefing[1]

Item Number	Latvian Translation	Errors[2]	Code[3]	Participant	Comprehension questions (Participants)
Sleep105	Es jutos atpūties(-usies)[4] pēc miega	1	Time Definition	P1:	Do you mean only sleep at night here? Or also my afternoon nap?
Sleep107	Mans miegs bija dziļš	2	Definition	P1:	What does deep mean? I didn't have any dreams or I didn't wake up or I slept for a long time? If no other explanation, I would see it in positive way that I slept well from the moment I went to bed until waking up.
Sleep115	Es biju apmierināts (-a)[4] ar savu miegu	2	Ascertain-ment/ Definition	P1:	Not completely clear, to my mind. What does satisfied mean? There could be a lot of different reasons, maybe you could explain, that, for example, satisfied with the quality of sleep.
				P2:	What do you mean by satisfied? Ok or?
Sleep125	Es jutos draņķīgi, kad pamodos	1	Meaning	P3:	Clear better, but draņķīgi could mean a lot of different things, for example, I don't get enough sleep, I had nightmares etc.
Sleep20	Man bija problēmas ar miegu	2	Accuracy	P3:	Do you mean problems in general or only in consideration of my sleep?
			Ascertain-ment	P1:	What do you want to find out; what kind of problems apart from those mentioned above?

Table 5: Results of cognitive debriefing[1] (continued)

Sleep67	Es satraucos, ka nevarēšu iemigt	1	Time	P1:	To which time does it refer? Shortly before going to sleep? Hard to understand within scale - mazdrusciņ - is that a little bit worried every day of 7 days or some of the 7 days I was worried and other days not?
Sleep69	Man bija grūti apturēt savas domas, dodoties gulēt	1	Meaning	P5:	Are those positive or negative thoughts? Do I want to stop them? Those might be positive thoughts that I don't want to stop. If no explanation, I would think in negative way.
Sleep70	Es jutos skumji, dodoties gulēt	2	Ascertain ment	P2:	Was I sad in general or was I sad in context of my sleep?
				P6:	Was I sad in general or was I sad because I had to go to sleep? If no explanations, I would think in general sad.
Sleep72	Es ļoti centos aizmigt	1	Definition	P1:	Does it mean that I was trying for a long time or how hard I was trying - by using sleeping pills, for example.
Sleep78	Stress traucēja manu miegu	3	Meaning	P1:	How can I notice this while I am sleeping?
				P2:	I was already asleep but stress disturbed my sleep and then I could not sleep? How do I know that if I am already asleep?
				P4:	Is it meant that stress hindered me from falling asleep?
Sleep93	Es baidījos, ka vairs nespēšu iemigt pēc pamošanās	1	Meaning	P6:	This I don't understand but I guess it might be because I have not had that.

Table 5: Results of cognitive debriefing[1] (continued)

Sleep87	Man bija grūti palikt aizmigušam(-ai)[4]	5	Meaning	P1:	Not completely clear. How can it be difficult to stay asleep; when you are asleep you cannot think and control your actions (staying asleep or not).
				P2:	So do I wake up or not?
				P3:	Don´t understand.
				P4:	Did I sleep the night through or not?
				P5:	Problems with understanding.
Sleep90	Man bija traucēts miegs	2	Accuracy	P5:	Ok, could it be a bit more specific?
				P6:	Ok, only that word disturbed. Everyone could think of something different here; for one the pillow is too hard or the neighbours are too loud, or I was having nightmares.

[1] Error-free items are not listed in the table.

[2] Errors: indicates the number of participants who had comprehension difficulties.

[3] Code: Classification of the comprehensive difficulties into subgroups.

[4] Terms in brackets refer to grammatical gender (masculine/feminine).

3.5 Selected items for the probing technique

The preselected items for the probing technique and the questions given to the participants during our interviews are listed in Table 6.

