Setting-sensitive Konzeptualisierung und Erfassung der Lebensqualität in der telemedizinischen Versorgung

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Dipl.-Psych. Klara Greffin

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Dekan: Prof. Dr. Gerald Kerth

1. Gutachterin: Prof. Dr. Silke Schmidt-Schuchert

2. Gutachterin: Prof. Dr. Ulrike Ravens-Sieberer

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Setting-sensitive conceptualisation and assessment of quality of life in telemedical care

Content

Appendix

Overview: Studies of the doctoral thesis

This cumulative doctoral thesis comprises a series of five studies. The corresponding articles can be found in the Appendix.

Paper I

Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2021). Setting-sensitive conceptualization and assessment of quality of life in telemedical care - study protocol of the Tele-QoL project. *International Journal of Environmental Research and Public Health*, *18* (19). https://doi.org/10.3390/ijerph181910454

Paper II

Greffin, K., Muehlan, H., Rosenkranz, E., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2022). *Telemedicine and patient-reported outcomes in chronic conditions: concordance and discrepancy of purpose, concepts, and methods of measurement - a systematic literature review.* [Manuscript submitted for publication]. Department Health and Prevention, University of Greifswald.

Paper III

Greffin, K., Schmidt, S., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Muehlan, H. (2021). Same same - but different: using qualitative studies to inform concept elicitation for quality of life assessment in telemedical care: a request for an extended working model. *Health and Quality of Life Outcomes*, 1–14. https://doi.org/10.1186/s12955-021-01807-8

Paper IV

Muehlan, H., **Greffin, K.**, van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2022). *Towards adjunct setting-related quality of life assessment in telemedicine - cognitive debriefing, expert rating and pilot testing of the Tele-QoL instrument.* [Manuscript submitted for publication]. Department Health and Prevention, University of Greifswald.

Paper V

Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Speerforck, S., Schomerus, G., & Schmidt, S. (2022). *Measuring context that matters: Validation of the modular Tele-QoL patient-reported outcome and experience measure.* [Manuscript submitted for publication]. Department Health and Prevention, University of Greifswald.

1. Background

1.1 Current challenges in healthcare contexts

The German healthcare system is facing numerous challenges (Bundesministerium für Gesundheit, 2020). For instance, in light of general demographic change, the share of older people in society is steadily increasing (Robert Koch Institut, 2015). Consequently, the prevalence of chronic diseases, which strongly correlates with age (Dinkel, 2008), is on the rise (Robert Koch Institut, 2015). *Chronic diseases* are characterised as long-lasting and only partly curable. They require permanent or recurrent treatment and cause an increased use of healthcare services (Lange & Ziese, 2010). Conditions like arthritis, cardiovascular diseases, diabetes, cancer, and chronic respiratory diseases are currently among the most common and economically significant health problems in Germany (Lange & Ziese, 2010; Robert Koch Institut, 2021). Additionally, multi-morbidity is a widespread phenomenon (Nowossadeck, 2012). About 38 - 43% of the German adult population are affected by one or more chronic diseases (Robert Bosch Stiftung, 2021), which will likely lead to an increased demand for care. However, the German healthcare system is currently perceived to still focus on acute care rather than sustainable management of chronic conditions (Robert Bosch Stiftung, 2021). As a consequence, a lack of integrated patient-centred care, systematic patient education, and promotion of health literacy has been detected (Robert Bosch Stiftung, 2021), especially in rural regions with a low population density (van den Berg et al., 2015). Due to this deficit of adequate structures, the therapy of chronically ill persons continues to be challenging for healthcare professionals and costly for the respective funding providers. On the side of patients and their families, a chronic disease often causes limitations in everyday life due to symptoms, the effort associated with a respective treatment, functional impairments, or a lack of autonomy (Greffin, Schmidt, et al., 2021). These circumstances can result in a reduced socio-cultural *participation* (Scharn et al., 2019).

The treatment of *mental illnesses* within the German health system comes with multiple challenges, too. Jacobi and colleagues (2014) determined a 12-month prevalence of 27.7% for mental illnesses in the German adult population. The main groups of conditions in terms of prevalence are anxiety disorders (15.3%), affective disorders (9.3%) and substance use disorders (5.7%). About 40 - 50% of the cases suffer from multiple psychiatric disorders that often have a high recurrence rate, which makes diagnosis and treatment particularly challenging (Jacobi et al., 2014; Marx et al., 2021). However, despite high prevalence rates of psychiatric disorders, only 25 - 30% of patients use traditional therapy (Nübling et al., 2014). Causes are systemic factors such as inadequate cooperation between healthcare professionals or long waiting times as well as patient-related factors such as fear of stigmatisation or lack of information (Watzke et al., 2015). Despite expanding treatment services such as full in-patient, partial in-patient as well as out-patient therapy options, no decrease in prevalence rates can be observed (Thom et al., 2019). The authors present various explanations for the lack of improvement, such as overall low usage of healthcare services, long waiting lists, and insufficient quality of healthcare services. Furthermore, pathogenic societal changes such as discrimination, social inequality and competitive pressure contribute to an increase in psychosocial stress and growing morbidity of mental illnesses (Mulder et al., 2017; Spießl & Jacobi, 2008). Finally, there are large regional differences with regard to the spatial distribution of outpatient care options that limit *access to care*. A deficit of continuous treatment, particularly in rural regions, considerably jeopardises therapeutic progress (van den Berg & Hoffmann, 2019), and thus harms patients, their families, the health system and society as a whole.

Treating chronic physical or mental diseases is about managing the disease and maintaining an acceptable Quality of Life (QoL) in order to enable patients to live in *conditional health* (Franzkowiak & Hurrelmann, 2018) rather than just about curing the disease or reducing symptoms. In reaction to the changing demands for care, a shift has been observed away from a solely curative care system towards a supportive health system in which both, objective and subjective medical outcomes, are evaluated (Albrecht, 1996; Cleary, 1997; Hamilton et al., 2017).

In order to meet modern care demands caused by increased needs of an ageing population and a simultaneous shortage of appropriate medical care and staff, digital options are increasingly being adopted to manage chronic physical and mental illnesses, for instance via telemedical care solutions (Corbett et al., 2020; Lucht & Schomerus, 2013; Pan American Health Organization, 2016).

1.2 The role of telemedical care solutions

Telemedicine (TM) plays an essential part in meeting current and future needs in the health sector (Christiansen, 2017). According to the definition of the German Medical Association (2015), the term telemedicine comprises various medical and therapeutic care concepts in which health services in the areas of diagnostics, therapy, and rehabilitation as well as decision-making advice are provided across spatial distances via information and communication technology. Therefore, TM supplements the care spectrum in almost all medical disciplines and across a broad spectrum of patient characteristics[1] (Bundesärztekammer, 2010b).

Using TM entails various *benefits* for patients and their families, involved healthcare professionals, and the overall healthcare system, and it ameliorates some of the current systemic insufficiencies (Hwei & Octavius, 2021). For instance, digital technologies enable location-independent disease management, which can reduce costs for all stakeholders including patients and their families, the health system and society (Demirci et al., 2021; Krüger-Brand, 2007). Location-independent care directly diminishes transport requirements and waiting time for patients (Demirci et al., 2021). Treatment uptake as well as continuity of care can be increased because temporal, infrastructural, or financial barriers are significantly lowered (van den Berg & Hoffmann, 2019). Another key advantage of location-independent care is the flexibility it provides which enables people to better integrate their therapy into their everyday life (Dinesen et al., 2019). Lastly, the patients' relatives also benefit as their daily life is impacted less by the patient's disease management (Hahnel et al., 2020).

Healthcare professionals support sustainable disease management by using TM care concepts. For example, this can be achieved by integrated care procedures, e.g. in form of enhanced communication between care providers and between care providers and patients (Baldwin et al., 2002), as well as using a broader and more detailed database for better-informed and data-driven treatment decisions (Marx et al., 2021). Regular distant monitoring of patients enables faster intervention in the event of a decline in health, which can sometimes prevent secondary illnesses, re-hospitalisation, or even improve survival rates (Herold et al., 2018; Koehler et al., 2018). A significant component from the perspective of the healthcare system is that TM-based care features greater accessibility compared to traditional care, which can foster a more geographically balanced distribution of health services. Thus, TM, if well planned and implemented, can possibly contribute to reducing *health equity* (Nouri et al., 2020). Finally, economic advantages through increased efficiency, faster communication, and better utilisation of existing resources are essential in order to be able to provide therapeutic care to more people in the future (Zens & Dolle, 2015),

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[1] Note: Please be aware that I exclusively refer to the complementary use of telemedical applications for adult patients with chronic physical and/or mental illnesses in the following explanations.

while the quality of care remains high (Herzer & Pronovost, 2021). The above-mentioned advantages highlight the potential of TM applications in making a decisive contribution to more accessible, efficient and sustainable disease management in the future.

The added value of using TM concepts became particularly evident in the latest challenge facing the healthcare system, the *SARS-CoV-2 pandemic* (Adorjan et al., 2021; Omboni et al., 2022). Main advantages include greater availability of medical or therapeutic services as well as independence from a certain location and external circumstances (Marx & Beckers, 2015). Thus, it became possible to provide care for those who were infected. These advantages contributed to the rapidly increasing number of innovations in TM applications (Zipfel et al., 2021).

While the wave of innovation in TM has been welcomed by many professionals (Bundesärztekammer, 2010a), it also carries *risks and challenges* that require mitigation. In recent years, many digital applications have been developed and tested in a relatively short time. This has led to considerable heterogeneity among the applications, combined with a lack of consistent and sustainable testing, because most applications were developed and implemented within the context of short-term research projects (Marx & Beckers, 2015). Solutions for overarching challenges, e.g. aspects of data security (Garg & Brewer, 2011; Gogia et al., 2016), have not yet been identified. In addition, comparatively little attention has been paid to the question of for whom TM applications might be rather unsuitable or may perhaps even involve risks.

In reaction to this situation, the legal framework has been adapted in Germany in recent years. For instance, the *Digital Healthcare Act*[2] provides starting points on how digital applications can be remunerated and transferred into standard care (Bundesanzeiger, 2019). The corresponding guidelines for implementation, i. e. the Fast-Track Process for Digital Health Applications (known in German by the acronym DiGa) according to Section 139e SGB V (Federal Institute for Drugs and Medical Devices, 2019), stipulate that the certification of TM solutions requires an extensive evaluation of digital applications with the explicit inclusion of the patient's perspective via valid quantitative assessments (Lantzsch et al., 2022). This regulation acknowledges that successful treatment is not exclusively based on improving objective parameters but also on aspects of the subjective health and well-being (Frost

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[2] In German: “Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation“ (Digitale-Versorgung-Gesetz – DVG)

et al., 2007). Furthermore, it reflects a modern understanding of *patient-centred care*, in which patients are seen as treatment partners who should be empowered to competently manage their illness (Cordier, 2014).

1.3 The patients' voice in telehealth

Patient-reported outcomes (PROs) and their respective measurements (PROMs) represent the patients' voice in telehealth. They are "based on a report that comes directly from the patient (…) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else" (U.S. Department of Health and Human Services Food and Drug Administration, 2009, p. 32). As such, PROs "directly reflect the impact of disease and its treatment from the patient's perspective and can measure the tradeoff between efficacy of the treatment and what the patient is willing to tolerate" (Frost et al., 2007, p. S94).

Quality of life is used as a central PRO in TM studies (Bullinger & Quitmann, 2014; Knapp et al., 2021; Riva et al., 2015; Schmidt, 2007), as it enables evaluating "those aspects of self-perceived well-being that are related to or affected by the presence of disease or treatment" (Ebrahim, 1995, p. 1384)[3]. QoL is predominately measured using PROMs, thus quantitative "questionnaires assessing relevant dimensions with multiple questions and defined response formats" (Bullinger & Quitmann, 2014, p. 138).

The construct of QoL is defined heterogeneously (Bullinger, 2014; Karimi & Brazier, 2016), which "poses challenges in terms of concepts, methods, and applications in research and practice" (Bullinger & Quitmann, 2014, p. 137). This circumstance must be taken into account as it directly impacts the assessment's process and outcome (Bullinger & Quitmann, 2014; Tsang et al., 2017). To illustrate this connection, I compare three different definitions of QoL and their corresponding operationalisation below. Firstly, the terms 'QoL', 'health-related QoL', and 'disease-specific QoL' are partly used interchangeably (Karimi & Brazier, 2016) and are often imprecisely defined in respective studies. Bullinger and Quitmann (2014) describe that the "conceptual basis of health-related QoL research is closely tied to an operational definition, which identifies as its core dimensions the physical, social, and mental components within an overall model of perceived health" (Bullinger & Quitmann, 2014,

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[3] This description refers to health-related quality of life (HrQoL) in particular.

p. 138). Secondly, the World Health Organization (WHO) chooses a broader definition of QoL as “an individual's 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” (World Health Organisation (WHO), 1998, p. 11). Consequently, the WHOQOL-100, a questionnaire based on the WHO definition of QoL (World Health Organisation (WHO), 1998), includes additional domains that go beyond the physical, social and mental aspects. Lastly, proponents of the needs-based approach are in the opinion that “life gains its quality from the ability and capacity of the individual to satisfy their needs, either inborn or learned during socialization processes” (McKenna & Doward, 2004, p. S2). For this reason, it is essential to include items in a QoL assessment that measure the extent to which needs are met. The Quality of Life in Depression Scale (QLDS; McKenna & Doward, 2004) is an example for a needs-based assessment of QoL.

To summarize, different aspects of QoL can be assessed, depending on the underlying conceptual model and the selected instrument (Haraldstad et al., 2019). Therefore, it is essential in context of TM applications to reflect on *which aspects of QoL are of interest* in order to select a suitable measurement instrument for its evaluation.

1.4 Evaluating the impact of telemedical applications on Quality of Life

Evidence of medical benefit of a TM application is a prerequisite for its certification (Federal Institute for Drugs and Medical Devices, 2019) and therefore plays a special role in evaluating TM applications. Improving QoL is defined as a decisive evaluation criterion (Federal Institute for Drugs and Medical Devices, 2019) alongside improving health status, shortening the disease’s duration, and prolonging survival. Consequently, this leads to the central research question of whether the use of TM applications impacts QoL of patients and, if so, in what way(s).

When looking at empirical studies of the efficacy of TM applications for improving QoL, evidence appears to be inconclusive. Although there are indications that the use of TM applications can improve QoL in intervention groups compared to control groups, these effects are inconsistent (Clark et al., 2007; Eurlings et al., 2019; Hughes & Granger, 2014; Inglis et al., 2011; Königbauer et al., 2017; Maric et al., 2009; Pandor et al., 2013; Ritter & Bauer, 2006; Schmidt, 2007; Yang et al., 2018). For example, differences are not always clinically relevant or statistically significant and also differ with respect to the disease groups studied (Muehlan & Schmidt, 2012, 2013). In addition, effects on QoL are often limited to a selection of scales, and long-term effects are usually not evaluated (Muehlan & Schmidt, 2012, 2013).

From a methodological point of view, most studies have applied established generic, health-related or disease-specific QoL instruments (e.g. EQ-5D, SF-36/SF12, WHOQOL-100/WHOQOL-BREF; Greffin, Schmidt, et al., n.d.). However, these instruments do not comprehensively reflect the most relevant aspects of the intended outcomes of TM applications. For example, telemonitoring applications are mainly used to enhance home monitoring by medical staff and to increase the patients' disease-related safety and perceived control in their personal environment. These are aspects that are not yet assessed by existing QoL instruments. This is not surprising, since most QoL assessments were developed before the launch of digital treatment solutions that have since changed the healthcare context. However, a discrepancy between the primary implementation intention and the corresponding implementation evaluation of TM applications can be observed (Höhne, 2012).

The aforementioned elaborations strongly emphasise that there is a need for a more elaborate conceptual, operational, and psychometric framework of QoL in the context of TM. This framework should be derived from commonly used TM applications and frequently studied disease groups in order to be context-sensitive instead of disease- or treatment-related.

The goals of this doctoral thesis are therefore:

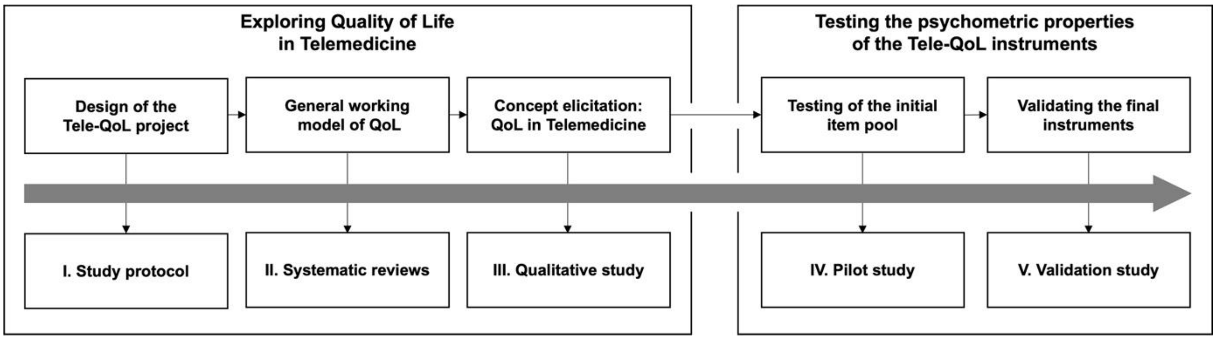
1) to explore the concept of Quality of Life in the context of telemedical applications; and
2) to develop and test a questionnaire for the setting-sensitive assessment of Quality of Life in the context of telemedical applications.

2. Core studies of the doctoral thesis

This doctoral thesis is based on data from the Tele-QoL project that aimed at a setting-sensitive conceptualisation and the development of an assessment for QoL in TM care. It consisted of two main phases (Figure I). The primary explorative study phase comprises planning of the study design, deriving of a general working model of QoL as well as the concept elicitation of QoL in TM settings. Based on these results, an initial questionnaire version was developed, tested, refined, and evaluated within the second project phase.

Figure 1

Structure of the Tele-QoL project

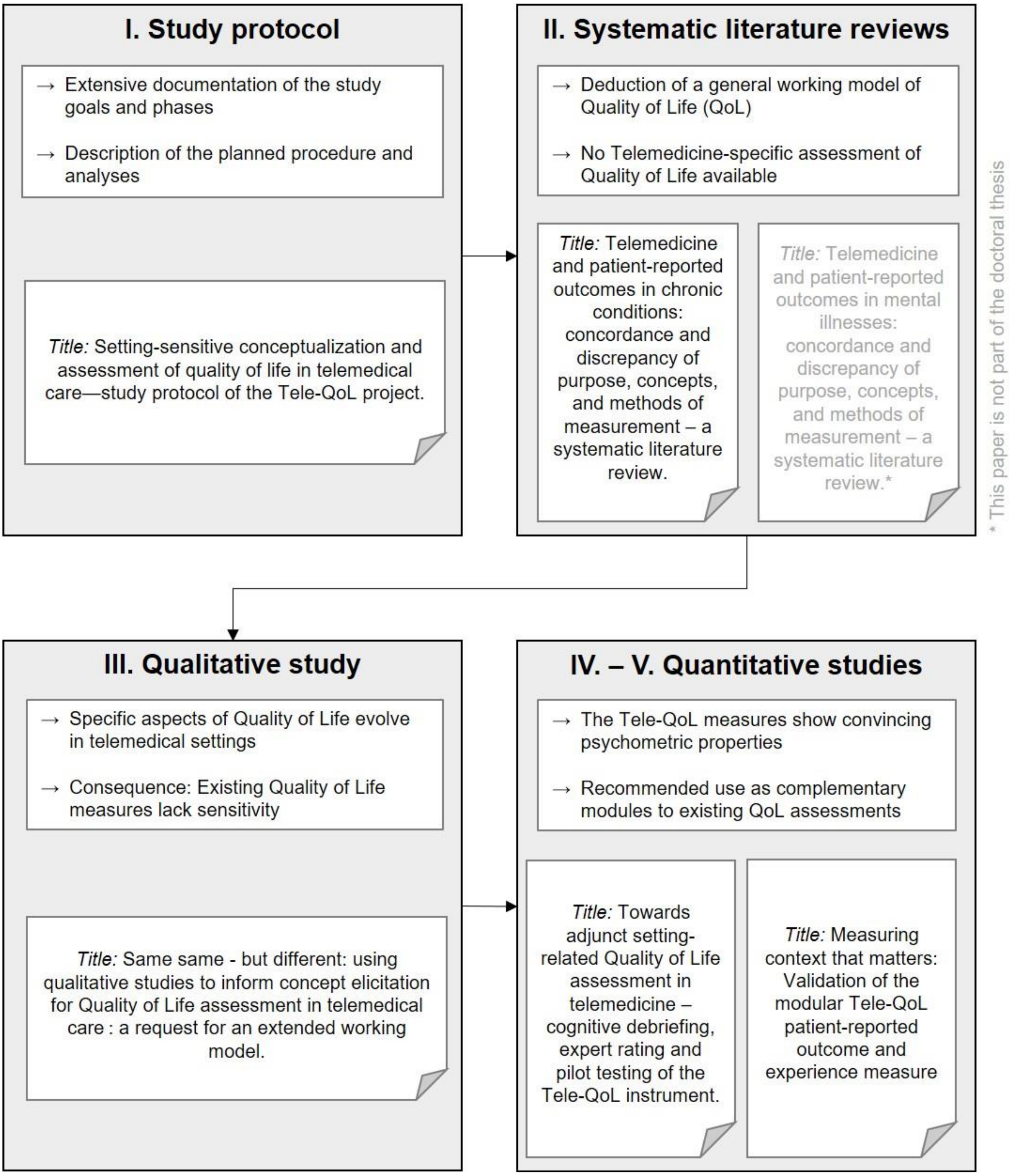


2.1 Overview

This cumulative doctoral thesis consists of five studies (Figure 2). The publications relate to (I) the study protocol of the Tele-QoL project, (II) a systematic literature review on chronic physical diseases, (III) a qualitative study about the impact of TM on QoL, (IV) the testing of the initial Tele-QoL questionnaires and (V) the evaluation of the final Tele-QoL questionnaires. In the following, each study will be described individually in more detail.

