



**Translation and psychometric validation of a Danish version
of the Medication-Related Quality of Life scale (D-MRQoL)
in a population of patients with polypharmacy**

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HÁSKÓLI ÍSLANDS

**Þýðing á skalanum *lyfjatengd lífsgæði* (MRQoL)
yfir á dönsku og próffræðileg athugun á
dönsku útgáfunni í hópi fjöllyfjanotenda**

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ABSTRACT

Translation and psychometric validation of a Danish version of the Medication-Related Quality of Life scale (D-MRQoL) in a population of patients with polypharmacy

Objective: The aim was to translate the original version of the Taiwanese Medication-Related Quality of Life (MRQoL) scale into Danish and validate the translated version in a population of patients with polypharmacy.

Methods: The study was conducted in Copenhagen, Denmark, from January to April 2017. A translation committee was appointed to follow a strict translation protocol. MRQoL was forward-translated into Danish, backward-translated into Chinese, pre-tested in eight patients, and administered to 120 polypharmacy patients. The factor structure was examined using Exploratory Factor Analysis (EFA) and internal consistency reliability was evaluated using Cronbach's alpha. Construct validity was examined in terms of convergent and discriminant validity by using the Beliefs about Medicines Questionnaire (BMQ) and the Medication Adherence Report Scale (DMARS-4).

Results: The Cronbach's alpha coefficient for the overall D-MRQoL scale was 0.96. Of hypothesized correlations to establish construct validity, only one was accepted. Total scores on D-MRQoL correlated statistically significantly and negatively with those on the BMQ subscale *concerns* ($r=-0.455$; $p=0.000$), but not with BMQ subscale *necessity* ($r=-0.029$; $p=0.754$). The correlation with DMARS-4 was positive and significant ($r=0.338$; $p=0.000$), indicating that D-MRQoL seems, contrary to hypothesis, related to medication adherence. D-MRQoL scale showed a two-factor structure if the eigenvalue was set at 1.0, but seemed clearly differentiated in terms of underlying concepts. This diverges from the original Taiwanese scale which showed a three-factor structure.

Conclusion: The D-MRQoL scale showed a high reliability and a two-factor structure which has face validity. Although convergent validity was somewhat established, the construct validity and known-group validity of D-MRQoL need further study. The D-MRQoL scale is still under development but is a promising assessment tool as a potential patient-reported outcomes measure.

ÁGRIP

Þýðing á skalanum *lyffjatengd lífsgæði* (MRQoL) yfir á dönsku og próffræðileg athugun á dönsku útgáfunni í hópi fjöllyfjanotenda

Markmið: Markmið rannsóknarinnar var að þýða Taiwanskan skala sem ætlað er að mæla *lyffjatengd lífsgæði* yfir á dönsku og meta próffræðilega eiginleika dönsku útgáfunnar (D-MRQoL) í hópi sjúklinga á fjöllyfjameðferð.

Aðferðir: Rannsóknin fór fram í Kaupmannahöfn á tímabilinu janúar til apríl 2017. Sérstök nefnd fylgdi kerfisbundnu verklagi við þýðinguna. MRQoL skalinn var þýddur yfir á dönsku, þýddur tilbaka yfir á kínversku, forprófaður á 8 manna hópi og að lokum lagður fyrir 120 fjöllyfjanotendur. Þáttauppbygging D-MRQoL var ákvörðuð með Exploratory factor analysis (EFA) og innri áreiðanleiki var skoðaður með aðferð Cronbach's alpha. Spurningalistarnir Beliefs about Medicines Questionnaire (BMQ) og Medication Adherence Report Scale (DMARS-4) voru notaðir til að meta aðgreini- og samleitniréttmæti.

Niðurstöður: Cronbach's alpha gildið fyrir skalann í heild var 0.96. Ein tilgáta var samþykkt af þremur til að meta hugtakaréttmæti skalans. Neikvæð fylgni á milli heildarskora D-MRQoL og BMQ undirþáttarins *áhyggjur* ($r=-0.455$; $p=0.000$) staðfesti að hluta til tilgátu um samleitniréttmæti, en engin fylgni var á milli heildarskora D-MRQoL og BMQ undirþáttarins *nauðsyn* ($r=-0.029$; $p=0.754$). Jákvæð fylgni var á milli heildarskora D-MRQoL og DMARS-4 ($r=0.338$; $p=0.000$), en það samræmist ekki tilgátu og því virðist sem D-MRQoL tengist meðferðarheldni. Skalinn sýndi tveggja meginþátta byggingu þegar eigið gildi var sett sem 1.0. D-MRQoL skalinn er ekki sambærilegur varðandi þáttabyggingu við upprunalega þriggja þátta skalann frá Taiwan.

Ályktun: Danska útgáfan af skalanum *lyffjatengd lífsgæði* sýndi fram á tveggja meginþátta byggingu með gott yfirborðsréttmæti og háan innri áreiðanleika. Samleitniréttmæti var að nokkru staðfest en frekari rannsókna er þörf á hugtakaréttmæti og réttmæti í ólíkum sjúklingahópi. Skalinn er enn í þróun og gæti hugsanlega nýst sem sjúklingamiðað útkomumælitæki.

ABBREVIATIONS

DRP	Drug-related problem
QoL	Quality of life
HRQoL	Health-related quality of life
MRQoL	Medication-related quality of life
PRO	Patient-reported outcome
SWB	Subjective well-being
D-MRQoL	Danish version of Medication-related quality of life scale
DMARS-4	Danish version of Medication adherence report scale
BMQ	Beliefs about medicines questionnaire
DK1	Initial forward translation from Chinese to Danish
DK2	Initial forward translation from Chinese to Danish
PI-DK	Preliminary initial translated version of the D-MRQoL scale
B-CH	Back-translated version of PI-DK from Danish til Chinese
PF-DK	Pre-final version of the D-MRQoL scale
KMO	Kaiser-Meyer-Okin method
EFA	Exploratory factor analysis
PCA	Principal component analysis

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“We should set the highest value, not on living,
but on living well”
Socrates

1. INTRODUCTION

The use of multiple medicines can be appropriate and beneficial in specific health conditions, but under certain circumstances, it can be associated with medication-related harm (Cadogan et al., 2016; Payne & Avery, 2011). Drug therapy, the most frequently used form of treatment intervention by a clinician, can cause a medication-related problem for the individual patient (Mannheimer et al., 2006). A treatment burden refers to the burden that can be experienced by a patient receiving medical treatment (May et al., 2009; Sav et al., 2013).

Living and coping with polypharmacy, or a chronic disease, can create a burden for patients (Eton et al., 2012; Krska et al., 2013). Patients tolerate medication use differently and their experiences of medicines can be positive, negative or both. On daily basis, a polypharmacy patient can be facing many different challenges, e.g. organizing medicine use, worrying about adverse events and interactions between medicines, medical costs, limitations to daily activities, and much more (Eton et al., 2015; Pound et al., 2005). Medication-related burden plays a significant role in influencing patients' general health, beliefs, and behavior towards medicines (Mohammed et al., 2016).

In all healthcare settings, there is a need to understand patients' individual needs to enhance patient-centered care (Bowling et al., 2012; Shoemaker & Ramalho de Oliveira, 2007). To aim towards medication optimization and more patient-centered approach, it is necessary to incorporate patients' value and preferences to achieve the best outcomes for the patient (NICE Medicines and Prescribing Centre (UK), 2015).

Constant review of health outcomes is of high importance to improve and provide sufficient healthcare (Davy et al., 2015). Clinical health outcomes, such as physical symptoms, adverse events, and death, are easier to measure than 'soft' subjective outcomes (Fried et al., 2014; Smith & Weldring, 2013). Bullinger and colleagues concluded that assessing the quality of life as a patient-reported outcome is a goal towards better care in clinical practice within the field of mental health (Bullinger & Quitmann, 2014).

Pharmacists are among healthcare professionals that can potentially reduce patients' medication burden by initiating appropriate interventions resulting in optimized medication use (Farley et al., 2014; Lenander et al., 2014). Even though clinical pharmacy is gaining acknowledge as an integral part of the interdisciplinary approach to patient care, the field still struggles to be recognized (White, 2014).

Pharmacists interventions have been studied in various settings, e.g. in hospitals and community pharmacies (Holland et al., 2008; Pottegård et al., 2011). But the quality of such systematic reviews has been considered to vary from moderate to poor (Melchior et al., 2012), and most of them evaluate pharmacists' interventions on 'hard' clinical outcomes (Johansson et al., 2016). Studies, that examined pharmacist interventions that aimed to reduce medication-related problems in a population of patients with polypharmacy, stated that there is a lack of evidence to evaluate whether pharmacists' interventions improve 'soft' outcomes that contribute to patient's health-related quality of life (Chumney & Robinson, 2006; Hanlon et al., 1996; Holland et al., 2008). Even though, literature seems to demonstrate that pharmacist's interventions have a positive impact on patient's 'hard' outcomes when focusing on specific medical conditions, e.g. diabetes mellitus (Rotta et al., 2015).

Researchers have developed various instruments, e.g. scales and questionnaires, that comprise of different domains, to evaluate and measure the impact of a treatment or certain disease on patient's quality of life (Katusiime et al., 2016; Mohammed et al., 2016). The quality of life term is multidimensional and covers all aspects of life. Health-related quality of life focuses on what affects patient's health (McHorney, 1999), such 'soft' subjective outcomes can be challenging to measure directly, where perception and personal values vary between individuals (Thomé et al., 2004).

'Generic' and 'disease-specific' measures are mostly used in literature to measure health-related quality of life (Patrick & Deyo, 1989), such as in a population of patients with polypharmacy (EuroQol Group, 1990; Loh et al., 2016). Furthermore, satisfaction measures are also used as an indicator of a quality of life (Atkinson et al., 2004; Atkinson et al., 2005; Bharmal et al., 2009; Sarid et al., 2017). That is because the definition of quality of life has often been evaluated in terms of life satisfaction (Moons et al., 2006). Which measure is used in a specific patient group depends on whether the domains of the measure are relevant, as well as the validity and reliability of the measure (Chen et al., 2005).

In literature, questions have been raised whether 'generic', 'disease-specific' and satisfaction measures are sensitive enough to detect the effect medication use has on patient quality of life (Chen et al., 2005). In current literature, there are many promising medication-related quality of life measures in development that seek to meet this need (Krska et al., 2014; Sakthong et al., 2015). Among measures is the medication-related quality of life measure developed by Tseng et al. in Taiwan (Tseng et al., 2016).

1.1. Polypharmacy

Polypharmacy is defined as the prescribing of multiple medicines. A patient taking five or more medicines is most often classified as polymedicated in the community and outpatient settings (Gnjidic et al., 2012; Lalic et al., 2016). The prevalence of polypharmacy is increasing in clinical practice, particularly among the elderly, or older than 70 years old (Hovstadius et al., 2010). Many factors may contribute to the increase in prevalence, including increasing life expectancy, an enhanced variety of effective drug treatments, and growing prevalence of chronic diseases (Guthrie et al., 2015). The use of multiple medicines can be appropriate and beneficial in specific conditions, e.g. diabetes mellitus, but under certain circumstances, it can be associated with medication-related harm (Cadogan et al., 2016). Hence, balancing the clinical benefits and risks of a treatment is a great prescribing challenge for clinicians (Payne & Avery, 2011).

1.1.1. “Too many” or “many” medicines

Polypharmacy has often been viewed negatively because a polymedicated patient is often seen as taking ‘too many’ drugs with the assumption it signifies inappropriate prescribing (Aronson, 2004). In addition, studies have contributed to that viewpoint by underlining the association between polypharmacy in older people and potentially inappropriate prescribing, as well as with adverse clinical outcomes (Cahir et al., 2010; Maher et al., 2014). However, a systematic review, designed to address the question of health outcomes associated with polypharmacy, indicated mixed results regarding these associations and highlighted the complexity of the relationship between outcomes and polypharmacy. One part of the results suggested that the number of medicines alone may not be an acceptable indicator of the quality of patients’ medication therapy (Fried et al., 2014). But in the literature, there is evidence that when polypharmacy is defined through the use of a numerical threshold it is associated with adverse outcomes (Cherubini et al., 2012). In such a case, the numerical threshold is used as a screening tool for polypharmacy to identify patients with medication safety risks. The validity of such approach is now questioned (Belfrage et al., 2015). Generally, in the literature, the term ‘polypharmacy’ still lacks a universally accepted definition (Cadogan et al., 2016).

1.1.2. Medication-related problems

Drug therapy is the most frequently used form of treatment intervention and can be associated with medication-related problems, or drug-related problems (DRPs) (Mannheimer et al., 2006). DRP is an undesirable event, experienced by a patient and involves patients' drug therapy, that interferes with an optimal outcome (Hepler & Strand, 1990). DRPs may result from medication errors, e.g. inappropriate prescription, wrong route of administration or inappropriate treatment duration, as well as contribute to adverse consequences (Krähenbühl-Melcher et al., 2007; van den Bemt et al., 2000). The risk of DRPs increases with age, as well as a number of diseases and prescribed medications (Simonson & Feinberg, 2005).

Treatment burden is theoretically different from a burden of illness (May et al., 2009). While the treatment burden refers to the burden experienced by a patient receiving medical treatment, the burden of illness represents the impact of chronic illness on a patient. A treatment burden in this context can be associated with the use of multiple medicines, or polypharmacy, as an aspect of medication burden (Sav et al., 2013). Medication burden can affect patients' quality of life, e.g. patient satisfaction, psychological well-being and social functioning (Eton et al., 2013). Study results have indicated that coping with polypharmacy, or a chronic disease, creates a burden for patients (Eton et al., 2012; Krska et al., 2013).

How patients tolerate medications used to treat chronic disease(s) or multimorbidity, varies between individuals, as well as what contributes to the potential perceived treatment burden. Patients' experiences of medicines can be positive, negative or both (Mohammed et al., 2016). Facing challenges, such as organizing medicine use, worrying about adverse events and medication-related risks, interactions, medical costs, changes in drug dosage, the number of medicines and complexity of the drug therapy regarding route and frequency of administration, are only few examples of what may impact on patients' experiences (Eton et al., 2015; Pound et al., 2005). A systematic review and meta-synthesis stated that medication-related burden plays a significant role in influencing patients' well-being and health, beliefs, and behavior towards medicine (Mohammed et al., 2016).

1.1.3. Medication optimization

Medication optimization includes many aspects of enhancing patients' medication use. Of importance, medical interventions should aim to improve the appropriate use of polypharmacy in older people (Avorn, 2010; Cooper et al., 2015). Optimizing polypharmacy among elderly should focus more on the clinical needs of the individual patient instead of

focusing on reducing the number of medicines a patient is taking because the appropriate number differs between individuals (Cadogan et al., 2016; Hughes et al., 2016).

In all healthcare settings, there is a recognized need to understand patients' individual needs to enhance patient-centered care (Bowling et al., 2012; Shoemaker & Ramalho de Oliveira, 2007). When striving towards medication optimization, it is necessary to incorporate patients' values and preferences to achieve the best outcomes for the patient (NICE Medicines and Prescribing Centre (UK), 2015). As mentioned earlier, patients' medication experiences may vary from one person to another, and are affected by a broad range of factors, e.g. drug convenience, the severity of disease(s), effectiveness and overall impact on general well-being and quality of life (Krska et al., 2013).

Pharmacists, including pharmacists in the community pharmacy setting, are among healthcare professionals that can potentially reduce patients' medication burden. By initiating appropriate interventions resulting in optimized medication use, it is possible that clinical and patient-reported outcomes can be improved (Rotta et al., 2015; Zargarzadeh et al., 2011).

1.2. Interventions by pharmacists

Clinical pharmacy is a specialty field of pharmacy. The role of clinical pharmacists is to improve the safety and effectiveness of patient's drug therapy, as well as to prevent drug-related concerns (Hepler, 2004). Pharmaceutical Care of Network Europe (PCNE) redefined 'Pharmaceutical Care' in 2013 as follows: "Pharmaceutical Care is the pharmacist's contribution to the care of individuals in order to optimize medicines use and improve health outcomes" (Allemann et al., 2014). The intention was to unify the current understanding of pharmaceutical care that originally was defined by Hepler and Strand in 1990 (Hepler & Strand, 1990), and then evolved over time causing confusion about what pharmaceutical care includes (van Mil & Fernandez-Llimos, 2013).

Over the last few decades, the clinical pharmacy field has moved away from the traditional tasks of dispensing and other administrative roles, by widening their scope of activity, towards more cognitive clinical aspects with a focus on the patient (Hepler & Strand, 1990; Hepler, 2004). The field has been gaining acknowledge more as an integral part of the interdisciplinary approach to patient care in various healthcare settings, especially in hospitals. Despite that, clinical pharmacy still struggles to be recognized by both the public and other healthcare professions (White, 2014).

1.2.1. Pharmacists in healthcare settings

Pharmacists practice in different healthcare settings, e.g. hospitals, community pharmacies, nursing homes, and managed care organizations. Pharmacists' interventions are both administrative and clinical (Kjeldsen et al., 2014; Pottegård et al., 2011). Various types of pharmacist interventions in different settings have been published in the literature (Farley et al., 2014; Hanlon et al., 1996; Holland et al., 2008). Although, it seems that the quality of the reviews varies from moderate to poor (Melchior et al., 2012), and most evaluate the impact of interventions on 'hard' clinical outcomes (Johansson et al., 2016).

Clinical pharmacists working in hospitals are among healthcare professionals who aim to detect and reduce the number of medication-related problems (Lenander et al., 2014). Most of their interventions are intended to reduce adverse events, evaluate the appropriateness and effectiveness of patient's medications, and help patients to understand and adhere to their medication regimens (Pérez-Moreno et al., 2016).

1.2.2. Effectiveness of pharmacists' interventions

A systematic review and meta-analysis, that aimed to determine the effects of pharmacist-led medication review in older people in a hospital and community care, detected no significant improvement in 'hard' outcomes, such as hospital admission and mortality. The same review also recorded data on drug knowledge, adherence, and adverse drug reactions and claimed that, medication review, may improve drug knowledge and adherence but insufficient data exists to evaluate whether the pharmacist interventions positively impact on patients' quality of life (Holland et al., 2008).

An overview study, that evaluated systematic reviews from 2000-2010, aimed to gather evidence of the impact of clinical pharmacy services on patient outcomes. The result of the study demonstrated, that although clinical pharmacy services seem to improve patients' health, there is a need to prove the effect and value of pharmacy services. Especially needed are studies of pharmacist's interventions targeting broader populations than a specific condition (e.g. hypertension), where 'soft' outcomes are measured, e.g. medication adherence and prescription appropriateness (Rotta et al., 2015).

A systematic review from 2013, that summarized the literature investigating the effect of pharmacist-led medication reviews in hospitalized patients, concluded that health-related quality of life was overall not reported affected by the clinical pharmacist intervention (Graabæk & Kjeldsen, 2013).

Studies, using pharmacist interventions to reduce medication-related problems in a population of patients with polypharmacy, demonstrated that interventions of such pharmaceutical care improved clinical outcomes, but lacked evidence to detect whether the interventions improved health-related quality of life (Chumney & Robinson, 2006; Hanlon et al., 1996). The results of these studies highlight the need in current literature to adopt a reliable approach to detect the effect pharmacist's interventions have on 'soft' outcomes that impact patients' health-related quality of life.

1.3. Health outcomes

The World Health Organization's (WHO's) definition of outcomes is "the effect the process has had on the people targeted by it. These might include, for example, changes in their self-perceived health status or changes in the distribution of health determinants, or factors which are known to affect their health, well-being, and quality of life" (World Health Organization, 2016). The result of what the patient receives from a healthcare intervention is what the term "health outcomes" focuses on, but not on what is done. Constant monitoring of health outcomes is of high importance to improve and provide sufficient healthcare (Davy et al., 2015). How health outcomes are measured varies according to the nature of the outcomes. Different scales, measures and instruments are used to assess the broad range of health outcomes (Leggett et al., 2016).

1.3.1. Clinical health outcomes

To assess the effects of medical interventions, clinicians must evaluate the potential risks that are evident and often associated with medication use. As well as, consider when the treatment is appropriate and cures and relieves symptoms of a disease in a way it is beneficial for the patient (Bradley et al., 2012; Parsons, 2017). These potential risks can be 'hard' clinical outcomes resulting from drug/drug interactions, adverse effects, and drug/disease interactions (Bushardt et al., 2008).