Table 6: Selected items for the probing technique

Item Number	Latvian Translation (English original)	Comprehension questions (Translation Team)
Sleep125	Es jutos draņķīgi, kad pamodos (I felt lousy when I woke up)	Is "draņķīgi" understood as physical unwellness?
Sleep105	Es jutos atpūties(-usies) pēc miega (My sleep was restful)	Did the probands understand the difference between item 105 and item 116?
Sleep116	Mans miegs bija atspirdzinošs (My sleep was refreshing)	Did the probands understand the difference between item 105 and item 116?
Sleep90	Man bija traucēts miegs (I had trouble sleeping)	Compare the understanding of the Mapi version and the Latvian translation team´s version. Man bija grūtības gullet. *I had disturbed sleep* vs *I had difficulties sleeping*

3.5.1 Results of the probing technique

“Drankigi” was understood by five out of six participants as “physically unwell”. Only one participant had difficulties answering item 125. The participant criticised the imprecision of the item and demanded more concrete reasons for feeling “physically unwell” such as “I did not get enough sleep” or “I had nightmares”. This criticism was directed towards the original item and therefore not part of this investigation.

All of the six participants understood the difference between item 105 ” Es jutos atpūties pēc miega“ [I felt rested after sleep] and 116 “Mans miegs bija atspirdzinošs” [My sleep was refreshing] and had no difficulties in answering the two items.

The item 90 “Man bija traucēts miegs” [I had a disturbed sleep] was analysed and compared with “Man bija grūtības gullet” [I had difficulties sleeping]. Here it was distinct the first version “I had a disturbed sleep” was understood by all participants that something disturbed the sleep after falling asleep. Examples were mentioned such as nightmares, loud neighbours. The other variant “I had difficulties sleeping” was understood as not to be able to fall asleep by two participants. The results from the cognitive debriefing interviews were taken into consideration when creating of the final version of the Latvian sleep disturbance item bank. During this step the translation team was provided with some items which were translated into Latvian by Mapi in an independent translation process *(*Mapi*, 2015).*

Before publishing, the final Latvian PROMIS Item Bank v1.0 - Sleep Disturbance was proofread and reviewed by the PROMIS Statistical Center.

3.6 Latvian PROMIS Item Bank v1.0 - Sleep Disturbance

Table 7 shows the final Latvian version of PROMIS Item Bank v1.0 –Sleep Disturbance opposed to the original English version of the items.

Table 7: Latvian PROMIS Item Bank v1.0 - Sleep Disturbance – calibrated items

Item Number	Original (English)	Final Translation (Latvian)
	In the past 7 days…	Pēdējo 7 dienu laikā...
Sleep105	My sleep was restful	Es jutos atpūties (-usies)[1] pēc miega
Sleep106	My sleep was light	Mans miegs bija trausls
Sleep107	My sleep was deep	Mans miegs bija dziļš
Sleep108	My sleep was restless	Man bija nemierīgs miegs
Sleep115	I was satisfied with my sleep	Es biju apmierināts (-a)[1] ar savu miegu
Sleep116	My sleep was refreshing	Mans miegs bija atspirdzinošs
Sleep125	I felt lousy when I woke up	Es jutos draņķīgi, kad pamodos
Sleep20	I had a problem with my sleep	Man bija problēmas ar miegu
Sleep44	I had difficulty falling asleep	Man bija grūti aizmigt
Sleep65	I felt physically tense at bedtime	Dodoties gulēt, jutos fiziski sasprindzis
Sleep67	I worried about not being able to fall asleep	Es uztraucos, ka nevarēšu aizmiegt
Sleep68	I felt worried at bedtime	Jutos uztraukts (-a)[1], dodoties gullet
Sleep69	I had trouble stopping my thoughts at bedtime	Man bija grūti apturēt savas domas, dodoties gulēt
Sleep70	I felt sad at bedtime	Es jutos skumji, ejot gulēt
Sleep71	I had trouble getting into a comfortable position to sleep	Man bija grūti atrast ērtu pozīciju, kurā aizmigt
Sleep72	I tried hard to get to sleep	Es ļoti centos aizmiegt
Sleep78	Stress disturbed my sleep	Stress traucēja mana miegu
Sleep86	I tossed and turned at night	Es naktī daudz grozījos pa gultu
Sleep93	I was afraid I would not get back to sleep after waking up	Es baidījos, ka vairs nespēšu iemigt pēc pamošanās
	Answer block I (intensity scale)	
	○ Not at all ○ A little bit ○ Somewhat ○ Quite a bit ○ Very much	○ Nemaz ○ Mazdrusciņ ○ Vidēji ○ Diezgan daudz ○ Ļoti daudz