Figure 2

Overview of the publications included in this doctoral thesis



I. Study protocol

→ Extensive documentation of the study goals and phases

→ Description of the planned procedure and analyses

Title: Setting-sensitive conceptualization and assessment of quality of life in telemedical care—study protocol of the Tele-QoL project.

II. Systematic literature reviews

→ Deduction of a general working model of Quality of Life (QoL)

→ No Telemedicine-specific assessment of Quality of Life available

Title: Telemedicine and patient-reported outcomes in chronic conditions: concordance and discrepancy of purpose, concepts, and methods of measurement – a systematic literature review.

Title: Telemedicine and patient-reported outcomes in mental illnesses: concordance and discrepancy of purpose, concepts, and methods of measurement – a systematic literature review.*

* This paper is not part of the doctoral thesis

III. Qualitative study

→ Specific aspects of Quality of Life evolve in telemedical settings

→ Consequence: Existing Quality of Life measures lack sensitivity

Title: Same same - but different: using qualitative studies to inform concept elicitation for Quality of Life assessment in telemedical care : a request for an extended working model.

IV. – V. Quantitative studies

→ The Tele-QoL measures show convincing psychometric properties

→ Recommended use as complementary modules to existing QoL assessments

Title: Towards adjunct setting-related Quality of Life assessment in telemedicine – cognitive debriefing, expert rating and pilot testing of the Tele-QoL instrument.

Title: Measuring context that matters: Validation of the modular Tele-QoL patient-reported outcome and experience measure

2.2 *Introduction to the individual publications*

Paper I - Design of the Tele-QoL project

Quality of Life is a core PRO in healthcare research, alongside primary clinical outcomes. A conceptual, operational, and psychometric elaboration of QoL in the context of TM is needed, because standardised instruments to assess QoL do not sufficiently represent essential aspects of intended outcomes of TM. Therefore, the overall aim of the Tele-QoL project is to develop an instrument that can adequately assess QoL in TM. In order to do this, we first look at how QoL has been assessed in TM studies so far. In a next step, we interview patients and experts to find out whether there are aspects of QoL that play an important role in the context of TM, but that have not been assessed so far. If necessary, an instrument will be developed, tested, refined and validated that captures those aspects of QoL that are influenced by TM.

The initial exploratory study section includes (a) systematic literature reviews, (b) a qualitative study for concept elicitation, as well as (c) pre-testing of the initial items using cognitive debriefings with patients and an expert survey. The second quantitative section consists of two patient surveys for piloting and validation of the newly developed instruments.

The resulting modular instrument will assess central experiences of patients regarding TM applications and its impact on QoL more sensitively. Its use as adjunct instrument will lead to a more appropriate evaluation of TM and contribute to the improvement of care tailored to patients’ individual needs.

Paper II - General working model of Quality of Life

PROs are increasingly considered when assessing the efficacy and feasibility of TM applications. However, the evidence on whether TM applications contribute to an improvement of PROs in general and QoL in particular is inconsistent. Preliminary studies suggest that these inconsistencies may also be due to discrepancies between implementing TM applications and their corresponding evaluation. The aim of this systematic literature review was to investigate whether there is a gap between defined purposes of TM use, the concepts chosen to evaluate TM interventions, and the methods of measurement used in TM feasibility and efficacy studies. In addition, we were interested whether TM-specific instruments were applied.

PubMed, EBSCOhost, and reference lists were searched to identify feasibility and efficacy studies published between 1993 and 2019. In total, *n*=293 studies were eligible according to predefined criteria. Relevant information was extracted, and descriptive statistics were used to determine frequencies. The gap analysis was conducted by comparing the stated purposes, chosen concepts, and methods of measurement used within TM feasibility and efficacy studies. Two gaps were detected. The first one was observed between the defined purposes of TM use and the PROs used for their evaluation, the second one was found between the fit of PRO construct and the respective PROMs. In addition, a lack of documentation in TM studies was observed. Overall, only few TM-specific measures were used in the included studies. A general working model of QoL was derived from the most commonly used QoL assessments identified within the systematic literature review.

To increase the informative value and validity of TM studies, we emphasise the importance of aligning the purpose of TM use and respective evaluation criteria as well as documenting the complete evaluation procedure. At the same time, there is a need for further context-sensitive instruments that can be used for assessments in TM studies.

Paper III - Concept elicitation – Quality of Life in Telemedicine

Although TM applications are increasingly used in the area of both, mental and physical illness, there is no QoL instrument that considers the specific context of the healthcare setting. Therefore, the aim of this study was to explore QoL in TM context and to determine a concept of QoL in TM care to inform the development of a setting-sensitive PROM.

Overall, 63 semi-structured single interviews and 15 focus groups with 68 participants have been conducted to determine the impact of TM care on QoL. Participants were patients with chronic physical or mental illnesses, with or without TM-supported healthcare, as well as TM professionals. Mayring's content analysis approach (Mayring, 2014) was used to encode the qualitative data using MAXQDA (VERBI Software, 2017) software.

We found that the majority of aspects that influence QoL of patients dealing with chronic conditions or mental illnesses could be assigned to an established working model of QoL, which we previously identified within a systematic literature review. However, some aspects that were considered relevant (e. g. perceived safety) were not covered by the pre-existing domains, yet. For that reason, we re-conceptualised the working model of QoL and added a sixth domain, referred to as healthcare-related domain.

Interviewing patients and healthcare professionals brought forth specific aspects of QoL evolving in TM contexts. These results reinforce the assumption that existing QoL measurements lack sensitivity to assess the intended outcomes of TM applications. Within the Tele-QoL project, we address this deficiency by developing of a suitable add-on instrument based on the resulting category system of this study.

Paper IV - Testing of the initial item pool

Although QoL is discussed as key patient-reported outcome in TM, it is not setting-sensitive assessable. Therefore, we aimed to develop and test a content-valid "add-on" assessment, which is based on an extended concept of QoL in TM-settings, to capture specific aspects of QoL in TM contexts.

We used cognitive debriefings to test how relevant, plausible, and comprehensible the initial items were for patients (*n*=32). Additionally, an online expert survey amongst TM professionals (*n*=15) was conducted to assess the relevance, applicability, and scope of the derived item pool. Finally, the initial questionnaires were applied to patients with depression or heart failure, with or without TM care (*n*=200) to explore dimensionality of the item pool and analyse the psychometric performance on item and scale level.

The initial item pool comprised 227 items and was further refined by cognitive debriefings, excluding 122 items. In the expert survey, the remaining 105 items of the provisional instrument were rated and an average of about 20 items were assessed to be an optimal questionnaire length. Therewith, analyses of the data from the pilot study confirmed the multidimensional structure of the item pool and indicate a satisfactory psychometric performance. In a next step, we evaluate the psychometric performance of the final Tele-QoL instruments using an independent validation sample.

Paper V - Validating the final instruments

A setting-sensitive instrument for assessing QoL in TM care did not exist until now. To close this gap, a content-valid "add-on" measure was developed. In parallel, a brief index was derived featuring six items that summarise the main content of the multidimensional assessment. After pre-testing and pilot-testing the instruments, the psychometric performance of the final measures was investigated in an independent validation study.

The questionnaires were applied along with other standardised instruments of similar (e.g. perceived safety in TM) as well as associated, yet disparate concepts (e.g. disease-specific QoL, patient satisfaction) for validation purposes (e.g., VR-12, MLHFQ). The sample consisted of patients with depression or heart failure, with or without TM (*n*=200). Data analyses were aimed at calculating descriptive statistics and testing the psychometric performance on item, scale, and instrument level, including different types of validity and reliability.

As a result, the proposed factor structure of the multidimensional Tele-QoL measure has been confirmed. Reliability coefficients for internal consistency, split-half and retest reliability of the subscales and index reached convincing values. The Tele-QoL subscales and the index demonstrated Rasch scalability. Validity of both instruments can be assumed, as indicated by substantial associations between Tele-QoL outcome scales and perceived safety in TM as well as between Tele-QoL impact scales and perceived technological anxiety in TM. As expected, moderate associations could be observed with different indicators for QoL and satisfaction with healthcare, as well as patient activation, providing evidence for discriminant construct validity. Known-groups validity (hypotheses testing) was indicated by respective score differences for various classes of disease severity.

In conclusion, all Tele-QoL measures show convincing psychometric properties. The final multidimensional Tele-QoL questionnaires comprise three outcome domains and one impact domain, which each have two scales consisting of four items. Thus, in total, there are six outcome scales and two impact scales capturing (un-)intended effects of TM on QoL. In addition, the Tele-QoL index provides a short alternative for assessment. The Tele-QoL measures can be used as complementary modules to existing QoL instruments to capture healthcare-relevant, setting-sensitive aspects of QoL from the patients’ perspective in telehealth contexts.

3. Discussion

3.1 Main finding

The aims of this doctoral thesis were to explore a potential extension of existing QoL concepts, and to develop, pilot, and validate a setting-sensitive instrument suitable to assess QoL in the context of TM applications (Greffin, Muehlan, et al., 2021).

The comprehensive systematic literature review (Greffin, Muehlan, Rosenkranz, et al., n.d.) included in this doctoral thesis provides structured evidence of PRO assessment in TM studies. First, to understand how QoL is currently assessed in TM settings, a *general working model of QoL* was derived based on the domains of the most commonly used QoL questionnaires within the included TM studies. Second, it was identified that no instrument existed to assess healthcare-related aspects of QoL in the context of TM.

In the subsequent qualitative study, patients and TM professionals were consulted. The interviews and focus groups brought forth specific aspects of QoL evolving in TM contexts that were not yet covered by existing QoL concepts (Greffin, Schmidt, et al., 2021). For that reason, we re-conceptualised the pre-existing working model of QoL and added a domain, referred to as *healthcare-related domain*. This extension represents a conceptual contribution to the further development of QoL research, through which the healthcare context is now also considered.

Finally, our conceptual approach of QoL in TM was operationalized. Therefore, we have developed, tested, refined, and validated context-sensitive questionnaires that can be used in evaluating QoL in TM (Greffin, Muehlan, van den Berg, et al., n.d.; Muehlan et al., n.d.).

3.2 Implications for evaluating telemedical applications

The Tele-QoL instruments can be used as complementary modules to assess specific aspects of QoL that are perceived meaningful in the context of TM applications (Greffin, Muehlan, van den Berg, et al., n.d.). In addition to positive effects, which can be measured applying six scales, two further scales are available assessing the potential negative impact of TM on QoL. The questionnaires can thus be used in the context of evaluations to reflect both, intended and unintended effects of TM (Gogia et al., 2016).

The content of the questionnaires was derived directly form the patients' verbatims collected within the qualitative study (Greffin, Schmidt, et al., 2021; Tsang et al., 2017).

Moreover, the item generation was also inspired by a needs-based approached of QoL (McKenna & Doward, 2004). This approach was considered due to the perception that patients described the impact of TM on QoL partly as the extent to which their (healthcare-related) needs were met differently through the use of digital healthcare solutions. As a result, the Tele-QoL questionnaires may complement standardised assessment that are rather based on functional QoL definitions.

The use of setting-sensitive questionnaires is crucial because it provides a more valid evaluation of QoL in TM studies. Thus, an improved effectiveness measure was developed to use in the field of TM care programmes.

Finally, the broader consideration of the patient's perspective has the potential to function as a formative evaluation within the context of a continuous assessment of TM care services, and thus to strengthen the participatory parts of health services research. In this way, the professionals involved receive direct informational feedback on the psychosocial effects of TM applications and can initiate any necessary adjustments on that basis.

3.3 Relevance for patients' voice in telehealth

Through the Tele-QoL questionnaires, *patients* who use TM get the opportunity to better document the impact of TM on their QoL. The extended conceptualisation of QoL in TM settings may also result in potential improvements of TM applications and individualised TM care for patients with chronic diseases and mental disorders. This is possible because the Tele-QoL provides information for professionals involved on how a TM application should be developed, implemented, and evaluated in order to (better) adapt to (care) needs of individual patients. Indirectly, the burden caused by disease management for the *family* can be derived from the answers to the Tele-QoL items, which in turn provide information about where the patient-family dyad needs further support.

3.4 Strength and limitations

As recommended by Rothrock et al. (2011), an extended *mixed-methods design* was chosen to develop the Tele-QoL questionnaires. In addition, patients and stakeholders were rigorously included in this project, which is in line with guidelines for PROM development (Cheng & Clark, 2017; Rothrock et al., 2011). More precisely, we interviewed 131 participants that were either patients or TM professionals within the qualitative study to explore QoL in TM (Greffin, Schmidt, et al., 2021). Therewith, we included a large group of future users of the questionnaire, i. e. both, those filling it in or those evaluating it. Subsequently, a guided in-person expert workshop was organised to validate the extended setting-sensitive concept of QoL. After deriving an initial item pool from the qualitative data, the pre-testing of the preliminary instrument was conducted, firstly from the patients' perspective using the ‘think aloud’ technique within cognitive debriefings, and secondly in the context of a structured online survey among experts using a combination of open and closed questions. Moreover, the quantitative part of the project consisted of two questionnaire studies, each of which served to pilot or validate the developed instrument including a total sample of 400 participants (Greffin, Muehlan, et al., 2021). In summary, the Tele-QoL assessments were developed based on a *high patient and public involvement and engagement* (PPIE, Carlton et al., 2022; Grundy et al., 2019) combined with well-established qualitative and quantitative methods of data collection and analysis.

The overall sampling approach, considered in all stages of the project, aimed at including complementary groups of stakeholders (patients vs TM experts). Patients were selected with regard to their primary disease (chronic condition vs mental illness). It was essential that the selected disease groups are regularly treated with TM. For this reason, patients with depression or heart failure were recruited for our empirical studies (Lal & Adair, 2014; Oeff et al., 2008; Ryu, 2010; Schmidt et al., 2010). Furthermore, half of the respective patient groups were treated with an active (regular phone calls) or passive (monitoring) TM application, while the other half was recruited among care-as-usual patients. Consequently, the recruited sample was not arbitrary, but complementarily planned with respect to the disease, the treatment and the level of activity in relation to the treatment. With this sample selection, we wanted to represent as much heterogeneity as possible in terms stakeholder perspectives, diseases and treatments, aiming at gaining results that are more generalizable. In essence, we aimed to capture a variety of TM experiences from patients with different diseases, of different care spectrums, and from various sociodemographic backgrounds, as well as different TM experts as an informative data base. Within the context of research on TM applications, this sampling approach is a very elaborate starting point. In subsequent projects, however, it is necessary to focus on further chronic conditions and mental illnesses as well as different forms of TM applications in order to check whether the Tele-QoL questionnaires are also appropriate as assessment for different illnesses and TM applications.

Some of the aspects described by patients and healthcare professionals that we summarised as an additional healthcare-related domain are already known from previous discussions and other healthcare contexts. Examples include concepts like patient satisfaction, patient empowerment, and perceived safety. Consequently, it is questionable why it is legitimate to combine the identified constructs to an additional QoL domain. One could argue that it simply describes the interaction of the environment with disease-specific aspects like symptoms and the patient's functional status (Bakas et al., 2012; Wilson, 1995). Certainly, the healthcare-related domain interacts with established domains of health-related and disease-specific QoL. However, these do not adequately cover aspects reported by our study participants. The qualitative study of the Tele-QoL project provides evidence that the aspects of the healthcare-related domain have a clear impact on patients' QoL, because they were independently stated when asked about the individual understanding of QoL and whether or not TM treatment affects it. In terms of patient orientation, we should bring more attention to the fact that patients refer to these aspects as belonging to their QoL than to rely on pre-existing conceptual thought patterns. Consequently, we should generally reflect on our traditional concepts against the background of a patients' state of conditional health and innovative treatment application - our proposal for the extension of the QoL concept in the context of TM care is a first step in that direction.

Finally, the efforts of the Open Science Initiative have spread throughout Germany as the project progressed. We have attempted to implement the Open Science idea in our research in the best possible way. Therefore, we have prepared a study protocol (Greffin, Muehlan, et al., 2021) and published our study results, the questionnaires, the manual, and the data analysis code as open access material. The data of the project is also available on request. In this way, we would like to contribute to a more sustainable and transparent research culture. In future studies, I would like to pursue the open science approach further, for example by pre-registering studies and, especially in the context of qualitative research, keeping open lab notebooks.

4. Conclusion & outlook

The Tele-QoL measures are the first questionnaires ever to evaluate the TM-specific impact of a treatment on QoL of patients with chronic physical and/or mental illnesses. This is an important and necessary contribution to developing, implementing, and evaluating telemedical applications.

In the future, the Tele-QoL will undergo additional testing, for example through larger implementation studies in which diverse diseases and TM-applications will be included. Moreover, we will further adapt our approach so that it can also be used for children and adolescents (new development of a Tele-QoL Kids) as well as in other countries (cultural adaptation and translation) facing similar healthcare challenges.

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6. Abbreviations

DiGA	*Digital Health Applications*
DVG	*Digitale-Versorgung-Gesetz*
EQ-5D	*European Quality of Life 5 Dimensions*
MLHFQ	*Minnesota living with heart failure questionnaire*
PRO	*Patient-reported outcome*
PROs	*Patient-reported outcomes*
PROMs	*Patient-reported outcome measures*
QLDS	*Quality of Life in Depression Scale*
QoL	*Quality of Life*
SARS-CoV-2	*Severe acute respiratory syndrome coronavirus type 2*
SF12	*Short Form-12*
SF-36	*Short Form-36*
SGB V	*Sozialgesetzbuch (SGB) Fünftes Buch (V)*
Tele-QoL	*Quality of Life in Telemedicine questionnaires*
TM	*Telemedicine*
VR-12	*Veterans RAND 12-Item Health Survey*
WHO	*World Health Organization*
WHOQOL-100	*World Health Organisation Quality of Life instrument - 100*
WHOQOL-BREF	*World Health Organisation Quality of Life instrument - short form*

7. List of Figures

Appendix

i. Manuscripts: Studies of the doctoral thesis

Paper I

Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2021). Setting-sensitive conceptualization and assessment of quality of life in telemedical care - study protocol of the Tele-QoL project. *International Journal of Environmental Research and Public Health*, *18*(19). https://doi.org/10.3390/ijerph181910454

Setting-sensitive conceptualization and assessment of Quality of Life in telemedical care – Study protocol of the Tele-QoL project

Klara Greffin [1,*], Holger Muehlan [2] , Neeltje van den Berg [3], Wolfgang Hoffmann [4], Oliver Ritter [5,6], Michael Oeff [6], Georg Schomerus [7] and Silke Schmidt [8]

[1] Chair of Health and Prevention, Department of Psychology, University of Greifswald, Greifswald, Germany; Klara.Greffin@uni-greifswald.de

[2] Chair of Health and Prevention, Department of Psychology, University of Greifswald, Greifswald, Germany; holger.muehlan@uni-greifswald.de

[3] Department of Health Care Epidemiology and Community Health, Institute of Community Medicine, University Medicine Greifswald, Greifswald, Germany; nberg@uni-greifswald.de

[4] Department of Health Care Epidemiology and Community Health, Institute of Community Medicine, University Medicine Greifswald, Greifswald, Germany; wolfgang.hoffmann@uni-greifswald.de

[5] Brandenburg Medical School Theodor Fontane, Neuruppin, Germany; Brandenburg City Hospital, Brandenburg an der Havel, Germany; o.ritter@klinikum-brandenburg.de

[6] Brandenburg City Hospital, Brandenburg an der Havel, Germany; michael@oeff.eu

[7] University of Leipzig Medical Center, Leipzig, Germany, georg.schomerus@medizin.uni-leipzig.de

[8] Chair of Health and Prevention, Department of Psychology, University of Greifswald, Greifswald, Germany; silke.schmidt@uni-greifswald.de

***** Correspondence: Klara.Greffin@uni-greifswald.de; Tel.: 0049 3834 420 3808; KG

Abstract: Quality of life (QoL) is a core patient-reported outcome in health-care research alongside primary clinical outcomes. A conceptual, operational, and psychometric elaboration of QoL in the context of TM is needed, because standardized instruments to assess QoL do not sufficiently represent essential aspects of the intended outcomes of telemedical applications (TM). The overall aim is to develop an instrument that can adequately capture QoL in TM. For that purpose, an extended working model of QoL will be established. Subsequently, an instrument will be developed and validated that captures those aspects of QoL that are influenced by TM. The initial exploratory study section includes (a) a systematic literature review, (b) a qualitative survey for concept elicitation, and (c) pre-testing using cognitive debriefings with patients and an expert workshop. The second quantitative section consists of an online expert survey and two patient surveys for piloting and validation of the newly developed instrument. The resulting questionnaire will capture central experiences of patients regarding telemedical applications and its impact on QoL more sensitively. Its use as adjunct instrument will lead to a more appropriate evaluation of TM and contribute to the improvement of care tailored to patients' individual needs.

