

**“Cross-cultural translation, validity and reliability of the Norwegian  
Version of the Neurophysiology of Pain Questionnaire”**



Master thesis

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## FORORD

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## ABSTRACT

**Background:** The Neurophysiology of Pain Questionnaire (NPQ) was developed as a tool for assessing how individuals conceptualize their pain experience. It can be used to evaluate to what extent health professionals and patients understand current knowledge about the neurophysiology of pain, and whether the questionnaire is a potential tool for use in clinical practice.

**Aim:** To develop a Norwegian version of the NPQ by translating and adjusting the questionnaire to the Norwegian language, and to investigate its content validity and test-retest reliability.

**Methods:** The translation of the NPQ was based on the 2005 ISPOR (the International Society for Pharmacoeconomics and Outcomes Research) international guidelines and standards for the translation and cultural adaptation of patient-reported outcome measures (PROM). For exploration of content validity, an expert panel consisting of three patients and three therapists were interviewed using the “think aloud” technique. Test-retest reliability was investigated by having a sample of 20 patients completing the NPQ two times, approximately one week apart. The demographic variables of the patient sample were examined using descriptive statistics. The level of agreement of separate items of the NPQ from test to retest was examined by Kappa statistics and percent agreement. Interclass Correlation Coefficient (ICC) with 95% confidence intervals and within-subject standard deviation (Sw) was used to examine test-retest reliability of NPQ sum scores of both the 19 items version and the 12 items version of the questionnaire.

**Results:** The translation and adaptation procedure resulted in a Norwegian version of the NPQ. The content validation study revealed challenges with the use of medical words and terms in the statements. In line with the Kappa values, all except two items, item 4 and 9, had satisfactory agreement. The sum score of the 19 items version showed satisfactory reliability, ICC being 0.793, while it was too low, 0.569, for the 12 items version. The smallest detectable change (SDC) was 6.8 for the 19 items version and 7.0 for the 12 items version.

**Conclusion:** Comprehensibility, being an aspect of content validity, demonstrated some difficulties with understanding some of the items. The Norwegian version of the 19 items version of NPQ had better test-retest reliability of the sum scores compared to the 12 items version, although agreement was low for two items. Further research is needed to ensure a larger sample size in test-retest reliability investigations, and a broader aspect of the content validity needs to be explored.

**Keywords:** NPQ, long lasting pain, pain neuroscience education

## SAMMENDRAG

**Bakgrunn:** The Neurophysiology of Pain Questionnaire (NPQ) ble utviklet som et verktøy for å vurdere hvordan individer konseptualiserer sin egen smerteopplevelse. Spørreskjemaet kan bli brukt for å evaluere om helsepersonell og pasienter forstår dagens kunnskap om smertens nevrofysiologi, og om skjemaet er et potensielt hjelpemiddel for bruk i klinisk praksis.

**Hensikt:** Å utvikle en norsk versjon av NPQ ved å oversette og adaptere spørreskjemaet til norsk språk, for så å undersøke skjemaets innholdsvaliditet og test-retest reliabilitet.

**Metode:** Oversettelsen av NPQ ble basert på 2005 ISPORs (the International Society for Pharmacoeconomics and Outcomes Research) internasjonale retningslinjer og standard for oversettelse og kulturell tilpasning av pasientrapporterte resultatmål. For undersøkelser av innholdsvaliditet ble en ekspertgruppe bestående av tre pasienter og tre terapeuter intervjuet med "think aloud" metoden. Test-retest reliabilitet ble undersøkt ved å la 20 deltakere fylle ut NPQ to ganger med ca. én ukes mellomrom. Demografiske data av utvalget ble undersøkt med deskriptiv statistikk. Graden av enighet mellom de enkelte variablene i spørreskjemaet ble undersøkt med Kappa statistikk og prosentvis enighet. Interclass Correlation Coefficient (ICC) med 95% konfidensintervall og within subject standard deviation (Sw) ble brukt for å undersøke test-retest reliabilitet av sum skårene fra NPQ, både 19-variabel versjonen og 12-variabel versjonen.

**Resultater:** Oversettelses- og tilpasningsprosessen resulterte i en Norsk versjon av NPQ. Undersøkelsene av innholdsvaliditet avdekket utfordringer med bruk av medisinske ord og begreper i utsagnene. Kappaverdiene viste at alle variablene, bortsett fra testleddene 4 og 9, hadde en tilfredsstillende enighet. Sum skårene fra 19-variabel versjonen hadde tilstrekkelig reliabilitet, med en ICC verdi på 0.793, mens den var for lav, 0.569, for 12-variabel versjonen. The smallest detectable change (SDC) var 6.8 for 19-variabel versjonen og 7.0 for 12-variabel versjonen.

**Konklusjon:** Undersøkelser av forståelighet, et aspekt innen innholdsvaliditet, avdekket vanskeligheter med forståelse av enkelte termer i utsagnene. Den Norske versjonen av 19-

variabel NPQ hadde bedre test-retest reliabilitet enn 12-variabel versjonen, selv om graden av enighet var lav for to av testleddene. Videre datainnsamling for minst 30 ytterligere deltakere er nødvendig for å sikre et tilstrekkelig sterkt anslag for reliabilitet, og videre er det behov for å gjennomføre en mer omfattende validitetsundersøkelse.

**Nøkkelord:** NPQ, langvarig smerte, pasientundervisning, smertefysiologi



## 1. INTRODUCTION

### 1.1. Musculoskeletal pain

Musculoskeletal disorders are common and among the most important causes of sick leave and disability benefits in Norway (Folkehelseinstituttet, 2015). Chronic pain has been recorded to be the cause of approximately 50% of disability benefits, and musculoskeletal pain to be the most common type of chronic pain (Folkehelseinstituttet, 2018). According to Kinge et al. (2015), 18% of Norwegian men and 27 % of Norwegian women reported musculoskeletal disorders lasting for six months or more. Low back pain and neck pain were found to be the most common diagnoses, and prevalence was found to increase with age (Kinge et al., 2015). Musculoskeletal disorders have a considerable impact on the use of primary and specialist health services (Kinge et al., 2015).

Recent data from the United Kingdom (UK) estimates that 28.9% of the total population in the UK live with a musculoskeletal condition. In the poor part of the British population 40% of men and 44% of women report chronic pain. For the richer part, 24% of men and 30% of women report the same. Musculoskeletal conditions, like for instance low back pain, are the top causes of years lived with disability. The prevalence of musculoskeletal conditions in the working population is increasing, and by 2030 an estimated 40% of the working age population will have a long-term condition. Conditions such as back pain account for around 40% of all sickness absence in the British National Health Service (NHS) (Arthritis Research UK, 2018).

The data presented above gives us a clue as to the impact of living with pain. The International Association for the study of pain (IASP) defines pain as “*an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage*” (IASP, 2017). Many individuals report pain in the absence of tissue damage or any likely pathophysiological cause. Distinguishing between pain caused by tissue damage and pain without the presence of tissue damage can be difficult, if not impossible, as pain is always a subjective experience. If an individual regards his or her experience as pain, it should, accordingly, be accepted as pain (IASP, 2017). Pain can be acute or chronic, being

chronic when it persists past normal healing time. Usually pain is regarded as chronic when it lasts for longer than 3 to 6 months (Treede et al., 2015).

Pain is a subjective experience and presents itself very differently between individuals. An individual's pain experience is a sum of many different factors such as genetic, environmental and psychogenic, some of which will be discussed below. There is a strong association between chronic pain and low socioeconomic status. Individuals with lower socioeconomic status are, according to a review by Bonathan et al. (2013), more likely to develop chronic pain and to experience a greater amount of disability and distress than individuals with a higher status. A prospective study by Hagen et al. (2000) also found that back pain, which is one of the most common types of musculoskeletal disorders, is most common in parts of the population with lower socioeconomic status. This association between musculoskeletal disorders and socioeconomic status seems to be increasing (Dahl et al., 2014). According to reports from The National Institute of Occupational Health in Norway (STAMI), back pain is most frequent in jobs requiring physical labour. Working in an office is associated with a higher prevalence of neck pain, but this seems to mainly include acute and short-term conditions (Veiersted et al., 2017, Tynes et al., 2008). Also, people seem to have more long-lasting pain in jobs with less flexibility in their working situation (Froud et al., 2020).

Neuroinflammatory mechanisms are considered to be central in the pathophysiology of many chronic pain conditions (Backryd et al., 2017). In chronic inflammation, the body is in a state where the immune cells release the same mediators as found in chronic disease (Seaman, 2013). Data from the Tromsø (Schistad et al., 2017) study showed that chronic inflammation was associated with increased pain sensitivity, suggesting that inflammation plays a potential role in experimental pain. This may also apply to the development of clinical pain.

There is an association between chronic pain and mental health challenges like depression and anxiety (Lien et al., 2011, Vassend et al., 2017). The mechanisms involved are, however, not completely clear. Genetic and environmental influences on neuroticism, anxiety, depression and musculoskeletal symptoms in a twin-study were examined, and a common underlying susceptibility to musculoskeletal symptoms and to symptoms of depression and anxiety was found (Vassend et al., 2017). Further, there is evidence suggesting that chronic pain is a risk

factor for suicidality (Racine, 2017). This reflects the severe effects that chronic pain may have on the lives of individuals.

Pain sensitivity is highly variable between humans. A substantial part of this variability seems to be heritable (Sorge et al., 2012). Nielsen et al. (2012) conducted a systematic review of twin-studies of pain, and found heritability to explain approximately 50% of chronic widespread pain and 35% of back and neck pain. Diatchenko et al. (2005) identified three different genetic variants that were designated as low pain sensitivity (LPS), average pain sensitivity (APS) and high pain sensitivity (HPS).

Chronic pain conditions are characterized by heightened pain sensitivity (Diatchenko et al., 2005, Butler and Moseley, 2017), or sensitization. IASP describes sensitization as increased responsiveness of nociceptive neurons to their normal input, and/or recruitment of a response to normally subthreshold inputs (IASP, 2017). Nociception is integrated with our feelings, thoughts and behaviour, and the sensitivity of our nervous system constantly develops and changes as a result (Butler and Moseley, 2017). Heightened pain sensitivity is also associated with challenges in coping with pain, as is often seen in people suffering from widespread pain (Bernardy et al., 2010).

The factors presented above are only some of the factors affecting the pain experience in an individual. There are several other factors that can also be of importance, like overweight and sleep problems. Overweight and obese people have been found to have a higher prevalence of chronic pain. A higher body mass index (BMI) is also associated with a lower functional capacity and reduced quality of life in people suffering from chronic pain (Arranz et al., 2014). Sleep problems significantly increase the risk for reduced pain tolerance, and sleep problems in combination with pain have been linked to a higher level of disability (Sivertsen et al., 2015).

## 1.2. Current approach to chronic pain understanding and management

When practicing evidence-based medicine (EBM) new treatment regimens have to be adopted and sometimes existing regimes have to be discarded. With respect to chronic pain, the view

that pain is always caused by tissue damage has been abandoned (Moseley, 2003).

Traditionally, pain has been viewed as purely sensory and a result of tissue damage. It was assumed that the pain experience was proportional to the peripheral damage (Turk et al, 1984). This understanding of chronic pain has been widely criticized (Moseley 2003, O'Sullivan, 2011). More recent evidence supports the idea that psychosocial factors are important in the development of chronic pain (Moseley, 2003).

The present understanding of chronic pain is based on the biopsychosocial model (Engel, 1977). Biological (nociception), psychological (feelings, knowledge, beliefs etc.) and social (interactions with our surroundings) factors are seen as potential influencers to pain experience, and all these factors are recommended to be considered when addressing someone's pain experience (Butler and Moseley, 2017). Genetic factors interact with psychosocial factors, including stress and pain catastrophizing, which makes the experience of pain unique in each individual (Fillingim, 2004). Furthermore, chronic pain is not necessarily a warning of tissue damage but is often a result of a development of a hypersensitive nervous system (Hush et al., 2018).

The growing understanding of the complexity of pain experience from a biopsychosocial viewpoint has led to the development of cognitive-behavioral approaches to pain management. These approaches attempt to integrate psychosocial and behavioral factors with somatic ones. They have an emphasis on beliefs, expectations, prior learning history and reinforcing behavior (McMahon et al., 2013). Addressing fear-avoidance behavior in individuals suffering from chronic musculoskeletal pain (Vlaeyen et al., 2012) has become an important part of these treatment approaches. The Norwegian guidelines for treatment of low back pain recommends multidisciplinary cognitive rehabilitation for individuals suffering from chronic low back pain (Helsedirektoratet, 2007).

Patient education in mechanisms underpinning chronic pain, Pain Neuroscience Education (PNE), has become a part of today's treatment of chronic pain. This approach seems to improve the knowledge of pain in patients suffering from chronic pain, contributing to reduce pain as well as improving function and lowering disability (Louw et al., 2016). The patient education is based on current knowledge about the neurophysiology of pain.