Table 7: Latvian PROMIS Item Bank v1.0 - Sleep Disturbance – calibrated items (continued)

Item Number	Original (English)	Final Translation (Latvian)
	In the past 7 days…	Pēdējo 7 dienu laikā...
Sleep110	I got enough sleep	Es pietiekami izgulējos
Sleep42	It was easy for me to fall asleep	Man bija viegli aizmiegt
Sleep45	I laid in bed for hours waiting to fall asleep	Es pavadīju vairākas stundas, guļot gultā un gaidot, kamēr aizmigšu
Sleep50	I woke up too early and could not fall back asleep	Es pamodos par agru un vairs nevarēju aizmiegt
Sleep87	I had trouble staying asleep	Man bija grūti nogulēt visu nakti nepamostoties
Sleep90	I had trouble sleeping	Man bija traucēts miegs
Sleep92	I woke up and had trouble falling back to sleep	Es pamodos un man bija grūti atkal aizmiegt
	Answer block II (frequency scale)	
	○ Never	○ Nekad
	○ Rarely	○ Reti
	○ Sometimes	○ Dažreiz
	○ Often	○ Bieži
	○ Always	○ Vienmēr
Item Number	**Original (English)**	**Final Translation (Latvian)**
	In the past 7 days…	Pēdējo 7 dienu laikā...
Sleep109	My sleep quality was:	Mana miega kvalitāte bija:
	Answer block III (overall sleep quality)	
	○ Very poor	○ Ļoti slikta
	○ Poor	○ Slikta
	○ Fair	○ Vidēja
	○ Good	○ Laba
	○ Very good	○ Ļoti laba

[1]Terms in brackets refer to grammatical gender (masculine/feminine)

The result of this work is a Latvian version of PROMIS Item Bank v1.0 - Sleep Disturbance developed according to the PROMIS translation guidelines. In a second step, which is not part of this work, the Latvian items will be tested on a random sample from the general Latvian population as well as on a random sample of patients suffering from sleep disturbances so that translation can become a valid instrument for use in

Latvian medicine. In the following section, the essential results will be discussed in relation to other translations of PRO measures.

4. Discussion

The previous chapter presented the results of the translation process for the PROMIS Sleep Disturbance item bank from English into Latvian. In this chapter, the results will be critically analysed. The main results will be listed in Chapter 4.1 and discussed in the associated chapter: either 4.2 “Translation” process or 4.3 “Cognitive debriefing”. At the end of the discussion in Chapter 4.4, the limitations will be outlined, and in Chapter 5, the conclusion and outlook will be presented.

4.1 Main results

The aim of this work was to develop a Latvian translation of the PROMIS Sleep Disturbance item bank. It is the first time that an entire PROMIS item bank has been translated into a language belonging to the Baltic group of the Indo-Germanic language family. The Latvian items are now available for field testing, calibration, and psychometric validation. An increasing number of clinical studies are being carried out using PROs on an international and therefore also multicultural level (Stober, 2003). Therefore, there is a great need for PROM translations according to international standards. The differences in the results of nation-wide studies involving PROs should not be due to errors in the translations of the reporting instruments and databases; they should only be the result of real cultural differences between countries and nations. Precise translations are an essential component in the integrity of scientific results using PRO measures in international research (Wild et al., 2005).