Keywords: Quality of life, telemedicine, patient-reported outcome, questionnaire development, study protocol, chronic disease, mental illness

1. Introduction

Telemedicine (TM) is a vital part of today's patient care [1,2]. It affects how healthcare services are provided on a structural level, and therewith also influences clinical and patient-reported outcomes (PRO). Quality of Life (QoL) is one of the central PROs in the context of TM efficacy studies [3]. However, evidence-based attempts to evaluate the effectiveness of TM applications in improving QoL reveal ambiguous evidence. Although there is some documentation that using TM applications can improve QoL [4], many findings remain inconsistent [5–12]. As such, the reported effects are often not clinically relevant or statistically significant, and they also differ depending on the disease groups studied [13,14]. From a methodological perspective, QoL is frequently assessed with standardized instruments that do not sufficiently represent the most important aspects of the intended outcomes of TM applications. For instance, remote patient monitoring applications are mainly used in heart failure patients to improve distant monitoring of health parameters by medical staff [15]. For the patient, TM use aims to increase patients' disease-related security [16] and control experience in their personal environment. Those aspects are linked to QoL of patients', but are not yet assessed within efficacy studies [17]. Thus, there is a discrepancy between the primary implementation intention and the corresponding evaluation in TM applications.

Furthermore, current assessment-related problems of QoL include that item formulations of patient-reported outcomes are based on very specific disease-related symptoms or experiences. There are challenges in the comparability due to the heterogeneity of TM applications, models of care, and the different target groups [18]. Additionally, effects on QoL are often limited to a selection of specific scales and long-term effects are usually not evaluated [13,14]. Thus, there is a need for a generic patient-centred measurement approach that can capture the expected overall impact of TM [19]. An assessment of the QoL in TM derived from such an approach should consequently refer to frequently used TM applications and be based on frequently studied disease groups. Until now, there is no QoL assessment that is sensitive for the TM setting and takes these points into account. As a conclusion, there is a need for a more elaborate conceptual, operational, and hence psychometric foundation of the construct of QoL in the context of TM applications. The Tele-QoL project aims at adapting a general concept of QoL to the TM context. As a next step, an appropriate survey instrument to assess QoL in TM settings will be developed.

2. Relevance

An increasing life expectancy and a low birth rate mean the global population is on average getting older. This demographic change [20] will increase demand for TM healthcare solutions. A growing absolute number of older people will lead to increasing age-associated chronic diseases and multi-morbidity [21–23]. In order to ensure high-quality healthcare in the future –

especially in rural areas – various innovations have been developed in primary and secondary care that have integrated TM applications as a central component [24]. Recently, these TM applications have been the subject of many studies and reviews to investigate or prove their effectiveness [5–12]. While morbidity and clinical indicators have been defined as primary outcome indicators for TM applications in selected disease groups like chronic heart failure, QoL has been defined as primary outcome indicators from patients' perspective. Reviews have shown [12,25] that it has not yet been possible to document the effect of telemonitoring on QoL, and the findings are inconsistent across specific clinical patient groups and different TM applications [5–11]. However, the effects of telemonitoring on the daily life of patients as well as their QoL, well-being, and the subjective experience of control appear to be considerable: They go beyond the intended health effects and also affect psycho-social and ethical aspects [13,26]. This results in a substantial deficit in considering the patient perspective with regard to the content of patient-reported outcomes in TM studies. The Tele-QoL questionnaire will assess the neglected aspects from a patient's perspective. Additionally, the project results will have great relevance with regard to different levels:

Improvement of TM applications: A sensitive assessment can result in improvements of TM applications and individual TM-care for patients with chronic diseases and mental disorders, making patient-reported and care-relevant information accessible to all professionals. This also includes recommendations on the design of the development, implementation, and evaluation of TM applications to be even better-tailored to patient needs.

Improvement of effectiveness monitoring: Both the expected increase in numbers of patients and the decrease in the number of primary care physicians in rural regions require flexible, effective, and evaluated concepts of healthcare provision, particularly to ensure primary care for the population [24]. The expected results of the Tele-QoL project are crucial because they refine the assessment of patient-reported outcome measures (PROMs)/patient-reported experience measures (PREMs) in TM studies. Thus, an enhanced effectiveness monitoring can be made available in the field of TM care delivery, which takes the patients' perspective into consideration.

***Improvement of quality assurance*:** The QoL of patients is an essential outcome for therapies. Especially for elderly patients with chronic diseases and psychiatric patients, the focus is often not on full recovery but on disease management, i.e. the limitation of symptoms and circumstantially satisfactory QoL [27,28]. The results of this project are vital, because they improve and extend the recording of PROMs and PREMs in TM studies. This can help to implement more valid and reliable outcome measures in TM-care settings which in turn helps ensure the quality of care.

3. Materials and Methods

3.1. Ethics

The planned study is committed to the ethical standards of the Declaration of Helsinki. In addition, researchers guarantee to meet relevant legal and ethical requirements as well as all relevant safety regulations. The project was approved by the Ethics Committee at the University Medicine Greifswald (BB 023/18) and the State Medical Association of Brandenburg (AS466 (bB)/2018). Participating patients will be informed about the aims of the project and study procedures in written and oral form. Written informed consent will be obtained from all participants. Although the planned study is not a clinical trial and no specific medical interventions are conducted - apart from those treatments the patients are already receiving independently of the study as part of their individual treatment plan -, there are ethical challenges regarding possible problems caused by potential negative psychological effects arising in the interviews that need to be taken into account. Previous experience with qualitative health services research among chronically ill patients suggests that such effects are rare and can be avoided if a therapeutically qualified person is available upon request.

3.2. Aims of the study

1. *Gap analysis:* Are there potential gaps between defined purpose, chosen constructs, and methods of measurement used within TM feasibility and efficacy studies that lead to inconsistent findings?
2. *Concept elicitation:* Re-conceptualization of QoL in the context of TM applications.
3. *Instrument development:* Development of an adjunct instrument to assess QoL in TM settings, piloting and validation study for testing the psychometric performance of the instrument.

3.3. Design and methods

The design includes an explorative study section that consists of a systematic literature review (gap analysis) and a qualitative survey (concept elicitation). A second quantitative approach with structured assessment (instrument development, pre-testing, piloting and validation of the instrument) will follow.

Systematic literature review: Prior to the empirical investigations, a systematic literature review of existing outcome definitions, criteria of TM applications and PROM's/PREM's from TM studies will be conducted. It aims to identify potential gaps between defined purpose, chosen constructs, and methods of measurement used within TM feasibility and efficacy studies.

Qualitative studies (concept elicitation): Interviews and focus groups will be conducted using semi-structured questionnaires to capture responses and discussions on expectations of, experiences with, and evaluations of TM applications. Additionally, the perceived impact of TM applications on QoL will be explored. While focus groups will be conducted in person, patients and TM professionals will be interviewed in person or via phone. The intensive use of qualitative survey methods is in line with existing recommendations of international PROMs/PREMs research [29].

Quantitative studies (testing): First, a pretesting of the questionnaire using the cognitive debriefing method “think aloud” will be conducted. Afterwards, piloting and validation of the instrument for psychometric testing will follow in two independent samples.

3.4 Study participants

3.4.1 Sample size

Overall rational. The sample of the qualitative and quantitative study part is designed to represent the heterogeneity of TM applications and patient populations to ensure that the results are more generalizable. Therefore, we will include the main groups of TM healthcare professionals and chose patient groups that are contrary with regard to their primary disease (e.g. mental vs. physical chronic disease), but often included in TM studies (e.g. depression vs. heart failure). Additionally, we will examine active and passive TM applications and compare them to standard care. Patients in the active TM application group received regular phone calls, while patients in the passive TM application group were automatically monitored by a medical device. In essence, we aim to capture a variety of TM experiences from patients with different diseases, of different care spectrums, and from various socio-demographic backgrounds (gender, age) as well as different TM experts.

Qualitative studies (concept elicitation): The number of focus groups and interviews with n= min. 30 is chosen in order to reach content saturation [30–32] and is described in Table 1. We aim at the realization of:

- Focus groups with a total number of 32 patients to be able to allocate the number of patients from four groups equally (each n=8). The four groups are a combination of patient’s disease (heart failure/depression) and type of care (TM/care as usual)

- Focus groups with a total number of 30 TM professionals
- 32 single interviews with patients to be able to allocate the number of patients from four groups equally (each n=8). The four groups are a combination of patient's disease (heart failure/depression) and type of care (TM/care as usual)
- 30 single interviews with TM professionals.

Quantitative studies (testing): Thirty-two patients (cognitive debriefing; [33]) and at least 5 experts (expert workshop) will be invited for pretesting. The estimation of the sample size needed for piloting and validation is based on the preconditions of the more complex psychometric procedures such as exploratory and confirmatory factor analysis and differential item functioning. However, the size of the item pool, the communalities of the items, and the number, item sizes, and eigenvalues of the factors are still unknown [34,35]. For the approximation of the necessary case numbers, we reference simulation studies and reviews [36–38]. For piloting, we assume an estimated item size of about 50+/-10 items, for validation about 25+/-10 items. For group comparison with two comparison groups per characteristic, consisting of type of care and disease group, in the final validation step, the approximated ratio of number of cases: items for piloting and validation is approximately equivalent to 4:1 (3:1 to 5:1) and thus corresponds to established practice in the PRO area [36]. Taking reasonable effort and benefit into account, this results in a number of cases of n=200 for the pilot and validation study as a sufficient number for the analyses to be performed.

3.4.2 Recruitment

Recruitment will be implemented by four study nurses in the three recruitment centers of the project's partners in the German cities of Brandenburg, Greifswald, and Leipzig. The study population will be recruited from patients who are receiving or have received TM care or who are receiving standard treatment for depression or heart failure. The study nurses will contact patients according to standardized criteria that include type of disease and type of care with a verbal or written invitation. Patients must suffer from a chronic physical or mental condition. The sampling procedure aimed for an equal distribution of sex, age groups, and clinical severity. Moderate to severe impairment of cognitive functions (e.g. comorbid neurological diseases) and non-proficient knowledge of German are exclusion criteria. A research assistant will recruit professionals via email, in person or by phone. Professionals need to be working in the field of TM. All participants had to be at least 18 years old.

Table 1.

Sample sizes per study section.

Project task	Patients	Professionals
Interviews for concept elicitation	n=32 patients in total n=16 patients with chronic diseases (8 each with or without TM care) n=16 patients with mental disorders (8 each with or without TM care)	n=30 professionals with TM experience
Focus groups for concept elicitation	n=32 patients in total n=16 patients with chronic diseases (8 each with or without TM care) n=16 patients with mental disorders (8 each with or without TM care)	n=30 professionals with TM experience (natural working groups/ teams of variable size)
Workshop for expert validation of conceptual model		Expert workshop (at least n=5)
Pretesting of item pool	Cognitive debriefings n=32	Online-Survey for Expert-Ratings (at least n=10)
Piloting of preliminary instrument	n=200 total patients n=100 patients with heart failure (50 each with or without TM care) n=100 patients with depression (50 each with or without TM care)	
Validation of final instrument	n=200 total patients n=100 patients with heart failure (50 each with or without TM care) n=100 patients with depression (50 each with or without TM care)	

3.4.3 Study assessment and measures

Qualitative studies: The interviews and focus groups will be conducted following semi-structured interview guides, which will be published within the respective qualitative article.

Quantitative studies: Primarily for validation purposes, the following standardized, established instruments will be used in addition to the item pool of the newly developed Tele-QoL instrument (see Table 2):

Socio-demographic characteristics will be assessed based on the “Demographic Standards”, a joint recommendation of the Arbeitskreis Deutscher Markt- und Sozialforschungsinstitute e.V. (ADM), the Arbeitsgemeinschaft Sozialwissen-schaftlicher Institute e.V. (ASI), and the Federal Statistical Office [39]. We will use a slightly adapted form of a single item for assessing the perceived relative health status from a questionnaire by Renner, Hahn & Schwarzer (1996; [40]). Moreover, we will phrase questions with regard to disease- or health-related information (e.g. “Do you use telemedicine?”).

Technology commitment will be assessed using the “Brief measure of technology commitment (TB)” (German original version: [41]). Participants rate their agreement to statements regarding their individual attitudes towards modern technology (e.g. “I am often frightened to fail when dealing with modern technology.”) on five response options: 1 = “strongly disagree”, 2 = “disagree”, 3 = “undecided”, 4 = “agree”, 5 = “strongly agree”. Internal consistency of the subscales “technology acceptance” and “technology competence” was excellent (α = .84), for the subscale “technology control” reliability was good (α = .74).

Table 2.

Questionnaires and items employed at the different study assessments.

Study Assessments & Measures	**Number of Items**	**Study time points**		
		Pilot study	**Validation study (I)**	**Validation study (II)**
General information				
● Sociodemographic characteristics	7	X	X	
● Perceived relative health status	1	X	X	X
● Disease- & health-related information	8	X	X	X
Psychological instruments				
● Technology commitment (TB)	12		X	
● Heart failure severity (Goldman scale & NYHA)	6		X	X
● Depressive symptoms (PHQ-9)	10	X	X	X
● Quality of life in the context of telemedical care (Tele-QoL-A)	?	X	X	X
● Quality of life in the context of standard care (Tele-QoL B)	?	X	X	X
● Perceived security in telemedicine (SeCu-20)	20	X	X	X
● Patient satisfaction (ZUF-8)	8	X	X	
● Healthcare satisfaction – general item (YHC-SUN)	1		X	
● Patient activation (PAM-13)	13		X	
● Body-related self-consciousness – subscale “private” (KSA)	6		X	
● Body-related locus of control – subscale “health” (KLC)	5		X	
● Health literacy (HLS-6)	6		X	X
● Digital health literacy (D-HLS-6)	6		X	X
● Disease-specific quality of life - Depression (WHO-5)	5		X	X
● Disease-specific quality of life – Heart failure (MLHFQ)	21	X	X	X
● Health status (VR-12)	12	X	X	X
● Health-related quality of life (EQ-5D)	6		X	
● General quality of life (WHOQOL-BREF)	26	X	X	

Note. The selection of questionnaires within a study phase further depends on the group to which the patient belongs (heart failure or depression, with or without telemedical treatment).

The “Goldman Specific Activity Scale” (Original version: [42]) will be used to assess heart failure severity. Participants are asked to rate whether they are able to perform specific daily activities (e.g. “shower without stopping”) and based on their answers classified in four Specific Activity Scale Functional Classes (Class I = least burdened, Class IV = most burdened). It is complemented by the “New York Heart Association Classification” (NYHA; Original version: [43]; German version: [44]). The participant must choose the most appropriate statement regarding shortness of breath in daily activities (e.g. “I experience shortness of breath in rest.”) in order to be classified in four possible classes (NYHA 1 = least burdened, NYHA 4 = most burdened).

Depressive symptoms will be assessed with the “Patient Health Questionnaire – 9 (PHQ-9)” [45]. Participants are asked to rate how often they have been bothered by problems over the last 2 weeks (e.g. “Little interest or pleasure in doing things”) with the response options 1 = “not at all”, 2 = “several days”, 3 = “more than half the days”, 4 = “nearly every day”. Internal reliability (α = .89) and test-retest reliability after 48 hours (r = .84) are excellent.

The new “Tele-QoL” measure will be developed for the assessment of QoL in the context of telemedical care (version A) and standard care (version B), as comparator. Participants evaluate statements regarding their telemedical experiences in the previous four weeks (e.g. “Because of the telemedical treatment, I know how to interpret my symptoms.”). The following response options are available: 1 = “strongly disagree”, 2 = “disagree”, 3 = “agree”, 4 = “strongly agree”. Our study is primarily directed at generating initial evidence for the psychometric performance of the Tele-QoL measure.

With the “SeCu” questionnaire (German original version: [46]) participants will be asked to evaluate statements regarding their perceived security in experiences with telemedical care in the last four weeks (e.g. “I can rely on the telemedical application in everyday life.”). The response options are: 1 = “strongly disagree”, 2 = “disagree”, 3 = “agree”, 4 = “strongly agree”. The internal reliability of the four scales “technology anxiety”, “perceived security”, “physician-patient-relation”, and “perceived autonomy” is good to excellent (α = .70-.89).

Patient satisfaction will be assessed by the *“Fragebogen zur Messung der Patientenzufriedenheit (ZUF-8)*“ (original version: [47]; German version: [48]). Participants answer questions regarding their general satisfaction with the hospital and the received treatment (e.g. “How satisfied are you with the received treatment generally?”) on four varying response options. Internal reliability is excellent (α = .92). Additionally, the general item of the “Youth Health Care Measure (YHC-SUN)” [49] is used to assess the general satisfaction with the treatment ("Have you been satisfied with your health care provision in general?"). Response options were: 1 = "not satisfied", 2 = "partly satisfied", 3 = "satisfied", 4 = "very satisfied", 5 = "extremely satisfied" .

With the "Patient Activation Measure (PAM13-D)" (original version: [50]; German version: [51]) patient activation will be assessed. Participants are asked to evaluate their agreement to statements (e.g. "I know the causes of my symptoms.") on four response options: 1 = "strongly disagree", 2 = "disagree", 3 = "agree", 4 = "agree strongly". Internal reliability is excellent (α = .84).

To assess body-related self-consciousness the subscale "private" of the "Body-related Self-Consciousness (KSA)" questionnaire (German original version: [52]) will be used. Participants evaluate their agreement to statements (e.g. "I often can feel my heart beating.") on five response options: 1 = "strongly disagree", 2 = "disagree", 3 = "neither agree nor disagree", 4 = "agree", 5 = "agree strongly".

From the "Body-related Locus of Control (KLC)" questionnaire (German original version: [53]; [54]) for the assessment of body-related locus of control the subscale "health" will be used. Participants are asked to choose the most appropriate response options for statements (e.g. "Who never falls ill is just lucky.") out of five options: 1 = "strongly disagree", 2 = "disagree", 3 = "neither agree nor disagree", 4 = "agree", 5 = "agree strongly". Internal reliability range between α = 0.76 und α = 0.79.

The "European Health Literacy Survery (HLS-EU-Q6)" (original version in multiple languages: [55]) will be used to assess health literacy. Participants are asked to evaluate how easy or difficult it is for them to perform different tasks related to health information (e.g. "On a scale from very difficult to very easy, how easy would you say it is to find information on how to manage mental health problems like stress or depression?"). Response options are: 1 = "very difficult", 2 = "fairly difficult", 3 = "fairly easy", 4 = "very easy". Internal reliability is good (α = .80).

Correspondingly, we will implement a newly adapted version of HLS-EU-Q6 for digital health care, referred to as D-HLS-EU-Q6. This scale is used to assess digital health literacy by asking patients how easy or difficult they would say it is to perform different tasks regarding digital health information (e.g. "On a scale from very difficult to very easy, how easy would you say it is to find information on how to manage mental health problems like stress or depression with the help of digital health applications?"). The same response options as in the HLS-EU-Q6 are used and preliminary estimation of internal reliability is excellent (α = .89).

With the ”WHO-Five Well-Being Index (WHO-5)” [56]; [57] the QoL of participants with depression will be assessed. Participants are asked how often they felt the described mood in the last two weeks (e.g. “In the last two weeks I felt calm and relaxed.”). The available response options are: 1 = “all the time”, 2 = “mostly”, 3 = “a little more than half of the time”, 4 = “a little less than half of the time”, 5 = “occasionally”, 6 = “at no instant”. Internal reliability is excellent (α = .92).

The “Minnesota Living with Heart Failure questionnaire (MLHFQ)” will serve for the assessment of the QoL of patients with heart failure ([58]; [59]). Participants rate how often they feel prevented from their wished way of life because of the stated symptoms in the last four weeks e.g. “Did your heart failure prevent you from your wished way of life in the last month, whilst you suffered from shortness of breath?” The possible responses are: 1 = “very little”, 2, 3, 4, 5 = “very strong” and “no” = not applicable. Internal reliability is excellent (α = .92; [60]).

To assess the health condition of the participants, the “Veterans RAND 12 Item Health Survey (VR-12)” (original version: [61]; German version: [62]) will be used. Participants are asked about their overall health condition and had the response options: 1 = “excellent”, 2 = “very good”, 3 = “good”, 4 = “not so good”, 5 = “bad”, how much they feel currently restricted in the stated tasks (response options: 1 = “yes, strongly restricted”, 2 = “yes, a little restricted”, 3 = “no, not restricted at all”), if they experienced the stated problems at work or in daily activities because of their physical condition and because of their mental health in the last four weeks (response options: 1 = “never”, 2 = “seldom”, 3 = “sometimes”, 4 = “usually”, 5 = “always”), to which extent pains restricted usual work at home or at work in the last four weeks (response options: 1 = “not at all”, 2 = “a bit”, 3 = “moderate”, 4 = “fairly”, 5 = “very much”), how often they felt the stated emotions in the last four weeks (response options: 1 = “always”, 2 = “usually”, 3 = “quite often”, 4 = “sometimes”, 5 = “seldom”, 6 = “never”), and how often physical and mental problems restricted the contact to other people in the last four weeks (response options: 1 = “always”, 2 = “usually”, 3 = “sometimes”, 4 = “seldom”, 5 = “never”).

The health-related QoL will be assessed with the “European Quality of Life 5 Dimensions (EQ-5D)” (original version: [63]; [64]). Participants describe their today’s health regarding mobility, taking care of oneself, daily activities, pain/physical afflictions and anxiety/depressiveness on the response options 1 = “no problems”, 2 = “mild problems”, 3 = “moderate problems”, 4 = “big problems”, 5 = “not able”. Additionally, they evaluate their current health on a visual analogue scale (VAS) from 0 to 100.