Lorimer Moseley and David Butler first published “Explain Pain” in 2003, as an assistance to health care professionals in helping their patients understand the concept of pain. Their aim was to give patients the information that they needed to have a better understanding of their own situation and as a result be less frightened or uncertain of the pain they experience and make good choices in pain management. “Explain pain” outlines modern models of pain management and provides the treatment essentials for overcoming pain and returning to normal life (Butler and Moseley, 2003). Moseley and Butlers work is based on a biopsychosocial understanding of pain. The experience of pain is considered subjective and individual. Nociception is integrated with our attitudes, beliefs and lack of understanding, and our behaviour, and the sensitivity of our nervous system changes along with our reactions and experiences. The nervous system works together with the other protective systems in our bodies, the sympathetic, motor, immune and cognitive systems. All these systems interact and can change the way our bodies work and how we feel. Treatment, according to Moseley and Butler, is centred around the identification of threats and uncertainty, and graded exposure. The graded exposure requires merging with the complexity of the context. Knowledge is a very important part of this treatment approach (Butler and Moseley, 2017). On this theoretical foundation the Neurophysiology of Pain Questionnaire was developed.

### 1.3. Neurophysiology of Pain Questionnaire

The Neurophysiology of Pain Questionnaire (NPQ) was developed by Lorimer Moseley, and first presented in 2003, see Appendix 1. As a part of the reconceptualization of the explanation of chronic pain, patient education and information about the current understanding of the neurophysiological mechanisms of chronic pain have been implemented in the treatment regime (Moseley, 2003). The NPQ was developed as a tool for assessing how an individual conceptualize the pain that he or she experiences (Catley et al., 2013). When applying the questionnaire one can evaluate whether health professionals and patients understand the current accurate information about the neurophysiology of pain, and further evaluate whether health care professionals accurately estimate the ability of patients to understand the neurophysiology of pain (Moseley, 2003).

The NPQ contains 19 statements about current knowledge of neurophysiology of pain. The statements are based on questions from postgraduate medicine students' exam papers. This knowledge test was originally completed before and after education about neurophysiology of pain. The items in the test reflected the material presented in the education sessions. There are two different versions of the NPQ, one for patient use and one for professionals. The differences in the two versions are related to terminology. In the patient version some words are modified to make it more understandable for individuals without a medical background. Each item in the NPQ is presented with three alternative answers; true, false or undecided (Moseley, 2003). The sum score ranges from 19-57.

#### 1.4 Measurement properties of assessment tools

Assessment tools should be valid and reliable. Measurement properties of the NPQ have been examined in several studies, addressing translation and cross-cultural adaptation, internal consistency, test-retest reliability and content validity.

Translation of a measurement instrument has to be executed according to standardized guidelines and culturally adapted to the target language. COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) describes cross-cultural validity as *“the degree to which the performance of the items on a translated or culturally adapted health-related patient-reported outcome (HR-PRO) instrument are an adequate reflection of the performance of the items of the original version of the HR-PRO instrument”* (Mokkink et al., 2010). NPQ has been translated and culturally adapted to Dutch (Meeus et al., 2010) and French (Demoulin et al., 2017).

Reliability is defined as *“the degree to which the measurement is free from measurement error”* (Mokkink et al., 2010). Test-retest reliability is defined as *“the extent to which scores for patients who have not changed are the same for repeated measurement over time”* (Mokkink et al., 2010). The interclass correlation coefficient (ICC) is often used as the calculating parameter for reliability. On a scale from 0-1, a value above 0,70 is considered acceptable (de Vet et al., 2011). Test-retest reliability of the NPQ has been investigated by

Catley et al. (2013), Meeus et al. (2010) and Demoulin et al. (2017), and evidence seem to be satisfactory.

Internal consistency is defined as *“the degree of the interrelatedness among the items”* (Mokkink et al., 2010). Internal consistency is often assessed using the calculating parameter Cronbach’s alpha. A Cronbach’s alpha of between 0,70 and 0,90 is considered satisfactory (de Vet et al., 2011). Internal consistency of NPQ was investigated by Meeus et al. (2010) and Catley et al. (2013) with satisfactory results. Demoulin et al. (2017) also investigated internal consistency of NPQ, but the results were not acceptable.

Content validity is defined as *“The degree to which the content of a health-related patient-reported outcome instrument is an adequate reflection of the construct to be measured”* (Mokkink et al., 2010). It is considered the most important measurement property. The items of a Patients Related Outcome Measure (PROM) have to be relevant, comprehensive and comprehensible to the construct of interest and to the target population (Mokkink et al., 2017). Content validity can be assessed by asking patients and professionals about relevance, comprehensiveness and comprehensibility of the items, response options and instructions of the measurement instrument being investigated (Terwee et al., 2018). The COSMIN panel presented the COSMIN Risk of Bias Checklist in 2018, updating the original COSMIN guidelines for assessing content validity (Mokkink et al., 2018). According to the COSMIN Study Design Checklist for patient-reported outcome measurement instruments investigation of content validity should include the following;

- a. Asking patients about relevance
- b. Asking patients about comprehensiveness
- c. Asking patients about comprehensibility
- d. Asking professionals about relevance
- e. Asking professionals about comprehensiveness

(Mokkink et al., 2019)

## 1.5 Studies on measurement properties of NPQ

Lorimer Moseley developed the NPQ in conjunction with a study that aimed to evaluate whether patients and professionals were able to understand relevant information on the subject, and to see whether health professionals were able to estimate the patients' ability to understand the information. 276 patients with chronic pain and 288 professionals were tested with NPQ either before or after education about the neurophysiology of pain. The professionals were also asked to estimate how a typical patient would perform on this test. Both patients and professionals in the study seemed to have poor knowledge of relevant theories regarding the neurophysiology of chronic pain initially, and both groups were able to understand the information provided and benefit from education on the subject. Health professionals did not, however, accurately estimate the patients' ability to understand the information. According to these data, health professionals tend to underestimate the patients' ability to understand the neurophysiology of pain (Moseley, 2003).

Meeus et al. (2010) translated and developed NPQ into a Dutch version. It was translated from English to Dutch by two independent translators. The two versions were compared and discussed, and developed into a common version. The translation process does not seem to have been executed according to any set of standardized guidelines. The Dutch version was tested on 61 patients with chronic fatigue syndrome (CFS) and on 31 health care professionals to investigate reliability and validity. Patients were tested two times, with retest 24 hours after the initial test. The findings of Meeus et al. supported the validity and reliability of the test. The validity was evaluated by comparing the scores of the patients and the professionals, expecting better scores in the group of professionals, which was also found in the study. A statistically significant difference in scores was demonstrated between the two groups. Both test-retest reliability ( $ICC = 0,756$ ) and internal consistency (Cronbach's  $\alpha = 0,769$ ) were satisfactory for CFS patients with chronic pain (Meeus et al., 2010).

Catley et al. (2013) pointed out that the questionnaire was widely used, but had not been thoroughly investigated concerning content validity, and they aimed to identify possible items that would be a threat to its content validity. They performed a Rasch Analysis of data from a group of patients with chronic spinal pain. The findings suggested that the NPQ targeted the sample adequately and had acceptable internal consistency and test-retest reliability. Seven



items were identified as possible threats to validity, and the data was reanalysed with these items excluded. Superior psychometric properties were observed in the reanalysis, which indicate that the NPQ could be improved by excluding the seven items. However, the conclusion was that the NPQ, with the 7 items included, was considered a useful tool for assessing patients' conceptualization of the biological mechanisms that underpin their pain, and to evaluate the effects of cognitive interventions for this group of patients (Catley et al., 2013).

Demoulin et al. (2017) translated and developed a French version of NPQ. The translation of NPQ was executed according to "the guidelines for the process of cross-cultural adaptation of self-report measures" developed by Beaton et al. (2000). The French version of NPQ was tested on a group of patients with spinal pain. Data analysis was performed on both the original version of the NPQ and the shorter version, excluding the seven items suggested by Catley et al. (2013). The short version of the NPQ did not demonstrate better psychometric properties than the original longer version. On the contrary, the short version of the NPQ had a lower test-retest reliability for the total score, and it included a few items with a very low item-total correlation or a very low reliability. They therefore challenged the use of the short version. Demoulin et al. (2017) also performed a test-retest reliability investigation on the scores of 70 patients who completed the 19 items NPQ. The questionnaire was filled out twice with one week's interval. Test-retest reliability was found acceptable (ICC = 0,644), but internal consistency was low (Chronbach's  $\alpha = 0,44$ ). However, they concluded that the French version of the NPQ is linguistically accurate, and has acceptable basic psychometric properties (Demoulin et al., 2017).

## 2. PURPOSE AND RESEARCH QUESTION

Patient education in understanding pain mechanisms is an important part of the treatment of individuals suffering from chronic musculoskeletal pain, and further research is needed to support existing evidence on its effect. To be able to do further examinations, tools for assessing the effect is needed.

Existing evidence supports the validity and reliability of the NPQ, although there are some differences in results between translated versions. The NPQ can be useful in further research as an instrument for assessing the effect of education in pain neuroscience. To my knowledge, a Norwegian version of the NPQ does not exist.

The aim of this study is to develop a Norwegian version of the NPQ by translating and adjusting the questionnaire to the Norwegian language, and then to investigate the content validity and test-retest reliability of both the 19 items version and the 12 items version of the questionnaire.

### 3. MATERIALS AND METHODS

#### 3.1 Choice of research design and setting

The present research project was conducted in two stages. First, the NPQ was translated into Norwegian and culturally adapted to the Norwegian language. Second, the translated instrument was completed by patients and therapists to investigate content validity and test-retest reliability.

The translation of the NPQ was based on the 2005 ISPOR (the International Society for Pharmacoeconomics and Outcomes Research) international guidelines and standards for the translation and cultural adaptation of patient-reported outcome measures. The aim was to create a Norwegian version that was as similar as possible to the English version, but at the same time took cultural differences into account (Wild et al., 2005).

#### 3.2 Translation into Norwegian and cultural adaptation of The Neurophysiology of Pain Questionnaire

The process of translation according to the ISPOR guidelines consist of 10 steps:

1. Preparation
2. Forward translation
3. Reconciliation
4. Back translation
5. Back translation review
6. Harmonization
7. Cognitive debriefing
8. Review of cognitive debriefing results and finalization
9. Proofreading
10. Final report

(Wild et al., 2005 pp. 96-97)

The translation of a measurement instrument can affect the measurement properties of the instrument. Therefore, a number of key actors with different qualifications in language skills and academic knowledge are needed in the process. Cross-cultural validation is needed to ensure that the translated and adapted instrument measures the same construct as the original version (de Vet et al., 2011). Cross-cultural validity is defined as “the degree to which the performance of the items on a translated or culturally adapted patient related outcome instrument are an adequate reflection of the performance of items in the original version of the instrument” (Mokkink et al., 2010).

### 3.2.1 The translation process

The translation of the Norwegian version of the NPQ took place in the autumn of 2018. As project manager, I was the coordinator of the process and overlooked each stage.

#### *Preparation*

The plan for the project, including the translation of the NPQ, was described in a research protocol. The research protocol was approved by two supervisors from the University of Bergen, and we applied for approval from the regional committee for medical and health research ethics (REC). Approval from REC was received in October 2018 (ref. 2018/1531, Appendix 9).

The instrument developer is responsible for management of the instrument. Lorimer Moseley developed the NPQ (Moseley, 2003). A request was sent to Moseley (Appendix 10) asking for approval to translate the NPQ into a Norwegian version. He kindly gave his approval (Appendix 11), and referred us to Mark Catley for possible involvement in the process. Catley has been working closely with Moseley on managing the instrument. Catley’s response was positive, and he offered to assist us in the process (appendix 11).

#### *Forward translation*

According to the ISPOR guidelines, forward translation of a measurement instrument should be carried out by two independent translators. Translator 1, being a native speaker of the target Norwegian language and fluent in the English source language, was responsible for

developing the first forward translation (Appendix 2). Translator 1 is a practicing physician with education from Munich, and fulfils the requirements of having a relevant medical background. A separate forward translator, Translator 2, was responsible for the second translation from English to Norwegian (Appendix 3). He met the requirements concerning language skills as he is native Norwegian and fluent in English. He is educated as a mechanical engineer and has no medical background. It is recommended that the forward translators have experience in translating. This recommendation proved difficult to fulfil, and neither of our forward translators had experience in translating. The forward translators received written information about the project and a consent form (Appendix 12). After signing the form, they received the original English version of the NPQ. The questionnaire was translated independently by the two translators and sent back to the project manager by email.

#### *Reconciliation*

The reconciliation was carried out by the project manager and the supervisors from the University of Bergen (Appendix 4). The two independent versions were compared and reconciled into one. Some small changes were made; 1) to make sure that the language was understandable for people with no medical background, 2) to make sure that the academic content was preserved, and 3) for cultural adaptation.

#### *Back translation*

Translator 3 was responsible for the back translation from Norwegian to English (Appendix 5). Translator 3 is native English, but has lived and worked in Norway for many years and is fluent in Norwegian. Translator 3 is a physiotherapist, and has prior experience in translating. Like the forward translators, the back translator received information and a consent form and signed this before receiving the Norwegian version of the NPQ. Translator 3 did not have any previous experience with the instrument, and did not see the original version before the back translation was completed.

#### *Back translation review*

The result of the back translation was compared to the original version to investigate discrepancies between the two versions. Discrepancies were highlighted and discussed. This step of the translating process was carried out by the project manager and the supervisors.

### *Harmonization*

Harmonization entails a comparison of back translations of multiple language versions with each other and the original instrument. This step of the translation process will highlight discrepancies between the original version and translated versions, and achieve a consistent approach to translation problems (Wild et al., 2005). To complete this step, a harmonization meeting with key in-country consultants, or back translators representing each language is required. Harmonization was, however, too comprehensive to perform within the framework of this Master's project and was not carried out.