This work demonstrates the following main results:

Back translation is a very important and sensitive step in the developmental process of a questionnaire in a new language. This step offers a chance to reflect on the forward translations and control and adjust the translations.

Cultural adaptation plays a central role in the development of such a questionnaire. Its purpose is to avoid a word by word translation, and it should be carried out even if it results in a back translation that differs from the original item.

Many content questions arose during the cognitive debriefing process, in which the think aloud method was used. These questions are a possible indication that sleep disturbances are not a prominent issue in Latvian society and health care, and this is a further motivation for implementing of PROMIS Sleep Disturbance Item Bank in Latvia.

4.2 Translation

We strictly followed the PROMIS standard translation protocol as the basis for producing a high-quality translation. Overall, the translation of the items from English to Latvian was a non-linear, iterative process. The original PROMIS items underwent a thoroughly qualitative assessment by experts and respondents so that the items became easily readable and understandable. Modifications resulted in easy to read sentences, nouns instead of pronouns, active instead of passive language, and avoidance of hypothetical assertions or subjunctive tense (Wagner et al., 1998; Werner, 1970). This assessment guaranteed easily translatable items (Buysse et al., 2010).

Our task was not to provide a “word by word” translation. We went beyond the literal meaning of the items, accounting for the connotations of the originals and thereby providing a culturally adapted Latvian version. The cultural adaptation of the questionnaire was not a separate step; the researchers committed to questioning words and expressions until a consensus was found (Ljungberg et al., 2015). Most of the difficulties of this translation process arose from cultural and linguistic differences. Other researchers also mention these challenges in their translation processes (Wild et al., 2005, Oude Voshaar et al., 2012, Wahl et al., 2014).

All items which resulted in three to four versions in the first translation steps were defined as medium difficult to translate. This group included 13 out of 27 items.

One item (Sleep65) was composed of a combination of the two separate results of the forward translations, which differed from each other (see Table 3). The involvement of three members of the translation team introduced a more objective quality to the classification process. The results indicate that there were no major differences in translation difficulty. This classification system allowed us to identify distinct items for use with the probing technique.

For a few items, some degree of difficulty was added during the reconciliations, especially since we obtained additional translation variants out of the Mapi project, which led to further reconciliations and improvement of the results where necessary.

In this process, we either chose the Mapi version, created a new combined version, or decided that the version created by our own translation process would be the most suitable item for use with the Latvian population. Once again, the necessity of precise work and a step-by-step procedure to guarantee the linguistic validation of the instrument was demonstrated (Wild et al., 2005, Acquadro et al., 2008). The additional reconciliation by experts, which took place along with the Mapi Group, led to the creation of new item variants and quality improvements for some of the items. However, it is unclear whether additional reconciliation steps in partnership with an independent party yield measurable improvements. Does this procedure justify the greater amount of time and effort, or does it simply increase the number of item variants which must be audited?

In accordance with the translation standards given by Wild et al., we used a *back translation* with a subsequent *review of the back translation* to identify deficiencies in the forward translation (Wild et al., 2005). In this translation step, the first reconciled single target language translation was presented to an English native speaker with excellent knowledge of Latvian. Up to this point, the back translator was neither involved in the translation work, nor had any knowledge about the items. The purpose of the back translation was to obtain a largely word-by-word English version from the Latvian translation. Both the Latvian study group and one independent researcher at the Charité who supervised this thesis independently compared the back translation with the English original and with the associated forward translations.

This approach should be considered critically. There are several potential sources of error, which are described by Swaine-Verdier et al. as follows:

- A given forward translation can be of a very high quality, but if it takes all requirements into account, it may be very different in form and in apparent content from the source item.
- Consequently, the back translation accordingly varies from the original item. However, one should not be unsettled by this and, if necessary, change the translated item version.
- Another situation could arise if the back translators were used to test the forward translators, because this could lead to a critical report about the forward translation.