The short form of the “World Health Organization Quality of Life (WHOQOL-BREF)” (original version in multiple languages: [65]) will be used to assess the general QoL. Participants evaluate their QoL, life satisfaction, experiences, abilities, satisfaction in different life domains and negative feelings in the last two weeks on a five-point scale, An example item is “Do you have enough possibilities for leisure activities?”. The response phrasing is adapted to the specific type of question. Internal consistency was demonstrated with the following Cronbach’s alpha values: 0.82 in the Physical domain, 0.81 in the Psychological domain, 0.68 in the Social domain, and 0.80 in the Environmental domain [65].

3.5. Data evaluation

3.5.1. Data collection and management

A data protection concept will be prepared for the project, which will be in line with current regulations. This covers information and consent to the study, data collection, data transport, analysis and storage of the data. Moreover, the University of Greifswald will provide a project server and assign access rights among the members of the research team. The project server will be used for the secure storage of project data. Server usage will be in line with currently valid data protection laws.

Qualitative data will be recorded with a dictaphone after all participants have given their written informed consent and related questions were clarified. After the recording, the audio file will be stored on the project server until a transcript of the interview has been made. The audio file will then be deleted, while the transcript remains stored on the server.

Quantitative data will be collected using questionnaires. The study material will be prepared by the University of Greifswald and subsequently be sent to the recruiting clinical partner institutions. Participants will be asked to return the completed questionnaire material anonymously to the University of Greifswald using a pre-stamped envelope. After the questionnaires have been received, they will be entered into an Excel spreadsheet and stored on the project server. The original questionnaires will be filed and stored in locked cabinets in rooms to which only limited people with specific clearance have access.

3.5.2 Data analyses

Qualitative data: Qualitative data will be transliterated with the software f4 transcript [66] and subsequently analyzed with MAXQDA software [67]. For the coding of the data material, Mayring's content analysis approach [68] will be used. The analysis and coding of the transcripts will be made by two persons independently (research assistant, student assistant) and refined iteratively. Possibly deviating codings and contradictory interpretations will be discussed with a supervisor (person in charge of methodology) in a consensual procedure. The analysis will be directed towards identifying all text sequences/units that refer to personal experiences in connection with the application of TM and its impact on QoL. From these contents, categories will iteratively be created or content will be assigned to existing categories. The resulting category system and the structured contents will be the result of the analyses, which are to be generated from the data input of the qualitative studies. A workshop with experts from the fields of TM applications and QoL research will be conducted for the external validation of the results.

Quantitative data: Psychometric analyses on item and scale level according to classical and modern test theory will be performed after piloting and validation. The piloting will include the selection of an item pool based on the conceptual framework model, the pretesting of the items by cognitive debriefings, the pilot testing of the questionnaire on a sample as well as analyses of the descriptive and psychometric performance (e.g. exploratory factor analysis). The validation will include the selection and determination of the final item pool, including scale assignment on the basis of the piloting results, the validation of the measure with an independent sample as well as analyses of the descriptive and psychometric performance on item, subscale and instrument level (e.g. applying confirmatory factor analysis, item response modeling, and differential test functioning).

4. Discussion

This research project is expected to generate the following outcomes:

(i) *Patient-related (re-) conceptualization*: The results of the research project address the need for a stronger conceptual elaboration of the construct of QoL in the context of TM applications (especially telemonitoring) from the patient's perspective.

(ii) *Setting-sensitive assessment:* The specific items will capture central expectations and experiences of patients (e.g. perceived security and control beliefs) regarding TM applications more sensitively and can be used as integrated or additional modules of QoL assessments. The instrument allows a more appropriate assessment of the impact of TM on PROMs/PREMs (especially QoL) due to increased setting sensitivity.

(iii) *Care-relevant evaluation*: Such a conceptual framework and a corresponding instrument also provides the basis for (re-)evaluating the effectiveness of TM applications through PROMs/PREMs. This potentially allows a re-evaluation of discrepant and inconsistent findings of existing studies on the influence of PROM's/PREM's in general or TM applications on QoL in particular. As a result, evaluations of the influence of TM applications on QoL and other PROMs are more valid and reliable, which will considerably help to improve the funding situation [69]. In addition, the extended assessment of QoL in TM settings will lead to the improvement of these applications - for example, better care tailored to individual cases. Moreover, the results can provide concrete starting points on how this method can be further developed and adapted for other areas. As such, this project contributes to strengthening participatory parts of health services research.

5. Limitations of the project

The anticipated limitations of the study relate to the inclusion of TM applications. Within this project, those TM applications that are used to complement, but not replace, standard care will be included. Moreover, the landscape of TM is diverse and very dynamic. Consequently, despite aiming for broad applicability, the upcoming results of this study may not be fully generalizable for all future TM applications.

6. Conclusion

Telemedicine is an important healthcare solution which will continue to become more widespread in the future. The Tele-QoL project aims to add a questionnaire to the field of research which will enable healthcare professionals, researchers, and stakeholders to assess the impact of TM on QoL more sensitively. This project contributes to advancing telemedical care and to further highlighting the patients’ perspective.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee of University Medicine Greifswald (BB 023/18, date: 27 Febuary 2018) and the State Medical Association of Brandenburg (AS466 (bB)/2018, date: 09 April 2018).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Paper II

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Telemedicine and patient-reported outcomes in chronic conditions: concordance and discrepancy of purpose, concepts, and methods of measurement - a systematic literature review

Klara Greffin[1], Holger Muehlan[1], Elisa Rosenkranz[1], Neeltje van den Berg[2], Wolfgang Hoffmann[2], Oliver Ritter[3], Michael Oeff[4], Georg Schomerus[5], Silke Schmidt[1]

[1]University of Greifswald, [2]University Medicine Greifswald, [3]Brandenburg City Hospital, Medical University Brandenburg, [4]Brandenburg City Hospital, [5]University of Leipzig Medical Center

Abstract

Background: Patient-reported outcomes (PROs) are increasingly considered when assessing the efficacy and feasibility of telemedical (TM) applications. However, the evidence on whether TM applications contribute to an improvement of PROs in general and quality of life (QoL) in particular is inconsistent. Preliminary studies suggest that these inconsistencies may also be due to discrepancies between implementing TM applications and their corresponding evaluation.

Objectives: The aim of this systematic literature review was to investigate whether there is a gap between defined purposes of TM use, the concepts chosen to evaluate TM interventions, and the methods of measurement used in TM feasibility and efficacy studies. In addition, we were interested whether TM-specific instruments were applied.

Methods: We searched PubMed, EBSCOhost, and reference lists to identify feasibility and efficacy studies published between 1993 and 2019. Eligible studies (*n*=293) were selected according to predefined criteria. Relevant information to address the research question was identified and extracted, and descriptive statistics were used to determine frequencies. The gap analysis was conducted by comparing the stated purposes, chosen concepts, and methods of measurement used within TM feasibility and efficacy studies.

Results: Two gaps were identified. The first one between the defined purposes of TM use and the PROs used for their evaluation, the second one between the fit of PRO construct and the respective patient-reported outcome measures (PROMs). In addition, a lack of documentation in TM-studies was observed. Overall, only few TM-specific measures were used in the included studies.

Conclusion: To increase the informative value and validity of TM studies, we emphasise the importance of aligning the purpose of TM use and evaluation criteria as well as a complete documentation of the procedure. At the same time, there is a need for further context-specific instruments that can be used for assessments in TM studies.

Key words: telemedicine**,** patient-reported outcomes, patient-reported outcome measures, systematic literature review, quality of life.

INTRODUCTION

Background

Demographic change is causing an overageing of society in many industrialized countries (European Commission, 2020), which is associated with a surge in chronic diseases, such as cardiovascular diseases, diabetes mellitus, stroke, cancer, arthritis, or asthma (Atella et al., 2019; Christensen et al., 2009; Hung et al., 2011). An increasing number of patients with one or multiple chronic conditions is linked to additional burden on and challenges for *healthcare systems* (Atella et al., 2019; Brennan et al., 2017). To meet those emerging care demands without reducing quality of healthcare, the use of telemedicine (TM) is one attempt to adapt or supplement existing care models or to generate new ways of treatment (Corbett et al., 2020; Pan American Health Organization, 2016).

The spectrum of *TM applications* is diverse in terms of target groups, technologies applied, and effects intended (WHO Global Observatory for eHealth, 2010). It is not a coherent discipline by itself but can be understood as the integration of telematics into areas of medicine, with different use cases arising depending on the specific nature of the respective clinical discipline (Dierks, 2006). To evaluate the fast-growing variety of TM applications, different types of research, such as feasibility, efficacy, or cost-effectiveness studies, must be conducted (Demirci et al., 2021). The aims of these studies are to inform healthcare professionals, and to guide funding decisions in the public health insurance system (Federal Institute for Drugs & Devices, 2019). Meaningful and robust evaluation results with evidence of benefits or harms for patients and other stakeholders according to their perspectives and needs are considered essential requirements for the long-term implementation of TM applications (Demirci et al., 2021). Unfortunately, the quality of existing reviews on the effect of TM applications is often considered weak or insufficient (Eze et al., 2020; Wootton, 2012).

In addition to clinical and economical parameters, *patient-reported outcomes* (PROs) are increasingly being assessed and documented when conducting efficacy studies (Calvert et al., 2013; Knapp et al., 2021; Mercieca-Bebber et al., 2018; Weldring & Smith, 2013) by using patient-reported outcome measures (PROMs). We understand PROs as concepts that are assessed “based on a report that comes directly from the patient (i.e., study subject) about the status of a patient’s health condition without amendment or interpretation of the patient’s response by a clinician or anyone else” (U.S. Department of Health and Human Services Food and Drug Administration, 2009, p. 32). However, Knapp et al. (2021) reported in a systematic review that 21.4% of the PROMs used within the included studies were only self-developed, thus lack a proper development (Cheng & Clark, 2017; Rothrock et al., 2011).

Quality of life (QoL)[1] is often used as central PRO in TM studies (Knapp et al., 2021; Riva et al., 2015; Schmidt, 2007a), as it allows to assess ‘‘those aspects of self-perceived well-being that are related to or affected by the presence of disease or treatment’’[2] (Ebrahim, 1995, p. 1384). However, the evidence on whether TM applications contribute to an improvement of QoL in particular is inconsistent (Chan et al., 2021; Chen et al., 2015; Eurlings et al., 2019; Faruque et al., 2017; Han et al., 2021; Inglis et al., 2011; Marcano Belisario et al., 2013; Maric et al., 2009; McLean et al., 2011; Pandor et al., 2013; Pang et al., 2020; Schmidt, 2007b; Srikesavan et al., 2019; Tchero et al., 2018; Totten et al., 2016). Exemplary, in a systematic review on TM interventions for COPD (Gregersen et al., 2016), including studies with QoL as primary outcome using validated measures, significant improvements relative to control groups were observed only in 3 out of 18 studies. The authors concluded that TM „does not make a strong case for itself when exclusively looking at QoL as an outcome” (Gregersen et al., 2016).

Such inconsistencies are often interpreted as lacking evidence for TM to improve QoL. However, explanations reflecting on the status quo of the methodological and conceptual prerequisites of these studies are lacking. This is a major concern, as it is crucial to provide an valid base of research for the field of TM applications to ensure its beneficial use (Dinesen et al., 2016). Without reliable evidence, it is not possible to separate effective from non-effective applications, to grant funding for providers and thus make the use of TM not only accessible but safe for patients and healthcare professionals (Federal Institute for Drugs & Devices, 2019). Thus, the question of which factors lead to inconsistent findings needs to be addressed.

Previous studies (Eze et al., 2020; Höhne, 2012; Schmidt, 2007a) reflected on potential reasons of observed inconsistencies. As such, deficiencies in study designs, sample characteristics, intervention characteristics, instruments used, reporting quality or data accessibility, and the heterogeneity of construct domains sampled by instruments were named. Based on preliminary studies of our group (Höhne, 2012; Schmidt, 2007a), it was also suggested that there might be a gap between defined purpose, chosen concepts, and measures used within TM studies. Furthermore, TM-specific outcome criteria were not applied nor assessed in existing studies (Höhne, 2012). This can be considered problematic, as a recent study (Greffin et al., 2021) provided evidence that some important patient-related aspects in TM are not sufficiently covered by a working model of established QoL instruments. Accordingly, it is hypothesized that PROMs used in TM studies may not be sensitive enough to reflect key aspects of the actual intended outcomes of TM applications.

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[1] The terms quality of life, health-related quality of life, and disease-specific quality of life are partly used interchangeably (Karimi & Brazier, 2016) and are often not well defined within the respective studies. We will further use the term quality of life (QoL) to consider this circumstance and include all facets linked to QoL.

[2] This description refers to health-related quality of life (HrQoL) in particular.

Objectives

This systematic literature review aimed to examine whether potential gaps between defined purpose of TM interventions, chosen concepts, and methods of measurement used within TM feasibility and efficacy studies could be reasons for inconsistent findings in TM reviews on PROs. In addition, we wanted to update knowledge on whether TM-specific instruments were used in TM studies on a broad database across different diseases and applications.

2. MATERIAL AND METHODS

2.1 Search strategy and selection criteria

This systematic literature review was planned and conducted in accordance with the PRISMA statement (Moher et al., 2009), and a protocol was created according to PRISMA-P statement (Moher et al., 2015). However, the protocol could not be registered with PROSPERO (Editors, 2011) as PROSPERO currently does not accept registrations for systematic literature reviews.

We included all primary research articles published in peer-reviewed journals in German or English from January 01, 1993, to December 31, 2019. Studies were further eligible if their participants suffered from a chronic physical or mental disease, and were treated with a TM application. To work on the objectives, it was crucial that PROs were included and that the operationalization of these were reported properly. Table 1 summarizes all inclusion and exclusion criteria of this systematic literature review.

We searched PubMed, EBSCOhost (APA PsycArticles, Psychology and Behavioral Sciences Collection, APA PsycInfo, PSYNDEX), reference lists and further contacted study authors, when required. For identifying eligible studies within the electronic databases, we combined the following key words with regard to TM-aspects and PROs:

"eHealth" or "mHealth" or "mobile health" or "remote" or "telecare" or "teleconsultation" or "telehealth" or "telehome" or "telehomecare" or "telemed*" or "telemonitoring" or "telepsych*" or "telecardiology" AND "disease related quality of life" or "disease related quality of life" or "gesundheitsbezogene Lebensqualität" or "health-related quality of life" or "HRQoL" or "Lebensqualität" or "patient-reported experience*" or "patient-reported outcome*" or "patient safety" or "perceived safety" or "PRO" or "QoL" or "quality of life" or "patient security" or "wahrgenommene Sicherheit" or "well-being" or "Wohlbefinden").

In addition, we determined the language (German, English), the date of publication (first search 24.01.2018 to include year 1993-2017, second search 09.01.2020 to include year 2018-2019), the age of the participants (≥ 18 years), and that the participants must be humans.

Table 1

Inclusion and exclusion criteria

	Inclusion	**Exclusion**
Languages	German, English	Others
Search I	January 1993 - December 2017	Before 1993 and after 2018
Search II	January 2018 - December 2019	Before 2018 and after 2019
Participants	Humans	Non-human
Age	≥ 18 years	y < 18 years
Group of patients	Patients suffering from a chronic physical or mental disease	Risk behaviour without diagnosis, non-chronic condition like injuries
Treatment	Patients must be treated with TM	Patients without TM treatment
Technology	The use of a TM application must be clearly described	Studies without TM applications or with insufficient descriptions
Setting	Outpatient setting	Clinical setting
Study content	Intervention, therapies between healthcare professional and patient	Diagnostic-only studies, physician-physician TM, physician – caregiver intervention.
Outcome	Patient-reported outcome must be included in the study, PRO & PROM properly reported	Studies reporting only non-PRO parameters; inadequate PRO and PROM reporting
Operationalization	There must be significant information on the operationalization of the patient- reported outcome measure	Incomplete/ no data on patient-reported outcome measure
Type of data	Quantitative data	Qualitative data
Type of study	Empirical, peer-reviewed studies, primary source, efficacy or feasibility studies	Conference abstracts, protocols, dissertations, cost-effectiveness studies
Control group	Existing, clearly described	Not existing, insufficient described
Pub-Format	Printed and/or online full-text of scientific study available	Audio files like podcasts, notes, blog entries, newspaper articles
Research area	International	Not limited to region

2.2 Screening

Following database searches and duplicate removal (KG), two independent authors (KG, ER) got familiar with inclusion and exclusion criteria and screened titles and abstracts independently to identify eligible studies. In case of disagreement, the two authors (KG, ER) discussed the decision with a third researcher (HM) until consensus was reached. The two authors (KG, ER) assessed the full-text articles independently. They discussed inclusion or exclusion of the respective studies after completing the data extraction and the final data check.

2.3 Data extraction

First, we used Citavi version 5 and 6 (Swiss Academic Software GmbH, 2018) to collect search results, to screen for duplicates and check the abstracts. The extracted data of both searches was documented within a pre-structured Microsoft Excel 2013 sheet, which consists of 21 columns (table 2). The data sheet was later separated into two sheets, one summarizing studies referring to chronic physical diseases, the other to mental disorders. The results of analyzing studies including patients with *chronic physical conditions* are reported in this paper, while the results of the studies referring to *mental illnesses* will be published in a second paper.

Table 2

Pre-defined data aspects for full-text extraction

Pre-defined data aspects for full-text extraction		
Number of publication	Type of disease (chronic physical or mental)	Secondary PROs
Authors	Type of TM used	Secondary outcome measures
Title	Aim of the use of the TM application	Fit between target criteria and instrument
Year of publication	Control group	TM-specific instruments
Full-text available	Aim of the study	Project group
Origin of the research group	Primary PROs	Sample size
Disease	Primary outcome measures	Source of funding

For working on the research objectives, we summarized the extracted data and used descriptive statistics to determine frequencies (see table 3). The gap analysis was conducted manually, comparing defined purpose, concepts, and methods of measurement used within TM feasibility and efficacy studies to evaluate the fit. Risk of bias assessment was not undertaken as we were interested in the way a construct was assessed, not the efficacy of the intervention. The studies identified were heterogeneously with regard to disease, TM application and outcomes. Therefore, a narrative synthesis approach (Popay et al., 2006) was used to report the results of the systematic literature review.

Table 3

Aspects for which data was sought, including prioritization of main and additional aspects

Main aspects	Additional aspects
Aim of the use of the TM application	Disease
Primary patient-reported outcome(s)	Type of TM used
Primary outcome measure(s)	Aim of the study
Secondary patient-reported outcome(s)	Number of studies per year
Secondary outcome measure(s)	
Fit between target criteria and instrument	
TM-specific instruments	

3. RESULTS

3.1 General summary – studies on chronic physical diseases

The original searches yield 3.895 citations, which, once duplicates were removed, left 3.351 citations to be screened for inclusion (see Figure 1 and 2). While 2.716 did not meet selection criteria, 635 full-texts remained. After the final eligibility screening, 331 papers were included in the review. The number of studies identified in each step is presented in the PRISMA flow chart (Moher et al., 2009). The included studies were divided into 293 studies on *chronic physical diseases* reported here, and 38 studies on *mental diseases* reported in a second paper.

Our sample papers (*n*=293) were published between 1995 and 2019. A clear increase in the number of TM studies over time can be observed. While fewer than 15 studies per year were included between 1995 and 2012, the number increased to a range of 16-23 studies per year between 2013 and 2017, and finally 51-66 studies per year between 2018 and 2019.

3.2 Diseases treated via TM-applications

TM applications were used in feasibility and efficacy studies referring to fifteen different disease groups (Table 4). They were most frequently used for the treatment of cardiovascular diseases (*n*=79), neoplastic diseases (*n*=72), respiratory diseases (*n*=41), metabolic diseases (*n*=41), and neurological diseases (*n*=27). TM was most frequently applied in the treatment of heart failure (*n*=51). Various TM applications were applied for the treatment of chronic conditions: Overall, telemonitoring (*n*=119) was most widely used, followed by telephone interventions (*n*=85), online platforms (*n*=81), apps (*n*=50), and video call interventions (*n*=42). While telemonitoring was most prominent in cardiovascular diseases (*n*=57) and respiratory diseases (*n*=25), online platforms were commonly used in neoplastic diseases (*n*=30), and telephone interventions (*n*=20) in metabolic diseases (*n*=17) as well as neurological disorders (*n*=12).