### *Cognitive debriefing*

After receiving information and giving their written consent to participate in the study, a small group of people, consisting of both patients and physiotherapists, were given the reconciled Norwegian version of the questionnaire. They were interviewed individually about the wording, understandability, interpretation, and cultural relevance of the questionnaire. The interviews were taped and transcribed by the project manager (se appendix 8). These interviews were also used in the investigation of content validity, which will be discussed later.

### *Review of cognitive debriefing results and finalization*

The project manager and supervisors were responsible for reviewing the cognitive debrief. Each item of the reconciled Norwegian version was discussed to make sure the language was understandable for people with no medical background, to make sure the content was preserved, and for cultural adaptation. Any challenges pointed out by the contestants in the cognitive debrief interviews are addressed in the discussion.

### *Proofreading*

A final review of the translation was performed by the project manager and supervisors to highlight and correct any typographic, grammatical or other errors. The final version is presented in appendix 6.

### *Final report*

The project manager finalized a written report in Norwegian, documenting the translation process (appendix 7).

#### 3.2.2 Challenges in the translation process

##### *Words and concepts*

The forward translation of the questionnaire went quite smoothly, with only small differences in wording. The cognitive debriefing, on the other hand, revealed some challenges. The first one presents itself in the first item, the term “ion channels”. All of the participants in the expert panel points out that this can be a difficult concept for most people to understand unless they have a medical background. The term “ion channel” is included in two of the items in the questionnaire, item 1 and item 14. The term was discussed in the review of the cognitive debriefing. Some medical terms seem to be a part of the English language in a way that is not seen in the Norwegian language, and the term “ion channel” presents a challenge. Preferably, this term should be changed as a part of the cultural adaptation. It is, however, not possible to translate these two items without losing the original meaning. There are also other medical terms used in the questionnaire that presents similar challenges; “wall of the nerve”/”nerveveggen” (item 1), “pain receptors”/”smertereseptorer” (item 2 and item 12), “decending neurons”/”nedadgående nervebaner” (item 15).

##### *Items*

Item 9 in the original version states that “nerves adapt by increasing their resting level of excitement”. The two forward translations were identical – “Nervene tilpasser seg ved å øke deres spenningsnivå i hvile”. Translator 1 states that he is unsure whether this translation will reproduce the correct content of the statement. The item was discussed in the cognitive debriefing, and it was decided that the translation was not precise enough. As an attempt to ensure the original meaning of the statement, and at the same time make the language more understandable for people without a medical background, the item was changed to “Nervene tilpasser seg ved å bli mer følsomme for stimuli”.

### 3.3 Investigation of content validity of NPQ

Content validity is defined as *“The degree to which the content of a health-related patient-reported outcome instrument is an adequate reflection of the construct to be measured”* (Mokkink et al., 2010). Content validity is considered to be the most important measurement property by the COSMIN panel because “first of all it should be clear that the items of the PROM are relevant, comprehensive, and comprehensible with respect to the construct of interest and target population” (Mokkink et al., 2018).

As a part of the investigation of content validity an interviewing technique called “think aloud” was used. The method implies that the contestant completes the questionnaire with the researcher present and “thinks aloud” of the questions asked. The aim is to get a better understanding of the process of thought during the completion of the questionnaire, and of how the contestants understand the questions asked (Hak et al., 2008).

#### 3.3.1 Sample

For the exploration of content validity, an expert panel consisting of both patients and therapists was selected. The experts were representatives of the target population, as recommended by De Vet et al. (2011). The target population are in the best position to evaluate whether the items in a questionnaire are relevant, and to give an indication as to aspects that may be missing from the questionnaire (de Vet et al., 2011). The NPQ is aimed both at patients and therapists, and therefore both groups were represented in this expert panel.

The patients included suffered from widespread chronic unspecific pain, lasting for more than three months, and they were all older than 18 years. Most of the patients filled in the pain drawing both under and over a horizontal line, separating the lumbar and thoracic spine. Patients who report more widespread pain have more psychosocial problems and more difficulties coping with pain (Kvåle et al., 2001). The included therapists had all experience from treating patients suffering from chronic unspecific pain in the past 6 months.



In total, six persons participated in the investigation of content validity, three patients and three physiotherapists. They completed the questionnaire with the researcher present and “thought aloud” during the process. They were asked follow-up questions about the relevance, the comprehensiveness and the comprehensibility of the questionnaire.

### 3.3.2 Data collection

Participants for the content validation process were recruited from two different semi-private physiotherapist clinics, Madla Fysikalske Institutt in Stavanger and HelseInvest in Sola. The participants were informed about the process orally and in writing, and signed a consent form. They were given the questionnaire at the clinic and asked to read each of the 19 questions aloud. Further, they were asked to describe how they understood each question, and about the basis for giving their score. At the end of the interview they were asked about the contents of the questions as a whole. Each interview was recorded and transcribed by the project manager.

### 3.4 Test-retest reliability

The COSMIN panel defines reliability as “...the degree to which the measurement is free from measurement error”. Test-retest reliability investigations aim to figure out the extent to which scores for patients whose pain conditions have not changed are the same for repeated measurements over time.

In this investigation of test-retest reliability, a group of patients with long lasting musculoskeletal pain completed the questionnaire. According to de Vet et al. (2011), reliability investigations should be carried out in a group of people that mimics the group of people the instrument will be applied to in the future. The questionnaire was completed twice with minimal intervention between measurements. We wanted the measurements to be completed with the patient in the same state the second time as when they completed the questionnaire the first time. A short time interval would minimize the chance of significant change in their condition. A too short time interval, on the other hand, could mean that some

of the contestants would remember what scores they gave from the first to the second time. A time interval of approximately one week was chosen.

#### 3.4.1 Sample

Test-retest reliability was investigated by having a sample of 20 patients completing the NPQ two times, with a time lapse of at least one week between the first and second time. The patients included in this part of the study were chosen by the same criteria as for the content validity investigation. They suffered from widespread chronic unspecific pain, lasting for more than three months, were all older than 18 years, and reported pain both over and under a horizontal line separating the lumbar and thoracic spine in a pain drawing. According to de Vet et al. (2011), 50 participants are considered adequate by most researchers in reliability studies. Recruiting 50 participants is quite comprehensive. We chose to narrow it down to 20 participants to make it more manageable within the framework of a master thesis. Collection of data will continue after the master project is finished, and when having reached 50 participants a new data analysis will be performed aiming for an article to be published.

#### 3.4.2 Data collection

The participants in this part of the study was recruited from a semi-private physiotherapy clinic in Stavanger, Madla Fysikalske Institutt. Potential participants were given information about the study both orally, and in writing (Appendix 13), and then participants signed a declaration of consent. They were given the final version of the Norwegian NPQ and asked to complete the questionnaire. In addition to the NPQ, they were given a pain drawing where they marked areas of pain and filled out some personal information about gender and duration of pain. After approximately one week, they were to complete the NPQ again for a second time.

The declaration of consent, the pain drawing and demographic information about age, gender and duration of pain, and the two completed questionnaires were gathered in an envelope and stored in a locked archive cabinet that only the project manager had the key to. All the

information was handled anonymously, a code replacing names of participants. The project manager was the only one to have access to the list of codes attached to names.

### 3.4.3 Data analysis

The Statistical package for Social Sciences version 25 (SPSS 25) was used to perform statistical analysis of the data in the investigation of test-retest reliability. The demographic variables were examined using descriptive statistics.

The level of agreement of separate items of the NPQ from test to retest was examined by using Kappa statistics, and in addition percent agreement was calculated. Kappa is considered to be a more robust method than simple percent agreement as Kappa takes the possibility of agreement occurring by chance into account. While the Kappa value is influenced by the distribution of scores on the scale at the two assessments, the percent of agreement gives a measure of how often each score is exactly the same on test and retest. Percent agreement is accordingly easy to calculate and interpret directly.

The Kappa value ( $\kappa$ ) can range from -1 to +1. 0 represents the amount of agreement that is expected from random chance, and 1 represents perfect agreement between test and retest. A Kappa value of -1.0-0.0 indicates no agreement, 0.01-0.20 none to slight, 0.21-0.40 fair, 0.41-0.60 moderate, 0.61-0.80 substantial, and 0.81-1.00 as almost perfect agreement. When interpreting percent agreement 35-63% is considered moderate, 64-81% strong, and 82-100% as almost perfect (McHugh, 2012).

Interclass Correlation Coefficient (ICC) with 95% confidence intervals and within-subject standard deviation ( $S_w$ ) were used to examine test-retest reliability of NPQ sum scores. The  $S_w$  is the standard deviation of measurement error. In test-retest reliability, the measurement error for 95% of pairs of observations is 2.77  $S_w$ , called the smallest detectable change (SDC). This implies for an individual, that a change below this value will be considered within measurement error with 95% certainty, and not be a real change. ICC is considered a measure of relative reliability, expressed by a correlation coefficient, while  $S_w$  and SDC are measures of absolute reliability, agreement, expressed in scores of the measurement

instrument. The ICC is a value between 0 and 1. Values below 0.50 indicates a poor reliability, between 0.50 and 0.75 moderate reliability, between 0.75 and 0.90 good reliability and values above 0.90 indicates excellent reliability (Koo et al., 2016). An  $ICC \geq 0.70$  is usually considered satisfactory reliability of an assessment tool (de Vet et al., 2011).

## 4 RESULTS

The translated and adapted version of the NPQ is presented in appendix 6.

### 4.1 Content validity

Both therapists and patients answered the questionnaire while thinking aloud of how they understood the statements in the questionnaire. The transcribed responses and considerations are presented in appendix 8. Some of the items in the questionnaire were easily understood by all; item 2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 16, 17 and 18. Responses to these items will not be further outlined in this section. The following items were found more problematic to understand:

*Item 1: “Receptors on nerves work by opening ion channels in the wall of the nerve/nervenenes reseptorer fungerer ved å åpne ionekanaler i nerveveggen”*

Physiotherapist 1 points out that some of the anatomical terms and descriptions in the statement is not a part of the everyday Norwegian vocabulary in the same way as in the English language, and questions whether people with no medical background know what “ion channels” are. Physiotherapist 2 is not sure himself what “ion channels” are, and physiotherapist 3 says that the statement is understandable, but she needs a repetition of the subject to be sure what to answer. Both patient 2 and 3 do not know what “ion channels” are, and patient 3 also has trouble understanding the term “receptor”. They both say that not knowing what these words mean make them not understand the statement.

*Item 7: “The brain sends messages down your spinal cord that can change the message going up your spinal cord/hjernen sender signaler ned ryggmargen som kan påvirke signaler som kommer opp ryggmargen”*

Physiotherapist 1 says that he finds the wording of the statement a little confusing. Also, physiotherapist 2 finds this statement a little difficult to understand, and is confused about what is meant by “up” and “down”. He suggests to change the term “påvirke” (“affect”) to “endre” (“change”). This is the same wording as in the original version. The wording was changed earlier in the process because the word “påvirke” was thought to give a more accurate description of the mechanism.

*Item 14: “Nerves adapt by making ion channels stay open longer”/“nerver tilpasser seg ved å holde ionekanaler lengre åpne”*

As with item 1, the expert panel points out that “ion channels” are not something most people in Norway knows what is. Physiotherapist 2 is also not quite sure what “the nerves adapt”/“nervene tilpasser seg” means. Both patient 1 and 2 express a lack of knowledge about ion channels which makes the statement difficult to understand.

*Item 15: “Descending neurons are always inhibitory”/“nedadgående nervebaner er alltid hemmende”*

Physiotherapist 1 questions whether the term “inhibitory”/“hemmende” is understandable for people with no medical background, and suggests that maybe “dempende” would be more understandable for most people in this context. Patient 1 finds the item difficult to understand, and he says that the word “hemmende” is what makes him unsure. Patient 2 and 3 also find this statement difficult to understand, and relates difficulties to understanding the term “descending neurons”/“nedadgående nervebaner”.

*Item 19: “All other things being equal, an identical finger injury will probably hurt the left little finger more than the right little finger in a violinist but not a piano player”/ “når alle andre ting er like, vil en identisk fingerskade sannsynligvis gjøre mer vondt i den venstre lillefingeren enn den høyre lillefingeren hos en fiolinist, men ikke hos en pianist”*

The expert panel agreed that this statement has to be read a couple of times. The wording is understandable, you just have to use logic reasoning to conclude whether you think it is right or wrong.

For the NPQ as a whole, the expert panel problematize the use of words and terms that are difficult to understand for people without the relevant academic qualifications. To be able to answer a lot of the statements in the questionnaire you need extensive knowledge about pain physiology. Some of the questions are difficult to answer even for the physiotherapists who are supposed to have the academic qualifications needed.

## 4.2 Test-retest reliability

Twenty participants were included in the test-retest reliability investigation. Of these, 2 were men and 18 were women. The youngest participant was 24 years old, and the oldest 74. The mean age in the sample was 52.9 years. Eighty percent of the participants had experienced pain for longer than 4 years. When shading the areas of pain on a drawing of the body, 35% of the sample experienced pain in 2 quadrants, 20% in 3 quadrants and 45% in all 4 quadrants.