Clinical health outcomes can be measured in 'hard' clinical outcomes, such as physical symptoms, hospital re-admission rate, adverse events, and death. When clinician evaluates appropriate prescribing for a patient, several important factors need to be taken into consideration: what the patient wants and needs, along with scientific rationalism (Spinewine et al., 2007). Clinical outcomes that are reported by patients are considered 'soft' and are more difficult to measure directly (Fried et al., 2014; Smith & Weldring, 2013).

1.3.2. Patient-reported outcomes

In recent years there has been increasing focus on patient-centered care as a possible approach to advance healthcare (Dwamena et al., 2012). The consequences of disease or medical treatment on patient functional status or quality of life are gaining more attention as an important element to improve the quality of healthcare (Snyder et al., 2013). Patient-centered care is achieved through a relationship between patients and healthcare professionals. The clinician evaluates patient-reported outcomes and aims for the more patient-centered approach (Shoemaker & Ramalho de Oliveira, 2007). This collaboration aims to make decisions focused on meeting patients' individual needs (The American Geriatrics Society Expert Panel on Person-Centered Care, 2016).

Patient-reported outcomes (PROs) are derived from the patient's experience and perception of e.g. medication use, without any interpretation of the response by a clinician (Doward & McKenna, 2004; Lohr & Zebrack, 2009). In the literature, there is evidence that patient perception of quality of life can be different from healthcare professionals (Ferrans et al., 2005). The patient-reported outcomes are therefore used to understand the patient's needs and perception of a treatment or disease (Smith & Weldring, 2013). Assessing quality of life (QoL) as a patient-reported outcome can lead the way towards better care in clinical practice (Bullinger & Quitmann, 2014).

Different instruments can be used to evaluate relevant 'soft' outcomes. Before deciding which instrument is most suitable for assessing patient-reported outcomes, it is necessary to know what the construct of the instrument covers, and for what it is intended to measure (Eton et al., 2013). Measures that are mostly used in current literature to assess patient experiences concern patient satisfaction with treatment, medication adherence, subjective well-being and health-related quality of life (Doward & McKenna, 2004).

1.3.2.1. Patient Satisfaction

The term 'patient satisfaction' is subjective. In the literature, patient satisfaction is often used to measure quality and efficiency of healthcare or treatment, and is based on patient-reported outcomes and patient experiences (Hudak & Wright, 2000; Mohammed et al., 2016; Prakash, 2010). Therefore, measures of satisfaction are widely used in the literature to assess patient experiences, and to what extent a patient is satisfied (Katusiime et al., 2016). Instruments have been developed to measure satisfaction with medicines. But such measures have been criticized for only measuring selected aspects of medication use (Sakthong et al., 2015).

1.3.2.2. Medication adherence

Medication adherence is of clinical importance in assuring safe and effective medicine use and refers to whether patients take medications as prescribed, as well as if they continue to take a prescribed medication (Vrijens et al., 2012). The consequences of nonadherence include poor clinical outcomes that can be quite severe, contributing to the substantial worsening of the disease. Results from a systematic review stated that inadequate medication adherence increases the risk of patient morbidity, mortality, and hospitalization, resulting in increased healthcare costs (Conn, Ruppar, Enriquez, & Cooper, 2016).

The literature demonstrates that many patients with chronic illnesses do not adhere to prescribed medication regimen, or about 50% of patients (Brown & Bussell, 2011). For instance, older polypharmacy patients have low medication adherence (Pasina et al., 2014).

The responsibility for medication adherence not only relies on patients. The relationship between a patient and a healthcare professional is very important (Nordin Olsson et al., 2011), especially because the relationship can influence patients' perception of medicines (Krska et al., 2013).

1.3.2.3. Subjective well-being and health-related quality of life

Subjective well-being (SWB) is a multidimensional construct, and there is no consensus on a single definition of well-being found in the literature (Jorm & Ryan, 2014; Lucas et al., 1996). There is an agreement that well-being involves a wide range of aspects of how people perceive their life, and their overall cognitive awareness about life (Diener et al., 2008; Diener et al., 2002). Most often, SWB is measured by two components: life satisfaction and experiences of daily affect (Dolan & Metcalfe, 2012).

Health-related quality of life (HRQoL) will be discussed in more details in chapter 1.4.1. But of interest, several studies have investigated the mutual and/or distinct concepts of SWB and HRQoL (Magallares et al., 2014; Tessier et al., 2017). Studies show that SWB is associated with aspects of mental health, e.g. anxiety and depression, but to a lesser extent with physical health, e.g. pain (Oberjé et al., 2015). In conclusion, it seems that physical health contributes less to subjective well-being in comparison with HRQoL (de Haan et al., 2002).

A study among older Americans, that used component scores from a generic HRQoL measure (the 36-item Short Form Health Survey (SF-36)), suggested that only the physical, but not the mental component summary, was associated with the degree of polypharmacy

(Meraya et al., 2016). Many subjective outcome measures are based on HRQoL, but not on SWB. Such measures can partially evaluate well-being dimensions, but seem to lack the ability to detect the broader effect of disease or treatment on patient's subjective well-being, which seems to be a more contributing factor to mental health (Cubí-Mollá et al., 2014).

1.4. Patients' quality of life

The World Health Organization (WHO) defines the term 'quality of life' (QoL) as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" ('The World Health Organization Quality of Life assessment (WHOQOL)', 1995). Over the past decades, the concept of quality of life (QoL) has been gaining more interest, both in research and clinical practice, and is widespread in literature ('23rd Annual Conference of the International Society for Quality of Life Research', 2016).

The term 'quality of life' has been of importance in evaluating the quality and outcomes of healthcare (Bowling et al., 2013; Hartgerink et al., 2015). Although the concept is complex and incorporates various theoretical approaches and assessment methods, it is most appropriately defined in terms of life satisfaction and overall sense of well-being (Kimura & Silva, 2009; Moons et al., 2006). The quality of life concept is multidimensional and related to various factors that encompass all aspects of life. Those factors or domains include, e.g. emotional and social status, self-care, family support, health status, living environment, cultural and ethical values, religiosity, lifestyle, functional capacity, satisfaction with job and daily activities, perception of life events, general happiness and behavior and many more (Ann Bowling et al., 2003; Lai et al., 2015; Naylor et al., 2016; Sousa et al., 2003).

Health is one of the most important aspects of overall quality of life. Since the 1980s, the concept of health-related quality of life (HRQoL) has evolved to cover physical and/or mental perceptions that can affect health (McHorney, 1999).

1.4.1. Health-related quality of life (HRQoL)

Health-related quality of life (HRQoL) was initially introduced to narrow the focus to what affects patients' health. USA's Centers for Disease Control and Prevention (CDC) defined HRQoL as "an individual's or group's perceived physical and mental health over time" (Centers for Disease Control and Prevention, 2000). Patient-reported health outcomes include

subjective evaluations of both negative and positive aspects of life. These outcomes are challenging to measure directly because perceptions and personal values vary between individuals (Thomé et al., 2004). Therefore, researchers have developed various scales and questionnaires, or generic health-related quality of life measures, that cover different domains, to evaluate and measure the impact of treatment or diseases on patients' quality of life (Alrubaiy et al., 2015; Hickey et al., 2005). Such HRQoL measures are considered compelling indicators of unmet needs and intervention effects (Prazeres & Santiago, 2016). The measures are also used to understand and monitor patients' perception of a disease, overall health or potential medication-related burden (Katusiime et al., 2016; Mohammed et al., 2016).

1.4.2. Domains of HRQoL measures

HRQoL is most often multidimensional, although there is no formal consensus on the domains that should be included. Researchers have suggested different structural models that indicate the elements of HRQoL. The domains often include physical, social, psychological, and spiritual factors (Bakas et al., 2012; Haas, 1999). Furthermore, these broad domains can subsume dimensions that are more specific, e.g. cognitive function, economic status and emotions (Mandzuk & McMillan, 2005).

Mostly two types of HRQoL measures are used to measure individual experiences concerning health-related quality of life, a 'generic' and 'disease-specific' measure. The generic measures are intended to measure broad aspects of HRQoL across different patient groups. Conversely, the disease-specific measures focus on patients within a particular disease group and are used to compare different treatments for a specific condition (Patrick & Deyo, 1989). It is difficult to measure health-related quality of life directly. Therefore, a researcher should acknowledge that measures will never capture all parts of an individuals' life. However, the measures provide an assessment of patients' perception of a problem within the specific domain (Higginson & Carr, 2001).

1.4.3. HRQoL and satisfaction measures used in current literature

HRQoL measures are widespread in current literature and have been applied in various fields of clinical practice (Beijers et al., 2016; Bossola et al., 2010). Which measure is used in a particular setting depends on, for instance, whether the domains covered are relevant, the measure is valid, reliable and responsive, or if it will measure a difference between patients (Chen et al., 2005).

Although, a wide variety of HRQoL measures exists in literature (Alrubaiy et al., 2015; Coombes et al., 2016; Gerth et al., 2015), there has been an ongoing development of various disease-specific HRQoL measures that aim to understand patients' perceptions of a specific disease or treatment (Luquiens et al., 2015; Seneviwickrama et al., 2016).

The EuroQoL-5D (EuroQoL) is the most widely used 'generic' or 'non-disease-specific' instrument to measure HRQoL in this area of literature (Balestroni & Bertolotti, 2012). EuroQoL is a self-administered, 5-item measure that contains five different domains: anxiety/depression, self-care, usual activities, mobility and pain/discomfort (EuroQol Group, 1990). Even though it can be an appropriate indicator for a general evaluation of patient quality of life, it may lack the ability to detect the effect of medication use on the patient's health-related quality of life (Devlin & Brooks, 2017; Patterson et al., 2012).

The appropriate definition of 'quality of life' (QoL) has often been evaluated as in terms of life satisfaction (Moons et al., 2006). Therefore, use of satisfaction measures as an indicator of HRQoL is seen widely in the literature, e.g. the new Satisfaction With Life Scale (SWLF) (Sarid et al., 2017), as well as treatment satisfaction measures. There are two existing measures that are validated and measure treatment satisfaction. First, is the Treatment Satisfaction Questionnaire for Medication (TSQM) with 14 items that include four domains: side effects, the effectiveness of the medication, convenience of use and global satisfaction (Atkinson et al., 2004). TSQM has been developed as TSQM-9 and TSQM II questionnaire covering 4 and 3 domains respectively (Atkinson et al., 2005; Bharmal et al., 2009). Second, is the Treatment Satisfaction with Medicines Questionnaire (SATMED-Q) with 17 items that include six domains: treatment effectiveness, the convenience of use, impact on daily living activities, medical care, undesirable side effects and global satisfaction (Ruiz et al., 2008).

1.4.4. HRQoL measures used for polypharmacy patients

In a population of patients with polypharmacy, generic health-related quality of life measures are most often used to assess patient-reported outcomes (Ware & Gandek, 1998). Such measures, e.g. SF-36 and previously mentioned EuroQoL (Loh et al., 2016), or disease-specific instruments (Lukacs et al., 2014) are vital to assess impacts of patients' disease. But questions have been raised whether these measures are sensitive enough towards the effect medication use has on patient quality of life (Patterson et al., 2012).

A recent Spanish study, that aimed to describe medication-related factors associated with HRQoL in a population of patients with polypharmacy, used the EuroQoL-5D

instrument as a measure. The investigators concluded that the limiting factor of high quality of life for the polypharmacy patient group were factors that are found deep-rooted in patients, such as functional incapacity, cognitive impairment, and social and emotional problems (Montiel-Luque et al., 2017).

Regarding polypharmacy interventions, a Cochrane systematic review analyzed interventions aimed to improve the appropriate use of medicines in polypharmacy patients, and concluded that evidence was conflicting concerning the effect interventions have on medication-related problems. The same review argued that many studies did not assess outcomes, such as quality of life, and stated that it remains unclear if interventions resulted in improvements in patients' overall quality of life (Cooper et al., 2015).

1.4.5. Ongoing and future developments of medication-related measures

Measurement of medication-related quality of life for the individual patient is currently a hot topic (Mohammed et al., 2016; Montiel-Luque et al., 2017; Simonson & Feinberg, 2005). A systematic review, that included fifteen questionnaires covering various domains of medication use, demonstrated a need for further development and validation of existing patient-derived, multi-domain instruments. The review claimed that such tools may help patients to identify medication-related issues that affect their day-to-day life (Katusiime et al., 2016). Two instruments mentioned in the review, LMQ and PROMPT-QoL measures, are especially relevant to the topic of this thesis.

Krska and colleagues have been exploring the difficulties that arise involving long-term medication use and the impact of such use on day-to-day life for patients (Krska et al., 2013). The instrument, the Living with Medicines Questionnaire (LMQ), is in development. It was designed to reflect patients' perspectives living with long-term medication use. Currently, there is further development ongoing in Australia, Ireland, and Netherlands, as well as England. Results are expected from psychometric testing of the measure in near future (Krska et al., 2014).

Sakthong and colleagues recently published a new HRQoL measure, the Patient-reported Outcomes Measure of Pharmaceutical Therapy for Quality of Life (PROMPT-QoL), to detect the effect of medicines on patients' health-related quality of life. Authors envisage that the questionnaire could be of help to solve medication-related problems from a patient's perspective. As for the LMQ measure, a psychometric testing of the PROMPT-QoL measure will be carried out in near future (Sakthong et al., 2015).

1.5. Medication-Related Quality of Life (MRQoL) scale developed in Taiwan

In November 2015, Tseng and colleagues in Taiwan published a new medication-related quality of life measure for a population of patients with polypharmacy (Tseng et al., 2016). The aim was to meet the need to measure the effect of medication use on patients' quality of life. The instrument, MRQoLS-v1.0, was developed by focusing on the subjective well-being (SWB) of patients with polypharmacy. Tseng et al. proposed to conceptualize SWB according to de Haan et al. (de Haan et al., 2002). In the de Haan et al. study, the aim was to gain knowledge of how to assess subjective experiences of patients with mental disorders. The results indicated that the instrument, Subjective Well-Being Under Neuroleptics (SWN), was sensitive to changes in medication.

Tseng et al. study findings demonstrate that the MRQoLS-v1.0 measure is a reliable, appropriate, and valid tool to evaluate the medication-related quality of life of patients with polypharmacy. Figures 1 and 2 demonstrate the development and testing of the MRQoL scale in Taiwan, respectively (Tseng et al., 2016).

The development and testing of the MRQoL measure, conducted by Tseng and colleagues, is a valuable contribution to the current literature that seeks for an instrument to evaluate medication-related issues that can impact patients' quality of life. As well as, the possibility that the measure can detect the effect of interventions on HRQoL. The MRQoL measure only exists in Chinese. The applicability of the scale in different setting, culture, and language, needs further validation.

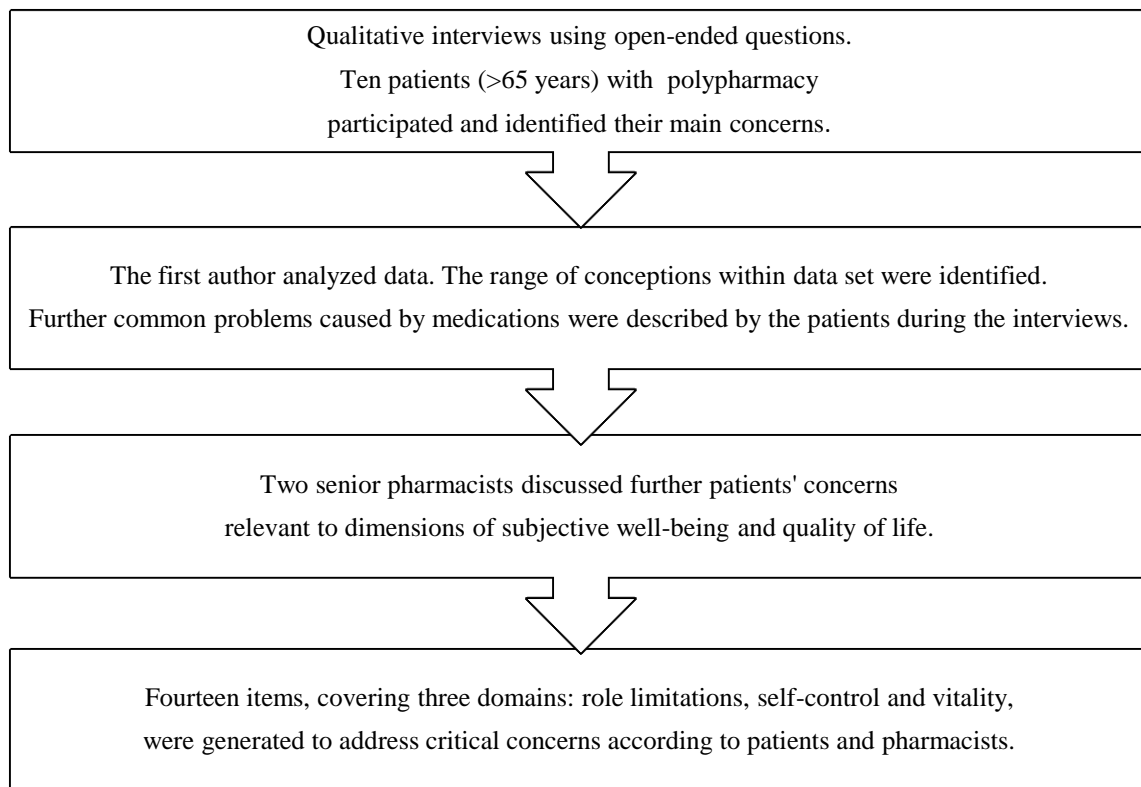


Figure 1: Development of the MRQoL measure conducted by Tseng et al. The 14-item MRQoL scale was generated from qualitative interviews with ten polypharmacy patients.

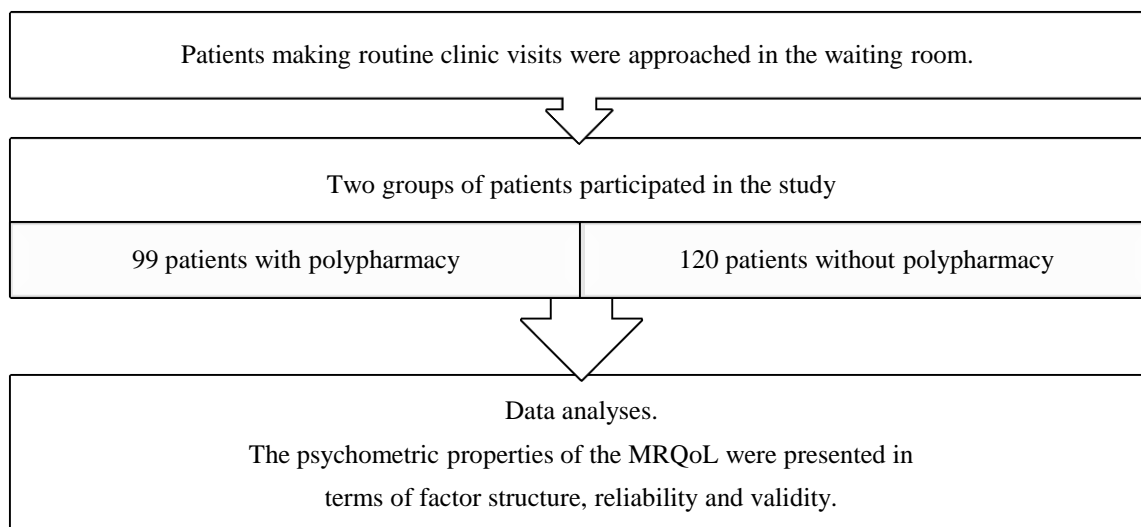


Figure 2: Psychometric testing of the MRQoL scale conducted by Tseng et al.

1.6. Scale as a research instrument

‘Questionnaire’ is the generic term for a measurement instrument, used in health and psychosocial studies, to obtain knowledge or information from a sample of individuals. Measurement instruments that comprise of multiple items answered on a defined rating scale, and are referred to as *scales*, are intended to reveal latent variables. Scales are developed when there is a need to measure phenomena, or a latent variable, that is difficult to measure directly, but is believed to exist because of a theoretical understanding of the world (DeVellis, 1991). Each scale has a factor structure or domains that suggest what the scale is intended to measure (Huijg et al., 2014) (Figure 3). Therefore, researchers are often more interested in the construct of a scale. The underlying construct that a scale is intended to reveal and measure, is called the latent variable. The latent variable is the cause of the item score and is evaluated by the strength of the true score. It is possible to examine the relationship between items that are caused by the same latent variable (DeVellis, 1991). Patient-reported outcomes are most often collected by using standardized scales, e.g. generic health-related quality of life measures and treatment satisfaction measures (Sullivan, 2003).