Figure 1

PRISMA flow chart (Moher et al., 2009) for the first search from 1993 until 2017

PRISMA 2009 Flow Diagram (1993-2017)

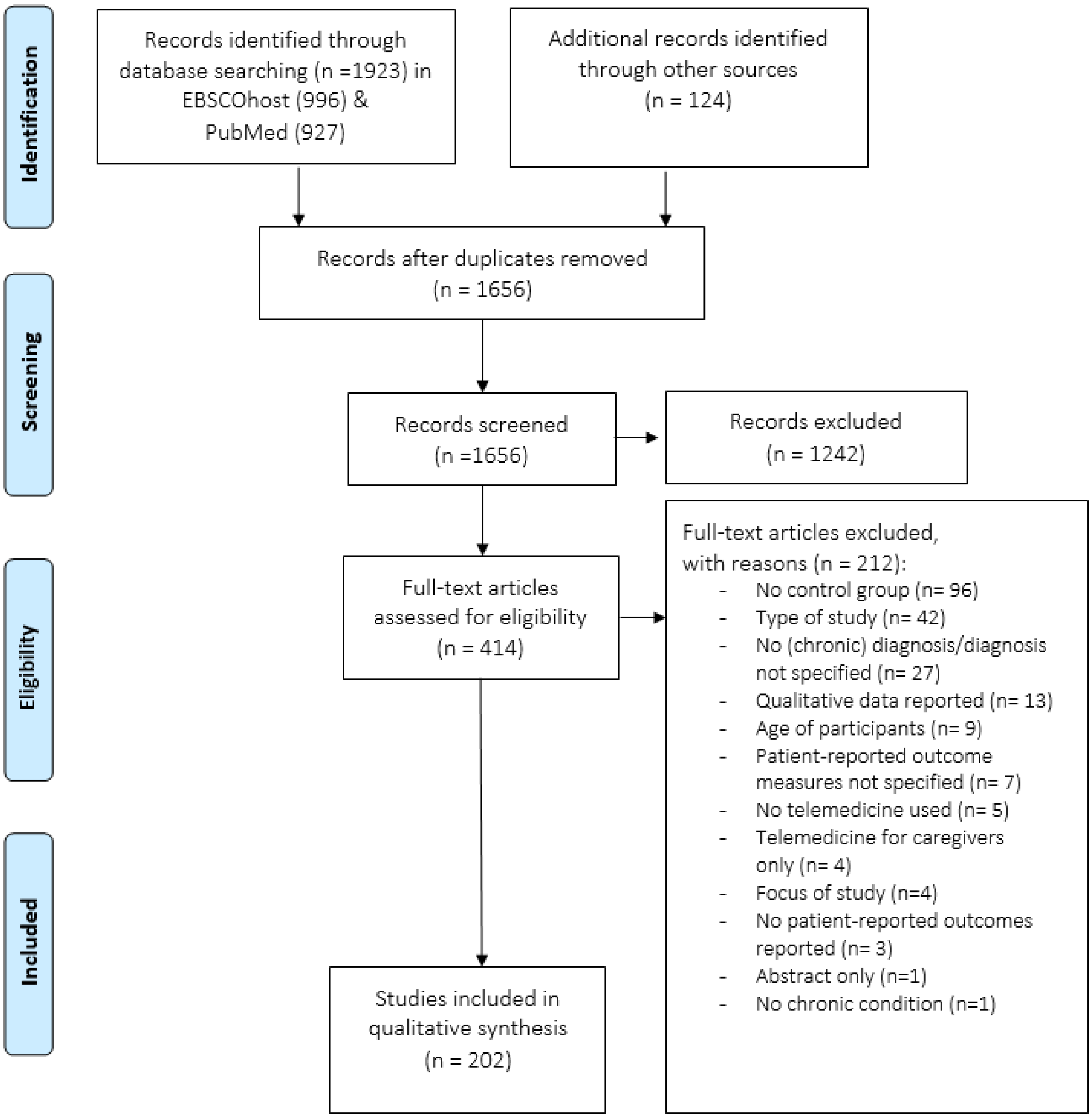

Figure 2

PRISMA flow chart (Moher et al., 2009) for the second search from 2018 until 2019

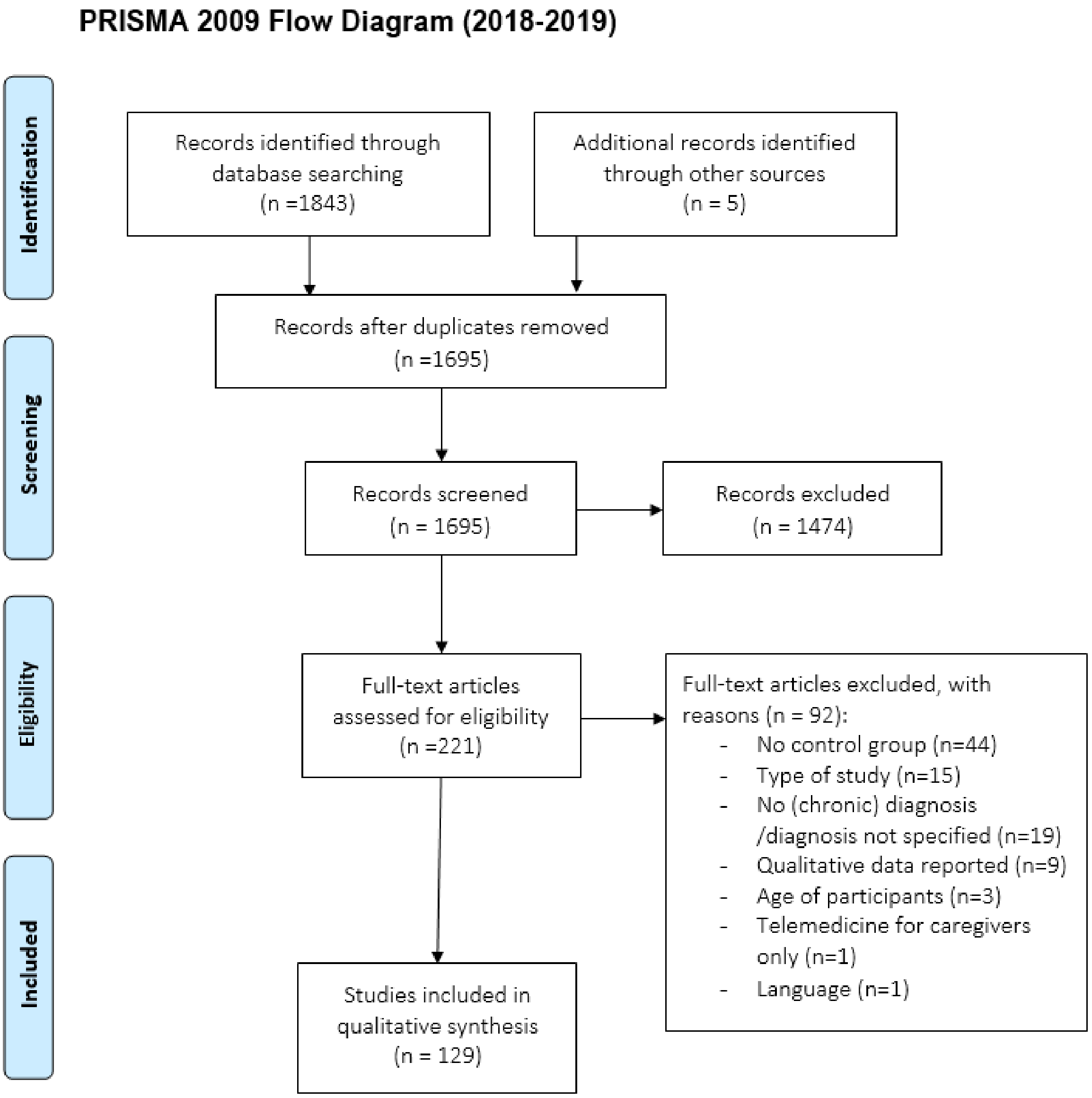

Table 4

Diseases and TM applications

Disease group		Disease		TM application
Cardiovascular disease (*n*=79)	• *per n*>4 • *per n*=4 • *per n*=3 • *per n*=2 • *per n*=1	• heart failure (n=51) | coronary artery disease (n=8) • congestive heart failure | heart failure patients with implantable cardioverter defibrillator • heart failure patients with pacemaker | hypertension • artial fibrillation | peripheral artery disease • angina | ischemic heart disease	• *per n*>4 • *per n*=4 • *per n*=3 • *per n*=1	• telemonitoring (n=57) | telephone intervention (n=23) | app (n=13) | online platform (n=11) | wearables (n=8) | video call intervention (n=7) • SMS | rest (telehealth communication device, attach to phone-line and internet; teleguidance by a medical Service Center, home TV-channel; self-care booklet; tele-PRO-system; robot-assisted therapy) • telemedical care network • electronic health record | software
Neoplastic disease (n=73)	• *per n*>2 • *per n*=2 • *per n*=1	• cancer (n=17) | breast cancer (n=18) | cancer survivors (n=13) | prostate cancer (n=7) | lung cancer (n=4) • chemotherapy-related cognitive dysfunction in breast cancer survivors | cholorectal cancer endometrial cancer with obesity | myeloproliferative neoplasm • gliomas | ovarian cancer | colon cancer | hematologic cancer | advanced solid cancer	• *per n*>2 • *per n*=2 • *per n*=1	• online platform (n=30) | telephone intervention (n=20) | app (n=19) | telemonitoring (n=9) | video call intervention (n=7) | wearables (n=5) | SMS (n=3) • e-mail | rest (video-aided presentation and booklet; handbook) • telemedical care network
Respiratory disease (n=41)	• *per n*>3 • *per n*=3 • *per n*=1	• chronic obstructive pulmonary disease (n=26) | asthma (n=7) • chronic/ advanced lung disease | chronic respiratory failure • allergic rhinitis | lung transplant Recipients	• *per n*>2 • *per n*=2 • *per n*=1	• telemonitoring (n=25) | online platform (n=9) | telephone intervention (n=7) | video call intervention (n=4) • app | SMS | rest (home mechanical ventilation; guided imagery CD) • e-mail | wearables | online video platform

Metabolic disease (n=41)	• *per n*>1 • *per n*=1	• diabetes (n=34) | obesity (n=5) • adipositas | cystic fibrosis	• *per n*>4 • *per n*=4 • *per n*=3 • *per n*=2 • *per n*=1	• telephone intervention (n=17) | telemonitoring (n=16) | online platform (n=10) | app (n=5) • video call intervention | SMS • e-mail • wearables • telemedical care network
Neurological disorder (n=27)	• *per n*>5 • *per n*=5 • *per n*=4 • *per n*=2 • *per n*=1	• stroke (n=8) • parkinson disease • multiple sclerosis • epilepsy | neurofibromatosis • mobility impairment resulting from spinal cord injury |chronic traumatic brain injury | combat related mild traumatic brain injury | chronic fatigue symptom | spinal cord dysfunction | migraine | amyotrophic lateral sclerosis	• *per n*>5 • *per n*=5 • *per n*=4 • *per n*=3 • *per n*=1	• telephone intervention (n=12) | video call intervention (n=10) • app • online platform • wearables | SMS | e-mail • telemonitoring
Gastrointestinal disease (n=11)	• *per n*>1 • *per n*=1	• inflammatory bowel disease (n=5) | irritable bowel syndrom (n=3) • crohn´s disease | gestational diabetes mellitus | patients with intestinal failure who are treated by home parenteral nutrition	• *per n*=4 • *per n*=2 • *per n*=1	• online platform | telemonitoring • app | SMS • online messaging | wearables | video call intervention | rest (home parenteral nutrition)
Pain (n=10)	• *per n*>2 • *per n*=2 • *per n*=1	• chronic pain (n=5) • chronic musculoskeletal pain | bladder pain syndrome/interstitial cystitis • nonspecific low back pain	• *per n*>1 • *per n*=1	• video call intervention (n=5) | online platform (n=5) | telephone intervention (n=2) • video based intervention | e-mail | SMS | app | rest (CD)

Sleep-related disorder (n=7)	• *per n*=4 • *per* n=3	• obstructive sleep apnea syndrom • insomnia	• *per n*=2 • *per n*=1	• online platform | telemonitoring • telephone intervention | wearables
Urologic disease (n=4)	• *per n*=2 • *per n*=1	• bladder pain syndrome/interstitial cystitis • refractory overactive bladder | fecal incontinence	• *per n*=2 • *per n*=1	• app • online platform | SMS | video based intervention | video call intervention | telemonitoring
Inflammatory diseases (n=4)	• *per n*=2	• rheumatic arthritis | inflammatory arthritis	• *per n*=1	• online platform | video call intervention | telephone intervention | SMS | telemonitoring
Ear-related disease (n=3)	• *per n*=2 • *per n*=1	• tinnitus • chronic vestibular syndrom	• *per n*=3	• online platform
Infections (n=2)	• *per n*=2	• HIV	• *per n*=1	• online platform | SMS | telemonitoring | app
Genitourinary diseases (n=1)	• *per n*=1	• dialysis patients with end-stage renal disease (ESRD)	• *per n*=1	• video call intervention | telephone intervention | telemonitoring
Degenerative disease (n=1)	• *per n*=1	• knee osteparthritis	• *per n*=1	• wearables | telephone intervention
Liver-related disease (n=1)	• *per n*=1	• liver transplantation	• *per n*=1	• telemonitoring | video call intervention

Note. The number of diseases differ from the number of studies and TM applications because of multiple mentions.

3.3 TM applications and purpose of use

The use of a TM application is mostly not limited to one purpose only (see table 5). However, despite the various uses of TM applications, it seems that the technology used and the level of activity within an application often allocates them to certain main use cases.

In our sample, the application of *telemonitoring* focussed on assessing health data (*n*=33), and improving QoL (*n*=19), clinical outcomes (*n*=14), or self-management (*n*=13), while the main purpose of *telephone interventions* (TI) and *online platforms* (OOP) were improvements in self-management (TI: *n*=18, OP: n=17), and education (TI: *n*=16, OP: *n*=13). *App* (A) and *video call* (VC) interventions were primarily used to enlarge the accessibility to healthcare (A: *n*=5, VCI: *n*=10) or improve QoL (A: *n*=14, VCI: *n*=9). Improving clinical outcomes was the main purpose of using *SMS* (*n*=4) and *wearables* (*n*=5), while *e-mails* were sent to provide tailored feedback or advice (*n*=3).

Table 5

TM application and intended outcome criteria

TM solution	**Purpose of TM application**
Telemonitoring (n=119)	
• *per n>11*	• assessment of health data (n=33) | improve QoL (n=19) | improve clinical outcomes (n=14) | improve self-management (n=13)
• *per n=11*	• decrease hospitalization | education
• *per n=9*	• prevention | decrease costs | greater access to health care
• *per n=8*	• provide tailored feedback | enhance self-care
• *per n=7*	• increase adherence/ compliance
• *per n=6*	• avoid unnecessary doctor visits
• *per n=5*	• improve disease management | improve psychological outcomes | support | improve quality of care
• *per n=4*	• improve medication management | improve satisfaction with care | conduct therapy
• *per n=3*	• improve health behavior | reduce treatment delays | improve motivation | decrease mortality
• *per n=2*	• improve functional outcomes | increase patient safety | emergency aid
• *per n=1*	• improve health outcomes | increase perceived security | compensate for limited resources | contact & communication | increase exercise participation | supervision | peer support | enhance self-efficacy | prevent relaps | patient empowerment
Telephone intervention (n=85)	
• *per n>15*	• self-management (*n*=18) | education (*n*=16)
• *per n=15*	• improve clinical outcomes
• *per n=14*	• support
• *per n=13*	• assessment of health data
• *per n=12*	• provide tailored feedback | improve QoL
• *per n=11*	• improve psychological outcomes
• *per n=9*	• conduct therapy

• *per n=6*	• contact & communication
• *per n=5*	• prevention
• *per n=4*	• decrease hospitalization | greater access to health care | improve health behavior | increase exercise participation | improve functoinal outcomes
• *per n=3*	• support coping | decrease costs | improve adherence/ compliance | emergency aid
• *per n=2*	• enhance self-efficacy | enhance self-care | improve quality of care | improve medication management | decrease mortality
• *per n=1*	• improve health outcomes | improve satisfaction with care | peer support | discharge support | prohibit comorbidity | avoid unnecessary doctor visits | decrease uncertainty | reduce waiting time | reduce treatment delays | patient activation
Online platform (n=81)	
• *per n>15*	• improve self-management (*n*=17)
• *per n=15*	• improve clinical outcomes
• *per n=14*	• improve psychological outcomes
• *per n=13*	• education
• *per n=12*	• improve QoL
• *per n=11*	• assessment of health data
• *per n=8*	• conduct therapy
• *per n=6*	• support | greater access to health care | improve health behavior
• *per n=5*	• increase exercise participation | provide tailored feedback/advice
• *per n=4*	• improve quality of care | improve functional outcomes | decrease costs
• *per n=3*	• prevention
• *per n=2*	• enhance self-efficacy | support coping | peer support | enhance self-care | patient empowerment
• *per n=1*	• increase adherence/ compliance | integrated care | improve medication management | decrease health care utilization | avoid unnecessary doctor visits | improve motivation | improve health outcomes | emergency aid | enhance locus of control | improve disease management | psychosocial support
App (n=50)	
• *per n>5*	• improve QoL (*n*=14)
• *per n=5*	• greater access to health care | improve quality of care
• *per n=4*	• support | provide tailored feedback
• *per n=3*	• education | improve health behavior
• *per n=2*	• improve functional outcomes | increase adherence/ compliance | enhance self-efficacy | increase patient safety | improve self-care | decrease hospitalization | increase exercise participation | conduct therapy
• *per n=1*	• improve self-management | improve clinical outcomes | improve medication management | Improve motivation | improve psychological outcomes | assessment of health data | prevention | decrease costs | compensate for limited resources | reduce treatment delays | contact & communication | anonymity | rest (overcome the limitations of pulmonary rehabilitation in clinical practice)
Video call intervention (n=42)	
• *per n<4*	• greater access to health care (*n*=10) | improve clinical outcomes (*n*=9) | improve QoL (*n*=9) | improve psychological outcomes (*n*=8) | contact & communication (*n*=6)
• *per n=4*	• assessment of health data | provide tailored feedback
• *per n=3*	• improve functional outcomes | decrease costs | education | conduct therapy
• *per n=2*	• improve satisfaction with care | improve quality of care | support | self-management
• *per n=1*	• emergency aid | enhance self-care | prohibit comorbidity | decrease hospitalization | peer support | save time & money | increase efficacy | avoid unnecessary doctor visits | improve functioning | improve disease management | improve adherence/ compliance

SMS (n=23)	
• *per n=4*	• improve clinical outcomes
• *per n=3*	• greater access to health care | provide tailored feedback/advice | improve QoL | contact & communication
• *per n=2*	• increase adherence/compliance
• *per n=1*	• improve health behavior | improve health outcomes | increase exercise participation | improve medication management | education | prevent relapse | improve motivation
Wearables (n=22)	
• *per n=5*	• self-management | improve clinical outcomes
• *per n=3*	• assessment of health data | improve QoL
• *per n=2*	• provide tailored feedback/ advice | improve psychological outcomes | improve functional outcomes | increase exercise participation | greater access to health care | decrease costs
• *per n=1*	• avoid unnecessary doctor visits | support | improve health behavior | improve adherence/compliance | improve motivation
E-mail (n=10)	
• *per n=3*	• provide tailored feedback/advice
• *per n=1*	• improve motivation | conduct therapy | improve QoL | support | improve functional outcomes | contact & communication
Rest (n=10)	
• *per n=3*	• conduct therapy
• *per n=2*	• decrease hospitalization | education | improve QoL
• *per n=1*	• decrease costs | support | reduce patient burden | greater access to health care | improve clinical outcomes
Telemedical care network (n=5)	
• *per n=1*	• assessment of health data | decrease hospitalization | integrated care | provide tailored feedback | improve medication management | improve self-care | improve health behavior
Video based intervention (n=2)	
• *per n=1*	• education | improve self-management
Electronic health record (n=1)	
• *per n=1*	• education | improve QoL| self-efficacy
Software (n=1)	
• *per n=1*	• rest (standardization of telephone case management)
Online video platform (n=1)	
• *per n=1*	• assessment of health data | self-management | patient empowerment
Online messaging (n=1)	
• *per n=1*	• contact and communication

Note. The number of TM applications differ from the number of studies and the number of outcome criteria because of multiple mentions.

3.4 Purpose of TM use and patient-reported evaluation criteria

First, categories were derived from our data to consistently describe the intended purposes of TM use. The final set of 53 categories is shown in table A1 (Multimedia Appendix).

In order to compare the purposes of TM use with the PROs used for its evaluation, it is necessary to distinguish between purposes that can be appropriately represented by PROs and those for whose evaluation clinician-reported outcomes (ClinROs), observer-reported outcomes (ObsROs), performance outcome measures (PerfOs), economic measures, or others would be a better fit. By excluding the studies whose purposes could not be or were not assessed using PROs from the further analysis, we obtain a sample of *n*= 269 studies. The selected studies were used to perform a gap analysis between intended purposes and defined PROs, whose results are described hereafter.

There were limitations with regard to conducting the gap analysis, as it was rarely explicitly reported which purposes of TM use should be evaluated by which PROs. It was therefore necessary to manually assign the purpose to the PRO. The assignment is attached in the appendix (table A2, Multimedia Appendix).

The assignment was explicit in only 164 of 269 cases. For example, there was a clear fit between purpose of TM use and PRO in a study by McIlhenny (2011): As such, the purposes of TM use were education, and improvement of QoL, self-management, as well as health behaviour, evaluated by using the PRO concepts knowledge, QoL, self-management techniques, and diabetes-related behaviour questions.

In 104 of 269 studies, assigning purposes to PROs was partly clear. Within this group, there have been *n*=80 studies in which several concepts e.g. education, patient empowerment, self-management, and quality of care have not been assessed via a respective PRO, but QoL. Finally, there was one study were purposes of TM use and PROs could not be matched together. Against the background of the not always clear assignment of purposes and PROs, the following results of the gap analysis should be interpreted with caution, thus, taking this context into account.

Considering the evaluation of purposes of use of TM applications, *n*=238 studies fully evaluated the intended purposes of TM use by using PROs. However, *n*=24 studies just evaluated some of the intended purposes of TM use, while *n*=7 studies did not assess the stated purposes. Therefore, there is a first gap between stating and evaluating purposes of TM use.