**Table 1. Demographic and pain variables of the patient sample, n=20**

Gender: men, women, %	10, 90
Age: yrs, mean, SD, range	52.9, 15.3, 24-74
Duration of pain, %	
3-6 mnth.	5
6 mnth. – 1 yr.	5
1-3 yrs.	10
4 yrs. +	80
Pain Drawing, %	
1 quad.	0.0
2 quads.	35.0
3 quads.	20.0
4 quads.	45.0

The Kappa value and percent agreement represent the level of agreement of the three-point response options of the NPQ items between the first test and the retest. The results reveal two items that have none to slight agreement, items 4 and 9, with Kappa values of respectively 0.16 and 0.11. Item 4 states as follows: “Special nerves in your spinal cord convey ‘danger’ messages to your brain/spesielle nerver i ryggmargen formidler signal om “fare” til hjernen”. Item 9 states this: “Nerves adapt by increasing their resting level of excitement/nervene tilpasser seg ved å bli mer følsomme for stimuli”

**Table 2. Test-retest reliability of 19 items of the Neurophysiology of Pain Questionnaire examined by Kappa statistics ( $\kappa$ ), 95% Confidence Interval (CI) and percent agreement. N=20.**

Item	$\kappa$ Value	95% CI	% Agreement
1	0.74	1.07, 0.41	90
2	0.65	1.28, 0.02	95
3	0.66	0.95, 0.37	85
4	0.16	0.45, -0.13	55
5	0.52	0.83, 0.21	70
6	0.74	0.99, 0.49	85
7	0.55	0.86, 0.24	75
8	0.67	0.94, 0.4	80
9	0.11	0.36, 0.14	45
10	0.84	1.04, 0.64	90
11	0.42	0.87, -0.03	80
12	0.62	0.97, 0.27	85
13	0.63	0.94, 0.32	80
14	0.47	1.06, -0.12	95
15	0.50	0.89, 0.11	80
16	0.59	0.88, 0.30	75
17	0.62	0.91, 0.33	75
18	0.59	0.88, 0.30	75
19	0.63	0.92, 0.34	80

Three items present a high level of agreement. Item 1, “Receptors on nerves work by opening ion channels in the wall of the nerve/nervenese reseptorer fungerer ved å åpne ione kanaler i nerveveggen”, and item 6, “Pain occurs whenever you are injured/smerte forekommer alltid når man er skadet”, have substantial agreement, both with Kappa values of 0.74. Item 10 has the highest Kappa value, 0.84, and is therefore considered to have a very high, almost perfect, level of agreement. Item 10 states that: “Chronic pain means that an injury hasn’t healed properly/kronisk smerte betyr at en skade ikke er skikkelig tilhelet”. Items 1, 2, 3, 6, 8, 12, 13, 17 and 19 are considered to have a strong level of agreement, with a Kappa value between 0.61-0.80.

Looking at percent agreement, 7 of the 19 items, items 1, 2, 3, 6, 10, 12 and 14, are considered to have an almost perfect level of agreement with an agreement of more than 82%. In line with the Kappa values, items 4 and 9 have the lowest scores, 55% and 45% respectively, and are



considered weak. Items 5, 7, 8, 11, 13, 15, 16, 17, 18 and 19 all have a percent agreement of between 64% and 81%, and are considered strong.

Items 4 and 9 stand out from the rest of the items with low scores on both the Kappa statistics and percent agreement.

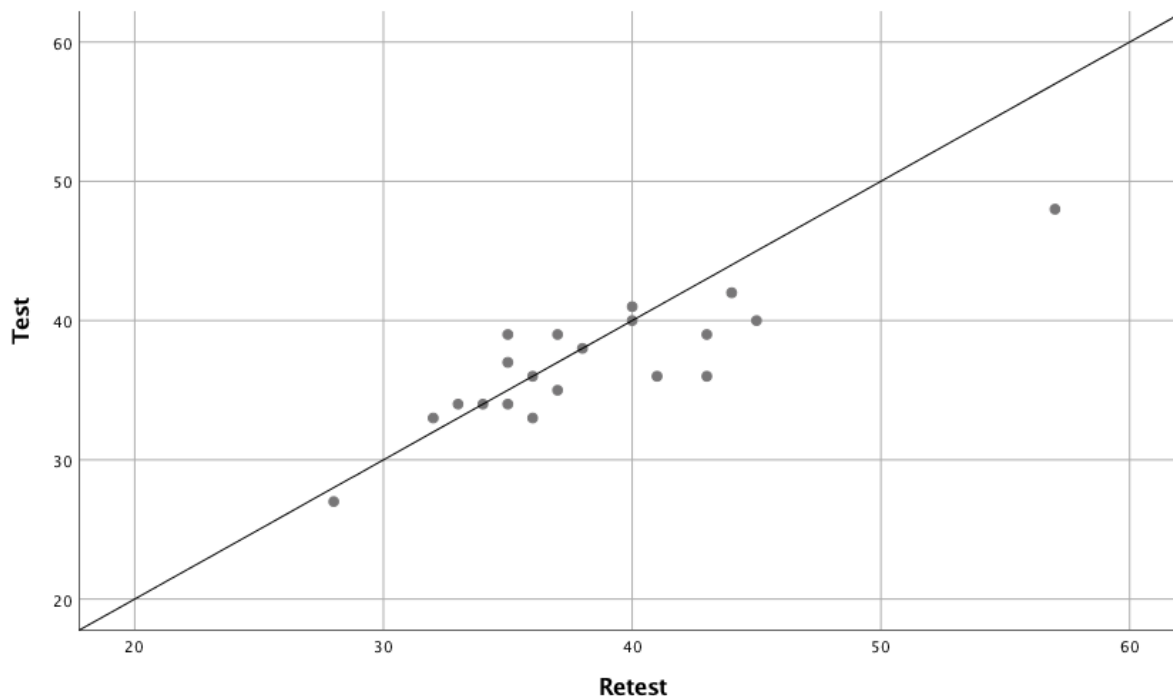
The mean difference from test to retest for the sum score of the 19 items version of the NPQ was -1.4. For the 12 items version the mean difference was -2.2. The 19 items version demonstrated an ICC value of 0.793, indicating a good reliability. The 12 items version demonstrated an ICC value of 0.569, indicating moderate reliability. The confidence interval of the ICC value for the 19 items version was 0.539,0.913, while for the 12 items version it was 0.089,0.818. The SDC for the 19 items version was 6.8, and for the 12 items version the SDC was 7.0.

**Table 3. Test-retest reliability of NPQ sum scores. Results of ICC Calculation using the 2-Way Random-Absolute-Agreement Model.**

	Test Mean (SD)	Retest Mean (SD)	Diff. Mean (SD)	ICC	95% CI	Sw	SDC
19item version	37.0 (4.3)	38.5 (6.2)	-1.5 (3.3)	0.793	0.539,0.913	2.46	6.8
12item version	21.3(2.8)	23.5 (4.1)	-2.2 (2.9)	0.569	0.089,0.818	2.51	7.0

A scatterplot of the sum scores of the 19 items version was created to illustrate the association between scores at test and retest. If a participant had the exact same scores at test and retest, the dots would be located on the diagonal of the scatterplot. If a participant scored very different at the first and the second time, an outlier would be visible in the scatterplot, the dot showing a large distance from the diagonal. As seen in the scatterplot, the dots of the participants are generally quite close to the diagonal. Inspecting the scatterplot, we see that four participants scored exactly the same on both occasions, while six scored higher at test and eight scored higher at retest. The sum score ranges from 19 to 57. The lowest sum score seen is 27 and the highest is 57. No participants had a sum score between 19 and 26. Only one participant stands out as an outlier. Participant 12 has a sum score of 48 in the test and 57 in the retest of the 19 items version.

**Figure 1. Scatterplot of test-retest sum scores of the 19 items NPQ. N=20.**



## 5 DISCUSSION

### 5.1 Main results

The aim of this study was to develop a Norwegian version of the NPQ by translating and adjusting the questionnaire to the Norwegian language, and then to investigate its content validity and test-retest reliability. The translation and adaptation procedure resulted in a Norwegian version of the 19 items NPQ with a strong level of agreement for most items and satisfactory reliability of the sum score (ICC 0.793). Both the change in mean scores from test to retest and the ICCs revealed a better reliability of the 19 items version when compared to the 12 items version, supporting the preference of the 19 items version of the NPQ. Two items, item 4 and 9, deviate from the rest with low scores on both the Kappa statistics and percent agreement, lowering the reliability. The content validation of the NPQ revealed challenges with the use of medical words and terms in the statements, and some items turned out to be difficult to comprehend for the participants.

### 5.2 Discussion of methods

The translation of the NPQ was based on the 2005 ISPOR international guidelines and standards for the translation and cultural adaptation of patient-reported outcome measures (Wild et al., 2005). Some of the requirements in the guidelines concerning language and academic skills and experience, proved difficult to fulfil. Also, the harmonization of the translation process was too comprehensive to perform within the framework of this project. It is difficult to say if completing the harmonization would have given us a different end result.

Initially, the plan was to recruit 50 participants for the test-retest reliability investigation. This sample size is considered adequate by most researchers in reliability studies (de Vet et al., 2011), but proved to be difficult to accomplish within the framework of this study. The sample was therefore limited to 20 participants, reducing the strength of the material. If this study is to be published, the recruitment of participants needs to continue to gain a sample of 50 participants. The sample should consist of representatives of the target population (de Vet et al., 2011). The sample of the test-retest reliability study consisted of 18 women, and only 2

men, reflecting a skewed distribution when it comes to gender. In further recruitment we need to recruit more male participants.

The items of a PROM need to be relevant, comprehensive, and comprehensible with respect to the construct of interest and target population (Mokkink et al., 2018). Investigation of content validity has to include exploration of relevance, comprehensiveness and comprehensibility. The focus in the interviews, however, mainly addressed whether the statements were comprehensible, if the therapists and patients understood the statements both in terms of words, concepts and content. Since the data material from this study mainly addresses comprehensibility, the exploration of content validity is limited to this aspect.

This study was conducted without any intervention and the participants did not have any prior education on the subject. For the statements in the questionnaire, knowledge is needed for participants to comprehend the statements presented, and thus for the tool to be relevant. The fact that a lot of the medical words and terms are not a part of the Norwegian language in the same way as in English language, may make the Norwegian version slightly more difficult to comprehend. The Norwegian version of the NPQ as a tool for assessing how an individual conceptualize their pain experience is therefore more questionable.

The interviewing technique “think aloud” implies that the contestant completes the questionnaire with the researcher present and “thinks aloud” of the questions asked. The aim is to get a better understanding of the process of thought during the completion of the questionnaire, and secondly, to find out how the participants understand the questions asked (Hak et al., 2008). The information given to the participants, and the discussion performed before filling in the questionnaires, can influence the focus of the contestants’ thoughts during the interview. Intervening by the interviewer during the interview could also affect the thoughts of the contestant and in this way shape the results. We wanted to influence the contestants as little as possible, and therefore kept the information and discussion beforehand to a minimum. As the aim of the NPQ is to investigate the contestants’ understanding of pain mechanisms, too much intervention can not only shape their thoughts during the interview, but also influence how they answer the questionnaire. Further exploration of content validity should ensure a wider investigation of relevance and comprehensiveness.

### 5.3 Discussion of results

The initial purpose of the NPQ was to develop a tool to evaluate whether health professionals and patients understand current information about the neurophysiology of pain, and to evaluate whether health care professionals accurately estimate the ability of patients to understand the neurophysiology of pain. In a daily practice this questionnaire can be used to conceptualize patients pain experience before and after a treatment session.

The expert panel that contributed to the content validation of the NPQ problematized the use of words and medical terms in the questionnaire. They found many terms difficult to understand for people without relevant medical background. To be able to answer some of the statements in the questionnaire you need extensive knowledge about pain physiology. The physiotherapists also struggled with some of the statements, either not understanding the medical terms or having forgotten knowledge that they used to have about pain physiology. The need for an update on pain physiology was expressed. It is likely that this is the case for many physiotherapists working with patients with long-lasting pain on a daily basis. It was pointed out by one of the physiotherapists that some of the anatomical terms and descriptions in the statements is not part of the everyday Norwegian vocabulary in the same way as in the English language. “Ion channels”/”ionekanal” and “receptors”/”reseptorer” were some of the words that the patients and physiotherapists mentioned that they had a hard time understanding, but they were also uncertain on the meaning of the words “inhibitory”/”hemmende” and “adapting”/”tilpasser seg”. Some of the patients didn’t understand the meaning of nerve signals “going up” or “going down”.

The statements from the NPQ were based on postgraduate pain medicine exam papers. The NPQ was initially completed before and after education about neurophysiology of pain, and the items in the questionnaire reflected the material presented in the education sessions. This explains the use of medical words and terms in the statements. Education about neurophysiology of pain would probably give patients a very different starting point when it comes to understanding the statements in the NPQ. If the Norwegian version of the questionnaire is to be used independently of education about neurophysiology of pain, some of the statements using medical words and terms need to be reformulated and adjusted to be more understandable for people without a medical background.