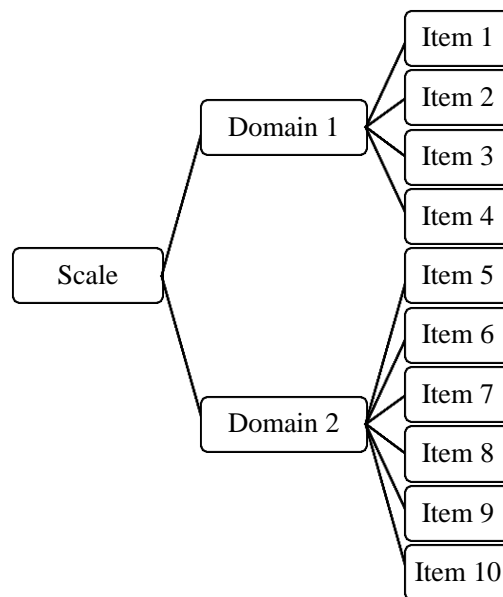


Figure 3: A fictitious example of a 10-item scale with factor structure composed of two domains. This diagram indicates that the latent variables, domains 1 and 2, influence mostly items number 1-4 and 5-10, respectively. This scale is designed to measure these two domains. Respondent answers each item on a Likert-scale with defined ranking, most often from 1 (Strongly agree) to 5 (Strongly disagree). An item can be a question or a statement written in a positive or negative wording. The sum of all individual's scores can reflect his or her perception towards the overall scale, or each domain.

1.6.1. Instrumentation

While an instrument is a device that is used to measure a construct, instrumentation is the process of developing, testing and using the device. The process of developing involves careful research of the background of the phenomenon of interest, where research questions and hypotheses are examined, and concepts well-defined. Furthermore, the population of patients is determined (Engelhart, 1970). At last, the instrument, e.g. scale, goes into psychometric testing (Bolarinwa, 2015).

1.6.2. Reliability and validity of a scale

Establishing reliability and validity of a scale is of high importance in developing the research instrument (Kimberlin & Winterstein, 2008). Reliability evaluates to what extent a scale produces consistent results. Validity focuses more on how well the scale measures what it is supposed to measure. Evaluation of these two cornerstones, reliability and validity, is achieved by testing and examining the psychometric properties of the scale (Bolarinwa, 2015; Mayo, 2015).

1.6.3. Translation of a scale

Measures that establish good reliability and validity are often translated into other languages. For instance, the Beliefs about Medicines Questionnaire (BMQ) has been translated into several languages, e.g. Portuguese (Salgado et al., 2013), Turkish (Cinar et al., 2016), Japanese (Iihara et al., 2008), Swedish (Jørgensen et al., 2006), and more. The challenge for instrument translation is to achieve cross-cultural equivalence despite of linguistic and cultural differences. It is of high importance to maintain the meaning of words and phrases as written in original version of the instrument (Villagran & Lucke, 2005).

Since the diversity is increasing in populations worldwide, a cross-culturally validated measure is necessary for researchers to compare different ethnic groups, as well as to increase the validity of a measure. Hence, it is desirable that a measure is validated among diverse cultural segments, and in other languages (Beaton et al., 2000; Guillemin et al., 1993).

Many guidelines are found in the literature that aim for good translation and cultural adaption processes (Sousa & Rojjanasrirat, 2011; Wild et al., 2005). The validity of a translated instrument can be questioned in a new context and a different setting. Lack of equivalence between the original and a translated version of a questionnaire can be a limitation to comparability of responses. It is preferable that a translated instrument undergoes a psychometric testing for reliability and validity (Beaton et al., 2000; Guillemin et al., 1993).

1.7. Danish version of the Medication-Related Quality of Life scale

Various articles have been published focusing on Danish community pharmacies and pharmaceutical care (Mogensen et al., 2012; Rossing et al., 2005). A study, conducted by Pottegård and colleagues, aimed to estimate the extent and type of pharmacists' interventions in a Danish pharmacy setting. The study reported that a rate of 10.2 interventions were conducted per 1000 prescriptions. The authors highlighted the need for further investigation to what extent these interventions hold clinical significance (Pottegård et al., 2011).

In Denmark, the community pharmacies are becoming more as an active part of healthcare, e.g. by providing remunerated pharmacist interventions for patients recently diagnosed with a chronic disease. This involves continuity of pharmaceutical care after hospital discharge, and a close relationship between hospital pharmacists and community pharmacists (Apotekerforeningen, 2016). To evaluate such care there is a need for a validated and reliable measure in Danish to detect the effect pharmacists' interventions have on patients' medication-related problems, as well as the effect medication use has on patients' quality of life. Currently, no such measure exists in Danish.

1.8. Summary

A patient-centered approach to optimize medication use is of high importance, and applies to various healthcare professionals, including pharmacists. Patients' perception of medication use varies between individuals, and these 'soft' patient-reported outcomes are difficult to measure. Currently, promising measures are in development that seek to detect the effect of medication use on patients' quality of life. Such measures, e.g. scales, need further validation including psychometric testing in different languages and populations of patients, e.g. polypharmacy patients. Psychometric testing is performed by testing a translated version in terms of factor structure, reliability and validity. In addition to use such measures to evaluate and understand patients' perception of medication use, it is envisaged that such measures can possibly detect the effect pharmacists' intervention have on patients' quality of life.

2. AIMS

The main aim of this study was to translate the original version of Medication-Related Quality of Life (MRQoL) scale from Chinese to Danish, and validate the psychometric properties of the Danish version in a population of patients with polypharmacy.

Research questions:

2.1. Psychometric properties of the D-MRQoL scale

What are the psychometric properties of the Danish version of Medication-Related Quality of Life scale in terms of factor structure, internal consistency reliability and construct validity?

2.2. Comparison of the translated version to the original version of MRQoL

Is the Danish version of Medication-Related Quality of Life scale comparable to the original version from Taiwan?

3. MATERIALS AND METHODS

3.1. Setting and study period

The study was conducted in Denmark from January to April 2017 in two steps. First, a translation phase took place that involved translation and transcultural adaption of the original Medication-Related Quality of Life scale (MRQoL) from Chinese to Danish. Second, a quantitative validation of the D-MRQoL was performed by psychometric testing the scale in terms of factor structure, internal consistency reliability and construct validity in a population of patients with polypharmacy. Table 1 presents the research locations for the testing of the scale.

Table 1: Research locations

Setting		
Pharmacy		Location in Denmark
1	Kastrup Apotek*	Copenhagen
2	Steno Apotek	Copenhagen
3	Østerbro Apotek	Copenhagen
4	København Sønderbro Apotek	Copenhagen
5	Slagelse Svane Apotek	Slagelse
Patient organisations		
6	Sundhedshus Amager – Københavns Kommune	Copenhagen
7	FAKS – Foreningen Af Kroniske Smertepatienter	Jutland
Hospitals		
8	Hvidovre Hospital (Emergency Department)	Copenhagen

*Data collected in the Pilot-Test

3.2. Danish translation of the Medication-Related Quality of Life scale

The translation of the medication-related quality of life scale (MRQoL) from Chinese to Danish was performed following a translation protocol proposed by Sousa and Rojjanasrirat (Sousa & Rojjanasrirat, 2011). A committee of three researchers was formed, consisting of the MSc Pharmacy student, a Professor, and a Ph.D. Pharmacy student. The committee was responsible for overall review and evaluation of the translation phase, as well as modifying the protocol described by Sousa and Rojjanasrirat, and for all final decisions on the wording of the D-MRQoL scale.

3.2.1. Process of translation and adaption

The original protocol (Sousa & Rojjanasrirat, 2011), was modified by the committee.

The revised translation protocol was performed in 6 steps, and no step needed to be repeated:

(1) Two forward translations from Chinese to Danish

Two professional bilingual and bicultural translators, one from oversætterne.dk and another from Tolkene.dk, were hired to get two initial translations from Chinese to Danish.

(2) Comparison of the two translated versions, DK1 and DK2

In addition to the committee, a native Danish speaker within the field of clinical pharmacy and an Associate Professor in the subject of Danish made a comparison of the translations, DK1 and DK2, and the English translation provided by the authors of the original measure (Appendix D). Ambiguities and discrepancies in terms of words, sentences and meanings were discussed and resolved, to generate the preliminary initial translated version of the measure, PI-DK.

(3) Blind back-translation of the preliminary initial version, PI-DK

One professional translator was hired to translate PI-DK from Danish to Chinese, resulting in a back-translated version, B-CH. The original translation protocol suggested using two translators, but in Denmark there is only one professional translator with adequate experience in translating from Danish to Chinese. The translator has Chinese (mainland Mandarin) as a first language and is bicultural.

(4) Comparison of the back-translated version, B-CH, with the original version

A native Chinese speaker (mainland Mandarin), gave an oral report on how the back-translated version, B-CH, aligned with the original Chinese version from Taiwan. In addition to the committee, a Danish Ph.D. student and a health-care professional, revised PI-DK by evaluating and comparing it to the report from the native Chinese speaker. Any discrepancies regarding cultural meaning and idioms in words and sentences of the instructions, items and/or response format were discussed for the PI-DK. Finally, the committee and the Danish Ph.D. student resolved ambiguities in the PI-DK to reach consensus on a version to be piloted in a pilot-test. The pre-final version is called PF-DK.

(5) Pilot testing of PF-DK in a monolingual sample: cognitive debriefing

The aim of the pilot-test was to evaluate if the questionnaire is understandable, and clear, among patients with polypharmacy. Eight participants that used five or more medicines, and were not healthcare professionals or researchers, evaluated the PF-DK in terms of clarity of the instructions, items and response formats. They were asked for their participation while waiting at Kastrup Apotek, a pharmacy in Copenhagen. After completing the 14-item PF-DK questionnaire, each participant answered a dichotomous scale (Appendix G). Everyone answered “yes” instead of “no”, when asked if the instructions, items, and response formats seemed clear to the respondent. The committee evaluated and decided that the results from these eight participants were adequate, and that the pre-final version, PF-DK, is the final version of the translated Danish version. The medication-related quality of life scale in Danish is called D-MRQoL.

(6) Psychometric testing of the final version, D-MRQoL

The translation phase was the first step of this study. The second step involves psychometric testing and validation of the final version, D-MRQoL.

The translation committee skipped one step after revision of the original translation protocol by Sousa and Rojjanasirrat. The step concerns the preliminary psychometric testing of the PF-DK in a bilingual sample. It should have been between steps 5 and 6. It was not realistic to get such a bilingual sample in Denmark. Instead, the committee decided to go directly into full psychometric testing of the final version (D-MRQoL), or step 6.

3.3. The study population

The D-MRQoL scale was tested in a population of patients with polypharmacy. Because ‘polypharmacy’ still lacks a universal definition, it was decided that the inclusion criteria for a polypharmacy patient should be the same as when the original version was validated in Taiwan. Therefore, all participants included in the study take five or more medicines daily, and speak Danish fluently.

Patients, waiting for services at the community pharmacies or hospitals listed in Table 1, and met criteria, were asked to answer a questionnaire concerning medication use and quality of life. The participation was voluntary, and no personal identity information was recorded. Therefore, all the data collection was completely anonymous. The anonymity was outlined on the cover page of the questionnaire.

3.4. Permission for the study

No specific permission was required for the study to take place. The reason is that the participation is without any recording of personal identity numbers, and therefore the respondents cannot be identified. This is according to answers received from the Danish Data Protection Agency, and the administration of Research and innovation at the Faculty of Health and Medical Sciences, University of Copenhagen.

3.5. Measures

The participants in the study answered a self-administered questionnaire in Danish (Appendix A). In total, the questionnaire comprised of 32 items, where 28 items consisted of three scales: D-MRQoL, DMARS-4 and BMQ-Specific. Responses to items were on a Likert scale, ranging from ‘Strongly disagree’ to ‘Strongly agree’ responses. The last four items were demographic questions concerning gender, age, highest education completed, and number of medicines taken on daily basis.

3.5.1. Medication-Related Quality of Life scale (MRQoL)

MRQoL is a 14-item questionnaire answered on a 6-point Likert scale with responses ranging from “Aldrig” (e. Never) to “Altid” (e. Always). The measure was developed in Taiwan in 2015 (Tseng et al., 2016). Permission was received from the authors in Taiwan to translate MRQoL into Danish and validate the scale (Appendix B).

3.5.2. Medication Adherence Report Scale (MARS-4)

The Medication Adherence Report Scale (MARS-4) was originally developed by Horne and colleagues, and has been used widely to measure patient adherence (Cohen et al., 2009; Horne & Weinman, 2002; Mora et al., 2011; Salt et al., 2012). The MARS-4 was translated into Danish, and validated by Jacobsen and colleagues in 2009 (Jacobsen et al., 2009). The Danish version of MARS-4 (DMARS-4) is a 4-item instrument that comprises of one factor, and is answered on a 5-point Likert scale ranging from 1, “Meget ofte” (e. Very often), to 5, “Aldrig” (e. Never). For this study, the participants are polypharmacy patients taking different medicines. Therefore, each item was slightly modified in Danish to “medicin” (e. medicine) instead of specific medicines, e.g. cardiac-and blood pressure medicines (Appendix A).

3.5.3. Beliefs about Medicines Questionnaire (BMQ)

The Beliefs about Medicines Questionnaire was initially developed by Horne (Horne et al., 1999). The instrument assesses cognitive representation of patient medication, and is divided in two sections. First, the BMQ-Specific comprises of two 5-item factors concerning beliefs about the *necessity* and *concerns* of prescribed medication. Second, the BMQ-General comprises of two 4-item factors concerning general beliefs about medicines. The BMQ has been translated and validated in many different languages, amongst them in Danish (Anderson et al., 2009). In this study, only the BMQ-Specific scale was used. The scale includes 10-items with 5-point Likert responses. Scores range from 1, “Meget enig” (e. Strongly agree), to 5, “Meget uenig” (e. Strongly disagree). The BMQ-Specific scale divides into two factors, *necessity* and *concerns*. Items number 1, 3, 5, 7, and 10 apply to the *necessity* factor, where 2, 4, 6, 8, and 9 to the *concerns* factor (Appendix A).

As for the DMARS-4 questionnaire, it was decided to slightly modify the items for the study population of polypharmacy patients. The intention was to relate the statements about their medicines in general, instead of specific kind of ‘medicine X’. According to Granas and colleagues, that compared three Scandinavian translations of Beliefs about Medicines Questionnaire (Granas et al. 2014), the Danish translation of BMQ is more specific towards a ‘medicine X’ than the translated versions in Norwegian and Swedish. That is, the original English version and the two other Scandinavian versions are more in general, meaning that the statements are less related to a specific ‘medicine X’. On these grounds, it was decided to slightly modify the items for this study. The polypharmacy patients score the statements of BMQ-Specific related to their ‘medicines’ (Appendix A).

3.6. Data Collection

Data collection for the psychometric testing of the D-MRQoL scale started on the 27th of February, and lasted for six weeks. In addition to the main researcher, three pharmacy students at the University of Copenhagen participated in the data collection during their internship at community and hospital pharmacies.

Each data collector was informed about the importance of anonymity and criteria of the study participants. It was emphasized that no rephrasing of items, or response formats by a data collector was allowed, that this is a self-administered questionnaire answered by the study participant. If a participant had some vision problems, e.g. an elderly patient, a data collector could read the instructions and items out loud for the participant.

3.7. Data analysis

Data analysis was performed using version 23 of the Statistical Package for the Social Sciences (SPSS). Missing values for items of the D-MRQoL scale were replaced by filling in the mean score of participants' responses for the item. Before conducting statistical analysis of psychometric properties of the D-MRQoL scale, total response scores for the D-MRQoL scale were reversed, as well as scores of the BMQ-Specific, *necessity* and *concerns*. Scores were not reversed for the scales when describing the data using descriptive statistics. Therefore, as the scales appear in Appendix A, higher scores of the D-MRQoL indicate lower medication-related quality of life. For BMQ-Specific, higher scores reflect patient's beliefs about medicine to be less *necessary*, and having less *concerns* about medicines. The DMARS-4 scale scores were never reversed, neither for descriptive or psychometric statistical analysis, for DMARS-4, higher scores reflect better medication adherence.

3.7.1. Descriptive statistics

Descriptive statistics was used to provide information about the study population, and to reveal participants' distribution of total scores for the D-MRQoL scale. Furthermore, participants answered four demographic questions with categorized responses. The questions concerned gender, age, highest education completed, and number of medicines taken on daily basis.

3.7.2. Sample size assessment

The Bartlett's sphericity test and the Kaiser-Meyer-Okin (KMO) method were used to determine whether the sample size was adequate to reliably extract factors of the D-MRQoL scale with factor analysis.

The KMO statistics varies between 0 and 1, where values between 0.5 and 0.7 are considered mediocre, values between 0.7 and 0.8 are good, values between 0.8 and 0.9 are great, and values above 0.9 are superb (Hutcheson & Sofroniou, 1999).

Before factor analysis can be conducted, there needs to exist a variance in the data set. Barlett's test of sphericity was used for testing of homogeneity, p-values below 0.05 ($p < 0.05$) confirm that factor analysis can be performed efficiently on the dataset. Where it is interpreted that if $X_0^2 < 9.488$, there is not a significant difference between variables, then a larger sample size is needed. However, if $X_0^2 > 9.488$, there is statistically significant value for Barlett's test of sphericity (Snedecor & Cochran, 1980).

3.7.3. Factor analysis

The purpose of factor analysis is to reduce a large set of data, to a smaller set, and determine the latent structure of variables for a further interpretation. The variables in this study are the items of the D-MRQoL scale. Exploratory factor analysis (EFA), using Principal component analysis (PCA), was performed to examine the factor structure of the D-MRQoL scale. Using Kaiser's criterion, as for the validation of the original version, factors with eigenvalues higher than 1 were extracted and rotated by using the varimax method.

3.7.4. Reliability and validity of the D-MRQoL scale

Internal consistency reliability of the D-MRQoL scale was analyzed using Cronbach's alpha coefficient. Reliability coefficient of 0.70 or higher is considered acceptable, and with good internal consistency (Bland & Altman, 1997; Streiner, 2003).

Face validity of the D-MRQoL scale was evaluated based on judgements from experts and the participants in the study. For the evaluation of whether the scale is measuring what it is believed to be measuring, construct validity of the D-MRQoL was evaluated as both convergent and discriminant validity using Spearman's Rho correlation coefficient. Two measures were selected to use in the validation, The Medication Adherence Report Scale (DMARS-4) and the Beliefs about Medicines Questionnaire (BMQ-Specific), both measures

are validated and available in Danish. The total scores from the DMARS-4 and BMQ-Specific measures were used to validate against the D-MRQoL measure by evaluating if correlations exist between measures. Before going into psychometric testing of the D-MRQoL scale, hypotheses were predicted about the type of correlation between measures.

For convergent validity, it was hypothesized that total scores for the D-MRQoL scale would correlate negatively with total scores from the subscale *concerns* of the BMQ-Specific measure, but correlate positively with total scores from the *necessity* subscale.

For discriminant validity, it was hypothesized that the D-MRQoL scale would not correlate with the total scores of the DMARS-4 scale.

4. RESULTS

In this chapter, the final translated version of D-MRQoL scale is presented, following clarifications about decisions taken during the translation phase. Demographics of the study population are revealed as well as participants' total scale scores for the DMRQoL. Results from psychometric testing of the scale in a population of patients with polypharmacy are demonstrated in terms of factor structure, internal consistency reliability, and construct validity. Furthermore, the findings are compared to psychometric properties of the original version of MRQoL from Taiwan.

4.1. Final version of the D-MRQoL scale

The final translated version of D-MRQoL scale (Figure 4) is written in Times New Roman, and appears with the same layout as the original version from Taiwan (Appendix C).