From a PRO-perspective, the number of PROs used was as many as needed to evaluate the respective purposes in *n*=161 studies. Thus, there is a fit between the number of purposes and PROs. However, in *n*=21 cases, not enough PROs were included to cover the purposes of the TM applications. In *n*=87 studies, more PROs were assessed than needed to evaluate the intended purposes. In this case, either all purposes were already covered by PROs and additional PROs were assessed, or PROs were assessed that did not match the respective purposes stated within the studies. Consequently, a second gap between the use of PROs to evaluate TM use and the defined purposes of TM use can be identified.

Based on these results, there is a gap between purposes of TM use, and PROs assessed, which is considered to be relevant with regard to inconsistent findings in TM reviews.

3.5 Patient-reported evaluation criteria and instruments used

This section describes whether the instruments used in the included studies were appropriate to assess the intended PROs, which should be influenced by the respective TM applications. For this purpose, it was compared whether there were differences between the construct to be measured and the construct for which the respective instrument was developed. This comparison is attached in the appendix (table A3, Multimedia Appendix).

Within the included studies (*n*=293), PROs were assessed 1.020 times in total. PROs were assessed as primary outcomes in *n*=104 studies, as secondary outcomes in *n*=81 studies, or as primary and secondary outcomes in *n*=108 studies. For this gap analysis, 606 PROMs were compared to the respective concepts. A clear fit between the construct to be measured and the selection of the instrument was found for 83.8% (n=508) of the PROMs. For a further 11.4% (n=69), the fit between the stated construct and the selected instrument can be confirmed to a limited extent. This was the case when the construct was assessed by an instrument developed for a related construct. For instance, health-related quality of life should be assessed, but a generic instrument was used in the respective study. In 3.8% (n=23) of the cases, the measurement instrument did not fit the construct that the authors intended to measure. Finally, in one case (0.17%), the fit between construct and instrument was given, but it was a paediatric questionnaire used in an adult sample. Based on these results, there is only a very small gap between PROs and PROMs used, which is not considered to be relevant with regard to inconsistent findings in TM reviews.

The outcomes QoL (*n*=269), depression (*n*=80), and anxiety (*n*=52) were assessed most frequently. However, QoL (*n*=116[3]), satisfaction (*n*=39), or self-efficacy (*n*=30) were assessed with the greatest variety of instruments. QoL was most frequently assessed by using the SF-36 or SF-12.

Looking more closely at the assessment of QoL concepts, it is noteworthy that 16.7% of the assessments used to measure general QoL were developed to measure another concept, e.g. depression. In contrast, only 6.7% of the instruments intended to measure health-related quality of life did not fit well. In comparison, there was no misfit between construct and instrument with regard to disease-specific quality of life.

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[3] Sum of frequency of quality of life (*n*=55), health-related quality of life (*n*=30), and disease-specific quality of life (*n*=21).

3.6 TM-specific instruments within our sample

Out of 293 publications, a low percentage (5.1%, *n*=15) reported the use of TM-specific instruments (table 6). The concepts measured were aspects related to satisfaction (*n*=10), access, organisation, training, reliability, usability, acceptance, usefulness, and satisfaction (*n*=1), satisfaction and usefulness (*n*=1) satisfaction and confidence in understanding and managing the illness (*n*=1), acceptance and perceived security (*n*=1), and Computer-Email-Web (CEW) fluency (*n*=1). Seven studies (Arora et al., 2014; Gellis et al., 2012; Izquierdo et al., 2003; Koff et al., 2009; León et al., 2011; Sicotte et al., 2011; Timmerberg et al., 2009) published the wording of the items partly or completely within the manuscript or the associated appendix. Two studies (Wood & Caplan, 2019; Y. Zhang et al., 2019) referred to another publication in which the items were published.

Three studies reported psychometric criteria of the respective TM-specific measures used (Sicotte et al., 2011; X. Zhang et al., 2019; Y. Zhang et al., 2019) and stated that the instruments were reliable. Of these, two studies provided specific information on reliability (Sicotte et al., 2011; Y. Zhang et al., 2019), and two studies additionally highlighted that the items used were valid or validated (Sicotte et al., 2011; X. Zhang et al., 2019).

4. DISCUSSION

Diseases & TM applications

The number of studies assessing the feasibility and efficacy of TM applications in chronic physical conditions has increased rapidly in recent years. This makes it all the more important to differentiate useful applications from those that do not add value or even cause harm (Dinesen et al., 2016). Within this systematic literature review, we have learned that the spectrum of chronic physical diseases that can be treated or cared for with TM has broadened. While early TM was often used to monitor cardiovascular diseases (Oeff et al., 2008; Ritter & Bauer, 2006; Ryu, 2010; Schmidt et al., 2010), we could identify fifteen different chronic disease groups where TM was used to treat or care for patients until 2019. Corbett et al. (2020) acknowledged this development as a major change for the treatment of patients suffering from chronic conditions. As such, “telehealth provides several advantages to combat the major pitfalls of office visit” (Corbett et al., 2020) like “avoiding disruption in patient care”, involving family members, and increasing health literacy by education. The extension of TM care offers is driven by technical progress (Strode et al., 1999). In addition to classic TM applications such as telemonitoring and telephone, there were more applications available that can be better integrated into everyday life (e.g. apps), or that offer multiple functions (e.g. online application with (video-)chats, videos, texts and exercises), which in turn expand the target groups.

Table 6

Essential information for gap analysis, extracted from studies using TM-specific assessments (publications are listed in chronological order).

Authors, year	Disease/s	TM-specific instrument/s	Construct/ Concept	Psychometric criteria	Items reported within the publication
Wood & Caplan, 2019	Inflammatory arthritis	"… previously published rheumatology TM questionnaires …" (p. 42)	Satisfaction	x	Cross reference to Poulsen et al., 2015
Zhang et al., 2019	Cancer	Items to asses satisfaction with the TM program	Program satisfaction	"…the instruments used for the study were valid and reliable…" (p. 1567)	x
Zhang et al., 2019	Cardio-vascular disease	Computer-Email-Web (CEW) Fluency Scale	CEW fluency	"…reliability coefficient of 0.64-0.89…" (p. 1057)	Cross reference to Bunz, 2004
Arora et al., 2014	Diabetes	"… locally developed mHealth satisfaction survey …" (p. 748)	Participants' program satisfaction	x	Items displayed within the publication (table 3)
Pedersen et al., 2012	Crohn's disease	"SQ (Satisfaction Questionnaire) (…) consisted of eight questions, covering: (i) satisfaction with the web program; (ii) satisfaction with the educational component; and (iii) satisfaction with the impact of the web program on CD." (p. 843)	Satisfaction with the web program	x	x

Zissman et al., 2012	Multiple sclerosis	"… six questions regarding satisfaction with the call center, each question scaled differently." (p. 474)	Satisfaction with telecare	x	x
Gellis et al., 2012	Heart or chronic respiratory failure	"Patient Satisfaction Survey. (…) developed by the home care agency assessed satisfaction with services. Six questions included the patients' satisfaction with the telehealth experience, problems using the equipment, concerns about privacy when using the equipment, whether the telehealth intervention helped to improve their overall health, helped them stay healthier, and improved their understanding of their illness. Patients were asked to rate their care, using a Like scale from 1 to10, with "10" being the highest satisfaction rating." (p. 545)	Satisfaction	x	Items partly displayed within the publication (table 3)
León et al., 2011	HIV	"Parameters regarding access, organisation of the system, the need for training, reliability, usability, acceptance, usefulness and satisfaction" (p. 6)	Access, organisation, training, reliability, usability, acceptance, usefulness, satisfaction	x	Items displayed within the publication (table 2)
Sicotte et al., 2011	COPD	"… the satisfaction with the telemonitoring intervention was measured using validated scales: five for the patients' perceptions and two for the nurses' perceptions …" (p. 96)	Satisfaction, usefulness	"... measured using validated Likert scales…" (p. 96), Cronbach's a=0.58 to 0.94	Items displayed within the appendix

Koff et al., 2009	COPD	"… patient satisfaction with the equipment used at home was assessed (…) from 1 to 10 (1 being strongly dissatisfied and 10 completely satisfied) to each of the individual pieces of equipment used during their 12-week enrolment …" (p. 1035)	Equipment satisfaction	x	Items partly displayed within the publication (table 7)
Timmerberg et al., 2009	Diabetes	Telemedicine Patient Satisfaction Survey	Satisfaction	x	Items displayed within the publication (table 3)
Schmidt et al., 2008	Chronic heart failure	"… attitudes toward telemonitoring, (…) acceptance of the use of telemonitoring …" - "… acceptance and perceived security were measured with brief measures (5-point Likert scale) that have been systematically developed in telemedicine studies …" (p. 427)	Acceptance and perceived security	x	x
Jansà et al., 2006	Type 1 diabetes and poor metabolic control	"… specifically designed Telecare Satisfaction Test (scale of 1–10 with 1 being the lowest) …" (p. 28)	Satisfaction	x	x
Dunagan et al., 2005	Heart failure	"… locally developed 13-item instrument evaluating (…) satisfaction with care and confidence in understanding and managing their illness." (p. 360)	Satisfaction with care and confidence in understanding and managing the illness	x	x
Izquierdo et al., 2003	Diabetes	"… subjects participating in the telemedicine group also completed the Telemedicine Patient Satisfaction Survey (17), which evaluated their satisfaction with the telemedicine service." (p. 1004)	Satisfaction	x	Items displayed within the publication (table 4)

Purposes of TM use & PROs

Within this systematic literature review, it was shown that many purposes of TM use are already assessed via PROs, so efforts to strengthen the patient perspective seem to have positive results (Hsiao & Fraenkel, 2017; Roorda et al., 2019). Nevertheless, two aspects stood out while analyzing the included studies. Firstly, it should be reviewed which purposes of TM use, that are currently not assessed from the patient's point of view, can be evaluated via PROs. Secondly, the reporting of the respective TM application, the purpose of TM use, as well as PRO evaluation criteria, and the PROM applied must be improved, i.e. documented more transparently. This is the only way to understand on which information and decisions the evaluation of TM applications is based. At the same time, the quality of data collection can be improved through transparent documentation, for example in study protocols, by identifying potential misfits, and discussing them among peers.

When allocating the purposes of TM use and PROs, it was noticed that QoL was a.o. frequently in studies in which a) the association between purpose and PRO was only partially clear, or b) more PROs were reported than would have been necessary to evaluate the purposes. The latter underlines the fact that QoL is kind of higher-level construct that provides valuable information beyond specific purposes of TM use, and is therefore used with high frequency. However, when allocating purposes and PROs was only partially clear, QoL was often used to reflect other, specific concepts such as self-management or education. With regard to some of these concepts, this approach is consistent with an approach by Greffin et al. (2021), which shows that specific, healthcare-related aspects of QoL evolve in TM contexts. However, this study was only recently published, which is why it is considered that the specific concepts were simply not assessed. At the same time, it reflects the impression that QoL is used as a kind of one-for-all construct. It remains unclear whether it is frequently assessed out of interest or definitional ambiguity (Karimi & Brazier, 2016; McKenna & Doward, 2004).

The identified gaps in included studies regarding purposes of TM use and PROs should thus be addressed by a) formulating purposes of TM use in such a way that they can be evaluated via PROs, b) evaluating all intended purposes of the specific TM use, c) using appropriate PROs according to the purposes, and d) providing complete and transparent documentation in study protocols and research articles.

PROs & PROMs

QoL, satisfaction, and self-efficacy were concepts measured with the greatest spectrum of instruments in the included studies. The prominence of these concepts is in line with the context of TM applications in many countries: Complementary to standard care, they are mainly used to improve QoL of chronically ill patients and to strengthen self-efficacy with regard to the management of the disease. At the same time, satisfaction is assessed in order to document the patients' perception of the technology-supported applications and thus to be able to justify the use of TM treatment alternatives from a patient perspective. Therefore, it is not surprising that the majority of TM-specific questionnaires also captures this construct. However, the construct of satisfaction is treated step-motherly. Self-generated, non-validated items are often used in its assessment. This circumstance can be criticized and a call can be made for properly developed, context-specific instruments. At the same time, this construct in particular is prone to ad-hoc developed items, as researchers aim to adapt items to an intervention as much as possible in order to best represent patients' perceptions. Consequently, there is a trade-off between a high content validity of the items on the one hand and a high degree of psychometric foundation on the other hand. For this reason, a broad spectrum of satisfaction instruments should be developed properly to meet the need for specific instruments. Alternatively, standards and recommendations are needed to make the minimum requirements for self-developed items available.

Similar efforts are needed to accurately assess QoL. QoL is the most frequently assessed PRO in the studies included in this review. It was most often measured with the SF-36, which is in line with a recently published review (Pequeno et al., 2020). However, one gets the impression that it is assessed as a kind of “minimum or one-for-all PRO” in order to take patient-centeredness in studies into account. In up to 32.7% of the cases, the fit between the construct of QoL and the instrument used was partly unsatisfactory. This circumstance suggests definitional uncertainties in relation to the construct, which is in line with the literature (Karimi & Brazier, 2016). The proportion of misfits decreases the more specific QoL - in the form of health-related or disease-specific QoL - is assessed. For this reason, it can be assumed that the fit between QoL and an instrument increases the more precisely the components to be assessed are reflected, determined and chosen.

The identified gap between PROs and PROMs in TM should thus be addressed by carefully defining construct components that are of interest in a respective study first. Afterwards, a suitable instrument should be chosen conscientiously and, if necessary, discussed with interdisciplinary colleagues.

TM-specific instruments

TM-specific instruments were used in 15 of 292 TM studies. Concepts related to satisfaction (e.g. program satisfaction) were the most frequently assessed constructs. This finding is consistent with the literature (Hajesmaeel-Gohari & Bahaadinbeigy, 2021). At the same time, four aspects become evident: Firstly, TM-specific instruments are used in about 5% of the studies investigated. It can be assumed that TM-specific aspects of care (Greffin et al., 2021) are therefore insufficiently covered by the existing instruments (Höhne, 2012). Secondly, more than two-thirds of the TM-specific assessments analyzed refer to satisfaction. Until now, TM-specific instruments are therefore only available for a limited range of concepts (Hajesmaeel-Gohari & Bahaadinbeigy, 2021). Thirdly, we consider QoL as a central PRO in the field of TM (Knapp et al., 2021; Riva et al., 2015; Schmidt, 2007a). However, there is no instrument for assessing QoL in the context of TM. Fourthly, the use and documentation of TM-specific instruments is currently still rather unsystematic. Moreover, the instruments used have rarely gone through the process of rigorous step-by-step instrument development (Cheng & Clark, 2017; Knapp et al., 2021; Rothrock et al., 2011). For these reasons, we recommended to better document the selection and use of (TM-specific) instruments, and to focus on developing elaborated instruments in the future. Finally, we agree with Knapp et al. (2021) that PROM collection should be standardized in TM evaluation studies.

Limitations

To the best of our knowledge, such an extensive systematic literature review addressing the link between the study purpose and the evaluation of the respective outcomes in TM context has not yet been published. However, the approach's novelty also implies limitations that should be taken into account when reflecting on the study.

One limitation of the review is the search string. Based on the experience made, the search string should be broader and include more PROs (e.g. satisfaction) as well as digital health terms (e.g. app or online-platform). At the same time, the current search string emphasizes QoL too much compared to other PROs, even though it is a central patient-reported outcome. Finally, the inclusion of German-language terms did not prove to be of added value.

A second search was conducted in an attempt to keep the study up to date. However, scientific research in the field of TM has increased considerably, especially in recent years. We have made every effort to include all relevant studies, but there is a possibility that some other studies may have been overlooked.

Furthermore, information essential for the gap analysis was only reported to a limited extent in the original studies.

Finally, within the included studies, the evaluation of PROMs has mostly been conducted in the context of projects, rather than in the context of everyday telemedical care. Recent developments have led to a broader implementation of telemedical care for patients with heart failure, for example, by the inclusion in the standard catalogue of services provided by the health insurance funds in Germany (Spethmann & Köhler, 2022). This means that telemedicine is now also offered and reimbursed on a regular base and independently of projects. It remains to be explored whether this in turn has an influence on patients' evaluation of PROMs.

5. CONCLUSION

This systematic literature review showed that there are relevant gaps between defined purpose, chosen concepts, and methods of measurement used within TM feasibility and efficacy studies. However, these gaps are relatively small. In conclusion, they may further foster existing inconsistencies, but will not be the main reason for them. Nevertheless, we emphasise the importance of aligning the purpose of TM use and evaluation criteria as well as a complete documentation of the procedure coherently.

More importantly, only a small number of TM-specific instruments was used. Therefore, we highlight the need for further setting-specific instruments that can be used for assessments in TM studies.

Ethics

The project was approved by the Ethics Committee at the University Medicine Greifswald (BB 023/18) and the partner department (AS466 (bB)/2018).

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Paper III

Greffin, K., Schmidt, S., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Muehlan, H. (2021). Same same - but different: using qualitative studies to inform concept elicitation for quality of life assessment in telemedical care: a request for an extended working model. *Health and Quality of Life Outcomes*, 1–14. https://doi.org/10.1186/s12955-021-01807-8

Same same – but different. Using qualitative studies to inform concept elicitation for quality of life assessment in telemedical care: a request for an extended working model

Klara Greffin[1*], Silke Schmidt[1], Neeltje van den Berg[2], Wolfgang Hoffmann[2], Oliver Ritter[3], Michael Oeff[4], Georg Schomerus[5], Holger Muehlan[1]

*Corresponding author

[1]University of Greifswald, Department of Psychology, Chair of Health and Prevention, Robert-Blum-Str. 13, 17487, Greifswald, Germany.

[2]University Medicine Greifswald, Institute of Community Medicine, Department of Health Care Epidemiology and Community Health, Ellernholzstraße 1-2, 17475 Greifswald, Germany.

[3]Brandenburg City Hospital, Brandenburg Medical School Theodor Fontane, Fehrbelliner Str. 38, 16816 Neuruppin, Germany.

[4]Brandenburg City Hospital, Hochstraße 29, 14770 Brandenburg an der Havel, Germany.

[5]University of Leipzig Medical Center, Semmelweisstraße 10, 04103 Leipzig, Germany.

Background: Although telemedicine applications are increasingly used in the area of both mental and physical illness, there is no quality of life (QoL) instrument that takes into account the specific context of the healthcare setting. Therefore, the aim of this study was to determine a concept of quality of life in telemedical care to inform the development of a setting-sensitive patient-reported outcome measure.

Methods: Overall, 63 semi-structured single interviews and 15 focus groups with 68 participants have been conducted to determine the impact of telemedical care on QoL. Participants were patients with heart failure or major depression, with or without telemedicine supported healthcare as well as telemedical professionals. Mayring's content analysis approach was used to encode the qualitative data material using MAXQDA software.

Results: The majority of aspects that influence the QoL of patients dealing with chronic conditions or mental illnesses could be assigned to an established working model of QoL. However, some aspects that were considered important (e. g. perceived safety) were not covered by the pre-existing domains. For that reason, we re-conceptualized the working model of QoL and added a sixth domain, referred to as *healthcare-related domain*.

Conclusion: Interviewing patients and healthcare professionals brought forth specific aspects of QoL evolving in telemedical contexts. These results reinforce the assumption that existing QoL measurements lack sensitivity to assess the intended outcomes of telemedical applications. We will address this deficiency by a telemedicine-related re-conceptualization of the assessment of QoL and the development of a suitable add-on instrument based on the resulting category system of this study.

Key words: Telemedicine, Quality of Life, Patient-Reported Outcome Measure, Concept Elicitation

Background

Telemedical applications (TM) are widely used for the treatment of physical and mental illnesses. They represent a way to ensure healthcare is available to people in rural areas or during times of crisis either as a supplement or substitute to standard care.

The use of supplementary telemedical applications aims to improve patient-centered healthcare management (1–3) and targets challenges that arise in continuity of care (4). In general, telemedical applications are defined heterogeneously (5). In line with the World Health Organization (WHO), we understand telemedicine as “the delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities” (6). In Germany, this type of healthcare is provided either by healthcare professionals in medical institutions or by commercial companies. So far, only some of the telemedical services are financed by statutory health insurers. The legal framework for the evaluation and financing of telemedical applications has only been created in recent years. Currently, digital healthcare is systematically expanding with numerous new regulations. For example, criteria for reimbursing telemedical applications are being debated and there is ongoing development of digital health technologies, including the design of more user-friendly telematics infrastructure, the promotion of digital networking, and the use of health apps in nursing care.