- Another variant would be a forward translation which is done in a very technical and literal way. This method could result in a back translation which is nearly identical to the original text. To interpret this obvious matching as the best translation possible is a major source of error (Swaine-Verdier et al., 2004).

The results of this work suggest that these are legitimate concerns. When reviewing of the back translation, with a new point of view about the items due to the input from Mapi, we concluded that some of the back translations were inadequate or inaccurate. This conclusion was confirmed when two items which were changed during the cognitive debriefing were designated as equivalent with regard to content by the PROMIS developers.

Nevertheless, equivalence testing is an important measure for the cultural adaptation of questionnaires (Wild et al., 2005). Inappropriately translated items could be clearly identified by performing back translation reviews. Altogether, 4 out of 27 items were revised for a more effective transfer of the underlying content.

Therefore, it can be concluded that accurate work in the back translation review process (done in collaboration with researchers at the Charité and the PROMIS translation director) contributes significantly to the conceptual equivalence and international comparability of the translation, as long as the method's weaknesses are accounted for (Eremenco et al., 2005).

During a translation process, it is extremely important to implement cultural adaptation aspects. Neglecting this can lead to the alteration of meanings and result in reduced reliability and validity of the translated measures (Ljungberg et al., 2015).

A typical example, occurring throughout the whole translation process, is the tendency of the Latvian language to describe situations with an adverb rather than a noun, as in the original English questionnaire.

Item 105 *My sleep was restful* is translated as "*Es jutos atpūties pēc miega*". Taken literally, it means "*I felt rested after sleep*", which is the commonly used Latvian term (see Table 3). The same grammatical expression is also present in item 92. "I woke up and had trouble falling back to sleep" became, in Latvian: "Es pamodos un man bija grūti atkal aizmigt". Here again, it literally means not "I had difficulties", but "it was difficult for me" (see Results, Table 3). This change was necessary to adapt the questionnaire culturally and leads to more natural reading and understanding for Latvians.

Another question we had to deal with was the correct translation for “to fall asleep” for 8 items overall [Item 44: *I had difficulty falling asleep*; Item 67: *I worried about not being able to fall asleep*; Item 71: *I had trouble getting into a comfortable position to sleep*; Item 72: *I tried hard to get to sleep*; Item 42: *It was easy for me to fall asleep*; Item 45: *I laid in bed for hours waiting to fall asleep*; Item 50: *I woke up to early and could not fall back to sleep*; Item 92: *I woke up to early and had trouble falling back to sleep*].

The two forward translators used the verb “*aizmiegt*” or “*izmiegt*”; both verbs are translated as “to fall asleep”. After detailed consideration, Latvian language experts defined “*izmiegt*” as being a softer and slower process of falling asleep in comparison with “*aizmiegt*”, which describes the process more neutrally. We decided to use “*aizmiegt*” throughout the whole item bank. Furthermore, we had to solve the problem of ambiguity in the Latvian language. The word “nepiecelšos” means “to wake up*”,* but also “to stand up*”*. In this case, we chose a less ambiguous word, “pamošanās”, which means *to wake up* and excludes the implication of postural hypotension symptoms. This problem also arose in Item 125: *I felt lousy when I woke up* and Item 93: *I was afraid I would not get back to sleep after waking up.*

During the analysis of the available results, it was confirmed that the translation of an instrument from one language area to another requires a few consistently performed adjustment steps before it can be used for psychometric validation (Acquadro et al., 2008)

4.3 Cognitive debriefing

Cognitive debriefings are important tools in the development stage of a questionnaire for clarifying how the respondent:

- understands questions and specific terms
- retrieves information from memory
- decides to answer a question, and
- sorts an “internally determined” answer into a technical answer category.

(Prüfer and Rexroth, 2005)

In general, the cognitive debriefings enabled us to evaluate how the respondents understood the items and to determine which details needed improvement, if any.