The Kappa value and percent agreement represent the level of agreement of the three-point response options of the NPQ items between the first test and the retest. Looking at the Kappa statistics, 10 out of 19 items were considered to have either a strong or an almost perfect level of agreement, and 17 out of 19 items to have a percent agreement that is considered strong or almost perfect. Items 4 and 9 deviates from the rest of the items with low scores on both the Kappa statistics and percent agreement. Item 4 reads as follows: “Special nerves in your spinal cord convey ‘danger’ messages to your brain/spesielle nerver i ryggmargen formidler signal om “fare” til hjernen”. Item 9 goes like this: “Nerves adapt by increasing their resting level of excitement/nervene tilpasser seg ved å bli mer følsomme for stimuli”. Based on the findings in the content validity investigation, it was interesting to see whether the items with a low level of agreement also seemed to be challenging to comprehend, and if the low level of agreement could be related to lack of understanding the statement. This seems to be the case in item 9, but not in item 4. Item 9 includes the term “adapting” which was pointed out to be difficult to understand by the expert group in the content validity investigation.

Reliability is defined as “the degree to which the measurement is free from measurement error”, and demonstrates the extent to which scores of patients who have not changed are the same for repeated measurements. The SDC implies a “change beyond measurement error” (De Vet et al., 2011). A change in score is only considered to represent a real change in an individual with 95% certainty if it is larger than the SDC (Van Kampen et al., 2013). When performing a test-retest reliability investigation, with approximately one week between testing and with no intervention, we do not expect to see a change in the participants’ responses. If there is no change in the participant, the change in sum score from test to retest should be zero or at least smaller than the SDC. On the other hand, if the change in an individual is above the SDC value, there is indication of a real change. The change in mean scores for the 19 items version and the 12 items version, are -1.5 and -2.2, respectively. This indicates a higher consistency in sum scores from test to retest of the 19 items version than of the 12 items version. The ICC of the 19 items version of the NPQ was 0.793. An ICC value of 0.75 and 0.90 indicates a good reliability. The 12 items version had an ICC value of 0.569, considered not to be a sufficiently high relative reliability (recommended to be  $\geq 0.70$ ). Both absolute and relative reliability was better for the 19 items version of the NPQ when compared to the 12

items version of the questionnaire. Based on the evidence from our study we support the use of the original version with 19 items.

The sum scores from test to retest for each participant in the test-retest reliability investigation are presented in a scatterplot (figure 1) to evaluate the change between the two tests. This allows us to see whether the results are similar from one test to the next, or if any of the participants have a larger change than the rest. The distribution of scores along the sum scale is also illustrated. Most of the participants scored quite similar from test to retest, but one outlier was spotted. Participant 12 had a change in sum score that was larger than the calculated SDC. The two tests were done with approximately one week in between, and with no intervention, we did not expect to see a change in the participants' responses. Intervention in the present study with a questionnaire assessing understanding of pain mechanisms, implies learning more about pain mechanisms. We cannot know whether participants searched the literature for clarification of words and terms after filling out the questionnaire the first time, in order to respond more correctly the second time. The outlier had a sum score of 57 on the retest. To score 57, you need to answer "undecided"/"uvisst" on all items. This indicates a larger amount of insecurity when answering the questionnaire for the second time.

Catley et al. (2013) presented the shorter 12 items version of the NPQ after a Rasch analysis, claiming that this shorter version had superior psychometric properties compared to the original 19 items version. The results from the study by Demoulin et al. (2017) do not support the use of the short version. According to their results the short version of the NPQ has a lower test-retest reliability for the total score, and it includes a few items with a very low item-total correlation or a very low reliability. The results from our study also support the preference of the 19 items version.

## 6 CONCLUSION

The Norwegian version of the 19 items NPQ seems to have a strong level of agreement for items and a good test-retest reliability for the sum score. Both the change in mean scores and the ICC values reveal a better reliability for the 19 items version than the 12 items version in our study. The Norwegian version of the NPQ might be a useful tool to evaluate knowledge acquisition in connection with patient education on neurophysiology of pain, and can be used as a tool to educate patients in conceptualizing their pain experience. The usefulness of the questionnaire as a tool to manage pain was, however, not addressed in this study.



## 7 ETHICAL CONSIDERATIONS

This study was carried out according to the ethical guidelines presented in the Declaration of Helsinki – Ethical Principles for medical research involving human subjects (World Medical Association, 2013). The principle of informed consent is described in the declaration of Helsinki's §25-31. Participants should receive information about the study in which they are participating, and participation should be voluntary. They should have information of what information will be collected and what the purpose of the study is. Participants should have the possibility to withdraw from the study at any time (World Medical Association, 2013).

According to §23 of the Declaration of Helsinki, the research protocol of studies on human beings has to be approved by the regional committee for medical and health research ethics (REC). A research report with findings and conclusions should be submitted to REC after the study is completed (World Medical Association 2013). According to REC student assignments need approval from REC to fulfill scientific requirements and approval is needed if the student assignment has the purpose of acquiring new knowledge about health and diseases (Regionale Komiteer for Medisinsk og Helsefaglig Forskningsetikk 2015). The research protocol and the final report will be sent to REC West. The research protocol was approved by REC West before the data collection took place. Approval from REC was received in October 2018 (ref. 2018/1531, Appendix 9).

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## APPENDICES

## Appendix 1: The original version of the NPQ, test with answers

		T	F	?
1	<i>Receptors on nerves work by opening ion channels in the wall of the nerve.</i>			
2	When part of your body is injured, special pain receptors convey the pain message to your brain.			
3	Pain only occurs when you are injured or at risk of being injured.			
4	Special nerves in your spinal cord convey 'danger' messages to your brain.			
5	<i>Pain is not possible when there are no nerve messages coming from the painful body part.</i>			
6	Pain occurs whenever you are injured.			
7	<i>The brain sends messages down your spinal cord that can change the message going up your spinal cord.</i>			
8	The brain decides when you will experience pain.			
9	<i>Nerves adapt by increasing their resting level of excitement.</i>			
10	Chronic pain means that an injury hasn't healed properly.			
11	<i>The body tells the brain when it is in pain.</i>			
12	<i>Nerves can adapt by producing more receptors.</i>			
13	Worse injuries always result in worse pain.			
14	<i>Nerves adapt by making ion channels stay open longer.</i>			
15	Descending neurons are always inhibitory.			
16	When you injure yourself, the environment that you are in will not affect the amount of pain you experience, as long as the injury is exactly the same.			
17	It is possible to have pain and not know about it.			
18	When you are injured, special receptors convey the danger message to your spinal cord.			
19	<i>All other things being equal, an identical finger injury will probably hurt the left little finger more than the right little finger in a violinist but not a piano player.</i>			

Adapted from Moseley, GL, Unraveling the barriers to reconceptualization of the problem in chronic pain: the actual and perceived ability of patients and health professionals to understand the neurophysiology, *Journal of Pain*, 2003; 4(4): 184-189.

Items in italic writing are not included in the 12 item version.

## Answers

Item		T	F	U
1	Receptors on nerves work by opening ion channels in the wall of the nerve.	#		
2	When part of your body is injured, special pain receptors convey the pain message to your brain.		#	
3	Pain only occurs when you are injured or at risk of being injured.		#	
4	Special nerves in your spinal cord convey 'danger' messages to your brain.	#		
5	Pain is not possible when there are no nerve messages coming from the painful body part.		#	
6	Pain occurs whenever you are injured.		#	
7	The brain sends messages down your spinal cord that can change the message going up your spinal cord.	#		
8	The brain decides when you will experience pain.	#		
9	Nerves adapt by increasing their resting level of excitement.	#		
10	Chronic pain means that an injury hasn't healed properly.		#	
11	The body tells the brain when it is in pain.		#	
12	Nerves can adapt by producing more receptors.	#		
13	Worse injuries always result in worse pain.		#	
14	Nerves adapt by making ion channels stay open longer.	#		
15	Descending neurons are always inhibitory.		#	
16	When you injure yourself, the environment that you are in will not affect the amount of pain you experience, as long as the injury is exactly the same.		#	
17	It is possible to have pain and not know about it.		#	
18	When you are injured, special receptors convey the danger message to your spinal cord.	#		
19	All other things being equal, an identical finger injury will probably hurt the left little finger more than the right little finger in a violinist but not a piano player.	#		

Note: T = true; F = false; U = undecided; # denotes the correct answer.

## Appendix 2: First forward translation from English to Norwegian

		R	G	U
1	Reseptorer på nervene fungerer ved å åpne ionekanaler i nerveveggen			
2	Når en del av kroppen din er skadet, formidler spesielle smertereseptorer beskjed om smerte til hjernen din			
3	Smerte oppstår kun når du er skadet eller I fare for å bli skadet			
4	Spesielle/spesialiserte nerver I ryggmargen formidler beskjeder om "fare" til hjernen din			
5	Smerte er ikke mulig når det ikke er beskjeder fra nerver som kommer fra den vonde kroppsdelene			
6	Det oppstår alltid smerte når man er skadet			
7	Hjernen sender beskjeder ned ryggmargen som kan forandre beskjeder som går opp ryggmargen din			
8	Hjernen avgjør når du opplever smerte			
9	Nervene tilpasser seg ved å øke deres spenningsnivå i hvile			
10	Kronisk smerte betyr at en skade ikke er skikkelig tilhelet			
11	Kroppen forteller hjernen når den har vondt			
12	Nervene kan tilpasse seg ved å produsere flere reseptorer			
13	Større skader medfører alltid mer smerte			
14	Nerver tilpasser seg ved å holde ionekanaler åpne lenger			
15	Nedadgående nerveceller er alltid hemmende			
16	Når du skader deg, vil ikke omgivelsene påvirke styrken på smerten du opplever så lenge skaden er akkurat den samme			
17	Det er mulig å ha smerter uten å vite om det			
18	Når du er skadet formidler spesialiserte reseptorer beskjeden om fare til ryggmargen din			
19	Når alle andre ting er like, så vil en lik fingerskade sannsynligvis gjøre mer vondt i venstre lillefinger enn høyre lillefinger hos en fiolinist, men ikke hos en pianist			

R: Riktig

G: Galt

U: Uvisst

## Appendix 3: Second forward translation from English to Norwegian

		R	G	U
1	Reseptorer på nervene fungerer ved å åpne ionekanaler i nerveveggen			
2	Når en del av kroppen din blir skadet, sender spesielle smeretreseptorer beskjed om smerte til hjernen din			
3	Smerte oppstår kun når du er skadet eller står i fare for å bli skadet			
4	Spesielle nerver I ryggmargen formidler beskjeder om `fare` til hjernen din			
5	Smerte er ikke mulig når det ikke kommer beskjeder om smerte fra den smertefulle kroppsdel			
6	Det oppstår alltid smerte når man er skadet			
7	Hjernen sender beskjeder ned ryggmargen din som kan endre beskjedene som kommer opp ryggmargen din			
8	Hjernen avgjør når du opplever smerte			
9	Nervene tilpasser seg ved å øke deres spenningsnivå i hvile			
10	Kronisk smerte betyr at en skade ikke er skikkelig tilhelet			
11	Kroppen forteller hjernen når den har vondt			
12	Nerver kan tilpasse seg ved å produsere flere reseptorer			
13	Større skader medfører alltid mer smerte			
14	Nerver tilpasser seg ved å holde ionekanaler åpne lengre			
15	Nedadgående nerveceller er alltid hemmende			
16	Når du skader deg vil ikke omgivelsene påvirke styrken på smerten du opplever så lenge skaden er akkurat den samme			
17	Det er mulig å ha smerter uten å vite om det			
18	Når du er skadet vil spesielle reseptorer formidle beskjed om smerte til ryggmargen din			

19 Når alle andre ting er like, vil en lik fingerskade sannsynligvis gjøre mer vondt i den venstre lillefingeren enn den høyre lillefingeren hos en fiolinist, men ikke hos en pianist			
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R: Riktig

G: Galt

U: Uvisst

## Appendix 4: Reconciliation of the two forward translations

		R	G	U
1	Nervenes reseptorer fungerer ved å åpne ionekanaler i nerveveggen.			
2	Når en del av kroppen din er skadet, formidler spesielle smertereseptorer signal om smerte til hjernen.			
3	Smerte forekommer kun når du er skadet eller står i fare for å bli skadet.			
4	Spesielle nerver i ryggmargen formidler signaler om «fare» til hjernen.			
5	Smerte er ikke mulig når det ikke kommer signaler gjennom nervene om smerte fra den smertefulle kroppsdelen.			
6	Smerte forekommer alltid når man er skadet.			
7	Hjernen sender signaler ned ryggmargen som kan påvirke signaler som kommer opp ryggmargen.			
8	Hjernen avgjør når du vil oppleve smerte.			
9	Nervene tilpasser seg ved å bli mer følsomme for stimuli i hvile.			
10	Kronisk smerte betyr at en skade ikke er skikkelig tilhelet.			
11	Kroppen forteller hjernen når den har det vondt.			
12	Nerver kan tilpasse seg ved å lage flere reseptorer.			
13	Større skader medfører alltid mer smerte.			
14	Nerver tilpasser seg ved å holde ionekanaler lengre åpne.			
15	Nedadgående nervebaner er alltid hemmende.			
16	Når du skader deg vil ikke omgivelsene dine påvirke graden av smerte du opplever, så lenge skaden er akkurat like stor.			
17	Det er mulig å ha smerter, og ikke vite om det.			
18	Når du er skadet vil spesielle reseptorer formidle signal om smerte til ryggmargen.			
19	Når alle andre ting er like, vil en identisk fingerskade sannsynligvis gjøre mer vondt i den venstre lillefingeren enn den høyre lillefingeren hos en fiolinist, men ikke hos en pianist.			