Patient-reported outcomes came to the fore within efficacy studies of telemedical applications, next to clinical or economical evaluation criteria (7–9). Quality of life (QoL) became established as the most commonly applied patient-reported outcome (10). It is assessed not only within efficacy studies, but also in the context of economic evaluations (11). To take the impairment of physical or mental states into account (12), not only generic, but also health-related or disease-specific QoL can be measured in the context of (chronic) health conditions. Different aspects of QoL are assessable, depending on the content focus of the underlying model and the resulting instrument (13). Reviews about the impact of telemedical care on QoL show inconsistent results (14) for most commonly addressed specific diseases like e.g. heart failure (15–21) or depression (22, 23). Studies have applied established generic, health-related or disease-specific QOL instruments (e.g. EQ-5D, SF-36/SF12, WHOQOL-100/_BREF; (24)), that may not be sensitive enough to assess setting-related aspects of QoL in telemedical contexts. A contributing factor is that QoL assessments were designed before the use of digital treatment solutions that changed the healthcare context. Research has shown, that the implementation of telemedicine has an enormous impact on patients’ daily lives and lived experiences. A qualitative study provides evidence that telehealth is perceived as helpful in managing everyday life and enables patients to better self-manage their condition

(25). They also report that increased contact with healthcare professionals and the level of continuity of treatment enables trusting relationships to be formed over distance which alleviates feelings of isolation. Moreover, a sense of security, feelings of relief and support in self-care through access to telehealth data has been described (25). In addition, telehealth applications can support independent living at home and controlling the health state (26). A major gap is that patient-reported instruments sensitive for these issues are missing. So far, several patient-reported instruments applicable in the telemedical setting have been developed, e.g. for measuring satisfaction (27, 28), subjective usability (29), or patients' impressions of the risks and benefits (30). However, none of these instruments address the assessment of QoL from the patient’s perspective in the context of telemedicine in particular.

For this reason, our study aimed to explore the impact of telemedical care on QoL of patients with chronic diseases or mental illnesses. We applied a qualitative approach to derive a concept of quality of life (QoL) in telemedical care. This concept elicitation will inform the development of a setting-sensitive instrument to assess patients’ QoL in telemedical healthcare. Until now, this is the first study to address the observed inconsistencies by challenging the adequacy of existing QoL assessments for telemedical healthcare services.

Methods

Study design and population

Sample and research context

We conducted a qualitative, observational, cross-sectional study. The participants were enrolled according to inclusion criteria, but not randomized. This study focused on expectations and experiences of patients and professionals regarding telemedical healthcare as compared to standard care and was not blinded.

The sample aimed to represent the heterogeneity of telemedical applications and patient populations to ensure more generalizable results. Therefore, we included the main groups of telemedical healthcare professionals and chose patient groups that are heterogeneous with regard to their primary disease (mental and physical chronic disease), but often included in telemedical studies (heart failure and depression). In addition, we included active (regular phone calls) and passive (monitoring) telemedical applications. Therewith, we wanted to capture a variety of telemedical experiences from patients with a diverse disease, gender, age and care spectrum as well as from different telemedical professionals. The number of focus groups and interviews was chosen in order to reach content saturation (31–33) and is described in Table 1. We aimed to undertake a) focus groups with a total number of 32 participants (patients), b) focus groups with a total number of 30 participants (telemedicine professionals), c) 32 single interviews with patients, and d) 30 single interviews with telemedicine professionals. We aimed for a minimum case number of *n*=30 in all groups.

However, in the focus groups and interviews with patients, we included at least *n*=32 participants to ensure an equal distribution of condition (physical vs. mental) and type of care (telemedical care vs. care as usual) resulting in *n*=8 in each combination.

All patients were recruited by the associated telemedical nurse during treatment in two university hospitals in Mecklenburg-Western Pomerania and Brandenburg, Germany; professionals were recruited nationwide via e-mail, phone or in-person contact by the first author. All eligible participants had to be 18 years or older and German speaking. Moderate to severe impairment of cognitive functions (e.g., comorbid neurological diseases) were defined as exclusion criteria. Further criteria were defined per group in terms of the disease (heart failure or depression), and the telemedical experience (with or without telemedical experience). Participation in the study was voluntary; there was no disadvantage in not participating. Participants received an expense allowance. All participants provided written informed consent.

Data collection

As recommended for concept elicitation (34, 35), we conducted open-ended, semi-structured in-person focus groups and individual interviews with either patients or telemedical professionals. Every conversation was voice-recorded. All focus groups were led by the first author and a student transcript writer, and took place at the patients' respective treatment clinic or in the natural work environment of the professional groups. The duration of the groups varied between 60 and 100 minutes. In addition, we conducted open-ended, semi-structured expert interviews. All interviews with professionals were led by the first author and were conducted in-person at a place chosen by the professional or via phone. Interviews with patients were conducted by associated telemedical study nurses at the patients' respective treatment clinic or via phone. The duration of the interviews varied between 30 and 90 minutes. All participants were only interviewed once. All interviews and focus groups were conducted between July 2018 and February 2019. Finally, an expert workshop for external validation of the results was conducted as a group discussion, with six experts from the fields of TM applications and QoL research.

Interview and focus group guides

The interview and focus group guides consisted of mostly open-ended formulated questions and were divided into three main parts: a) individual understanding of QoL, b) personal description of current healthcare situation, and c) subjective impact of healthcare on QoL. All participants could indicate not to answer a question. The different versions of the interview and focus group guides are attached in the supplementary appendix (Supplementary A & B). The questions were partly adapted to the person being interviewed. Spontaneous questions for improved understanding were possible.

Data analysis

The recording of interviews and focus groups were transcribed word-for-word in standard German by student research assistants using the software f4transkript by audiotranskription (36). Mayring's content analysis approach (37) was used to encode the qualitative data material with MAXQDA software (38). The analysis aimed to identify all text sequences or units of meaning that refer to the personal meaning of QoL, the personal experience in connection with the telemedical application or standard healthcare, and its impact on QoL. At first, deductive categories were defined, that were used to structure the organization of inductive categories. These were iteratively derived from the material by two staff members independently. After the initial coding, the inductive categories were discussed and uniformly labelled. In the following step, the material was newly assigned to existing categories independently, before the two staff members discussed the final assignment. Possible divergent codings and contradicting interpretations were discussed with a third supervising person in a consensual procedure.

Quality of Life - a working model

QoL instruments assess different core areas of the construct: some are rather generic, while others are health-related or disease-specific. For this reason, we initially created a general working model of QoL on which we could map the results of this qualitative study. As part of a systematic literature review, we summarized telemedical efficacy studies that addressed either chronic physical or mental conditions and included QoL as primary or secondary outcome. On this basis, we identified the most commonly used generic (EQ-5D: 23x; WHOQOL-100/ WHOQOL-BREF: 17x), health-related (SF-36/ SF-12/ SF-8/ SF-6: 81x), or disease-specific (EORTC QOL-C30: 41x; MLHFQ: 33x; FACT: 17x) QoL instruments in telemedical efficacy studies (24). In the next step, domains and subdomains of these instruments were analyzed. Finally, we integrated the findings on a general working model of QoL with the following domains: Biological domain, psychological domain, social domain, functional domain, and a disease-specific domain. The next paragraph describes the mapping procedure of the results of our qualitative study on this working model of QoL.

Results

In total, 38 randomly assigned patients participated in 8 focus groups of four to five participants. Patients were between 18 and 84 years old, from Northeast Germany (Federal States of Mecklenburg-Western Pomerania and Brandenburg), and of various social backgrounds. 21

patients were male and 17 female. 18 heart failure patients (*n*=9 each with or without telemedical treatment) and 20 patients with major depression (*n*=10 each with or without telemedical treatment) participated. All patients received a compensation of €40 to cover expenses.

Furthermore, we conducted seven semi-structured focus groups nationwide with pre-existing working teams from a telemedical background. The teams were interviewed in their natural work environments: a) a telemedicine unit for depression (*n*=8 from university or commercial setting), b) a telemedicine unit for heart failure (*n*=14 from university or commercial setting), c) a telemedical team in a private cardiology practice (*n*=6), and d) a start-up for telepsychiatric care (*n*=3). The group size varied between three to six participants per group with a total number of 31 participants. All professionals received a compensation of €75.

Additionally, we conducted 63 semi-structured single interviews. Our participants were patients (*n*=33) with heart failure (*n*=16, 8 with and without telemedical treatment) or with mayor depression (*n*=17, 9 with and 8 without telemedical treatment). All patients received a compensation of €40 to cover expenses.

Finally, we conducted semi-structured expert interviews with 30 telemedicine professionals from Germany and Austria, of which nine participants were male. The professionals came from five different areas: a) research (*n*=13), b) provider of commercial telemedical care (*n*=9), c) telemedical care in hospitals or private practices (*n*=6), d) politics (*n*=1), and e) health insurance companies (*n*=1). All professionals received a compensation of €75.

Table 1

Recruited sample for focus groups and individual interviews consisting of patients and professionals

	Focus Groups		Interviews		**Total**
Patients	TM	no TM	TM	no TM	
Depression	10	10	9	8	37
Heart Failure	9	9	8	8	34
Total (Patients)	38		33		71
Professionals	31		30		132

Note. TM = with telemedicine, no TM = without telemedicine

Treatment of patients in the telemedical group

Patients with depression received telephone support in addition to standard treatment. A telemedical contact person called the patient at individually defined times in variable intervals for an average of 30 to 50 minutes. At the beginning of each telephone call, standardized questionnaires were used to document the course of the disease, followed by a discussion of individual topics. Patients were able to reach their telemedical contact person in an emergency. Patients with heart failure were integrated into a telemedicine system, and received an electronic scale to take home as well as a digital device that automatically sends data to their hospital. After an introduction, patients were asked to weigh themselves every morning at home. If the automatically transmitted values exceeded a predefined tolerance range, the patients were contacted by a heart failure nurse and, if necessary, further steps were taken to manage the situation (e.g., making doctor's appointments, adjusting medication). Patients had the possibility reach their telemedical contact person in case of an emergency.

Derived conceptual framework

In the following section, we describe various facets of QoL domains that study participants referred to and give examples of how they are impacted by telemedical healthcare. A quantitative summary of the data evaluation can be found in supplementary appendix (Supplementary C). Participants' quotes are highlighted with italic formatting. They were slightly edited within the translation process for improved comprehensibility.

Pre-existing domains

Biological domain

According to the participants, sleep and pain are crucial aspects of QoL that can be assigned to the biological domain *("I also have other problems where I have a very poor quality of life: For example, I can walk twenty meters without pain. Above twenty meters I have pain in my calves. Above forty meters it becomes unbearable.")*. We conclude from the data that telemedicine impacts those two essential aspects, for example by monitoring the patients' symptoms, by helping them increase their health literacy, and by adapting clinically rational medication based on increased availability of data.

Psychological domain

In the context of the psychological domain of QoL, the facets of psychological *well-being, mood, cognitions,* and *self-esteem* play a decisive role in everyday life with chronic physical or mental diseases. *Psychological well-being* comprises aspects like fear, self-care, meaning and perspective, vulnerability as well as the feeling of being left alone with the disease *(“I don't go out alone anymore because I am afraid. I get dizzy more often and that's why I'm so afraid to go out on the street alone and my husband has been dead for 26 years, I have no one else.”)*. It can be improved by telemedicine through increased health literacy and knowledge about the disease and treatment options *(It is clearly the content that has an influence. The content is also taught in outpatient therapy. But I also believe that digital medium plays a very important role. The user has to become active, which creates an additional therapeutic effect. / I think the patient is more likely to become an educated patient, that he*she understands himself*herself and his*her disease or health condition better, that he*she gets a better feeling and can act more at eye level with the doctor.).* Moreover, patients appreciate the opportunity of talking to a neutral contact person from telemedical personnel to discuss fears and issues that concern them *(The moment we have a phone conversation and I can tell my problems, I feel better already.).*

If we look at *mood*, it is noticeable that many respondents associate positive mood with QoL, but often suffer from negative mood and feelings (e.g. frustration) in the context of their disease and the associated treatment *(“I observe depressive moods more often. I am not depressed per se, but I immediately view everything negatively without any plausible reason. (...) This accompanies me much more strongly in my life than when I still had a healthy heart.”).* According to the reports, telemedicine is a way to improve mood and can help to deal with negative feelings: Applications can improve it by assisting with questions, difficulties with treatment, disease management, or topics from everyday life *(It's fun talking to the telemedicine nurse. I tell her something and she can give me advice on how to handle a situation better.).* In addition, communication between telemedicine personnel and patients can have a distracting and relaxing effect. Lastly, some patients simply enjoy using telemedicine *(When I know that the telemedicine nurse is calling, I lie down on the couch and take the phone with me. It's really nice and relaxed. Not as stiff as with the psychologist.).*

Negative thoughts, indifference, and guilt shape the statements that can be assigned to the facet of *cognitions (“For me, quality of life is to be able to get up in the morning without carrying negative thoughts all day.”).* This is addressed by telemedicine through additional communication, shared reflection processes, and symptom management *(In our program, an important part is needs and goals in life. People actively deal with how they actually want to live. At that moment, they already reflect on what they spend their time on, what they want to spend their time on, what they want to change. It can be a change in private life, so that one takes more time for positive activities, for family and friends, for self-care. And at the same time also at work, e.g. problem solving is often an issue.).*

Finally, it was described that *self-esteem* can be reduced by chronic diseases. Patients report they feel less valuable or that they are a burden for others due to their disease *(“It's such a burden, it's so stupid, I'm burdening my husband with it.”).* Here, telemedical applications can increase the self-efficacy experience of patients with regard to their disease and coping with their everyday lives *("Quality of life of depressive patients means they can experience self-efficacy despite their illness. Be it in social contact, be it in a professional or voluntary context, or even in sports activities or creative pursuits.")*. It is crucial that patients feel competent in dealing with their own disease. Moreover, therapy and disease management can be simplified, e.g. by providing distant treatment so that patients do not have to rely on help for transport. Simplifying care can help patients perceive themselves as less of a burden on their relatives. Therefore, information should be tailored to patients' current life situation. Additionally, patients should receive support in disease management and suitable adjustments of the type of treatment. Finally, the communication between patient and telemedical personnel seems to build self-esteem *("Did you have any expectations about the telemedicine care beforehand?" - "No expectations, because I didn't yet know what was in store for me. (...) From today's point of view, I have to say that it is very positive, I experience it as constructive for me, stimulating. And above all, my self-esteem is strengthened again, particularly when things are going badly for me.").*

Social domain

With regard to the social domain of QoL, study participants stated that *social relations, support, norms,* and the *environment* play an important role. They describe that the disease's impact can lead to avoidance behavior that impedes socializing or maintaining contacts, and often leads to social isolation, which harms the patients' QoL. In contrast, the existence of relatives or friends is experienced as beneficial. Telemedical treatment can address the effect of feeling socially isolated as it often provides an additional contact to communicate with *("Well, even if you're alone, like I was, and I was always single in between, you're not left alone. You don't sit alone and kill yourself because there's no one there to stop you, right? (.) They call me every week. You didn't even get to kill yourself.")*. Unlike with family and friends, the relationship to the telemedical personnel is mostly unidirectional with the patient's needs in the center of attention, and no expectation of reciprocity. While regular telemedical contacts can disburden private contacts when patients can communicate about their disease with competent staff, private contacts of the patient can also be involved in the treatment, for instance in educational sessions or conversations about everyday life challenges.

Study participants describe perceived *social support* as beneficial. However, it is often missing due to social isolation or social contacts being helpless *("When I'm open with the people around me and say that I am not doing so well, and tell them what is not going well, my problems, I felt it puts people in a position that very few people can handle and want to handle.").* Consequently, patients perceived it as supportive to stay in touch with competent telemedical staff that can provide help for coping with everyday life. As such, a regular contact to the telemedical staff can partly compensate for missing social support by patients' private contacts.

Third, *social norms* play a role for the interviewees in evaluating their QoL. A perceived pressure to perform was described, which often arose from the comparison with other (healthy) individuals. In addition, they noticed a lack of societal sympathy for the disease's symptoms or the treatment's side effects, and often felt misunderstood. Finally, some of the patients reported to be responsible for partners or a children in need of care, and that they find it difficult to deal with the feeling that they cannot always live up to this responsibility because of their disease. To reflect the self-image, the perceived pressure, and to find solutions for challenging situations via telemedicine can often relieve patients. Again, a regular and competent contact can support coping processes, educate about disease management skills or tools, and make everyday life more livable.

Finally, the *social environment* has an impact on the participants' QoL. As such, patients described it as positive to be in pleasant surroundings and live together with people they love and appreciate. As telemedicine can be brought to the patient, it supports the desire to be treated in a familiar environment.

Functional domain

In the context of the functional domain of QoL, the facets of *autonomy, general level of function*, and *level of activity or participation* play a decisive role in everyday life with chronic diseases.

Autonomy was described as the ability to meet basic needs, to handle the everyday tasks independently, to be mobile, and to manage one's own daily schedule *(I am afraid of becoming more and more of a burden for others. That's in the back of my mind, it is terrible. I have always been active, I have had four children and raised a grandchild. (...) With many, many things I am now dependent. It's so terrible, unbelievable.).* It is also understood as having financial resources or property, and the option to travel and go on vacation *("I am very proud of the fact that I am now working again and can therefore afford a car again.")*. However, patients suffering from a chronic condition often face limited possibilities in managing their everyday life independently, and the extent of their autonomy is often linked to the severity of the disease. Telemedicine can be used to improve patients' autonomy in several aspects: Firstly, it can provide location-independent healthcare which is also accessible for immobile patients, and it saves travel costs and efforts *(What patients mentioned repeatedly: Many of them did not dare to leave their homes anymore. Travelling were not possible because they somehow thought, 'Well, if something happens, I have to get to my cardiologist or to the hospital quickly'. Now that they are supported by telemedicine, they can take their device with them and "have the doctor in their pocket". That way, patients can go on a trip again.).* Secondly, some telemedical applications can be used flexibly with regard to time and duration while others provide daily orientation and therewith a certain stability in everyday life *(What I really appreciated about telemedicine (...) was that the length of the telephone call was always based on my needs. I determined the length. When I was feeling bad, the call was longer, and* *when I was feeling better, the call was shorter. I found that very, very nice compared to outpatient therapy.)*. In conclusion, telemedical treatment may be better integrable. Thirdly, telemedicine may provide help for self-help and guidance within the everyday context to increase autonomy in a real-life situation.

The *general level of functioning* influences QoL *("Sometimes I feel like my mind is still young, but my body no longer works well and that makes me sad, it hinders me. You want more than you can actually do.")*. For instance, being able to work, maintaining a structured daily routine, work-life-disease balance, and the degree of avoidance behavior were described as crucial. Telemedical applications may help in symptom management and provide help for self-help. Continuous treatment supports patients in structuring and organizing their day. Finally, guided stimulation of exposure, followed by a reflective process may help to improve the general level of functioning.

The *level of activity or participation* comprises physical and mental participation, career opportunities, hobbies, and sports *("Sure, it is important for the quality of life to pursue one's own needs and hobbies as well").* A higher level of participation was described as beneficial for the perceived QoL. However, many patients feel limited by their disease. Telemedical applications may improve the level of activity by providing support in symptom management, help for self-help, and guided participation *(Activation is simple, the patient gets up, turns on the tablet, answers his*her questionnaire, maybe even listens to his*her inner self, which can be positive. Of course, he*she is also activated by various things: We included sports programs and pedometers that motivated the patients, we provided recipes where the patients say: 'Man, I haven't tried that yet', and they go out and buy ingredients that they have never worked with before. He*she expands his*her knowledge, his*her spectrum and attention.).*

Disease-specific domain

According to study participants, the impact of the *disease, disease-related environmental factors*, and the *acceptance* of the disease are key elements that influence QoL.

The perceived *impact of the disease* was described by the interviewees stating limitations due to symptoms *("Quality of life for me is to live as I lived before the disease. Of course, I also have to admit to myself that I can no longer do everything the way I did before. But I still want to do as much as I can.")*, physical as well as mental effects of the disease, the stability of the course of the disease and sometimes a limited life expectancy. Most importantly, telemedical treatments should support the monitoring, limitation, and management of symptoms, and accompanying the patient as emotional support.

Moreover, *disease-related environmental factors* play an important role: Handicapped accessible means of transport, inner-city infrastructure (e.g. public toilets), or easy-accessible medical facilities are appreciated, whereas the lack of these leads to tremendous effort on the side of the patient, or avoidance behavior. Even though telemedicine cannot change the social environment of the patient, it can make the treatment more and easier accessible, as it can be brought to the patient's home or place of choice via information and communication technologies.

Finally, the *acceptance* of the disease and the (self-) destigmatization are important processes that can change QoL in a patient *("And you simply have to realize that you have to allow yourself these breaks. If you're sick, you're sick, that's just the way it is.")*. At that point, it is appreciated if telemedicine supports through communication, education, and the exchange of experiences. In addition, telemedicine can broaden the access to care *("We also know that there are groups of patients who would not dare to go to a psychiatric clinic for fear of stigmatization. Telemedicine services can also help these patients to access care).*

Model extension – new findings based on our qualitative studies

The majority of aspects that influence the QoL of patients dealing with chronic conditions or mental illnesses could be assigned to the identified working model. However, some aspects that were considered important were not covered by the pre-existing domains yet. For that reason, we extend the working model of QoL and added a sixth domain to it, referred to as *healthcare-related domain*.

Healthcare-related domain

The healthcare-related domain summarizes healthcare-related aspects that increase or decrease patients' QoL. It comprises four facets: a) needs-oriented care: aspects primarily from healthcare-side, b) needs-oriented care: aspects primarily from patients' side, c) aspects primarily related to information and activation, and d) aspects primarily related to perceived control and safety (Figure 1).