These debriefings serve to uncover any unconscious incorrect understanding of the question on the part of the respondent. They minimize the risk of handling wrong

information or of missing information during the collection of PRO data (Wild et al., 2005). The debriefings were done according to the “think aloud method,” which clarifies whether the participants´ comprehension of the item is satisfactory or if changes are necessary.

In addition, we specified cognitive debriefings with the probing technique and selected some items for which we expected some understanding difficulties.

Most of the items could be answered by participants without any difficulties. One specific item (Item 87, see Table 3) proved difficult to understand in the cognitive debriefing process; therefore, it was revised in this context. Because we discussed arising questions with the participants directly, we received many helpful suggestions.

The “think aloud method” also exhibited some weaknesses. Latvian people are not used to expressing or stating their own opinion and point of view in public. The social reason for this is the recent history of the Latvian State. From the Second World War until 1990, Latvia was a part of the Soviet Union. This involuntary affiliation led not only to undemocratic social conditions with restricted freedom of expression and speech, but also to a targeted Russification of the country. This cultural assimilation had severe consequences on the use of Latvian as the national language (Gasimov, 2012). In 2013, the Central Statistics Bureau of Latvia published a study indicating that 62.1% of the population speak mostly Latvian at home. Russian is the second most popular language spoken at home (37.2%). Languages such as Belorussian, Ukrainian, Polish, Lithuanian, etc. make up 0.7 % of the spoken languages of the population. In some places like Zilupe, 92.1% of the people speak Russian at home, and even in Riga, the capital city, more than 50% of the population (55.8%) speak Russian at home (Central Statistical Bureau of Latvia, 2013). Different cultural backgrounds, in addition to different languages, can make the assessment of sleep disturbances in Latvia challenging. The relationship between items and the underlying construct across different ethnic groups may vary. Not only the underlying construct, but also subtle differences in the meaning of the items between different groups need to be considered. If this phenomenon is neglected, problems may arise in the interpretation of assessments between groups (Gibbons and Skevington, 2017). The sometimes unsatisfying communication between physician and patient or (in a figurative sense) interviewer and respondent could have its roots in social conditions, recent Latvian history, and the fact that different ethnic groups live alongside one another, as mentioned in the introduction. In particular, the large Russian proportion of the Latvian population gives rise to the question whether Russian PRO studies, in

addition to Latvian studies, are necessary to obtain sufficient information about Latvian society.

The “think aloud method” does not reliably provide useful information which can clarify comprehension questions or contribute to item improvement. A training phase is mandatory and requires a significant expenditure of time. In addition, data analysis is time-consuming because answers are given in the participants’ own words and not by using prepared responses. The participants´ statements are not strictly limited, and sometimes a large amount of text with very limited information content is produced. Furthermore, the “think aloud method” can lead to artificial answers because the participants want to give socially acceptable responses in the debriefing situation. As a result, respondents could come under pressure to present their own personal situations in a positive light that may not reflect reality (Crowne and Marlowe, 1964; Prüfer and Rexroth, 2005).

The participants’ questions during the cognitive debriefing suggest that sleep disturbances are not widely detected and do not seem to be a subject of discussion in Latvian society and especially not in physician-patient relationships (see Results Table 5). The reasons for this situation may include a deficit in clinicians’ skills to detect sleep disturbances, insecurity of treatment, and referral of patients (Roth et al., 2002). This fact is another motivation for the development of a Latvian questionnaire to more reliably detect hidden sleep disturbance problems.

Using the probing technique, existing uncertainties could be clarified; one item was revised and optimised through this step. This method provides ample additional information about the quality of the translated items. Therefore, it is a recommended step in the translation process of a questionnaire.