## Appendix 5: Back translation from Norwegian to English

		R	G	U
1	Nervenes reseptorer fungerer ved å åpne ione kanaler i nerveveggen <i>Receptors on nerve (endings) work by opening ion channels in the nerve wall</i>			
2	Når en del av kroppen din er skadet, formidler spesielle smertereseptorer signal om smerte til hjernen <i>When part of your body is injured, special pain receptors send (convey) a pain signal to your brain</i>			
3	Smerte forekommer kun når du er skadet eller står i fare for å bli skadet <i>Pain only occurs when you are injured or in danger of being injured</i>			
4	Spesielle nerver i ryggmargen formidler signaler om «fare» til hjernen <i>Special nerves in the spinal cord send «danger» signals to the brain</i>			
5	Smerte er ikke mulig når det ikke kommer signaler gjennom nervene om smerte fra den smertefulle kroppsdelen <i>Pain cannot be felt when no pain signals come from the painful part of the body</i>			
6	Smerte forekommer alltid når man er skadet <i>Pain always occurs when one is injured</i>			
7	Hjernen sender signaler ned ryggmargen som kan påvirke signaler som kommer opp ryggmargen. <i>The brain sends signals down the spinal cord which can influence signals coming up the spinal cord</i>			
8	Hjernen avgjør når du vil oppleve smerte <i>The brain decides when you experience pain</i>			
9	Nervene tilpasser seg ved å bli mer følsomme for stimuli i hvile			

	<i>Nerves adjust to become more sensitive to stimuli at rest</i>			
10	Kronisk smerte betyr at en skade ikke er skikkelig tilhelet <i>Chronic pain means that an injury is not properly healed</i>			
11	Kroppen forteller hjernen når den har det vondt <i>The body tells the brain when it experiences pain</i>			
12	Nerver kan tilpasse seg ved å lage flere reseptorer <i>Nerves can adapt by establishing more receptors</i>			
13	Større skader medfører alltid mer smerte <i>Worse injuries always give more pain</i>			
14	Nerver tilpasser seg ved å holde ionekanaler lengre åpne <i>Nerves adapt by holding ion channels open longer</i>			
15	Nedadgående nervebaner er alltid hemmende <i>Descending nerve pathways are always inhibitory</i>			
16	Når du skader deg vil ikke omgivelsene dine påvirke graden av smerte du opplever, så lenge skaden er akkurat like stor <i>When you injure yourself, your environment will not influence the amount of pain you experience, providing the damage is the same</i>			
17	Det er mulig å ha smerter, og ikke vite om det <i>It is possible to have pain and not know you have it</i>			
18	Når du er skadet vil spesielle reseptorer formidle signal om smerte til ryggmargen <i>When you are injured special receptors will transmit a signal to the spinal cord</i>			
19	Når alle andre ting er like, vil en identisk fingerskade sannsynligvis gjøre mer vondt i den venstre lillefingeren enn den høyre lillefingeren hos en fiolinist, men ikke hos en pianist <i>All things being equal, an identical finger injury will probably cause more pain in the left little finger than in the right in a violinist, but not in a pianist</i>			



## Appendix 6: Final version (NPQ-NO)

**Smertens neurofysiologi**

Nr.		R	G	U
1	Nervenes reseptorer fungerer ved å åpne ionekanaler i nerveveggen			
2	Når en del av kroppen din er skadet, formidler spesielle smertereseptorer smertesignal til hjernen			
3	Smerte forekommer kun når du er skadet eller står i fare for å bli skadet			
4	Spesielle nerver i ryggmargen formidler signal om «fare» til hjernen			
5	Smerte er ikke mulig når det ikke kommer nervesignaler fra den smertefulle kroppsdelen			
6	Smerte forekommer alltid når man er skadet			
7	Hjernen sender signaler ned ryggmargen som kan påvirke signaler som kommer opp ryggmargen			
8	Hjernen avgjør når du vil oppleve smerte			
9	Nervene tilpasser seg ved å bli mer følsomme for stimuli			
10	Kronisk smerte betyr at en skade ikke er skikkelig tilhelet			
11	Kroppen forteller hjernen når den har det vondt			
12	Nerver kan tilpasse seg ved å lage flere reseptorer			
13	Større skader medfører alltid verre smerte			
14	Nerver tilpasser seg ved å holde ionekanaler lengre åpne			
15	Nedadgående nervebaner er alltid hemmende			
16	Når du skader deg vil ikke omgivelsene dine påvirke graden av smerte du opplever, så lenge skaden er akkurat like stor			
17	Det er mulig å ha smerter, og ikke vite om det			
18	Når du er skadet vil spesielle reseptorer formidle signal om smerte til ryggmargen			
19	Når alle andre ting er like, vil en identisk fingerskade sannsynligvis gjøre mer vondt i den venstre lillefingeren enn den høyre lillefingeren hos en fiolinist, men ikke hos en pianist			

**R:** Riktig **G:** Galt **U:** Uvisst

Oversatt fra originalversjon "Neurophysiology of Pain Questionnaire".

Moseley, GL, Unraveling the barriers to reconceptualization of the problem in chronic pain: the actual and perceived ability of patients and health professionals to understand the neurophysiology, *Journal of Pain*, 2003; 4(4): 184-189.

## Appendix 7: Final report of the translation process

Oversettelse av NPQ etter guidelines fra Wild et al. (2005).

### 1. Forberedelse

Prosjektet, inkludert oversettelsen av NPQ, ble beskrevet i en prosjektplan. Etter denne var godkjent av veiledere ved UiB, ble det søkt om godkjenning fra Regional Etisk Komité (REK). Metoden som er beskrevet av Wild et al. (2005) ble gjennomgått sammen med veiledere, og vi gikk gjennom hvilke kvalifikasjoner de ulike oversetterne måtte inneha. Utvikleren av testverktøyet, i dette tilfellet Lorimer Moseley, ble kontaktet på e-post og bedt om tillatelse til å bruke testverktøyet. Han henviste videre til Mark Catley, som også har arbeidet mye med NPQ, for evt. involvering i prosessen. Responsen fra Catley var positiv, og han sa seg villig til å være behjelpelig i prosessen. Rekruttering av oversettere ble gjort underveis i prosessen.

### 2. Oversettelse fra Engelsk til Norsk

For oversettelse fra engelsk til norsk var det behov for to uavhengige oversettere. Disse skulle begge ha norsk som morsmål og være flytende i engelsk. Den ene oversetteren burde ha medisinskfaglig bakgrunn og den andre burde ikke ha medisinskfaglig bakgrunn. Den første jeg rekrutterte til denne oppgaven var min svoger, Jostein Eiane Heggebø. Han er norsk, og har norsk som morsmål, man har bodd, studert og jobbet i utlandet i mange år og er flytende i engelsk. Han er lege, og har derfor den medisinskfaglige bakgrunnen som jeg hadde behov for. Den andre oversetteren er min mann, Henrik Eiane Heggebø. Han er også norsk, og har norsk som morsmål. Han har også studert og jobbet i utlandet, bl.a. i USA, og er flytende i engelsk. Han har ikke medisinskfaglig bakgrunn. De fikk tilsendt samtykkeskjema hvor de også fikk en beskrivelse av prosjektet de sa seg enige i å delta i. De fikk det originale spørreskjemaet på engelsk. Oversetteren uten medisinskfaglig bakgrunn hadde ikke så mange spørsmål rundt det faglige innholdet i påstandene. Oversetteren med medisinskfaglig bakgrunn var usikker på hvordan han skulle oversette påstand nr. 9. Oversettelsen av påstand nr. 9 var lik i begge de norske oversettelsene, og lød slik: «Nervene tilpasser seg ved å øke

deres spenningsnivå i hvile». Han var usikker på om det ble riktig fagterminologi, men var usikker på en bedre måte å si det på. Ellers var det noen små variasjoner i språket i de to versjonene, f.eks. ord som beskjed/signal. Vi satte oss sammen over skype for å gjennomgå de to versjonene og sette dem sammen til en versjon.

### 3. Forsoning

Etter den samlede versjonen var klar, satte jeg meg sammen med veiledere ved UiB for gjennomgang. Det ble gjort en del endringer for å sørge for at språket er forståelig for mannen i gaten, for å sørge for at det faglige innholdet er beholdt og for kulturell tilpasning. F.eks. ble påstand nr. 9, som ble problematisert i den første oversettelsen til norsk, oversatt til: «Nervene tilpasser seg ved å bli mer følsomme for stimuli i hvile». Denne endringen ble gjort da det er en mer korrekt gjengivelse av det faglige innholdet i påstanden.

### 4. Tilbakeoversettelse

Rekrutteringen av oversettere til denne oppgaven viste seg å være litt mer problematisk. Oversetteren til denne oppgaven måtte ha engelsk som morsmål, snakke flytende norsk og ha medisinskfaglig bakgrunn. Det var vanskelig å finne noen som hadde alle disse kvalifikasjonene. Som et kompromiss fant jeg to fysioterapeuter som jobber sammen hvor den ene har engelsk som morsmål og snakker norsk, dog ikke flytende, og den andre har norsk som morsmål og er flytende i engelsk. Begge med medisinskfaglig bakgrunnen. Det tok litt tid å vente på oversettelsen, og jeg fikk etterhvert beskjed om at de ikke ville kunne gjøre den jobben likevel da den ene oversetteren var reist bort på ubestemt tid. Jeg måtte da finne et annet alternativ. Jeg ble tipset om en fysioterapeut ved Stavanger Universitetssykehus, Susan Carol Maun. Hun er britisk, og har engelsk som morsmål. Hun har bodd i Norge i mange år og er flytende i norsk. Hun har også den medisinskfaglige bakgrunnen. Hun fikk tilsendt samtykkeskjema med informasjon om prosjektet og den norske versjonen som vi var kommet frem til i forrige punkt.

### 5. Gjennomgang av tilbakeoversettelse

Tilbakeoversettelsen på Engelsk ble sammenlignet med den originale Engelske versjonen. Ved et par anledninger ble det brukt synonymmer for noen begreper, f.eks. gjelder dette «message»/«signal» og «danger»/«at risk». Det er også et par tilfeller der ordenes rekkefølge er noe endret, f.eks. «the wall of the nerve»/«the nerve wall». Påstand 6 var noe annerledes formulert; «pain occurs whenever you are injured»/ «pain always occurs when one is injured». Det ble imidlertid konkludert med at innholdet i de to versjonene var like nok. Utsagn nr. 9 er også ulike, «nerves adapt by increasing their resting level of excitement»/«nerves adjust to become more sensitive to stimuli at rest». Denne påstanden ble imidlertid endret en del i oversettelsesprosessen fra engelsk til norsk, og ulikheten i påstandene i de to engelske versjonene kan forklares på denne måten.

#### 6. Harmonisering

Harmonisering ble ikke gjennomført.

#### 7. Kognitiv debrifing

En liten gruppe deltakere, bestående av både pasienter og terapeuter, ble presentert for den versjonen av spørreskjemaet som man kom frem til etter å ha forsonet de to ulike oversettelsene til norsk. De ble intervjuet individuelt om hvordan de forsto de ulike påstandene. Eventuelle momenter deltakerne bet seg merke i ble tatt med i den videre bearbeidingen av spørreskjemaet.

#### 8. Gjennomgang av kognitiv debrifing

Jeg, i rollen som prosjektleder, og veiledere fra Universitetet i Bergen var ansvarlige for gjennomgangen av den kognitive debrifingen. Hver påstand i den foreløpige versjonen av NPQ var diskutert for å sikre at språket var forståelig for folk uten medisinskfaglig bakgrunn, at innholdet i påstandene ble bevart og for å tilpasse til norsk kultur. Momenter påpekt av deltakerne i den kognitive debrifingen ble tatt opp i diskusjonen.

#### 9. Korrekturlesing

En siste gjennomgang av det oversatte spørreskjemaet ble utført av prosjektleder og veiledere for å korrigere typografiske, grammatiske eller andre feil.

## 10. Avsluttende rapport

Denne rapporten dokumenterer oversettelsesprosessen.

## Appendix 8: Description of the examination of content validity (think aloud)

## Completing the questionnaire using the think aloud method

3 physiotherapists and 3 patients

## Terapeut 1:

1.	Jeg forstår spørsmålet, men i det norske språket har vi ikke tatt inn en del av de anatomiske beskrivelsene og faglige vokabularet som de bruker i engelsk. Så spørsmålet er om folk flest vet hva ionekanaler er. Det kan være problematisk for en del å forstå. Resten av spørsmålet bør være forståelig. Jo mer skolerte deltakerne er jo mindre problematisk vil dette antakeligvis være.
2.	Det synes jeg er enkelt og greit. Tror reseptorer er et ord som er innarbeidet i språket hos de fleste.
3.	Kan ikke se at noe skal misforstås her. Tror det er greit.
4.	Tror de fleste forstår hva som menes med fare her, tror den og er greit.
5.	Lurte på om det var en annen måte å si det på «smerte er ikke mulig når...», men innholdet – du skjønner jo hva det betyr.
6.	Grei.
7.	Signaler som kommer opp – kan man heller f.eks. skrive som kommer inn til ryggmargen. Ville vurdert formuleringen der, kan være litt forvirrende. Essensen er at informasjon fra hjernen kan påvirke de signalene som kommer inn fra kroppen til hjernen.
8.	(vil). ...når du opplever smerte?
9.	Forståelig. Om man kan svare på spørsmålet er en annen ting. Skjønner «nervene tilpasser seg».
10.	Enkel og greit, rett frem.
11.	Forståelig.
12.	Reseptorer igjen, tror de fleste forstår reseptorer. Evt. endret følsomhet, men det blir kanskje ikke helt det samme. Nei, jeg tror den er greit.
13.	Den er greit.
14.	Der er du igjen i ionekanalland. Kanskje folk flest vet mer enn man tror? Man kan jo ikke finne opp nye ord, det blir heller ikke riktig. Man kan jo heller svare «vet ikke»?
15.	Jeg vil forstå hemmende som dempende. Mulig at dempende vil være litt mer forståelig i den sammenhengen?
16.	Den er greit.
17.	Kan ikke gå feil med den.
18.	Tror den er greit.