4.1.1. Sequence of items

In comparison with the original version, the sequence of items was slightly modified in the final translated version of D-MRQoL scale. The decision was taken right before going into step 5 of the translation protocol, or the pilot testing of PF-DK.

In the final version of D-MRQoL, translated items numbered 1, 2, and 3 are the same items that are numbered 7, 8, and 9, respectively, in the original version from Taiwan. Committee members and researchers, who were asked to evaluate the scale in terms of wording, often stumbled upon a specific item. That was item number 1 of the scale: „*du har brugt mindre tid på arbejde eller daglige aktiviteter?*”. The committee evaluated the item as unfit as a starting question. The reason is because of difficulties understanding the meaning of the question, and the possibility that it could affect participant's perception of the overall scale in a negative manner. Items number 7, 8, and 9 in the translated version were moved up, thereby getting numbers 1, 2, and 3. That specific item causing the change of the sequence, is now positioned as item number 4 in the final translated version of the D-MRQoL scale.

Spørgeskema om medicinbrug og livskvalitet

De forskellige spørgsmål på næste side er relevante for dit medicinbrug, som i løbet af den seneste måned har påvirket din dagligdag. For hvert spørgsmål, vælg venligst det svar, der passer bedst på det du har oplevet. For hvert udsagn på næste side bedes du med en ring markere det tal (1, 2, 3, 4, 5 eller 6) der bedst beskriver din holdning til spørgsmålet.

Har du inden for den seneste måned i forbindelse med brugen af medicin følt, at...

	Aldrig	Sjældent	Nogle gange	Ofte	Meget ofte	Altid
1. du har haft svært ved at koncentrere dig i forbindelse med arbejde eller daglige aktiviteter?	1	2	3	4	5	6
2. du har været træt, udmattet og haft svært ved at overskue arbejde eller daglige aktiviteter?	1	2	3	4	5	6
3. du har haft færre dage med fuld energi?	1	2	3	4	5	6
4. du har brugt mindre tid på arbejde eller daglige aktiviteter?	1	2	3	4	5	6
5. du har haft mindre overskud til at klare arbejdsopgaver eller daglige aktiviteter i forhold til det, som du gerne vil?	1	2	3	4	5	6
6. du har klaret færre af dine arbejdsopgaver eller andre aktiviteter?	1	2	3	4	5	6
7. du har skullet anstrenge dig for eller haft sværere ved at gennemføre arbejdsopgaver eller daglige aktiviteter?	1	2	3	4	5	6
8. du har haft svært ved at deltage i socialt samvær med familie eller venner?	1	2	3	4	5	6
9. du ikke har haft overskud til dine fritidsaktiviteter, f.eks. sport og se TV?	1	2	3	4	5	6
10. du har været frustreret eller ked af det?	1	2	3	4	5	6
11. du har været en belastning for andre?	1	2	3	4	5	6
12. du har været bange for at skuffe andre?	1	2	3	4	5	6
13. det har været nødvendigt at du aflyste en aftale eller en fælles aktivitet?	1	2	3	4	5	6
14. du har været nødt til at afbryde arbejde eller daglige aktiviteter?	1	2	3	4	5	6

Figure 4: The final translated version of D-MRQoL scale

4.1.2. The discrepancies resolved regarding wording and phrasing

Documents from the translation phase are found in the Appendix section of this thesis. The two initial translations from Chinese to Danish, DK1 and DK2, are found in Appendix E, and the original version of MRQoL from Taiwan in Appendix C. The committee's preliminary initial version (PI-DK) is found in Appendix F.

The committee generated the preliminary initial translated version of the MRQoL measure, PI-DK, after making comparison of the two translated versions, DK1 and DK2 (Table 2). Decisions for choosing the items of PI-DK were more often based on translated items from the DK2 translated version, rather than DK1. The committee decided to use question marks after each question, but neither of DK1 or DK2 had translated question marks from the original version from Taiwan. Furthermore, the committee decided not to use the formal second-person pronoun to address with, such as translation DK2 suggested, e.g. "*Følt Dem trist og deprimeret*", but instead, every item starts with "*du har...*" as seen in Table 2.

Between the final decisions of PI-DK, and going into pilot-testing, two more changes were initiated. The sequence of the scale was changed, as discussed earlier, as well as the last change of wording. Instead of "*du har haft mindre tid til arbejde...*" for item 1 in PI-DK (Table 2), it was decided to rewrite the question as "*du har brugt mindre tid til at arbejde...*". It was decided that the modified version of PI-DK would be used in the pilot-test as a pre-final version, but now called PF-DK (Appendix F).

The dichotomous scale used in the pilot-test, to evaluate the clarity of PF-DK in terms of clarity of the instructions, items and response formats, can be found in Appendix G. No further changes were made on the PF-DK after the pilot-test. Therefore, decision was taken by the committee, that PF-DK is the final version of the translated Danish version of MRQoL, and is called D-MRQoL scale (Figure 4).

Table 2: Comparison of the initial translated versions, DK1 and DK2, and the resulting version of the committee, PI-DK. The translated PI-DK was revised many times during steps 1-4 of the translation protocol, and later evolved into PF-DK which was used in pilot-testing of the Danish version of MRQoL scale.

	DK1	DK2	PI-DK	Discrepancies and decisions
Title	<i>Spørgeskema om medicinbrug og relevant livskvalitet*</i>	Spørgeskema om medicinforbrug og livskvalitet	Spørgeskema om medicinbrug og livskvalitet	DK1 translation slightly modified and used (*).
Instructions 1/3	De forskellige spørgsmål nedenunder er relevante for dit medicinbrug, som i løbet af den seneste måned har påvirket dig. For hvert spørgsmål, vælg venligst det svar, der bedst matcher dine oplevelser.	De nedenstående spørgsmål drejer sig om Deres indtryk vedrørende problemer i forbindelse med Deres medicinforbrug i den sidste måned. Besvar hvert spørgsmål ved at finde det svar, der passer bedst på Dem.	<i>De forskellige spørgsmål på næste side er relevante for dit medicinbrug, som i løbet af den seneste måned har påvirket din dagligdag. For hvert spørgsmål, vælg venligst det svar, der passer bedst på det du har oplevet.**</i>	Neither instructions were directly used, both were considered unusual in Danish. The meaning of the translations was discussed in detail by the committee, and it was decided to rephrase the instructions when the committee reached a consensus on wording (**).
Instructions 2/3	Har du på grund af indtagelse af medicin i løbet af den seneste måned haft nogen af de følgende problemer i dit dagligliv?	Inden for den sidste måned: Har De oplevet noget problem med Deres medicinforbrug, som har følgende påvirkning:	<i>Har du inden for den seneste måned i forbindelse med brugen af medicin følt, at... **</i>	Neither instructions were directly used, both were considered unusual in Danish. The meaning of the translations was discussed in detail by the committee, and it was decided to rephrase the instructions when the committee reached a consensus on wording (**).
Instructions 3/3	Sæt kun ét kryds for hvert spørgsmål)	Besvar hvert spørgsmål ved at sætte et cirkel om svar	<i>For hvert udsagn på næste side bedes du med en ring markere det tal (1, 2, 3, 4, 5 eller 6) der bedst beskriver din holdning til spørgsmålet**</i>	Neither translated instructions were directly used. It was decided to use some common Danish translations for instructions on how to answer Likert responses (**).
Likert responses	Aldrig – Meget lidt – Nogen gange – Tit – Fleste tid - Altid	Aldrig - Sjældent - Somme tider - Tit - En hel del - Altid	<i>Aldrig – Sjældent – Nogle gange – Ofte – Meget ofte - Altid**</i>	Neither translated instructions were directly used. It was decided to use some common Danish translations for Likert responses (**).
Item 1	<i>Du har mindre tid til arbejde eller daglige aktiviteter*</i>	Har formindsket tid til arbejde eller daglige aktiviteter	du har haft mindre tid til arbejde eller daglige aktiviteter?	DK1 translation used (*).

Item 2	Den arbejds mængde eller daglige aktiviteter, som du ønsker at udføre, bliver ormindsket	<i>Er arbejds mængde eller daglige aktiviteter blevet mindre i forhold til det, som De gerne vil*</i>	du har haft mindre overskud til at klare arbejdsopgaver eller daglige aktiviteter i forhold til det, som du gerne vil?	DK2 translation slightly modified and used.
Item 3	Du bliver begrænset i arbejdsopgaver eller andre aktiviteter, som du plejer at kunne udføre	Været begrænset i arbejde eller andre typer af aktiviteter	<i>du har klaret færre af dine arbejdsopgaver eller andre aktiviteter? **</i>	Neither translations were directly used, both were considered unusual in Danish. The meaning of the translations was discussed in detail, and decided to rephrase the question. It was done after the committee reached a consensus on the meaning of the question. The rephrasing was inspired by the DK1 and DK2 translations. The word “ <i>begrænset</i> ” (e. limited) was not used, it is commonly not used in this context in Danish. Instead the wording “ <i>klaret færre af dine arbejdsopgaver</i> ” was used.
Item 4	Udførelse af arbejde eller aktiviteter bliver vanskelige eller hårde for dig	<i>Har haft svært / sværere ved at gennemføre arbejde eller daglige aktiviteter*</i>	du har skullet anstrenge dig for eller haft sværere ved at gennemføre arbejdsopgaver eller daglige aktiviteter?	DK2 translation used. The committee did not like the slash (“/”) symbol, it was erased. Instead of “ <i>arbejde</i> ” (e. job), it was decided to use “ <i>arbejdsopgaver</i> ” (e. jobtasks) instead. To focus on tasks that can come with work, instead of the job in general, because jobs can vary.
Item 5	Dine relationer til familie og venner bliver forstyrret	<i>Har haft svært ved at være sammen med familie og venner*</i>	du har haft svært ved at deltage i socialt samvær med familie eller venner?	DK2 translation slightly modified and used. It was thought to be more understandable to say in Danish “ <i>svært ved at deltage i social samvær</i> ”, instead of just “ <i>svært ved at være sammen med</i> ”.
Item 6	Dine fritidsaktiviteter bliver forhindret, f.eks. sport og se TV	Blevet forstyrret i Deres fritidsaktiviteter, f.eks. sport eller se TV	<i>du ikke har haft overskud til dine fritidsaktiviteter, f.eks. sport og se TV? **</i>	Neither translations were directly used, both were considered unusual in Danish. The meaning of the translations was discussed in detail, and decided to rephrase the question after the committee reached a consensus on the meaning of the question.

Item 7	Din koncentration i arbejde eller dagligliv bliver forringet	<i>Har haft svært ved at koncentrere i arbejde eller daglige aktiviteter*</i>	du har haft svært ved at koncentrere dig i forbindelse med arbejde eller daglige aktiviteter?	DK2 translation used (*).
Item 8	Du er mere træt og ude af stand til at udføre daglige aktiviteter eller arbejde	<i>Følt Dem træt og udmattet og haft svært ved at overskue arbejde eller daglige aktiviteter*</i>	du har været træt, udmattet og haft svært ved at overskue arbejde eller daglige aktiviteter?	DK2 translation used (*).
Item 9	<i>Du har færre dage med fuld energi*</i>	Følt Dem mindre frisk fra dag til dag	du har haft færre dage med fuld energi?	DK1 translation used (*).
Item 10	Du er frustreret og ulykkelig	Følt Dem trist og deprimeret	<i>du har været frustreret eller ked af det? **</i>	Neither translations were directly used, both were considered unusual in Danish. The meaning of the translations was discussed in detail, and decided to rephrase the question when the committee reached a consensus on the meaning of the question (**).
Item 11	Du er en byrde for andre	<i>Følt Dem som en belastning for andre mennesker *</i>	du har været en belastning for andre?	DK2 translation used (*).
Item 12	Du er bange for at andre vil blive skuffet	<i>Er bange for at skuffe andre*</i>	du har været bange for at skuffe andre?	DK2 translation used (*).
Item 13	<i>Det er nødvendigt at du aflyse en aftale eller en fælles aktivitet*</i>	Blevet nødt til at aflyse planlagte møder og arrangementer	det har været nødvendigt at du aflyste en aftale eller en fælles aktivitet?	DK1 translation used (*).
Item 14	Det er nødvendigt at stoppe med at arbejde eller daglige aktiviteter for at løse relevante medicinske spørgsmål eller problemer	<i>Blevet nødt til at afbryde arbejde eller daglige aktiviteter for at løse problemer, som opstår i forbindelse med indtagelse af medicin*</i>	du har været nødt til at afbryde arbejde eller daglige aktiviteter?	DK2 translation slightly modified and used. It was decided to erase this following part in DK2, “for at løse problemer, som opstår i forbindelse med indtagelse af medicin”. The decision was based on the committee’s evaluation that it was not necessary to state that in the question, because every item should be answered with in mind: “i forbindelse med brugen af medicin” (*).

4.2. Descriptive statistics

4.2.1. The study population

A total of 120 patients participated in the study (Table 3). The largest proportion of data was collected from polypharmacy patients at Sønderbro Apotek, a pharmacy located in the Amager district of Copenhagen, Denmark. Of 120 participants in the study, the main researcher collected data from 101 participants. The researcher noticed that the average time was approximately 10 minutes for the 101 respondents to complete the 32-item questionnaire in total. But the cover page of the questionnaire stated that it took around 10-15 minutes.

Table 3: Distribution of participants considering location setting.

Setting				
Pharmacy		Location in Denmark	n (%)	Data collector*
1	Steno Apotek	Copenhagen	4 (3,3%)	EDJ
2	Østerbro Apotek	Copenhagen	40 (33,3%)	EDJ
3	København Sønderbro Apotek	Copenhagen	52 (43,3%)	EDJ
4	Slagelse Svane Apotek	Slagelse	4 (3,3%)	ZÖ
Patient organisations				
5	Sundhedshus Amager – Københavns Kommune	Copenhagen	4 (3,3%)	EDJ
6	FAKS – Foreningen Af Kroniske Smertepatienter	Jutland	1 (0,8%)	EDJ
Hospitals				
7	Hvidovre Hospital (Emergency Department)	Copenhagen	15 (12,5%)	CS, IVR
Total			120 (100%)	

*Data collectors are listed in Appendix H

n: Number of participants

%: Proportion of participants

4.2.2. Demographics of the study population

Of all study participants, 45% were male and 55% female. Largest proportion of participants were 70 years or older (59%). Half of the participants used 6-10 medicines on a daily basis (50%). Participants without a University degree are in total 53% (Table 4).

Table 4: Demographics of the study population. Additionally, each category is presented by gender.

Variables		n total (%)	n male (%)	n female (%)
Age	< 60 years	19 (15,8%)	8 (42,1%)	11 (57,9%)
	60-69 years	30 (25,0%)	18 (60,0%)	12 (40,0%)
	≥ 70 years	71 (59,2%)	28 (39,4%)	43 (60,6%)
Highest education completed	Public school	32 (26,7%)	14 (43,8%)	18 (56,2%)
	Vocational school	18 (15,0%)	10 (55,6%)	8 (44,4%)
	High school	14 (11,7%)	5 (35,7%)	9 (64,3%)
	3 years of University studies	20 (16,7%)	5 (25,0%)	15 (75,0%)
	More than 3 years of University studies	36 (30,0%)	20 (55,6%)	16 (44,4%)
Medicines	5 medicines	41 (34,2%)	19 (46,3%)	22 (53,7%)
	6-10 medicines	60 (50,0%)	30 (50,0%)	30 (50,0%)
	More than 10 medicines	19 (15,8%)	5 (26,3%)	14 (73,7%)

n: Number of participants

%: Proportion of participants

4.2.3. Completeness of responses to the D-MRQoL scale

In total, there were only five missing values of the D-MRQoL scale. Items number 4 and 12 had two missing values, and item number 7 had one missing value. Mean scores for the three items with missing values are found in Appendix I.

4.2.4. Responses to the D-MRQoL on a 6-point Likert scale

The response, *None of the time* ("Aldrig"), was most often selected by the respondents in comparison with other Likert scale responses, or for more than half of the questions. The frequency of the response is marked blue in the left part of the columns in Figure 5. For instance, questions (or items) number 1, 8, 11, and 12 were answered by more than 45 participants as the statement *None of the time* ("Aldrig"). Overall, responses to the scale by respondents are skewed, towards more 'disagreeing' scaled responses (Figure 5). Disagreement indicates a higher medication-related quality of life. For each item separately, histograms of distribution of respondents' responses can be found in Appendix J, and the mean value in Figure 6. In terms of location setting, the 15 participants from Hvidovre Hospital showed more variability in responses on the Likert scale in comparison to the community pharmacies.

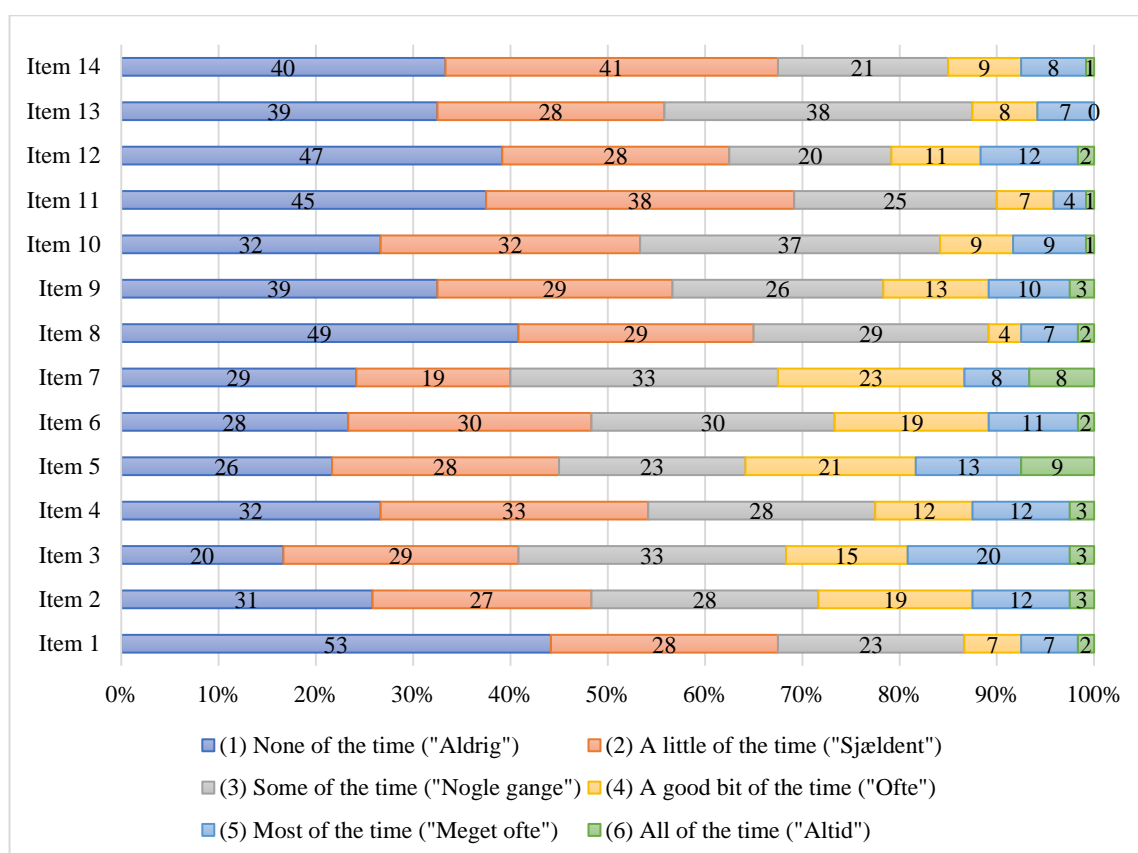


Figure 5: Frequency of responses for each point of the Likert Scale of all 14-item D-MRQoL.