Currently, there are three different methods for the development of intercultural instruments: the simultaneous, the parallel, and the sequential approach (Bullinger et al., 1996). In the simultaneous approach, the instruments are developed at the same time in different countries. Given that a cross-national and cross-cultural consensus about the relevant item dimensions has been created, all countries contribute from the beginning to the content of the instrument. Therefore, each country can refer to its own individual instrument, which is comparable to the instruments developed in other countries within the common project (Kuyken et al., 1994). The parallel approach deals with all internationally relevant concepts for the final language version before the item

development begins. However, the instrument is developed in one language only and is translated into other languages during later stages. Finally, with the sequential method, a pre-existing instrument is adapted to other languages and cultures.

The results of this work illustrate that even with a very careful translation process, conceptual equivalence cannot be guaranteed.

It can be hypothesized that some questions, regardless of the quality of their translation and for various other reasons, may not be suitable for application in another culture (Marquis et al., 2005).

This hypothesis suggests that an internationally usable instrument, applicable to different countries and languages, is most likely to be produced through the simultaneous approach. However, one must consider that compared to the relatively cheap and time- saving sequential translation methods, the simultaneous development of an instrument is significantly costlier and more time-consuming.

4.4 Limitations

In general, the translation team faced typical challenges for a questionnaire which investigates sleep disturbances. In contrast to a questionnaire which evaluates current physical functions while the subject is conscious, sleep attendant symptoms are reported in the past. The symptoms of interest are not present at the time of reporting because the patient is awake while answering the items. Reduced awareness during sleep and brief retrograde amnesia during sleep onset also affect the validity of sleep measurements (Wyatt et al., 1997). Usually, we sleep in blocks every 24 hours, and variations in our sleep-wake function are common; thus, sleep questionnaires need longer time frames and must survey an adequate number of days to derive stable estimates for the evaluation in comparison to other PROs (Buysse et al., 2010). Due to this fact, it may not be possible to properly investigate a patient’s sleep disturbances over the course of seven days; a longer time frame may be needed.

In this work, we did not include the large Russian proportion of Latvian society, but only conducted the cognitive interviews with a representative sample of Latvian speakers. In the discussion, we raised the question of whether a Russian PROMIS Sleep Disturbance item bank should also be implemented in Latvia to ensure that sleep disturbances can be measured across all parts of society.

5. Conclusion and outlook

The results of this study indicate that the sequential development method is applicable to the Latvian language. This method enabled us to establish the Latvian version of the PROMIS Sleep Disturbance item bank, which is characterized by a high degree of conceptual equivalence and can therefore be used as a basis for other international studies of PROs relating to sleep disturbance.

In the future, a quantitative study will confirm and validate the translated item bank. The next steps include a survey of a large sample of Latvian people using the Latvian PROMIS Item Bank v1.0 - Sleep Disturbance. The data obtained will be used to calibrate the item parameters and to assess its psychometric performance.

The translated and culturally adapted version of the PROMIS Item Bank v1.0 - Sleep Disturbance offers a valid and reliable means of standardised assessment of sleep disturbance in the Latvian community based on state-of-the-art psychometric methods.

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Statutory declaration

“I, Vera Bergstrand, by personally signing this document in lieu of an oath, hereby affirm that I prepared the submitted dissertation on the topic “Translation of the PROMIS item bank for sleep disturbances for application in Latvia”, independently and without the support of third parties, and that I used no other sources and aids than those stated.

All parts which are based on the publications or presentations of other authors, either in letter or in spirit, are specified as such in accordance with the citing guidelines. The sections on methodology (in particular regarding practical work, laboratory regulations, statistical processing) and results (in particular regarding figures, charts and tables) are exclusively my responsibility.

My contributions to any publications to this dissertation correspond to those stated in the below joint declaration made together with the supervisor. All publications created within the scope of the dissertation comply with the guidelines of the ICMJE (International Committee of Medical Journal Editors; www.icmje.org) on authorship. In addition, I declare that I am aware of the regulations of Charité – Universitätsmedizin Berlin on ensuring good scientific practice and that I commit to comply with these regulations.

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