19.	Da begynner jo folk å tenke på hvorfor den venstre lillefingeren vil være viktigere for en fiolinist enn en pianist. Man må tenke gjennom og gjerne lese gjennom et par ganger. Man må likevel lese gjennom et par ganger og tenke gjennom, se for seg, om man er fagperson.
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Oppsummert;

- Se litt på nr. 7
- Ionekanaler
- Reseptorer, men det tror jeg de fleste vil forstå.

#### Terapeut 2:

1.	Nerveneseptorer skjønner jeg jo. Men vet ikke helt om jeg skjønner det med ionekanaler i nerveveggen. Man skjønner jo hvis man har fulgt med på skolen, kommer an på hva man har av bakgrunn.
2.	Tydlig. Den skjønner jeg, og jeg tror folk flest forstår det.
3.	Vet ikke om folk kan svare på spørsmålet, men tror folk skjønner spørsmålet.
4.	Helt grei.
5.	Ingen vanskelige ord som jeg ser.
6.	Den er grei.
7.	Litt vanskelig å skjønne den ned og opp der, hva de egentlig spør om. Vet ikke helt hva de vil frem til. Kanskje «endre»? Stusser litt på den der.
8.	Den er grei, tror jeg.
9.	Jeg skjønner spørsmålet.
10.	Den tror jeg er grei.
11.	Den tror jeg og er grei.
12.	Litt vanskelig å skjønne. Jeg vet ikke om «tilpasser», kommer ikke på noe bedre forslag..
13.	Den er grei.
14.	Igjen «nervene tilpasser seg» som jeg stusser litt på.
15.	Kan tolkes litt for en pasient som om nedadgående nervebaner – at jo lenger fra hjernen man kommer, jo svakere er det?
16.	Jeg skjønner det og tror den er grei. Må bare lese gjennom spørsmålet et par ganger.
17.	Den er grei.
18.	Den skjønner jeg og tror den er bra.

19.	Jeg skjønner poenget, må bare lese den noen ganger. Man må bare tenke logisk, hva er den viktigste hånden. Det er et ganske bra spørsmål, kult spørsmål. Setter i gang en tankeprosess.
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### Terapeut 3:

1.	Skulle ha repetert litt, merker jeg. Men jeg skjønner spørsmålet.
2.	Det vet jeg.
3.	Usant, tenker det kan være et lurespørsmål.
4.	Jeg tenkte det var nociceptorer, ikke ryggmargen? Blir litt usikker på om man mener perifert eller sentralt.
5.	Skjønner spørsmålet.
6.	Nei, usant.
7.	Den mener jeg og er sann.
8.	Tror den er sann, altså.
9.	Sensitivisering, tenker man da? Her også tenker jeg sentralt eller perifert? Og mener man at det alltid er sånn, eller at det kan gå begge veier?
10.	Usant, mener jeg.
11.	(ingen kommentar)
12.	Kan jo gjøre sprouting. Må kripe til korset og svare vet ikke.
13.	Usant, mener jeg.
14.	Vet jeg ikke.
15.	Usant.
16.	Tror jeg er usant, men jeg er litt usikker.
17.	(ingen kommentar)
18.	Sant
19.	Mulig, men jeg vet jo ikke.

Oppsummert: Vil de ha noen innføring først? Hvis ikke kan det være litt avansert språk for en del. Det er ganske mye detaljert fysiologi.

### Pasient 1:

1.	Det tror jeg er sant.
2.	Det vet jeg er sant.



3.	- (ingen kommentar, bare krysser av)
4.	Det er vel sant.
5.	Sant.
6.	Det er usant. Man kan ha ting og tang i magen uten at man kjenner det, for eksempel.
7.	Det vet jeg ikke.
8.	Det er vel sant.
9.	Stusser litt. Nervene fører signalene frem og tilbake. Jeg skjønner ikke helt spørsmålet, så jeg svarer vet ikke.
10.	Ikke nødvendigvis.
11.	Sant.
12.	Det tror jeg er sant.
13.	Det er usant.
14.	Det skjønnte jeg ikke helt spørsmålet, så jeg svarer vet ikke. Har ikke så mye kunnskap om ionekanaler. Så vidt jeg ser det så ser jeg ikke hvordan det kan påvirke.
15.	Skjønner heller ikke helt spørsmålet. Hemmende er det som er vanskelig å forstå, må si vet ikke.
16.	Omgivelsene kjenner jo ikke på den smerten som jeg vil oppleve, så der må jeg skrive usant.
17.	Nei, smerte, det vet du at du har. Du kan ha skade uten at du vet om det.
18.	Ja.
19.	Spørs om han er høyre eller venstrehendt. Samme siden uavhengig av favoritt hånd? Ja, da vil jeg vel tenke sant.

- Nedadgående nervebaner
- Ionekanaler – skjønner bedre spørsmål 1, det er lettere å se for seg, mer logisk.

Spørsmålet var mer fortellende. Det var et lettere forståelig spørsmål enn nr. 14. Kan evt. komme med en forklaring som gjør at man ser for seg et bilde.

#### Pasient 2:

1.	Jeg vet ikke hva ionekanaler er. Så jeg vet ikke svaret og skjønner ikke helt spørsmålet. Men jeg tipper at hvis jeg visste hva det var, at jeg hadde forstått spørsmålet.
2.	Kanskje? Jeg tror jeg skjønner spørsmålet, men vet ikke helt svaret. Det eneste jeg ville lurt på er hva er forskjellen mellom spesielle og uspesielle.
3.	Nei. Vet ikke helt om jeg skjønner spørsmålet. Smerte kommer av at jeg er syk, men det kan og komme av at jeg frykter at jeg skal få vondt. Så svaret er sikkert ja da. Stusser litt på spørsmålet der.

4.	Føler ikke jeg har kompetanse til å vite det, men jeg skjønner spørsmålet. Jeg tenker hvertfall at hvis det er i det området, lurer igjen på hva som er spesielle og hva som er uspesielle. Jeg vet ikke om ryggmargen sender beskjeder, evt. om den sender beskjed om noe som potensielt kan skje. Jeg tror jeg forstår spørsmålet, jeg hadde hatt mer lyst til å skrive utfyllende svar.
5.	Jo, det tror jeg. Sånn som å få hodepine hvis kroppen bare vil ut av situasjonen.
6.	Man kan være skadet uten å få smerte, og kan få smerte uten å bli skadet. Jeg vil si usant.
7.	Jeg skjønner spørsmålet, men jeg vet ikke svaret.
8.	Jeg tipper ja, og jeg forstår spørsmålet.
9.	Jeg ville tenkt omvendt, men det kommer vel an på situasjon? Jeg tenker at i noen tilfeller ville de kunne bli mindre følsomme. Jeg ville tenkt at det kan gå begge veier. Jeg skjønner spørsmålet, men jeg ville tenkt at det kunne gå begge veier.
10.	Jeg ville tenkt nei. Jeg skjønner spørsmålet, men jeg er ikke enig. Så må svare usant.
11.	Sikkert, jeg skjønner spørsmålet igjen. Og jeg ville tenkt at det var sant.
12.	Igjen så skjønner jeg spørsmålet, men det står det kan tilpasses. Jeg skjønner, men kan ikke svaret.
13.	Jeg ville svart usant, men jeg skjønner spørsmålet uavhengig av svaret.
14.	Der er det igjen at jeg ikke vet helt hva det innebærer, vet ikke hva ionekanaler betyr. Og igjen tror jeg at jeg ville forstått spørsmålet om jeg visste hva det var.
15.	Jeg vet ikke hva det betyr. Skjønner ikke nedadgående nervebaner. Skjønner hemmende, da tenker jeg at det er noe som holder tilbake litt. Ikke nødvendigvis stopper. Hadde hjulpet å vite litt hva de ulike tingene er.
16.	Usant, og jeg skjønner spørsmålet.
17.	Sant? Hvis man føler at noe alltid ha vært der, og at noen andre kanskje ville tolket det som smerte? Kommer an på hva man tenker smerten er?
18.	Sikkert? Jeg føler ikke jeg har god nok kompetanse til å vite det sikkert? Jeg skjønner spørsmålet.
19.	Jeg må lese denne litt flere ganger... Kommer an på om fiolinisten er høyre- eller venstrehendt. Om man går ut fra at de spiller på venstre siden av kroppen. Ja, nei, kommer an på. Noen ting man spiller på piano er mer slitsomt på venstre side enn på høyre side, men sånn som spørsmålet er stilt virker det som om det er mer plagsomt for fiolinisten. Jeg skjønner spørsmålet, men igjen føler jeg at jeg kan diskutere.

### Pasient 3:

1.	Hvem er det som skal forstå det første spørsmålet? Et vanlig menneske vet ikke hva det er for noe. Både reseptorer og ionekanaler.
2.	Ja. Den er jo grei den. Det tror jeg alle skulle forstå.

3.	Jeg vil si at når du er blitt skadet, hvis ikke så er det psykisk. Da er det redselen som gjør at du kjenner smerter?
4.	Ja.
5.	Er det ikke da du blir litt lam? Jeg skjønner spørsmålet. Du kan se at du har brent deg, men kjenner ikke smerter? Hvis du ser, det er en ting. Synet av det i seg selv vil jo kunne.
6.	Nei, det er jo ikke. Av og til kommer det med en gang, av og til lenge etter.
7.	Det kan godt være, men jeg vet ikke. Jeg skjønner spørsmålet, men kan ikke svaret.
8.	Ja, kanskje?
9.	Det vet jeg ikke? Det er vel det som må forskes på?
10.	Ja.. huff.. Du kan jo si, nei. Jeg vet ikke. Det er jo noe kroppen har laget, ikke nødvendigvis noe som er skadet.
11.	Ja, kan godt være det.
12.	Kan den det? Ja, de kan vel lage nye, det synes jeg jeg har lest om.
13.	Nei, ikke nødvendigvis, nei?
14.	Hva er ionekanaler?
15.	Aner ikke det? Forstår ikke nedadgående nervebaner? Den er litt vanskelig å skjønne.
16.	Ikke helt enig om jeg er enig i det, kommer an på hvem du er med, hvem som hylar høyest.
17.	Har hørt om en familie i Italia som ikke kjenner smerte. Det er en an ting.
18.	Til ryggmargen? Det er enkelte ting man kan sjekke av sykdommer og sånn, jeg hat tatt spinalpunksjon. Det er ikke ryggmargen, det er vel nervene?
19.	Det har jo med hva man gjør, hvordan du bruker fingrene dine. Den var god.

## Appendix 9: Approval from the Regional ethics committee



Region: REK vest

Saksbehandler: Jessica Svård

Telefon: 55978497

Vår dato: 20.09.2018

Deres dato: 14.08.2018

Vår referanse: 2018/1531/REK vest

Deres referanse:

Liv Inger Strand

Inst for global helse og samfunnsmedisin

**2018/1531 Oversettelse og reliabilitetstesting av Neurophysiology of Pain Questionnaire** Forskningsansvarlig:  
Universitetet i Bergen

**Prosjektleder:** Liv Inger Strand

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK vest) i møtet 05.09.2018. Vurderingen er gjort med hjemmel i helseforskningsloven (hforsknl) § 10.

### Prosjektomtale

*The Neurophysiology of Pain Questionnaire (NPQ) ble utviklet for å undersøke kunnskap om smertefysiologi hos pasienter med langvarige smertetilstander. NPQ inneholder 19 spørsmål. Målet med denne studien er å oversette og utvikle en Norsk versjon av NPQ for så å undersøke test-retest reliabilitet og innholdsvaliditet. Oversettelsen av NPQ vil baseres på ISPOR (International Society for Pharmacoeconomics and Outcomes Research) internasjonale retningslinjer og standard for oversettelse og kulturell tilpasning av pasientrapporterte utfallsmål. Undersøkelse av test-retest reliabilitet og innholdsvaliditet vil gjøres etter retningslinjer fra COSMIN (Consensus-based Standards for the selection of health Measurement Instruments) checklisten. Et test-retest design vil bli benyttet og 50 pasienter fyller ut spørreskjemaet to ganger med 1-2 ukers mellomrom. Hvordan spørsmålene fortolkes undersøkes gjennom "think aloud" metode. Tre pasienter og tre terapeuter rekrutteres til denne us. av validitet*

### Vurdering

#### Forsvarlighet

Dette er et masterprosjekt hvor formålet er å oversette og utvikle en norsk versjon av The Neurophysiology of Pain Questionnaire (NPQ), for deretter å undersøke test-retest reliabilitet og innholdsvaliditet. NPQ er utviklet for å undersøke kunnskap om smertefysiologi hos pasienter med langvarige smertetilstander. 50 pasienter skal fylle ut spørreskjemaet to ganger med 1-2 ukers mellomrom. I tillegg skal det undersøkes hvordan spørsmålene i spørreskjemaet fortolkes gjennom en "think aloud"-metode. Tre pasienter og tre terapeuter skal rekrutteres til denne undersøkelsen av spørreskjemaets innholdsvaliditet. REK vest finner at prosjektet har ubetydelig risiko og er forsvarlig å gjennomføre.