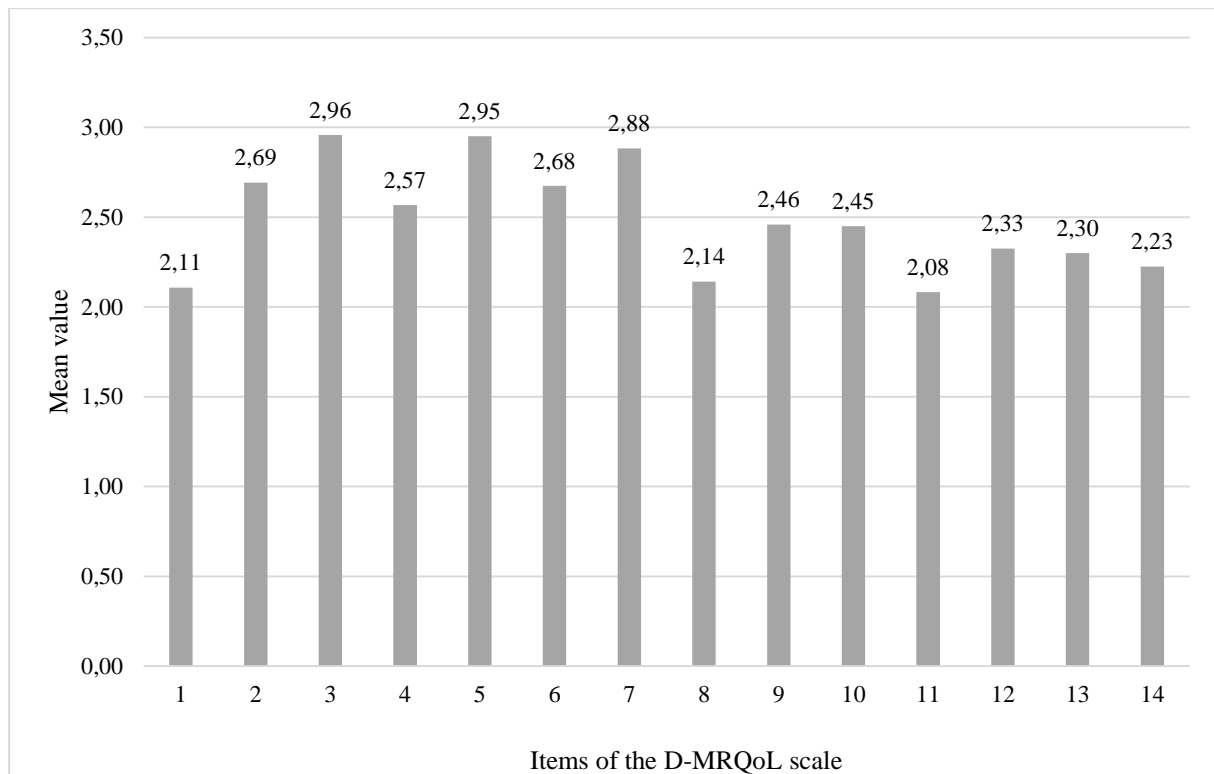


Figure 6: Mean value for each item of the D-MRQoL scale. Likert scale range: Aldrig (1), Sjældent (2), Nogle gange (3), Ofte (4), Meget ofte (5), Altid (6). The calculated mean value for all 14-item mean values is 2.49.

4.2.5. Distribution of total scores

The total scale scores for the 14-item D-MRQoL scale can range from 14-84. Higher total score on the scale indicates a patient's perception of low quality of life considering medication use, and a lower total score, the opposite. Figure 7 and Figure 8 present the distribution of total scores for the study population. The mean value for all total scores is 34.82 (SD = 14.86).

Results from descriptive statistics is found in Table 5. The highest total score of the scale was 75. The median value for all total scores on the D-MRQoL scale is 33.0, and is presented in the box plot in Figure 8 as a bold horizontal line that divides the box in two halves. The upper half of the box, and the long upper whisker, represent the 60 participants with total scores ranging from 33 to 75. The lower half of the box, and the short lower whisker, represent the 60 participants with total scores ranging from 14 to 33. Where precisely the whiskers begin to extend from the boxes, above and below those spots and towards the whiskers end, are the range of total scores for the 25% of the study population that scored highest (above) and lowest (below) on the D-MRQoL scale.

Two outliers in Figure 8 reflect two participants who had the highest total scores on the D-MRQoL scale of all study participants. Before conducting factor analysis on the data set it was decided not to drop these outliers. Having the outliers in the data set would not significantly change the result of the factor analysis.

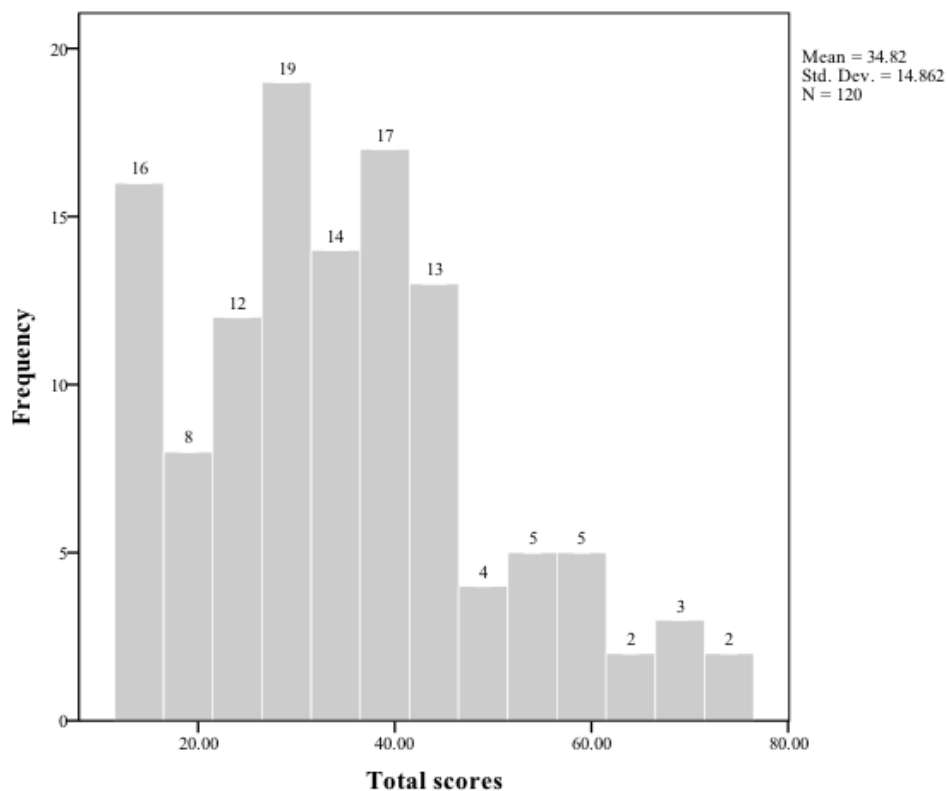


Figure 7: Distribution of total scores for the D-MRQoL scale in the population of patients with polypharmacy.

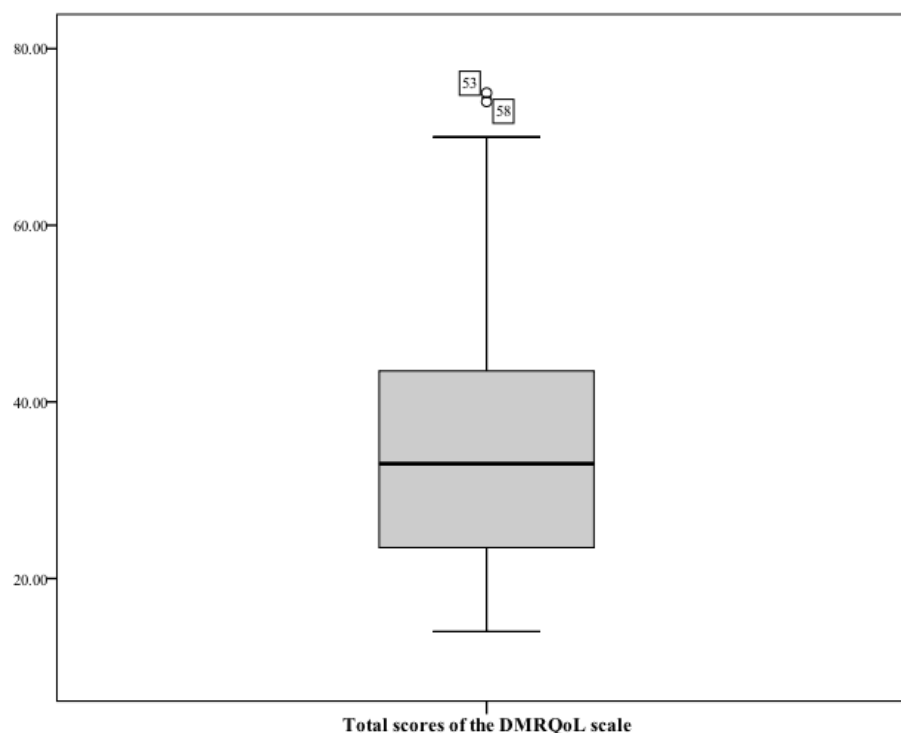


Figure 8: Box plot representing the distribution of total scores for the DMRQoL scale in the population of patients with polypharmacy. The median value (33.0) is represented with black horizontal line that divides the data in two halves. Two outliers are revealed, participants number 53 and 58. The highest total score by respondent is 75, and the lowest is 14.

Table 5: Descriptive statistics of the polypharmacy patient group for the D-MRQoL scale, as well as for the Medication Adherence Report Scale (DMARS-4), and Beliefs about Medicines Questionnaire (BMQ-Specific).

	Mean	Median	Standard error (SE)	Range (min - max)	Skewness	Range of possible total scores
D-MRQoL	34.82	33.00	1.36	14.00 - 75.00	0.59	14-84
DMARS-4	18.19	19.00	0.15	14.00 - 20.00	-0.79	4-20
BMQ-Specific necessity	9.08	9.00	0.26	5.00 - 17.00	0.53	5-25
BMQ-Specific concerns	15.26	14.00	0.44	5.00 - 25.00	0.17	5-25

4.2.6. Comments from respondents during the data collection

The study is quantitative. However, during the data collection, the main researcher received a few qualitative notes from the respondents after completing the D-MRQoL scale.

The respondent...

- felt it was difficult to look inwards overall, not to mention in relation to medication use.
- thought it was difficult to detect if low health-related quality of life was due to medication use per se, or also the fact that he or she is sick.
- felt it was somewhat difficult to relate medication use to the description of items.
- had not thought about before, whether the medication use is affecting his or her daily life, it could well be.
- had recently changed medical treatment, or for about two months ago, and therefore his or her HRQoL had improved a lot the past weeks.
- thought it was not difficult to answer the items.
- does not have any problems with his or her medications.
- felt so tired of taking all of these medications.
- felt as some of the items were asking about the same phenomena.

4.3. Psychometric statistics

Results from examination of psychometric properties of the Danish version of MRQoL scale are presented in terms of factor structure, internal consistency reliability, and construct validity. For the psychometric analysis, the scores for D-MRQoL and BMQ-Specific (*concerns* and *necessity*) were reversed, but not for DMARS-4.

4.3.1. Sample size assessment before psychometric testing of the D-MRQoL scale

The Kaiser-Meyer-Olkin (KMO=0.92) measure of sampling adequacy, and Bartlett's test of sphericity ($X^2_0=1525.87$, $p < 0.05$), suggested that the sample size was factorable.

4.3.2. Factor analysis of the D-MRQoL scale

Factor loadings from the Exploratory factor analysis (EFA), using Principal component analysis (PCA), are presented in Table 6. Two factors were extracted with eigenvalues >1.0 (Figure 9), accounting for 72.8% of the total variance. One of the two extracted factors contributed to the vast majority of total variance, or 63.7% (Appendix K).

Results from PCA of the D-MRQoL scale revealed that items 1-7 loaded higher on factor 1, and items 8-14 higher on factor 2 (Figure 10). The correlation matrix from PCA is presented in Table 7, where few items correlate over 0.80.

The potential third factor analysed, but not extracted in the factor analysis for the D-MRQoL scale, has the eigenvalue of 0.75 (Appendix K). That factor did not meet the preferred eigenvalue of 1.0 or higher. In Table 8, factor loadings of each item are presented if three factors had been extracted, as it did for the original version of MRQoL in Taiwan.

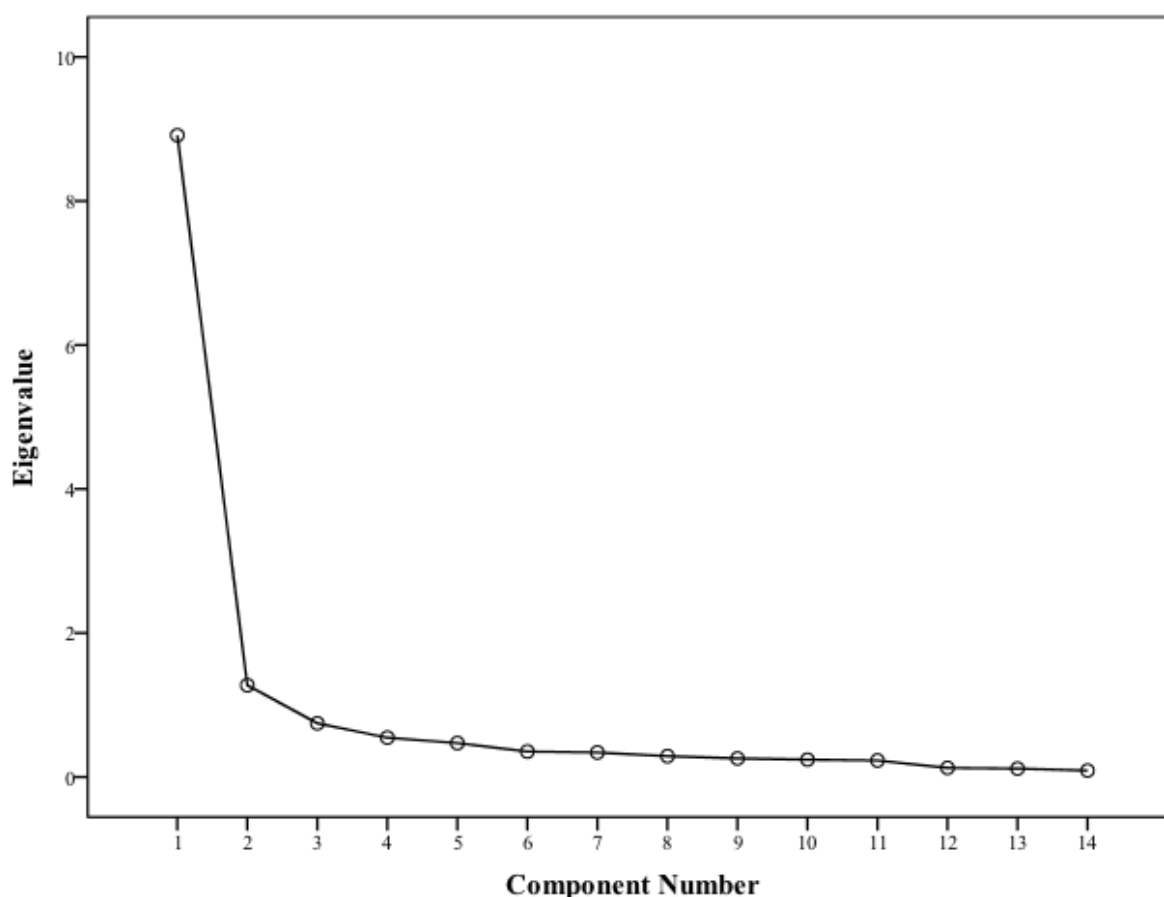


Figure 9: Scree plot from factor analysis representing two factors with eigenvalue >1.0 . The third potential factor would be extracted if the eigenvalue criterion is lowered to 0.7.

Table 6: Factor loadings on Factor 1 (F1) and Factor 2 (F2) of the D-MRQoL scale using PCA.

Items		Factor loadings	
Factor 1:		F1	F2
1.	du har haft svært ved at koncentrere dig i forbindelse med arbejde eller daglige aktiviteter?	0.558	0.497
2.	du har været træt, udmattet og haft svært ved at overskue arbejde eller daglige aktiviteter?	0.759	0.386
3.	du har haft færre dage med fuld energi?	0.849	0.242
4.	du har brugt mindre tid på arbejde eller daglige aktiviteter?	0.803	0.337
5.	du har haft mindre overskud til at klare arbejdsopgaver eller daglige aktiviteter i forhold til det, som du gerne vil?	0.878	0.314
6.	du har klaret færre af dine arbejdsopgaver eller andre aktiviteter?	0.799	0.439
7.	du har skullet anstrenge dig for eller haft sværere ved at gennemføre arbejdsopgaver eller daglige aktiviteter?	0.838	0.381
Factor 2:			
8.	du har haft svært ved at deltage i socialt samvær med familie eller venner?	0.388	0.759
9.	du ikke har haft overskud til dine fritidsaktiviteter, f.eks. sport og se TV?	0.540	0.554
10.	du har været frustreret eller ked af det?	0.367	0.687
11.	du har været en belastning for andre?	0.210	0.835
12.	du har været bange for at skuffe andre?	0.280	0.798
13.	det har været nødvendigt at du aflyste en aftale eller en fælles aktivitet?	0.387	0.801
14.	du har været nødt til at afbryde arbejde eller daglige aktiviteter?	0.375	0.708

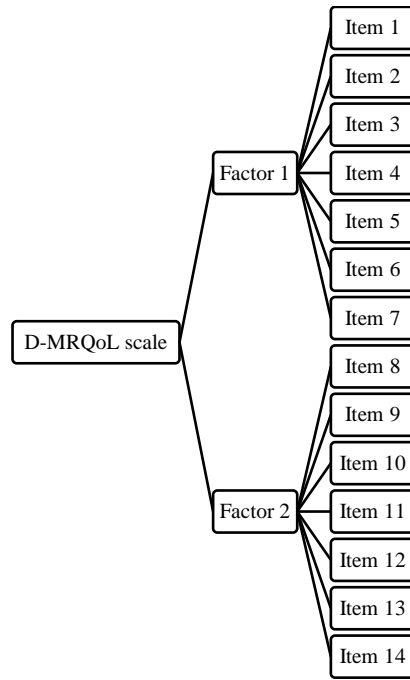


Figure 10: Schematic diagram illustrating the factor structure of two-factor D-MRQoL scale. Descriptions of items are listed in Table 6.

Table 7: Correlation matrix between all items of the D-MRQoL scale, few items correlate too highly, and are highlighted in bold text.

Items	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	1.000	0.684	0.583	0.524	0.621	0.604	0.620	0.584	0.479	0.545	0.588	0.515	0.561	0.452
2	0.684	1.000	0.695	0.701	0.740	0.699	0.769	0.581	0.518	0.592	0.483	0.564	0.588	0.481
3	0.583	0.695	1.000	0.727	0.782	0.719	0.740	0.538	0.609	0.441	0.401	0.455	0.511	0.512
4	0.524	0.701	0.727	1.000	0.762	0.799	0.747	0.543	0.584	0.507	0.460	0.509	0.606	0.581
5	0.621	0.740	0.782	0.762	1.000	0.869	0.844	0.545	0.627	0.553	0.467	0.521	0.586	0.546
6	0.604	0.699	0.719	0.799	0.869	1.000	0.831	0.639	0.632	0.629	0.538	0.588	0.634	0.612
7	0.620	0.769	0.740	0.747	0.844	0.831	1.000	0.621	0.697	0.550	0.508	0.492	0.640	0.598
8	0.584	0.581	0.538	0.543	0.545	0.639	0.621	1.000	0.658	0.535	0.675	0.633	0.749	0.669
9	0.479	0.518	0.609	0.584	0.627	0.632	0.697	0.658	1.000	0.506	0.521	0.560	0.668	0.560
10	0.545	0.592	0.441	0.507	0.553	0.629	0.550	0.535	0.506	1.000	0.593	0.707	0.596	0.532
11	0.588	0.483	0.401	0.460	0.467	0.538	0.508	0.675	0.521	0.593	1.000	0.683	0.651	0.598
12	0.515	0.564	0.455	0.509	0.521	0.588	0.492	0.633	0.560	0.707	0.683	1.000	0.685	0.524
13	0.561	0.588	0.511	0.606	0.586	0.634	0.640	0.749	0.668	0.596	0.651	0.685	1.000	0.806
14	0.452	0.481	0.512	0.581	0.546	0.612	0.598	0.669	0.560	0.532	0.598	0.524	0.806	1.000

Table 8: Factor loadings on Factor 1 (F1), Factor 2 (F2), and Factor 3 (F3), if the eigenvalue is 0.7 or more.

Items		Factor loadings		
Factor 1:		F1	F2	F3
2.	du har været træt, udmattet og haft svært ved at overskue arbejde eller daglige aktiviteter?	0.733	0.137	0.489
3.	du har haft færre dage med fuld energi?	0.828	0.265	0.166
4.	du har brugt mindre tid på arbejde eller daglige aktiviteter?	0.773	0.361	0.197
5.	du har haft mindre overskud til at klare arbejdsopgaver eller daglige aktiviteter i forhold til det, som du gerne vil?	0.852	0.264	0.271
6.	du har klaret færre af dine arbejdsopgaver eller andre aktiviteter?	0.764	0.369	0.333
7.	du har skullet anstrenge dig for eller haft sværere ved at gennemføre arbejdsopgaver eller daglige aktiviteter?	0.805	0.378	0.247
Factor 2:				
8.	du har haft svært ved at deltage i socialt samvær med familie eller venner?	0.327	0.676	0.434
9.	du ikke har haft overskud til dine fritidsaktiviteter, f.eks. sport og se TV?	0.492	0.631	0.205
13.	det har været nødvendigt at du aflyste en aftale eller en fælles aktivitet?	0.321	0.760	0.409
14.	du har været nødt til at afbryde arbejde eller daglige aktiviteter?	0.313	0.804	0.231
Factor 3:				
1.	du har haft svært ved at koncentrere dig i forbindelse med arbejde eller daglige aktiviteter?	0.526	0.126	0.636
10.	du har været frustreret eller ked af det?	0.322	0.262	0.748
11.	du har været en belastning for andre?	0.150	0.515	0.685
12.	du har været bange for at skuffe andre?	0.224	0.419	0.738

4.3.3. Internal consistency reliability

Results from Cronbach's alpha measure of internal consistency reliability, for the overall 14-item D-MRQoL scale, was 0.96. For the two extracted factors, the Cronbach's alpha coefficient was 0.95 for Factor 1, and 0.92 for Factor 2. If an item is deleted from the scale, the Cronbach's alpha coefficient for the overall scale, or the two factors, would not significantly improve (Appendix L).

4.3.4. Construct validity

Results from examination of construct validity of the D-MRQoL scale in terms of convergent and discriminant validity are found in Table 9. Of hypothesized correlations discussed in chapter 3.7.4. of this thesis, only one hypothesis was accepted. In addition to this result, the D-MRQoL scale as a whole was judged to have face validity by the research team. Figure 12 presents the results from evaluation of the type of correlation between all measures used for the validation of this study.

Table 9: Construct validity of the D-MRQoL scale. Correlations further examined for the extracted factors, F1 and F2.

D-MRQoL		DMARS-4	BMQ-Specific <i>necessity</i>	BMQ-Specific <i>concerns</i>
All items	Correlation coefficient	0.338**	-0.029	-0.455**
	p-value	0.000	0.754	0.000
	Hypothesis	Rejected	Rejected	Accepted
F1	Correlation coefficient	0.334**	-0.042	-0.426**
	p-value	0.000	0.647	0.000
	Hypothesis	Rejected	Rejected	Accepted
F2	Correlation coefficient	0.298**	-0.009	-0.472**
	p-value	0.001	0.919	0.000
	Hypothesis	Rejected	Rejected	Accepted

** Correlation is significant at the 0.01 level

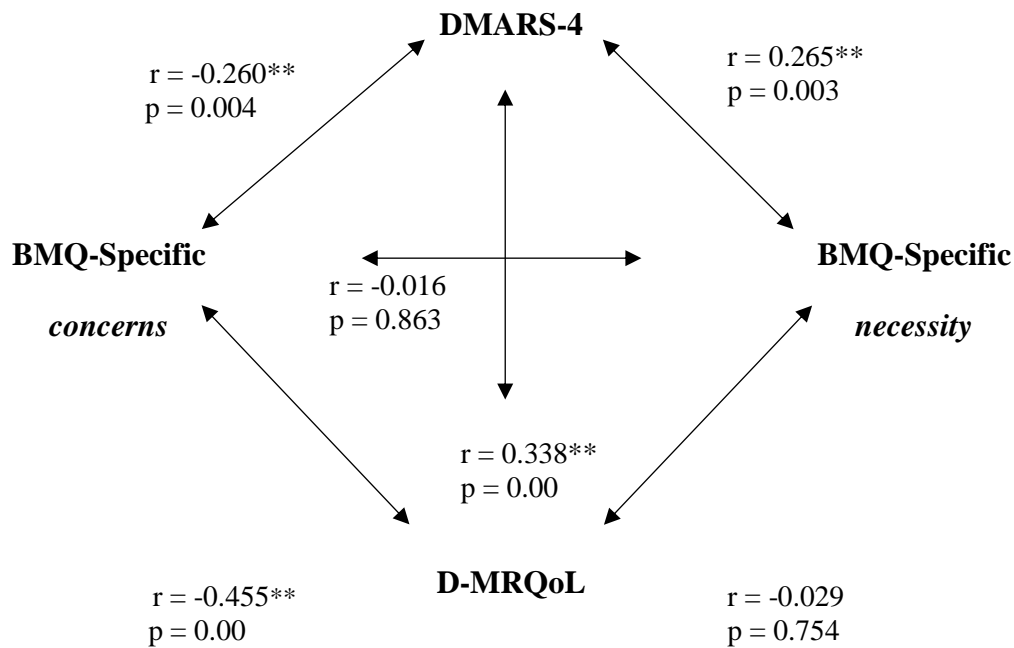


Figure 11: Schematic diagram of correlation results between all measures, D-MRQoL, DMARS-4, and *concerns* and *necessity* domains of the BMQ-specific. Correlation between measures is presented with **.

4.4. Comparison of results for the translated and original versions of MRQoL

Table 10 summarizes results from validation of the original version of MRQoL in Taiwan and the translated Danish version. Figure 12 demonstrates the factor structure of both versions for comparison of the description of items accounting for each factor, and for evaluation of a theme that exists or does not exist within each factor.

Table 10: Summary of results for the translated and original versions of MRQoL.

	Danish version of MRQoL (eigenvalue cut off 1.0)	Danish version of MRQoL (eigenvalue cut off 0.7)	Original version of MRQoL (eigenvalue cut off 1.0)
Number of factors extracted	2 factors	3 factors	3 factors
Internal consistency reliability Cronbach's alpha coefficient			
Overall scale	0.96	0.96	0.93
Factor 1	0.95	0.95	0.91
Factor 2	0.92	0.89	0.84
Factor 3	-	0.86	0.88
Total variance explained	72,7%	78,1%	70,4%
Construct validity	1 of 3 correlation hypotheses accepted	1 of 3 correlation hypotheses accepted	2 of 2 correlation hypotheses accepted
Known-group validity	Not tested	Not tested	Evidence confirmed
Scale sequence of items (where items for all versions are numbered as the original version)	7, 8, 9, 1, 2, 3, 4, 5, 6, 10, 11, 12, 13, 14	8, 9, 1, 2, 3, 4, 5, 6, 13, 14, 7, 10, 11, 12	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14

Items accounting for each factor (where items for all versions are numbered as the original version)	Factor 1: <i>Energy</i> Items 7, 8, 9, 1, 2, 3, 4 Factor 2: <i>Social engagement / Negative affect</i> Items 5, 6, 10, 11, 12, 13, 14	Factor 1: <i>Energy</i> Items 2, 3, 4, 5, 6, 7 Factor 2: <i>Social engagement</i> Items 8, 9, 13, 14 Factor 3: <i>Negative affect</i> Items 1, 10, 11, 12	Factor 1: <i>Role limitations due to medication</i> Items 1, 2, 3, 4, 5, 6 Factor 2: <i>Self-control</i> Items 10, 11, 12, 13, 14 Factor 3: <i>Vitality</i> Items 7, 8, 9
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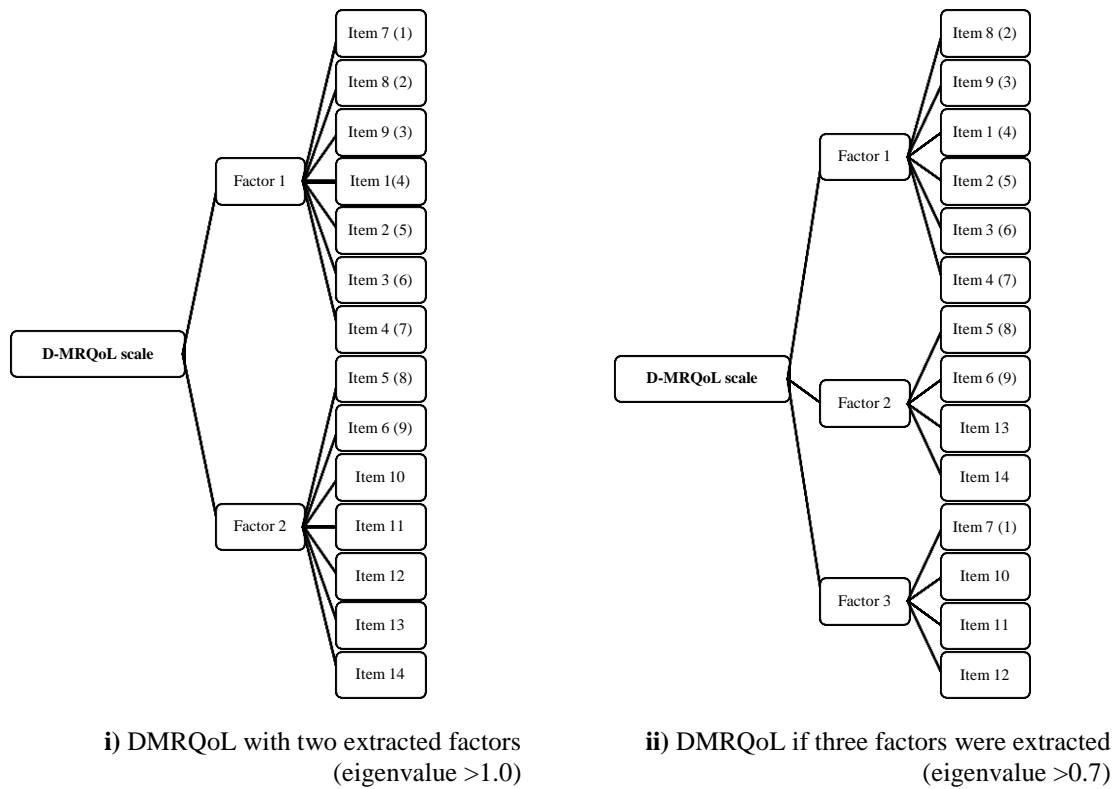


Figure 12: Comparison of factor structures between D-MRQoL and MRQoL. All items are numbered as for the original version of MRQoL. In brackets are the item numbers as listed in the D-MRQoL scale, if the sequence is different. Illustrations present the grouping of items contributing to each factor of the scales, i) DMRQoL, two factors ii) DMRQoL, if three factors iii) MRQoL, three factors.

5. DISCUSSION

The main aim of this study was to translate the original Taiwanese version of the Medication-Related Quality of Life (MRQoL) scale, from Chinese to Danish (D-MRQoL), and validate the Danish version in a population of patients with polypharmacy. Psychometric validation of the D-MRQoL scale was evaluated in terms of factor structure, internal consistency reliability and construct validity. Comparison between the translated and original version of MRQoL was evaluated considering psychometric properties of both scales.

In a study population of 120 patients with polypharmacy, results from psychometric testing of the D-MRQoL scale indicate that D-MRQoL is a valid scale in terms of convergent validity. The scale showed face validity and high internal consistency reliability with a structure of two measurable factors. In terms of factor structure, the study result diverges from the original Taiwanese scale. The original version showed a three-factor structure in the factor analysis conducted by Tseng et al. in Taiwan (Tseng et al., 2016).

5.1. Translation and adaption of the D-MRQoL scale

Taiwan is an island in East Asia with Chinese (Mandarin) as the official language, and is located with China to the west, and Japan to the northeast. Denmark is a country in Europe with Danish as an official language, and is located with Norway to the north and Germany to the south. There are about nine thousand kilometers between Taiwan and Denmark. It is given that there are cultural differences between these two countries. Such differences can be seen, for instance, in the languages. Cultural differences can cause language differences in, e.g. wording and phrasing (Villagran & Lucke, 2005). The Taiwanese researchers who conducted the development and validation of the MRQoL scale in Taiwan, were very likely aware of the possibility of language differences while granting the main researcher of this study permission to modify the MRQoL scale for translation purposes. Receiving this permission follows a responsibility, because one of the most challenging tasks of translating an instrument is to achieve equivalence between the translated and the original version (Beaton et al., 2000). Therefore, in the initial steps of the translation phase of the study, it was considered very important to choose an applicable translation protocol to follow during the process. The translation committee followed a modified version of Sousa and Rojjanasrirat translation protocol (Sousa & Rojjanasrirat, 2011). This protocol by Sousa and Rojjanasrirat is a

summarized guideline which was proposed after the authors had reviewed published recommendations of cross-cultural validation of instruments and scales.

Two of three members of the translation committee were Icelandic. However, that is not considered a problem. One of the Icelanders has lived in Denmark for many years and the third person is a native Danish speaker. And importantly, during different steps of the translation protocol, the addition of a Danish Ph.D. student in clinical pharmacy and another researcher linguistically proficient in Danish, was a valuable resource to the committee. They had a major impact on adjusting the items in Danish.

In the pilot-test of the D-MRQoL scale, none of the eight participants made any remarks about the wording of the 14-items or the instructions, nor did they provide any suggestions to rewrite the statements when asked. The most difficult decision taken by the committee was to change the sequence of the D-MRQoL items compared to the original MRQoL. The decision was taken because of item number 4 of the D-MRQoL scale.

In the study, only five response values were missing of the D-MRQoL scale, where item number 4 had two of them. The committee does not regret the decision of changing the items sequence, and still evaluates item number 4 as unfit as a starting question. The low rate of missing values by respondents in the study indicates high rate of data completeness and highlights the acceptability of the Danish scale in a population of patients with polypharmacy.

Nowadays, the diversity of populations within countries is increasing worldwide, which supports the need for more cross-culturally validated instruments or scales. Before this study was conducted, no medication-related quality of life scale existed in Danish. There are measures in English currently in development that seek to reflect patient's perspectives living with long-term medication use (Krska et al., 2014), and the effect of medication use on patients' health-related quality of life (Sakthong et al., 2015). However, to the best of our knowledge, no MRQoL scale currently exists in Europe that is validated and in use for a population of patients with polypharmacy.

5.2. Data collection

The largest proportion of data was collected from polypharmacy patients at the community pharmacy Søndrebro Apotek. The reason is because the main researcher spent most days collecting data at that specific pharmacy during the data collection period. Many polypharmacy patients seek services at Søndrebro Apotek, which is in the Amager district of Copenhagen, Denmark.

The main researcher received many refusals from the customers when asked to participate in the study. Customers claimed to be too busy, in a hurry, or picking up medicines for someone else. Furthermore, many customers did meet the inclusion criteria. From the main researcher's experience, collecting data at a community pharmacy is a difficult and challenging task. Each day is different at a busy pharmacy, and there is no way to guess how many polypharmacy patients will participate and answer the questionnaire. Such uncertainty can be frustrating for a data collector who stands the entire day in a pharmacy's waiting area.

The main researcher received data from data collectors at Hvidovre Hospital, and asked about their experience of collecting data at the hospital. Many patients had refused participation often due to tiredness and/or sickness. The same data collectors mentioned it would have been better to collect data at other departments of the hospital than the Emergency Department.

If similar study would be conducted, or this study repeated, it is recommended for the data collection to consider seeking a setting where the environment is quieter and at ease, rather than at a pharmacy. This could, for example, be in patient organisation groups, hospital waiting rooms, or a clinician's waiting room. For instance, the main researcher collected data at a meeting of a patient organisation at *Sundhedshus Amager*. Of nine members that attended that meeting, four met the inclusion criteria. In comparison with participants at the community pharmacies, the main researcher noticed that the participants from the *Sundhedshus* were more relaxed while answering the self-administered questionnaire. In general, it took them a longer time to respond to the items, probably because they took more time to carefully consider each item.

5.3. Interpretation of results

Demographics of the study population revealed that most of the participants were older than 70 years. This result aligns with the fact that polypharmacy is more common in the elderly (Maher et al., 2014), considering that the definition of polypharmacy in this study is when a patient is taking five or more medicines daily.

5.3.1. Responses to the D-MRQoL scale by the study population

Results from the frequency of responses seem graphically similar for each item, where all mean values are close to 2.4. And when calculated, the mean value of all 14-item mean values was 2.49. Such value indicates that the respondent's average response point was somewhere

between “Sjældent” and “Nogle gange”. The response distribution is skewed to the right for all 14 items of the scale, where ‘right’ refers to a long right tail, and the distribution appears as a left-leaning curve. When a distribution is skewed to the right, it often means that the mean value is greater than the median value. The majority of the respondents were selecting item responses at the left side of the Likert scale range.

Results reveal a lack of variability in responses to the items of the D-MRQOL scale. Such results indicate that a majority of the respondents are not experiencing themselves as having a low health-related quality of life (HRQoL) when relating the descriptions of D-MRQoL items to their medication use, and therefore tended to select responses on the left side of the Likert scale. Other potential reasons for how the respondents responded, could be due to the participants in the study being overall in good health in spite of using many medicines. Considering the location setting, community pharmacy customers may be in better health than patients who do not pick up their medicines themselves at a pharmacy. Additionally, some of the respondents from the pharmacies could have been in a hurry, possibly did not take each item for a careful consideration and quickly selected the first few responses on the Likert scale, and therefore increasing the potential for response bias.

Data was collected from Hvidovre hospital for a small part of the study population. The participants from the hospital showed more variability in responses. It could be that those 15 participants were possibly feeling worse than the study participants at the community pharmacies, and less in a hurry. Furthermore, it may be that the hospital patients took a longer time to answer the D-MRQoL items with a deeper thought and consideration.

Another possible explanation for the lack of variability in responses could be that the instructions of the D-MRQoL scale, *„Har du inden for den seneste måned...”,* asks the respondents to look back to the past four weeks while answering the items of the scale. Maybe at that time, some of the respondents did not experience medication use as affecting their lives. Furthermore, it could have been that a respondent had recently changed a medical treatment for the better. Such a respondent, who has experienced improved health-related quality of life on a new medical treatment for the past four weeks, probably selects responses towards ‘disagreeing’ responses, that is, on the left side of the Likert scale range.

If the responses are analysed further, for instance, nine participants selected the first response on the Likert scale, “Aldrig”, for all items of the D-MRQoL scale. Such results indicate that those participants do not relate their medication use, at all, as affecting their HRQoL when considering the descriptions of the 14-items of the scale. However, it may also be that the utility of the instrument is to identify those who have a low health-related quality

of life as a consequence of medication-related problems. Participants who responded to the items towards more ‘agreeing’ scaled responses (Likert points 3-6), are those who clinicians could put more focus on to aim for improved medical treatment.

5.3.1.1. Distribution of total scores for the D-MRQoL scale

The range of total scores by respondents is from 14 to 75. The mean value for all total scores is 34.82, and the median value is 33.0. The results indicate that half of the participants, or 60 respondents, have a total score under 33.0 in the range from 14-33. That is a narrow range and highlights the lack of variability in responses. The distribution of total scores for the study population is skewed to the right and appears as a left-leaning curve. The participants scoring on this narrow range share similar experiences when considering responses to the items of the scale, and have a good medication-related quality of life.

In contrast, the total scores for the other 60 participants are distributed from 33 to 84, which is a wide range and indicates that there are participants with total scores reaching to the highest possible score. Of 120 participants, 25% or 30 participants have total scores ranging from approximately 42 up to the highest total score of 75. Such results indicate that even though the distribution is skewed to the right, there are individuals in the study population that have a low medication-related quality of life and are possibly experiencing medication-related problems.

5.3.1.2. Distribution of total scores for the DMARS-4 and the BMQ-Specific

Results indicate that the medication adherence of the study population is very high. On a score range from 4-20, the mean value of responses on the Medication Adherence Report Scale (DMARS-4) was 18.19. The distribution of respondents’ responses on the D-MARS4 scale was skewed to the left and appears as a right-leaning curve, with most item responses towards “Aldrig”.