#### Rekruttering

Pasientene skal rekrutteres fra to private fysioterapiklinikker. Prosjektmedarbeider skal få assistanse fra behandlere ved de to klinikkene til rekruttering av pasienter. REK vest har ingen innvendinger til rekrutteringsprosedyren.

#### Datainnsamling og lagring

Data som skal innsamles er utfylt spørreskjema (NPQ), smertetegning, samt informasjon om kjønn, alder og varighet av smerter. Intervjuer med lydopptak. Opplysningene vil bli lagret avidentifisert med koblingsnøkkel. Når datainnsamlingen er gjennomført, vil koblingslisten makuleres, og dataene vil da være anonymisert. REK vest har ingen innvendinger til datalagringen.

### *Samtykke*

Samtykke vil bli innhentet fra både pasienter og behandlere i studien, og vil gjelde utfylt NPQ og smertetegning, samt informasjon om kjønn, alder og varighet av smerter. I tillegg vil man innhente samtykke fra personer som bidrar i oversettelsesprosessen.

### *Informasjons- og samtykkeskriv*

Informasjonsskrivene mangler logo til forskningsansvarlig institusjon (UiB).

Informasjonsskriv knyttet til studien må også revideres i tråd med ny mal på REKs nettsider, slik at informasjonen som gis til deltakerne er forenlig med ny personopplysningslov. Komiteen ber om at revidert informasjonsskriv ettersendes REK vest sammen med øvrig tilbakemelding.

Reviderte informasjons- og samtykkeskriv må sendes til REK vest til [post@helseforskning.etikkom.no](mailto:post@helseforskning.etikkom.no).

### **Vilkår**

Vi gjør oppmerksom på at det kreves et juridisk grunnlag for å behandle personopplysninger. Nytt av 20. juli 2018 er at REKs godkjenning ikke lenger gir et juridisk grunnlag for å behandle personopplysninger. Nå må denne behandlingen også oppfylle krav i personvernforordningen. Fortsatt skal alle forskningsprosjekter som omfattes av helseforskningsloven forhåndsgodkjennes av REK, men egen institusjon har ansvar for at behandlingen av personopplysninger er i henhold til personvernforordningen.

### **Vedtak**

REK har gjort en helhetlig forskningsetisk vurdering av alle prosjektets sider. Prosjektet godkjennes med hjemmel i helseforskningsloven §§ 10 og 33 på betingelse av at ovennevnte vilkår tas til følge.

### *Sluttmelding og søknad om prosjektendring*

Prosjektleder skal sende sluttmelding til REK vest på eget skjema senest 01.12.2020, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK vest dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

### *Klageadgang*

Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

▪

Informasjons- og samtykkeskriv må revideres etter ovennevnte merknader og sendes til REK vest til [post@helseforskning.etikkom.no](mailto:post@helseforskning.etikkom.no).

Med vennlig hilsen

Marit Grønning professor, dr.med. Komiteleder

**Kopi til:** [post@uib.no](mailto:post@uib.no)

Jessica Svärd rådgiver

## Appendix 10: Request to instrument developer

Ragnhild Rossebø Hansen  
Niels Juels gate 70  
4008 Stavanger  
Norway  
+4799320121  
[ragnhild.hansen@student.uib.no](mailto:ragnhild.hansen@student.uib.no)

Stavanger, 22.03.2018

Dear Prof. Moseley,

I am a postgraduate student, in health sciences – physiotherapy, at the University of Bergen, Norway. I have a special interest in chronic back pain, and have learned that we lack a Norwegian version of the Neurophysiology of Pain Questionnaire that can be used as a tool to assess how an individual conceptualizes the biological mechanisms of the pain that they experience. To my knowledge, a Norwegian translation and cultural adaptation of the NPQ does not exist. Therefore, as a part of my master's thesis I would like to translate the NPQ from English to Norwegian.

I am writing to ask for permission to translate a Norwegian version of the NPQ in collaboration with my supervisor, Professor, dr. philos. Liv Inger Strand. We would base the translation on the 2005 ISPOR international guidelines and standards for the translation and cultural adaptation of patient-reported outcome measures, aiming to create a Norwegian version that is as similar as possible to the English version. See reference below.

If you agree to this, would it be possible to consult you during the process if we have any questions/concerns?

To my understanding there is no fee for using the instrument.

Will you please indicate whether you approve or not by responding to this email?

Kind regards

Ragnhild Rossebø Hansen  
Physiotherapist, student of health sciences - physiotherapy

### *Reference:*

*Wild D., Grove A., Martin M., Eremenco S., McElroy S., Verje-Lorens A., Erikson P.. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: Report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Health, 8 (2005), pp. 94-104.*

## Appendix 11: Approval from instrument developer

-----Original post-----

From: Lorimer Moseley

Date: 2018-05-03

Title: Request to translate The Neurophysiology of Pain Questionnaire to Norwegian

Copy: Mark Catley

Hi there -

it is fine for you to translate it. i would **HIGHLY** recommend mark catley as a collaborator because he knows the questionnaire so well. i would expect him to advise on protocol, analysis and write up and of course be part of the authorship team.

best

Lorimer

-----Original post-----

From: Mark Catley

Date: 2018-10-11

Title: Neurophysiology of Pain Questionnaire

Dear Ragnhild

Apologies for my delay in replying to your email. I am not aware of any Norwegian versions either. I am by no means an expert in translation and, like many Australians, only speak English :(

I am reasonably handy with psychometrics though and have seen the NPQ translated into



several languages - I am happy to help you with any questions you have through the process.

I have attached word files of the version most widely used by Lorimer and our group.

If you have any questions, please let me know.

Kind regards

Mark

## Appendix 12: Information and consent form translators



Bergen, 4. oktober 2016

## **Forespørsel om deltakelse i forskningsprosjektet**

# OVERSETTELSE OG RELIABILITETSTESTING AV NEUROPHYSIOLOGY OF PAIN QUESTIONNAIRE

Dette er et spørsmål til deg om å delta i et forskningsprosjekt for å utarbeide en norsk versjon av spørreskjemaet Neurophysiology of Pain Questionnaire (NPQ). NPQ benyttes til å vurdere kunnskap om smertefysiologi som er sentralt i behandling av langvarige smerter.

Forskningsprosjektet er en del av en masteroppgave i fysioterapivitenskap ved Universitetet i Bergen. For å gjennomføre selve oversettelsen vil vi forespørre personer som har norsk som morsmål og er flytende i engelsk og personer som har engelsk som morsmål og er flytende i norsk. Profesjonelle oversettere vil også bli forespurt.

### **Hva innebærer prosjektet?**

I dette prosjektet vil NPQ bli oversatt til norsk i samsvar med internasjonale retningslinjer. Spørreskjemaet består av 19 påstander som besvares med tre svaralternativer. Målet er å skape en norsk versjon som er så lik som mulig den engelske originalversjonen, men som også tar hensyn til kulturelle forskjeller. Spørreskjemaet vil først bli oversatt fra engelsk til norsk av to uavhengige oversettere. De to versjonene sammenlignes og bearbeides til man har én norsk versjon, og spørreskjemaet vil så oversettes tilbake til engelsk av en tredje oversetter.

### **Mulige fordeler og ulemper**

Det er ikke knyttet noen risiko til deltakelse i prosjektet.

### **Frivillig deltakelse og mulighet for å trekke sitt samtykke**

Det er frivillig å delta i prosjektet. Dersom du er villig til å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte Ragnhild Rossebø Hansen, tlf. 99320121, [rrh@fys.no](mailto:rrh@fys.no).

**Forsikring**

Studien er ikke forbundet med noen form for risiko. Prosjektet er forsikret som masteroppgave gjennom Universitetet i Bergen.

**Godkjenning**

Regional komité for medisinsk og helsefaglig forskningsetikk har vurdert prosjektet, og har gitt forhåndsgodkjenning (2018/1531).

**Kontaktopplysninger**

Dersom du har spørsmål til prosjektet kan du ta kontakt med Ragnhild Rossebø Hansen, telefon 99320121, e-post: [rrh@fys.no](mailto:rrh@fys.no).

Du kan ta kontakt med Universitetet i Bergens personvernombud dersom du har spørsmål om behandlingen av dine personopplysninger i prosjektet

**Jeg samtykker til å delta i prosjektet**

---

Sted og dato

Deltakers signatur

.....  
Deltakers navn med trykte bokstaver

**Jeg bekrefter å ha gitt informasjon om prosjektet**

---

Sted og dato

Signatur

.....  
Rolle i prosjektet

Vennlig hilsen

Ragnhild Rossebø Hansen

## Appendix 13: Information and consent form participants



Bergen, 4. oktober 2018

## **Forespørsel om deltakelse i forskningsprosjektet**

# OVERSETTELSE OG RELIABILITETSTESTING AV NEUROPHYSIOLOGY OF PAIN QUESTIONNAIRE

Dette er et spørsmål til deg om å delta i et forskningsprosjekt for å utarbeide en norsk versjon av spørreskjemaet Neurophysiology of Pain Questionnaire (NPQ). NPQ benyttes til å vurdere kunnskap om smertefysiologi som er sentralt i behandling av langvarige smerter. Forskningsprosjektet er en del av en masteroppgave i fysioterapivitenskap ved Universitetet i Bergen. For å gjennomføre studien vil vi forespørre personer som har hatt utbredte smerter i kroppen i mer enn 3 måneder. Noen fysioterapeuter vil også bli forespurt om å delta.

### **Hva innebærer prosjektet?**

I dette prosjektet vil NPQ bli oversatt til norsk i samsvar med internasjonale retningslinjer. Den norske versjonen av spørreskjemaet må så besvares to ganger av minst 50 deltakere for å kunne vurdere om det er pålitelig, og i samsvar med originalversjonen. Deltakerne blir først bedt om å fylle ut spørreskjemaet på klinikken en gang, og så en gang til hjemme etter 1-2 uker og levere det utfylte spørreskjemaet på klinikken ved neste konsultasjon. Estimert tidsbruk for utfylling av skjemaet er ca. 20 min. For å se nærmere på hvordan innholdet i de ulike spørsmålene blir oppfattet vil tre pasienter og tre behandlere bli bedt om å «tenke høyt» mens de fyller ut spørreskjemaet. Dette vil tas opp på lydbånd. Deltakerne som er med på denne delen av prosjektet vil fylle ut skjemaet i forbindelse med konsultasjon hos sin behandler etter avtale. Estimert tidsbruk er ca. en time.

I prosjektet vil vi innhente og registrere opplysninger om deg. I tillegg til selve spørreskjemaet vil vi innhente opplysninger om kjønn og alder, og deltakerne skriver utbredelsen av smertene på en skisse av kroppen.

### **Mulige fordeler og ulemper**

Deltakelse i prosjektet vil ikke innebære noen avvik fra ordinær behandling. Det er ikke knyttet noen risiko til deltakelse i prosjektet.



### **Frivillig deltakelse og mulighet for å trekke sitt samtykke**

Det er frivillig å delta i prosjektet. Dersom du er villig til å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dette vil ikke få konsekvenser for din videre behandling. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte Ragnhild Rossebø Hansen, tlf. 99320121, rrh@fys.no.

### **Hva skjer med opplysningene om deg?**

Opplysningene som registreres om deg skal kun brukes slik som beskrevet i hensikten med prosjektet. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjenner opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun Ragnhild Rossebø Hansen og Liv Inger Strand som har tilgang til denne listen.

Prosjektleder har ansvar for den daglige driften av forskningsprosjektet og at opplysninger om deg blir behandlet på en sikker måte. Informasjon om deg vil bli anonymisert eller slettet senest fem år etter prosjektslutt.

### **Forsikring**

Studien er ikke forbundet med noen form for risiko. Prosjektet er forsikret som masteroppgave gjennom Universitetet i Bergen.

### **Godkjenning**

Regional komité for medisinsk og helsefaglig forskningsetikk har vurdert prosjektet, og har gitt forhåndsgodkjenning (2018/1531).

Etter ny personopplysningslov har Universitetet i Bergen og Ragnhild Rossebø Hansen et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet gar rettslig grunnlag i EUs personvernforordning.

Du har rett til å klage på behandlingen av dine opplysninger til Datatilsynet.



### **Kontaktopplysninger**

Dersom du har spørsmål til prosjektet kan du ta kontakt med Ragnhild Rossebø Hansen, telefon 99320121, e-post: [rrh@fys.no](mailto:rrh@fys.no).

Du kan ta kontakt med Universitetet i Bergens personvernombud dersom du har spørsmål om behandlingen av dine personopplysninger i prosjektet

### **Jeg samtykker til å delta i prosjektet og til at mine personopplysninger brukes**

---

Sted og dato

Deltakers signatur

---

Deltakers navn med trykte bokstaver

### **Jeg bekrefter å ha gitt informasjon om prosjektet**

---

Sted og dato

Signatur

---

Rolle i prosjektet

Vennlig hilsen

Ragnhild Rossebø Hansen