The mean value of the *necessity* items of the BMQ-Specific scale was 9.08, and for the *concerns* items was 15.26. These results of mean values, indicate that the study population has relatively high beliefs about the *necessity* of their medicines, but relatively low *concerns* about their medicines.

When these results are taking into consideration, the potential reporting bias can not be overlooked. The respondents answered the scales in environments where they could have felt the need to answer as being very adherent and responsible towards their medications.

Perhaps they would have answered the scales differently and more honestly, for instance at home, where they are not affected by the environment.

5.3.1.3. Comments from respondents during the data collection

The researcher assessed that it was appropriate to report participants comments, received during the data collection, because a few of them were an inspiration when evaluating the future research of the MRQoL scale. In the development of MRQoL in Taiwan, the scale was developed based on a qualitative study. The purpose of reporting the comments was not to draw any conclusions. However, the researcher noticed that there was a matching in the way how the participants who commented after completing the scale had responded to the overall D-MRQoL scale. These comments highlight the fact that every individual perceives their health-related quality of life and medication use differently.

5.3.2. Psychometric properties of the D-MRQoL scale

The translation protocol by Sousa and Rojjanasrirat suggested that the sample size for the psychometric testing of the translated version should depend on the psychometric approaches that are used in the statistical analysis. Generally, it is a ‘rule of thumb’ to use 10 subjects per item of a scale to test a factor structure using Exploratory factor analysis (Stevens, 2002). Because of short data collection period, and good results from pre-tests on sample adequacy and sphericity, it was decided to go into psychometric testing of the D-MRQoL scale with responses from 120 participants.

5.3.2.1. Factor structure

‘Factor loadings’ express the correlation of each item to the underlying factor, where the evaluation is based on the strongest association. Generally, in a Principal component analysis, each item of a scale loads on every factor extracted, but with higher loading on either one of them. For interpretations of factor analysis results, factor loadings are analyzed to evaluate which items load onto which factors.

A) Two-factor structure

Results from PCA of the D-MRQoL scale revealed a two-factor structure of the scale, where items 1-7 loaded higher for Factor 1 and items 8-14 loaded higher for Factor 2. The two extracted factors were accounting for 72,8% of the total variance. Meaning that the 14 items, or variables in the large dataset, have been summarized into these two factors that are capturing 72,8% of the maximum information that is possible from the original 14 variables.

Considering Factor 1 (F1), items 2-7 clearly loaded higher on F1, rather than Factor 2 (F2). Only item number 1 showed a very little difference in factor loadings on the two factors. Item number 1, „*du har haft svært ved at koncentrere dig i forbindelse med arbejde eller daglige aktiviteter?*”, loaded 0.558 on F1, but 0.497 on F2. Considering Factor 2 (F2), item 8 and items 10-14, clearly loaded higher on F2, rather than F1. But item number 9, „*du ikke har haft overskud til dine fritidsaktiviteter, f.eks. sport og set TV?*”, showed a very little difference in factor loadings on the two factors. The item loaded almost equally on F1 and F2.

The items that loaded higher on F1 (items 1-7), share a common theme in the descriptions of items. To some extent, they are all about whether the respondent has felt, he or she, as having less *energy* or *strength* to initiate some tasks, or to carry out normal daily activities. There is only one question that is a slightly different from that theme, that is item number 1, which was described earlier. The description of the item is more about whether the respondent has felt distracted and is having a hard time *concentrating* when initiating tasks.

The items that loaded higher on F2 (items 8-14), also share a common theme in the descriptions of items. They are more about whether the respondent's *feelings* and *social skills* have been affected by medication use. Only item number 9 is slightly different from this theme, but not entirely. Item number 9 is more about whether the respondent has felt *less motivated* to initiate leisure activities. This item description is a mix between both themes of F1 and F2, it is somewhat about both a lack of motivation *and* social engagement.

After interpreting the results, it seems that the factor structure applies to the description of items, but it should be considered whether item number 9, „*du ikke har haft overskud til dine fritidsaktiviteter, f.eks. sport og se TV?*”, should rather be listed as an item of F1 instead of F2. Also, whether item 1, „*du har haft svært ved at koncentrere dig i forbindelse med arbejde eller daglige aktiviteter?*”, should be listed as an item of F2 instead of F1.

The correlation matrix from PCA reveals that all items correlate fairly highly. Few items correlate over 0.80, but it is not necessary to consider eliminating one of the items because none of them correlate particularly highly, or over 0.90. If the items would have correlated over 0.9 it would be very likely that the items were measuring the same (Field, 2000).

B) Three-factor structure

For this study, the factor structure of D-MRQoL scale resulted in a two-factor structure with the eigenvalue cut-off based on Kaiser's criterion or above 1.0. As mentioned earlier, Tseng et al. used this criterion when validating the original version of MRQoL scale in Taiwan.

For a further evaluation of the number of factors to retain in factor analysis of the D-MRQoL scale, it is possible to use another criterion, e.g. Jolliffe's criterion. Jolliffe reported that Kaiser's criterion is too strict and recommended retaining factors above 0.70 (Jolliffe, 1972). If the eigenvalue cut-off for the factor analysis conducted in this study was lowered to 0.7, then the D-MRQoL revealed a three-factor structure.

When the factor loadings for the three-factor structure are analyzed, it seems that items number 2-7 loaded higher on Factor 1 (F1), items 8, 9, 13 and 14 on Factor 2 (F2), and items 1, 10, 11 and 12 on Factor 3 (F3). In comparison with the two-factor structure where there was very little difference in factor loadings on each factor for item number 1, for the three-factor structure, the same item 1 loaded higher on Factor 3. The item is sharing the third factor with items 10-12. Furthermore, these items share a common theme about whether the respondent has felt as being more *down-hearted* and/or *emotional* towards others. For Factor 2, the description of items indicates whether the respondent has felt a lack of will for a *social engagement*. Items of Factor 1, share the same theme as for the two-factor structure, whether the respondent has felt as having less *energy* or *strength* to initiate some tasks or normal activities.

The risk of overestimation in the number of factors extracted has been argued for both criteria, Kaiser's and Jolliffe's criteria. Even though extracting too many factors can cause undesirable error variance, extracting too few factors might result in leaving out valuable common variance (Field, 2009). When the eigenvalue cut-off is set as 0.7, none of the items of the D-MRQoL scale are close to being equally loaded on the three factors. Therefore, the analysis of which items load onto which factor seemed to be more clear for the three-factor structure, in comparison to the two-factor structure that had two items with similar loadings on F1 and F2. Furthermore, the three factors accounted for 78,1% of the total variance, where the two-factor structure accounted for 72,8% of total variance.

5.3.2.2. Internal consistency reliability

Results indicated acceptable internal consistency reliability with Cronbach's alpha being higher than 0.7 for all three evaluations (Streiner, 2003). For the overall 14-item D-MRQoL scale, Cronbach's alpha coefficient was 0.96, and for the two extracted factors, it was 0.95 for Factor 1, and 0.92 for Factor 2. This means, that the overall 14-item DMRQoL scale has a high internal consistency, where items are closely related and are probably measuring the same underlying construct. Furthermore, from this result, it can be interpreted that items of Factor 1 are probably measuring the same phenomena, and items of Factor 2 are probably measuring the same phenomena.

5.3.2.3. Construct validity

The decision to use Spearman's Rho correlation, instead of, e.g. Pearson's correlations, was based on the idea that Spearman's method is often used when evaluating correlations between ordinal variables, and if data is not assumed to be normally distributed (Field, 2009) which was the case in this study.

Results for the construct validity were evaluated in terms of hypotheses that were anticipated when measures were selected for the study. Results indicate that the D-MRQoL scale is somewhat valid in terms of convergent validity. Results did not confirm all the hypotheses regarding correlations. Of two hypotheses anticipated for convergent validity, only one was accepted. Results accepted that the *concern* subscale of BMQ-Specific correlated statistically significantly and negatively with D-MRQoL scale. But no correlation existed between D-MRQoL and the *necessity* subscale of BMQ-Specific. Results for the discriminant validity demonstrated a positive and significant correlation of D-MRQoL scale with the adherence scale, DMARS-4. Such result is contrary to hypothesis and indicates that scores on the D-MRQoL scale are related to medication adherence.

The developers of MRQoL scale suggested in the Taiwanese study, that a measure of satisfaction with medication, The Treatment Satisfaction Questionnaire for Medication (TSQM) (Atkinson et al., 2004), would be used in further studies, especially to establish convergent validity. In the initial steps of this study, before going into testing of the D-MRQoL scale, it was decided to use a Danish version of the TSQM scale to establish convergent validity. However, it was decided to change that decision and use the Specific scale of Beliefs about Medicines Questionnaire instead of TSQM. The reason was because of the description of TSQM items. The TSQM scale is more specific concerning "medicine X"

in contrast to the BMQ scale which has been more used concerning “a drug class”, that can be different medicines but of the same kind. Therefore, the BMQ-Specific scale was considered more applicable to a population of patients taking different medicines to establish the convergent validity of the D-MRQoL.

When selecting a measure to establish the convergent validity of a scale, that selected measure has to have the same, or at least similar, construct as the scale, because the scores on the two measures are hypothesized to correlate. The results for the convergent validity of the D-MRQoL came as a surprise, where only one hypothesis was accepted. No correlation existed between total scores of the D-MRQoL scale and the subscale *necessity* of the BMQ scale. On a range of possible total scores from 5-25 for the BMQ *necessity* subscale, the mean value for the subscale was 9.08. Lower total scores of the *necessity* subscale indicate beliefs about medicines to be more necessary. The interpretation of this result is that it seems like the majority of the study population believes that medicines are necessary, even though no correlation existed between the scores of the *necessity* subscale and the D-MRQoL scale. Possible reasons that could have influenced the lack of correlation, e.g. the size of the sample, lack of variability in respondents’ responses, reporting bias of the participants, and the description of BMQ items being too strict. A generic health-related quality of life measure, such as SF-36 or EuroQoL, could be recommended to establish the convergent validity of the D-MRQoL in future studies.

The decision to select the DMARS-4 to establish discriminant validity was based on ideas from the authors of MRQoL in Taiwan, that D-MRQoL responses do not reflect the medication adherence of the respondents. In the Taiwanese study, a medication adherence scale was used for establishing discriminant validity. The result of this study is that DMARS-4 correlates positively and significantly with D-MRQoL. Such a result indicates that medication-related quality of life is related to medication adherence. It could be that this specific group of polypharmacy patients were very adherent to their medication, where the mean value of DMARS-4 total scores for the participants was 19.0. That mean value is very high on a scale score that ranges from 4-20. Because of the high mean value for self-reported adherence, participants that scored differently on the D-MRQoL scale and had total scores at separate ends of the scale, can have similar high medication adherence. When choosing a measure to establish discriminant validity, the researcher selects a measure that is theoretically different, and where it is hypothesized that no correlation exists between the measures. From this results, it would be recommended to use another measure than medication adherence scale to establish discriminant validity of a MRQoL scale.

The construct validity was examined for each extracted factor of the D-MRQoL scale, F1 and F2. Results for each factor are the same as for the overall 14-item DMRQoL scale.

For the measures used in this study. There exists a weak correlation between the DMARS-4 scale and both of the subscales of BMQ-Specific. These results align with other studies that demonstrate a correlation between adherence and BMQ-Specific (Menckeberg et al., 2008; Sweileh et al., 2014).

Face validity of the D-MRQoL scale was established, where the content of the measure appears to reflect the construct being measured. This result is assessed by judgment, both from experts and the participants in the study. A respondent likes that a scale has face validity, in other words, when answering a questionnaire, a respondent does not like to feel as being tricked (Litwin, 1995). Therefore, based on overall completeness of the scale and conversations with participants after they had completed the scale, the D-MRQoL has face validity. But that does not say how well the measure is assessing the construct. Even though convergent validity was somewhat established, further studies are needed to confirm the construct validity of the D-MRQOL scale, as well as the known-group validity.

5.3.3. Comparison of the translated version to the original version of MRQoL

The result of this study is that the Danish version is not comparable to the original Taiwanese version regarding the factor structure. The Danish version of Medication-Related Quality of Life scale showed a two-factor structure, where items number 1-7 loaded on Factor 1 and items 8-14 on Factor 2. However, the original version showed a three-factor structure. Items of the two versions grouped somewhat differently on the extracted factors. Even though construct validity was somewhat established for both versions, there is a need for further study in both cases. Known-group validity was established for the original version, but not for this study. Both versions have high internal consistency reliability.

5.3.4. Evaluation of the three-factor structure of the original MRQoL and D-MRQoL

Exploratory factor analysis (using Principal component analysis) of the original Taiwanese scale resulted in extracting three factors, interpreted as: *role limitations caused by medication* (items 1-6), *self-control* (items 10-14), and *vitality* (items 7-9). In this study, when the eigenvalue for extracting factors was set as the same as in the test of the original version, or 1.0 and higher, the D-MRQoL only showed two factors. However, when the eigenvalue was lowered to 0.7 the D-MRQoL scale revealed a three-factor structure. In comparison to the

original MRQoL, the internal consistency reliability of the three-factor D-MRQoL scale was higher for the overall scale and all the three factors.

Analysis of the description of items, and how the items grouped together, captured researcher's attention while evaluating the three-factor structure of D-MRQoL. The items grouped differently than the original version. For instance, when examining Factor 3 (*vitality*) of the original MRQoL scale one item is about having difficulties concentrating while the other two items are about having less energy to initiate tasks. This may indicate that the face validity of the factors in the original version is not that clear. Furthermore, in practice, it would possibly be easier to interpret results of the three-factor structure D-MRQoL scale to assess patient's 'soft' outcomes because the factors are more clearly defined and seem to have higher face validity.

The three-factor structure of the Danish version of the Medication-Related Quality of Life scale was judged to have higher face validity by the research team compared to the original. The items grouped differently and more clearly within each factor in comparison to the original version. The first factor was interpreted as *energy*, the second as *social engagement* and the third as *negative affect*. When looking at each item in relation to these three domains they seem sensible. This is an unexpected finding that needs further investigation.

5.4. Strengths and limitations

The study is the first of its kind to translate the original Medication-Related Quality of Life scale into another language. No other measure exists in Danish to measure the effect of medication use on patient's health-related quality of life. The 14-item scale is rather brief, it takes within 10 minutes to complete, and is practical to administer. The translation phase involved forward-translation of the MRQoL scale into Danish, and backward-translation into Chinese. A pilot-test was conducted to assure clarity of the instructions and description of items. For the psychometric testing of the D-MRQoL scale in a population of patients with polypharmacy, the translated version (n = 120) was tested in larger sample than the original version (n = 99). The majority of the data collection took place in two types of settings, community pharmacies and a hospital department. This offers the possibility to compare differences in respondents' responses, and to discuss which location generates more suitable approach to ask for participation. For the community pharmacies, the data collection was implemented at different times during the day to increase the probability of including different

pharmacy clients. While answering the scale, respondents had to think about the past four weeks to recall their perception of medication use to respond to items, not the past few months or year, as many other scales which lowers the risk of recall bias.

The limitations of this study are the rather small sample size and the participants were a rather homogeneous group. This can lead to lower variability in responses on the 6-point Likert scale of the D-MRQoL scale. Many customers at the community pharmacies, and patients in the department's hospital refused participation for many different reasons, where those who declined could have been more ill individuals. There is a possibility of social desirability bias in respondents' responses because of the location of the research. Furthermore, during the translation phase only one back-translation was generated when two were recommended. Regarding the decision of changing the sequence of D-MRQoL items, it is not possible to predict whether respondents would have responded differently if the change had not been made, but it is certain that the responses would have been subject to error as the pilot phase of the study showed that respondents had difficulties starting with the original item 1.

5.5. Future research

This study of translation and validation of the Danish version of Medication-Related Quality of Life scale should be considered as a basis for further research within clinical practice, that aims for a patient-centered approach, where the measure can be applied in the clinic. Further testing of the scale in terms of applicability in different patient groups is suggested, especially in groups at risk of experiencing lower health-related quality of life because of medication use or any related problems.

Validity should be further investigated as the construct validity of the D-MRQoL scale is not fully established. A study that implements a Confirmatory factor analysis (CFA) on the data set of this study is suggested to test for the model fit of the D-MRQoL both of the original scale's factor structure and the other two possible factor structures found for D-MRQoL.

Furthermore, it would be interesting to see if two or three factors would be extracted in Exploratory factor analysis, with the eigenvalue cut-off set to 1.0, if the data collection of this study would be continued and would aim to collect data from at least 200 participants.

Further research is suggested on the responsiveness of the D-MRQoL scale to medication or dosage changes in a population of patients with polypharmacy. The D-MRQoL

scale could be tested to measure the effect of a clinician's intervention on patient's health-related quality of life (HRQoL). It is suggested that the responsiveness study would focus on clinical pharmacists' interventions, such as medication reviews.

The Medication-Related Quality of Life scale is now in development in two languages. Further research should aim to translate the MRQoL into other European languages, and validate the scale in a population of polypharmacy patients. For instance, if the scale would be translated into English, a bilingual sample of patients could complete the scale in both languages to evaluate the equivalence of the results. As the culture of English speakers is closer to the Danish culture and the two languages are much more related a translation of MRQoL from Chinese into English would provide valuable information about how cultural differences may play into the psychometric properties of the scale.

The researcher envisages that in the future, the Medication-Related Quality of Life scale will after further validation, be used to identify those who perceive their medication use as affecting their health-related quality of life. It could be a valuable assessment tool for a clinician who evaluates if an intervention is necessary, or should be initiated, to improve patient's health-related quality of life.

6. CONCLUSIONS

The psychometric properties of the Danish version of Medication-Related Quality of Life scale (D-MRQoL) showed a two-factor structure with high internal consistency reliability. The construct validity of the scale was established somewhat in terms of convergent validity and face validity, but further validity studies are needed. The MRQoL scale is now available in Danish, but is still under development. The translated version is not satisfactorily comparable to the original version because the factor structure diverges. The results of this study generate a valuable contribution to further development of the MRQoL scale, and provide a valuable input to the authors of the original scale in Taiwan.

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Specialestuderende: Elin Dröfn Jónsdóttir
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Februar/Marts 2017

DD/MM/YYYY:

Klokkeslæt:

Apotek:

Studerende:

I denne spørgeskema-undersøgelse vil du blive præsenteret for en række spørgsmål om dine holdninger til din medicin.
For hvert spørgsmål kan du vælge det svar der bedst passer til din holdning.

Deltagelsen er frivillig og fuldstændig anonym.

Svarene anvendes af en farmacistuderende ved Københavns Universitet i hendes speciale. Specialeprojektet handler om at måle tilfredshed og livskvalitet i forbindelse med brug af medicin.

Spørgeskemaet er på i alt 4 sider med 32 spørgsmål og tager omkring 10-15 minutter at besvare.

På forhånd, mange tak for din besvarelse!

Appendix A

Spørgeskema om medicinbrug og livskvalitet

De forskellige spørgsmål på næste side er relevante for dit medicinbrug, som i løbet af den seneste måned har påvirket din dagligdag. For hvert spørgsmål, vælg venligst det svar, der passer bedst på det du har oplevet.

For hvert udsagn på næste side bedes du med en ring markere det tal (1, 2, 3, 4, 5 eller 6) der bedst beskriver din holdning til spørgsmålet.

Har du inden for den seneste måned i forbindelse med brugen af medicin følt, at...

	Aldrig	Sjældent	Nogle gange	Ofte	Meget ofte	Altid
1. du har haft svært ved at koncentrere dig i forbindelse med arbejde eller daglige aktiviteter?	1	2	3	4	5	6
2. du har været træt, udmattet og haft svært ved at overskue arbejde eller daglige aktiviteter?	1	2	3	4	5	6
3. du har haft færre dage med fuld energi?	1	2	3	4	5	6
4. du har brugt mindre tid på arbejde eller daglige aktiviteter?	1	2	3	4	5	6
5. du har haft mindre overskud til at klare arbejdsopgaver eller daglige aktiviteter i forhold til det, som du gerne vil?	1	2	3	4	5	6
6. du har klaret færre af dine arbejdsopgaver eller andre aktiviteter?	1	2	3	4	5	6
7. du har skullet anstrenge dig for eller haft sværere ved at gennemføre arbejdsopgaver eller daglige aktiviteter?	1	2	3	4	5	6
8. du har haft svært ved at deltage i socialt samvær med familie eller venner?	1	2	3	4	5	6
9. du ikke har haft overskud til dine fritidsaktiviteter, f.eks. sport og se TV?	1	2	3	4	5	6

	Aldrig	Sjældent	Nogle gange	Ofte	Meget ofte	Aldid
10. du har været frustreret eller ked af det?	1	2	3	4	5	6
11. du har været en belastning for andre?	1	2	3	4	5	6
12. du har været bange for at skuffe andre?	1	2	3	4	5	6
13. det har været nødvendigt at du aflyste en aftale eller en fælles aktivitet?	1	2	3	4	5	6
14. du har været nødt til at afbryde arbejde eller daglige aktiviteter?	1	2	3	4	5	6

Din brug af medicin

Vi er interesserede i at få noget at vide om, i hvor høj grad du følger den anbefalede medicin. For hvert spørgsmål nedenfor skal du sætte en ring om det tal (1, 2, 3, 4 eller 5), der bedst beskriver hvor ofte, du oplever følgende udsagn.

1. Nogle mennesker forsøger at undgå at tage **medicin**. Gør du det?

1	2	3	4	5
Meget ofte	Ofte	Nogle gange	Sjældent	Aldrig

2. Nogle mennesker glemmer at tage deres **medicin**. Sker det for dig?

1	2	3	4	5
Meget ofte	Ofte	Nogle gange	Sjældent	Aldrig

3. Nogle mennesker springer over en dosis af deres **medicin** eller ændrer på doserne, så de passer til deres eget behov. Gør du det?

1	2	3	4	5
Meget ofte	Ofte	Nogle gange	Sjældent	Aldrig

4. Har bivirkninger ved noget af den **medicin**, du har anvendt, forhindret dig i at tage denne medicin?

1	2	3	4	5
Meget ofte	Ofte	Nogle gange	Sjældent	Aldrig

Din mening om din medicin

1. Mit nuværende helbred afhænger af min **medicin**

1	2	3	4	5
Meget enig	Enig	Usikker	Uenig	Meget uenig

2. Det bekymrer mig, at jeg er nødt til at bruge **medicin**

1	2	3	4	5
Meget enig	Enig	Usikker	Uenig	Meget uenig

3. Jeg kan ikke leve uden **medicin**

1	2	3	4	5
Meget enig	Enig	Usikker	Uenig	Meget uenig

4. Jeg er sommetider bekymret for langtidsbivirkningerne af min **medicin**

1	2	3	4	5
Meget enig	Enig	Usikker	Uenig	Meget uenig

5. Uden **medicin** ville jeg blive meget syg

1	2	3	4	5
Meget enig	Enig	Usikker	Uenig	Meget uenig

6. Min **medicin** er en gåde for mig

1	2	3	4	5
Meget enig	Enig	Usikker	Uenig	Meget uenig

7. Mit fremtidige helbred afhænger af min **medicin**

1	2	3	4	5
Meget enig	Enig	Usikker	Uenig	Meget uenig

8. **Medicin** forstyrrer mit liv

1	2	3	4	5
Meget enig	Enig	Usikker	Uenig	Meget uenig

9. Jeg er sommetider bekymret for at blive afhængig af **medicin**

1	2	3	4	5
Meget enig	Enig	Usikker	Uenig	Meget uenig

10. **Medicin** beskytter mig mod at få det værre

1	2	3	4	5
Meget enig	Enig	Usikker	Uenig	Meget uenig

Baggrundsspørgsmål:

Til sidst er der 4 spørgsmål som fortæller lidt om dig.

1. Køn:

- ☐₁ mand
☐₂ kvinde

2. Alder:

- ☐₁ yngre end 60 år
☐₂ 60-69 år
☐₃ 70 år eller ældre

3. Hvad er din højeste afsluttede uddannelse?

- ☐₁ Folkeskole
☐₂ Faglært håndværker
☐₃ Gymnasium/handelsskole
☐₄ Kort videregående uddannelse (mindre end 3 års studie)
☐₅ Længere videregående uddannelse (3 år, eller længere tid)

4. Hvor mange lægemidler tager du regelmæssigt?

- ☐₁ 5
☐₂ 6-10
☐₃ flere end 10

Tusind tak for besvarelsen!

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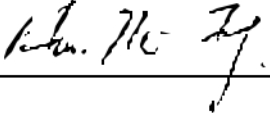
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Date: 2016/11/30

用藥相關生活品質量表

下列各項問題是關於過去一個月內針對您服用藥物的相關問題所帶來的感受，請針對每一問題選一最符合您感受的答案。

在過去一個月），您是否曾因為服用藥物的相關問題，而在生活方面有下列任何的問題？

	(每行請(圈選一項答案					
	大 部一 分直					
在過去一個月內，有多少時候因為 您服用藥物的相關問題，讓您感到…	從 很 有 經 時 都	不 少 時 常 間 是				
1. 做工作或日常活動的時間減少	1	2	3	4	5	6
2. 工作量或日常活動量比您想要完成的較少	1	2	3	4	5	6
3. 可以做的工作或其他活動的種類受到限制	1	2	3	4	5	6
4. 做工作或日常活動有困難或更加吃力	1	2	3	4	5	6
5. 您與親人或好友的相處關係受到干擾	1	2	3	4	5	6
6. 妨礙您的休閒活動，例如運動或看電視	1	2	3	4	5	6
7. 工作或日常活動的專注能力變差	1	2	3	4	5	6
8. 覺得筋疲力竭而無法執行日常活動或工作	1	2	3	4	5	6
9. 充滿活力的日數減少	1	2	3	4	5	6
10. 覺得挫折或悶悶不樂	1	2	3	4	5	6
11. 覺得自己是別人的負擔	1	2	3	4	5	6
12. 害怕讓別人失望	1	2	3	4	5	6
13. 需要取消已經約定好的約會或活動聚會	1	2	3	4	5	6
14. 需要停止工作或日常活動來處理服用藥物的相關問題	1	2	3	4	5	6

Medication Related Quality of Life Scale (MRQoL)

The following items are about how you view the use of medications and the nature of your experience of these drugs. Please read each of the following statements and circle the one answer that comes closest to the way you have been feeling.

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of medication**

(Choose one option for each item)

During the <u>past 4 weeks</u> , how you feel and how things have been with you as a result of any medication-related problems.	A good					
	None of the time	A little of the time	Some of the time	bit of the time	Most of the time	All of the time
How much of the time during the <u>past 4 weeks</u> ...						
1. cut down the amount of time you spent on work or daily activities.	1	2	3	4	5	6
2. accomplish the work less than you would like.	1	2	3	4	5	6
3. were limited in the work or other daily activities.	1	2	3	4	5	6
4. took extra effort or had difficulty performing the work or daily activities.	1	2	3	4	5	6
5. interfered with your social activities with family or friends.	1	2	3	4	5	6
6. interfered with your recreational activities, such as exercise or watching TV.	1	2	3	4	5	6
7. had difficulty focusing on the task at hand or daily activities.	1	2	3	4	5	6
8. had difficulty performing the work or daily activities as a result of feeling worn out.	1	2	3	4	5	6
9. reduced the number of days feeling full of pep.	1	2	3	4	5	6
10. felt frustrated or downhearted.	1	2	3	4	5	6
11. thought of yourself as a burden to others.	1	2	3	4	5	6
12. worried about disappointing others.	1	2	3	4	5	6
13. had to cancel scheduled appointments or meetings.	1	2	3	4	5	6
14. didn't do work or other activities as a result of medication problems.	1	2	3	4	5	6

Spørgeskema om medicinbrug og relevant livskvalitet

De forskellige spørgsmål nedenunder er relevante for dit medicinbrug, som i løbet af den seneste måned har påvirket dig. For hvert spørgsmål, vælg venligst det svar, der bedst matcher dine oplevelser.

Har du på grund af indtagelse af medicin i løbet af den seneste måned haft nogen af de følgende problemer i dit dagligliv?

(Sæt kun ét kryds for hvert spørgsmål)

I løbende af den seneste måned, har du på grund af
indtagelse af medicin følt, at...

	Aldrig	Meget lidt	Nogen gange	Tit	Fleste tid	Altid
1. Du har mindre tid til arbejde eller daglige aktiviteter	1	2	3	4	5	6
2. Den arbejdsmængde eller daglige aktiviteter, som du ønsker at udføre, bliver formindsket	1	2	3	4	5	6
3. Du bliver begrænset i arbejdsopgaver eller andre aktiviteter, som du plejer at kunne udføre	1	2	3	4	5	6
4. Udførelse af arbejde eller aktiviteter bliver vanskelige eller hårde for dig	1	2	3	4	5	6
5. Dine relationer til familie og venner bliver forstyrret	1	2	3	4	5	6
6. Dine fritidsaktiviteter bliver forhindret, f.eks. sport og se TV	1	2	3	4	5	6
7. Din koncentration i arbejde eller dagligliv bliver forringet	1	2	3	4	5	6
8. Du er mere træt og ude af stand til at udføre daglige aktiviteter eller arbejde	1	2	3	4	5	6
9. Du har færre dage med fuld energi	1	2	3	4	5	6
10. Du er frustreret og ulykkelig	1	2	3	4	5	6

11. Du er en byrde for andre	1	2	3	4	5	6
12. Du er bange for at andre vil blive skuffet	1	2	3	4	5	6
13. Det er nødvendigt at du aflyse en aftale eller en fælles aktivitet	1	2	3	4	5	6
14. Det er nødvendigt at stoppe med at arbejde eller daglige aktiviteter for at løse relevante medicinske spørgsmål eller problemer	1	2	3	4	5	6

Spørgeskema om medicinforbrug og livskvalitet

De nedenstående spørgsmål drejer sig om Deres indtryk vedrørende problemer i forbindelse med Deres medicinforbrug i den sidste måned. Besvar hvert spørgsmål ved at finde det svar, der passer bedst på Dem.

Inden for den sidste måned: Har De oplevet nogle problemer ved at have taget noget medicin, og at det har påvirket Deres dagligdag?

(Besvar hvert spørgsmål ved at sætte et cirkel om svar)

Inden for den sidste måned: Har De oplevet noget problem med Deres medicinforbrug, som har følgende påvirkning:

Aldrig - Sjældent - Somme tider - Tit - En hel del - Altid

1. Har formindsket tid til arbejde eller daglige aktiviteter
2. Er arbejdsomængde eller daglige aktiviteter blevet mindre i forhold til det, som De gerne vil
3. Været begrænset i arbejde eller andre typer af aktiviteter
4. Har haft svært / sværere ved at gennemføre arbejde eller daglige aktiviteter
5. Har haft svært ved at være sammen med familie og venner
6. Blevet forstyrret i Deres fritidsaktiviteter, f.eks. sport eller se TV
7. Har haft svært ved at koncentrere i arbejde eller daglige aktiviteter
8. Følt Dem træt og udmattet og haft svært ved at overskue arbejde eller daglige aktiviteter
9. Følt Dem mindre frisk fra dag til dag
10. Følt Dem trist og deprimeret
11. Følt Dem som en belastning for andre mennesker
12. Er bange for at skuffe andre
13. Blevet nødt til at aflyse planlagte møder og arrangementer
14. Blevet nødt til at afbryde arbejde eller daglige aktiviteter for at løse problemer, som opstår i forbindelse med indtagelse af medicin

Har du inden for den seneste måned i forbindelse med brugen af medicin følt, at...

	Aldrig	Sjældent	Nogle gange	Ofte	Meget ofte	Altid
1. du har haft mindre tid til arbejde eller daglige aktiviteter?	1	2	3	4	5	6
2. du har haft mindre overskud til at klare arbejdsopgaver eller daglige aktiviteter i forhold til det, som du gerne vil?	1	2	3	4	5	6
3. du har klaret færre af dine arbejdsopgaver eller andre aktiviteter?	1	2	3	4	5	6
4. du har skullet anstrenge dig for eller haft sværere ved at gennemføre arbejdsopgaver eller daglige aktiviteter?	1	2	3	4	5	6
5. du har haft svært ved at deltage i socialt samvær med familie eller venner?	1	2	3	4	5	6
6. du ikke har haft overskud til dine fritidsaktiviteter, f.eks. sport og se TV?	1	2	3	4	5	6
7. du har haft svært ved at koncentrere dig i forbindelse med arbejde eller daglige aktiviteter?	1	2	3	4	5	6
8. du har været træt, udmattet og haft svært ved at overskue arbejde eller daglige aktiviteter?	1	2	3	4	5	6
9. du har haft færre dage med fuld energi?	1	2	3	4	5	6
10. du har været frustreret eller ked af det?	1	2	3	4	5	6
11. du har været en belastning for andre?	1	2	3	4	5	6
12. du har været bange for at skuffe andre?	1	2	3	4	5	6
13. det har været nødvendigt at du aflyste en aftale eller en fælles aktivitet?	1	2	3	4	5	6
14. du har været nødt til at afbryde arbejde eller daglige aktiviteter?	1	2	3	4	5	6

Appendix F

Pre-test: D-MRQoL scale

Evaluation of the instructions, items and response format clarity

Dichotomous Scale

Køn:

- ☐ Kvinde
- ☐ Mand

Alder:

- ☐ Ældre end 65 år
- ☐ Yngre end 65 år

Jeg synes instruktionerne er klar:

- ☐ Ja
- ☐ Nej

Jeg synes svar skemaet er klart:

- ☐ Ja
- ☐ Nej

Om spørgsmålene

Jeg synes spørgsmålene er klar:

Spørgsmål	Ja	Nej
1	<input type="checkbox"/>	<input type="checkbox"/>
2	<input type="checkbox"/>	<input type="checkbox"/>
3	<input type="checkbox"/>	<input type="checkbox"/>
4	<input type="checkbox"/>	<input type="checkbox"/>
5	<input type="checkbox"/>	<input type="checkbox"/>
6	<input type="checkbox"/>	<input type="checkbox"/>
7	<input type="checkbox"/>	<input type="checkbox"/>
8	<input type="checkbox"/>	<input type="checkbox"/>
9	<input type="checkbox"/>	<input type="checkbox"/>
10	<input type="checkbox"/>	<input type="checkbox"/>
11	<input type="checkbox"/>	<input type="checkbox"/>
12	<input type="checkbox"/>	<input type="checkbox"/>
13	<input type="checkbox"/>	<input type="checkbox"/>
14	<input type="checkbox"/>	<input type="checkbox"/>

Hvis valgt er “Nej”

Give forslag til hvordan man kan omskrive spørgsmålene, svar skemaet eller instruktionerne for at gøre teksten mere klar.

Instruktionerne	
Svar skemaet	
Spørgsmål no.	
Spørgsmål no.	
Spørgsmål no.	

Data collectors

EDJ = Elín Dröfn Jónsdóttir

ZÖ = Zeynep Özkan

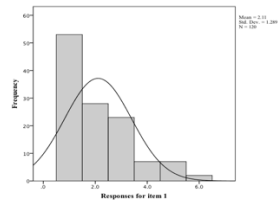
CS = Cecilie Schmidt

IVR = Ina Vierø Rinder

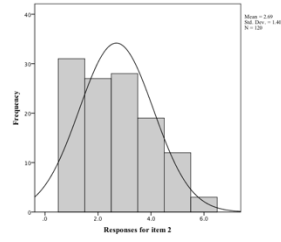
Item mean score for missing values

Scale	Item	Mean score
D-MRQoL	4	3
D-MRQoL	7	3
D-MRQoL	12	2
BMQ-Specific	3	2
BMQ-Specific	5	2
BMQ-Specific	6	3
BMQ-Specific	8	3
BMQ-Specific	9	3

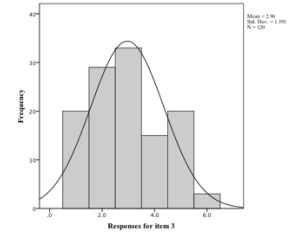
Appendix H and I



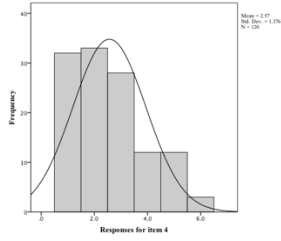
Item1



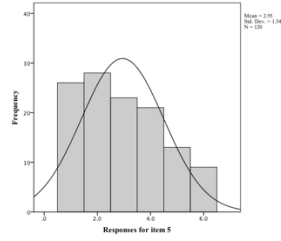
Item 2



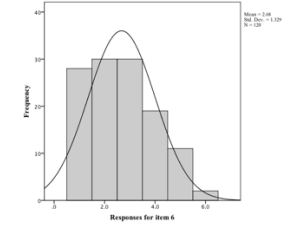
Item 3



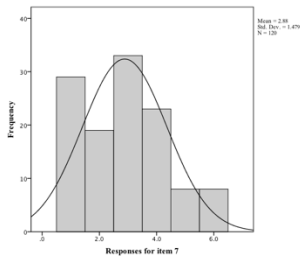
Item 4



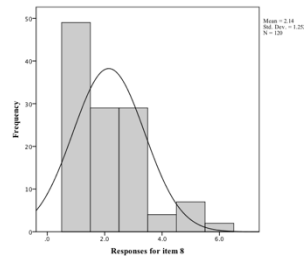
Item 5



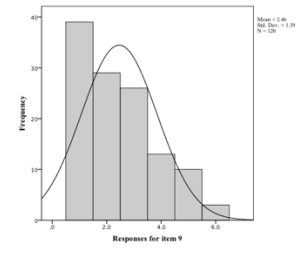
Item 6



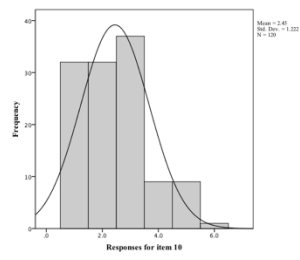
Item 7



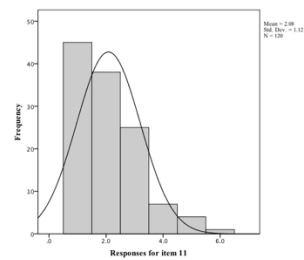
Item 8



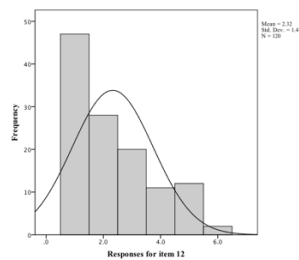
Item 9



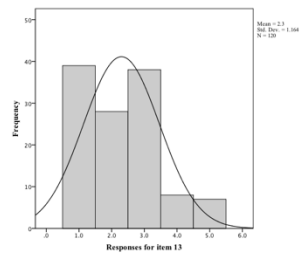
Item 10



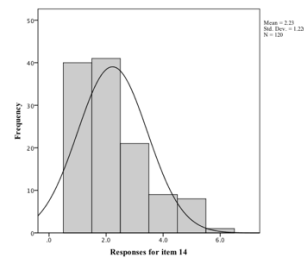
Item 11



Item 12



Item 13



Item 14

Appendix J

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	8.915	63.676	63.676	8.915	63.676	63.676
2	1.275	9.107	72.783	1.275	9.107	72.783
3	.746	5.330	78.113	.746	5.330	78.113
4	.546	3.902	82.015			
5	.471	3.367	85.382			
6	.354	2.526	87.908			
7	.341	2.432	90.340			
8	.290	2.072	92.412			
9	.258	1.842	94.254			
10	.242	1.725	95.979			
11	.229	1.639	97.619			
12	.127	.906	98.524			
13	.117	.834	99.359			
14	.090	.641	100.000			

Extraction Method: Principal Component Analysis.

Item-Total Statistics

D-MRQoL	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item- Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Item 1	58.2917	193.889	.706	.598	.953
Item 2	58.8750	188.631	.787	.745	.951
Item 3	59.1417	190.089	.752	.706	.952
Item 4	58.7500	189.315	.784	.723	.952
Item 5	59.1333	183.713	.828	.841	.951
Item 6	58.8583	187.736	.862	.850	.950
Item 7	59.0667	184.651	.847	.830	.950
Item 8	58.3250	192.809	.762	.699	.952
Item 9	58.6417	190.837	.732	.641	.953
Item 10	58.6333	195.612	.696	.615	.954
Item 11	58.2667	198.214	.680	.630	.954
Item 12	58.5083	191.311	.704	.694	.954
Item 13	58.4833	193.764	.795	.799	.952
Item 14	58.4083	195.034	.711	.714	.953