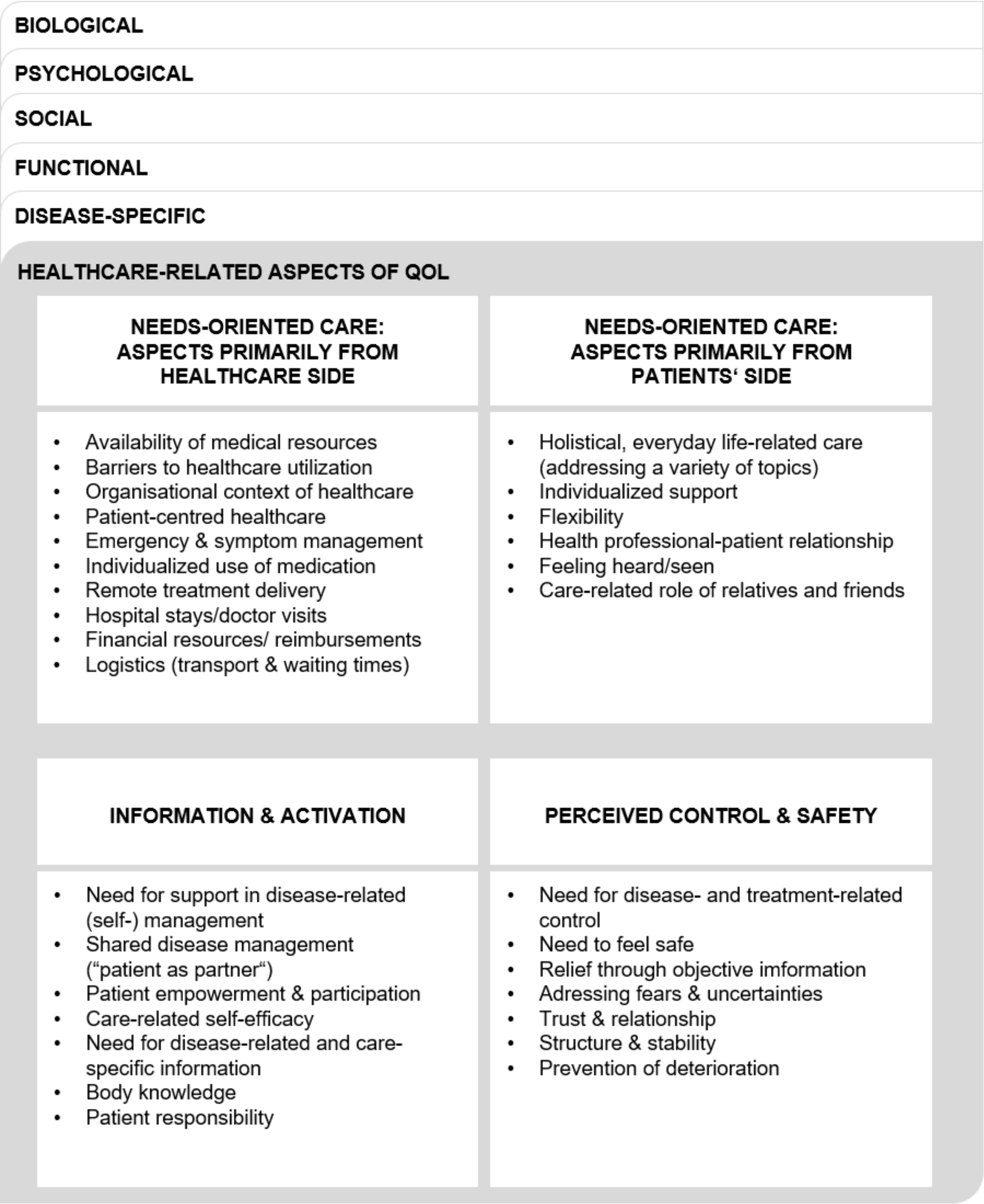
Needs-orientated care: aspects primarily from healthcare side

Firstly, organizational structures influence *needs-oriented care*. Limited available treatment resources and bureaucratic barriers were reported (e.g. required letters of referral). Patients often face a high number of doctor visits or hospital stays, which involves many journeys, long waiting times, and financial resources. Compared to standard care, they desire more patient-centered care that supports symptom limitation and quick emergency management *("When I don't feel well, it's very difficult to start a conversation to get help right away. It's an enormous relief for me that I can call telemedicine first. Sometimes, the doctor doesn't have time right away and then it's good that you first have a contact person with whom you can talk until you have an appointment with the specialist.")*. Study participants report that using telemedicine can help to improve needs-oriented care aspects that are primarily given by existing healthcare structures: As such, telemedicine is experienced as an easier way to access continuous treatment by an often multi-professional team that is connected within a network of care.

Patients undertake fewer journeys due to the location-independent treatment and experience fewer waiting times. Telemedicine enables quicker therapy adjustments and support of patients to achieve therapy goals in everyday life, including emergency aid. Complementary telemedicine can compensate for limited medical/therapeutical in-person resources and provide an efficient healthcare solution for both professionals and patients. Some patients report that digital treatment is helpful for the treatment process, as it seems to be easier to be honest about sorrows and non-compliance in a non-face-to-face setting. Finally, healthcare professionals who actively use telemedicine report better justified adaptation of medication based on long-term monitoring, and sometimes even a reduction of drugs.

Figure 1

Healthcare-related domain



BIOLOGICAL

PSYCHOLOGICAL

SOCIAL

FUNCTIONAL

DISEASE-SPECIFIC

HEALTHCARE-RELATED ASPECTS OF QOL

NEEDS-ORIENTED CARE: ASPECTS PRIMARILY FROM HEALTHCARE SIDE	NEEDS-ORIENTED CARE: ASPECTS PRIMARILY FROM PATIENTS‘ SIDE
• Availability of medical resources • Barriers to healthcare utilization • Organisational context of healthcare • Patient-centred healthcare • Emergency & symptom management • Individualized use of medication • Remote treatment delivery • Hospital stays/doctor visits • Financial resources/ reimbursements • Logistics (transport & waiting times)	• Holistical, everyday life-related care (addressing a variety of topics) • Individualized support • Flexibility • Health professional-patient relationship • Feeling heard/seen • Care-related role of relatives and friends
INFORMATION & ACTIVATION	**PERCEIVED CONTROL & SAFETY**
• Need for support in disease-related (self-) management • Shared disease management (“patient as partner“) • Patient empowerment & participation • Care-related self-efficacy • Need for disease-related and care-specific information • Body knowledge • Patient responsibility	• Need for disease- and treatment-related control • Need to feel safe • Relief through objective imformation • Adressing fears & uncertainties • Trust & relationship • Structure & stability • Prevention of deterioration

Needs-orientated care: aspects primarily from patients' side

Secondly, there are *needs-oriented aspects* that primarily arise from the patients and their living environment. These comprise different types of "relationships", like the relationship between healthcare personnel and patient. It is described as beneficial for individualized support if the telemedical personnel have a certain understanding for the everyday life of the patient. This closeness often leads to the patients feeling heard and seen. The other QoL-relevant relationship is the role of relatives, friends, partners or significant others in care-giving. The additional role as a caregiver often leads to a plethora of feelings for the patient (e.g. appreciation, guilt, or happiness) and the caring person (e.g. helplessness, excessive demand, or hope). A chronic condition or mental illness alters the relationship, which is experienced as challenging. More than regular care, telemedicine usually provides flexible possibilities to communicate with other concerned individuals or competent staff via phone, e-mail, or (video) chat. Patients and professionals stated to experience these instances of communication to be more at eye level as compared to traditional patient-doctor conversations *("As nurses, we naturally talk to patients differently than, for example, specialists. So you go into the conversation with a different vocabulary.")*. Patients appreciate the tone and continuity of communication. Patients and healthcare professionals highlight the freedom for individuality within some telemedical applications, and that patients benefit more from consistent care than from one-off doctor's appointments. Additionally, patients appreciate the opportunity to not only communicate about their condition and the treatment itself, but also about everyday life challenges that come along with it *("What I like about telemedical care is that you can talk about all problems. One's own needs are specifically addressed.")*. As a result, the telemedical communication is perceived as relieving. Some telemedical applications, such as regular phone calls by medical staff, are characterized by the consistency of a contact person, so that a bond and trust between the patient and the contact person can be built over time despite spatial distance. This often leads to increased honesty and willingness to discuss challenging topics, which can also benefit other, private relationships. It is not uncommon for relatives to be involved in telemedical care, too, for example to clarify questions. Finally, the flexibility with regard to time and location makes the practical treatment easier for both the patients and their social environment.

Aspects primarily related to information and activation

Thirdly, *information and activation* influence QoL. Patients and professionals describe it as the patients' need for knowledge about their specific disease and treatment, and sustained support for managing their condition. Education further enables patients to take on responsibility for their health-related behavior and to self- or co-determine treatment decisions *(Patients have the daily task of recording their vital signs. This already triggers something in many people* *because they have a feeling that they have made a contract with us and they feel responsible for fulfilling it. (...) Patients become more aware of what a certain behavior does to their body, and this also strengthens their personal responsibility again.)*. Professionals described the process to be most effective when healthcare professionals strongly guide disease management first, and then empower the patient stepwise to become an expert for their own body, mind, and condition – as far as possible. This process also promotes the development of care-related self-efficacy in patients or their social environment *("We receive feedback from the patients, or via therapists about their patients, in the form of quotes such as 'I managed that, I worked hard for that'. Therapists who work with patients in only face-to-face scenarios tend to get feedback like, 'I could never have done that without you.' So the success of the therapy is attributed a lot to the therapists, and in online therapy it is more often the case that the patients actually experience that they have certainly worked hard themselves to reach their goals.").* Both patients and healthcare professionals described that telemedicine is a way to empower patients' own disease management and thereby strongly improve QoL. As in traditional care situations, telemedical patients get information about their disease and about different treatment options. However, telemedical applications provide an active or passive guidance for patients in their daily lives, which goes far beyond one-off doctor's appointments. Consequently, patients can train newly learned health behavior or disease management skills, ask questions, and clarify misunderstandings in a simplified manner. Furthermore, patients appreciate the continuity of guidance and help for self-help, the consistency of a contact person, and the possibility to co-determine treatment decisions within the telemedical context. Lastly, patients and professionals appreciate the constant awareness about the course of the disease through objective data monitoring as an additional source of information *(We have observed that patients gain more peace of mind in the daily management of their disease by knowing that a health professional has the possibility to view patient-related follow-up data. This knowledge alone has a major effect. (...) Patients feel more secure, which is an essential component of improving the quality of life.)*.

Aspects primarily related to perceived control and safety

The fourth facet that influences QoL was named *perceived control and safety*. It is defined by statements by patients and professionals about how a disease can make the patient feel insecure in their daily life due to fears, lack of knowledge, uncertainty, or intransparent treatment. Primarily, patients describe to feeling relieved through certainty", which means they feel better after a doctors' appointment, because the doctor makes statements about the disease and the patient's state of health. An expert's opinion can satisfy the need for control and safety, but is often missing in between scheduled medical check-ups. Patients and professionals stated that the needs for control and safety can be better addressed in the context of telemedical treatment than in a care-as-usual context: The frequent monitoring of (objective) health-related parameters gives patients the feeling of structure and control *(“It is reassuring to know that the device would react and call the hospital in case of an emergency.”).* Often, telemedicine enables patients to monitor their disease and check their symptoms by themselves whenever they want. In addition, low-threshold follow-up care and prevention, e.g. by monitoring symptoms, can prevent worsening of the disease. Additionally, patients can often also get quick and direct professional feedback through active or passive guidance by telemedical personnel. Contact with socially and medically competent telemedical staff can build trust through a relationship experience, which can further reduce fear and uncertainties and increase the feeling of being supported. Hence, the decisive advantage of telemedical care lies in continuous care in the daily lives of patients and the possibility to quickly communicate with telemedical staff. Further, telemedicine is described as beneficial to bridge the time between a hospital stay and the next doctor’s appointment being back at home *(“It was like a little stepping stone: You still felt safe and you still had such a slight connection to the clinic. I found that very helpful.”).*

Some disadvantages of telemedical care were reported by a few patients. Some participants question the data processing and privacy protection of telemedical systems, while others even feel “spied on” by telemedical systems *(Some patients were afraid of surveillance or felt they were under surveillance because of the questionnaires. They did not take part in the study or became drop-outs).* These doubts for example can be resolved with the help of data-related information (e.g. data protection statement), technical introductions, and a high degree of transparency in order to increase utilization of and satisfaction with treatment.

Discussion

The assessment of patient-reported outcomes such as QoL plays a decisive role in evaluating and optimizing telemedical applications - and thus everyday care in the future for millions of patients. This qualitative study examined the impact of telemedical applications on QoL from the perspective of chronic physically or mentally ill patients, as well as telemedical healthcare professionals. As a result, we mapped the resulting category system on a working model of QoL, consisting of five widely established domains. Our results suggest that telemedical applications influence the patients’ QoL and that this impact is not fully covered by existing domains, yet. Therefore, we summarized the unmapped aspects stated by the participants and conceptualized them as a sixth QoL domain, referred to as healthcare-related domain. From a conceptual perspective, this domain is associated with already established domains integrated in existing operational models of QoL and related to the provision of healthcare, such as impact of “treatment” or “medication”. However, telemedical applications transcend such treatment-specific QoL approaches, as they shape a principal new kind of healthcare delivery and have some essential characteristics in common (e.g. use of ICT technology, absence of medical professionals).

Relevance

The increase in chronic physical and mental illnesses is changing the role of treatment. As a result of medical progress, we are able to live with a disease and therapy for longer periods of time. The treatment of a disease therefore plays a crucial, even everyday role in the lives of those affected. It is no longer a matter of merely regulating symptoms. Rather, the influence of treatment on the individual and his or her environment must be considered holistically. Aspects such as organizational structures of care, the patient's development of competences, the relationship with healthcare professionals, and the inclusion of the social environment, time expenditures, and emotional as well as financial burdens are increasingly receiving attention. Now it seems necessary to extend the existing QoL concept in order to take into account the special features of the treatment context in the evaluation of telemedical applications compared to standard care. A specification of the assessment context has been successfully achieved in the past with regard to the development of disease-specific instruments. We now propose a broadening of the perspective, in which not only specific aspects of a disease, but also its treatment setting is considered as variable influencing QoL.

Integrating study results and previous research

Our findings are consistent with previous research, indicating that most of the facets and categories mapped onto the healthcare-related domain were also found to be important in other qualitative studies within the context of telehealth:

Needs-oriented care: In a study about patient experiences to osteoporosis care delivered virtually by telemedicine, Palcu et al. describe “convenience of timely care close to home as well as a reduction of burden of travel and costs” (39) as benefits of telemedicine, which is in line with our results. Powell et al. (40) state benefits with regard to convenience and costs, too, adding that the patients can be in their own supportive environment during the treatment as another advantage. Brunton and colleagues (25) conducted a qualitative meta-synthesis about telehealth user experience in COPD. They found out that telehealth was perceived as helpful in managing everyday life and enabled patients to self-manage their condition. They also report that increased contact to healthcare professionals and the level of continuity enables trusting relationships to be formed which alleviated feelings of isolation. In addition, many telehealth solutions are designed in a way that family members become more actively involved. This qualitative meta-synthesis further supports our findings. However, only Lee et al. (26) related constructs of needs-oriented care to QoL: As such, easy access to the doctor and convenient healthcare services are perceived as important components for improving quality of life.

Information and activation: In a study about hip fracture patients’ experiences with testing an app, Jensen et al. (41) reported that telemedical applications are a way to support information and education for patients and hence address individual learning and health literacy needs. They proved in an elderly sample that an app has the potential to support the ability to perform self-care and the desire for autonomy. Therefore, empowering patients seems to be crucial. According to Clemensen et al. (42) patients will have a more dominant role in taking care of their own health against the background of demographic change. Brunton et al. (25) describe similarly that patients play a more active role in their care e.g. by taking on monitoring of symptoms. By becoming more involved in managing and shared decision making, patients develop a stronger sense of accomplishment with regard to their health outcome. Lee and colleagues (26) explained that patients using telehealth for type 2 diabetes management perceived telehealth as help to live independently at home and to “be in more control over their own health state” (26). All these described components could be retrieved from our qualitative study, too, and are integrated within the facet information and activation.

Control and safety: Aspects relating to the facet control and safety were discussed in a qualitative meta-synthesis by Brunton and colleagues (25). Telehealth “provided patients with a sense of reassurance and a strong sense of feeling ‘looked after’” (25) through increased contact between patient and healthcare-provider as well as the knowledge that the health data is being remotely monitored. They describe a “sense of security” (25) reported by study participants due to regular contacts and through access to telehealth data. Moreover, a sense of relief and the feeling of being supported in self-care was stated. Also negative, intrusive aspects of telemedicine were reported: Powell and colleagues (40) describe that some participants in a study about patient perceptions of telehealth primary care video visits had concerns about privacy of the conversations. In our current study, this aspect is captured within the facet of control and safety and can be linked to the privacy dimension of the obtrusiveness concept by Hensel, Demiris, & Courtney (43).

What this study adds to the literature

By mapping the qualitative results to a general working model of QoL, it was shown that there are relevant patient-reported constructs that are not yet represented by the concepts of the existing instruments (summarized within the healthcare-related domain). For the most part, these constructs also play a role in standard care and some have already been examined in other telehealth studies, e.g. empowerment (41) or sense of security/ reassurance (25). Nevertheless, there is no integrated concept of these constructs with regard to their effect on QoL of patients. Thus, the extension of previous QoL concepts described in this study represents an attempt at conceptual integration to fill this research gap. Finally, our study implies that existing QoL instruments are not comprehensive enough for the context of telemedical care, whereas existing telemedicine-specific instruments are not dedicated to measuring QoL.

Is this QoL we are talking about?

Some of the aspects described by patients and healthcare professionals, which we summarized as a complementary healthcare-related domain, are already known from previous discussions and other healthcare contexts. Examples include patient satisfaction, patient empowerment, or perceived safety. Consequently, would it not make sense to simply use existing instruments of these constructs in evaluations of digital applications? This would certainly be a good first step forward making the evaluation of digital applications more patient-centered. However, we are more concerned with the question of whether it is legitimate to combine the identified constructs into a sixth QoL domain. One could argue that we simple describe the interaction of the environment with disease-specific aspects like symptoms, and the patient's functional status (44, 45). Certainly, the healthcare-related domain interacts with established domains of health-related and disease-specific QoL. However, these do not adequately cover aspects reported by study participants. Our qualitative study provides evidence that the aspects of the healthcare-related domain have a clear impact on patients' QoL, as they were independently stated when asked about the individual understanding of QoL and whether or not treatment affects it. In terms of patient orientation, we should bring more attention to the fact that patients refer to these aspects as belonging to the QoL than to rely on pre-existing conceptual thought patterns. As a consequence, we should generally reflect on our traditional concepts against the background of a patients' state of conditional health and innovative treatment application – our proposal for the extension of the QoL working model in context of telemedical care is a first step in this direction.

Strengths and limitations

The strength of this study is the qualitative deductive-inductive approach including complementary groups (chronic physical vs. mental illness; active vs. passive telemedical approaches; patients vs. healthcare professionals). The resulting data does not only inform the research question, but also provides the basis for item generation of the "add-on" patient-reported outcome instrument we are aiming to design. Thus, we meet the call for contemporary PRO instrument development (34, 46). Finally, our data is characterized by high content validity and a large sample size. The limitations of the study relate to the implementation, the selection of included telemedical applications, and language issues. First, we cannot determine what difference it made to study participants whether the interview is conducted by a study nurse or a research assistant. In addition, we included only those telemedical applications in our study that are used to complement, not replace, standard care. Third, the landscape of telemedicine is very heterogeneous. For this reason, the results presented here are not generalizable to all other telemedical applications. Finally, all data were collected in the German language and therewith also may reflect some content specific to a German context.

Conclusion and outlook

Three main points can be derived from the results of this study: First, the complementary use of telemedical applications can lead to an improvement in patients' QoL - but only if it is meaningfully integrated into everyday care and developed together with patients and healthcare professionals in order to meet their healthcare needs. Second, in order to evaluate whether telemedical applications have an impact on patients' QoL, suitable instruments must be used. Existing QoL instruments are not sufficiently context-sensitive for this purpose. Because the impact of the healthcare-related domain is not covered by existing instruments yet, we will develop an “add-on” questionnaire to use in addition to traditional QoL instruments in the context of evaluating telemedical applications. The qualitative data from this study is used for concept elicitation and serves as a pool for item development. This newly developed instrument shall help to generate reliable evidence within the evaluation of telemedical applications. Herewith it will not only support e.g. health insurance companies to evaluate and fund telemedical applications, but also patients and professionals to benefit from innovative additional care.

Declarations

Ethics

The project was approved by the Ethics Committee at the University Medicine Greifswald (BB 023/18) and the partner department (AS466 (bB)/2018). All participants provided written consent to participate. Quality criteria of qualitative research according to Mayring (47) were taken into account in planning, realization, and evaluation of this study.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

KG, HM and SiS prepared the qualitative study, KG and HM developed the guidelines, NvdB, WH, KG, OR & MO recruited the participants, KG and the study nurses conducted the interviews and focus groups, student assistants transcribed the interviews and focus groups, KG, HM, TR and student assistants analyzed the qualitative material, KG and HM wrote the article, all authors read and approved the final manuscript.

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Paper IV

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Towards adjunct setting-related quality of life assessment in telemedicine - cognitive debriefing, expert rating and pilot testing of the Tele-QoL instrument

(1) Holger Muehlan; holger.muehlan@uni-greifswald.de;
University of Greifswald, Department Health and Prevention, Germany
(ORCiD: 0000-0001-8048-5682)*

(2) Klara Greffin; klara.greffin@uni-greifswald.de
University of Greifswald, Department Health and Prevention, Germany
(ORCiD: 0000-0003-0947-6091)*

(3) Neeltje van den Berg; neeltje.vandenberg@uni-greifswald.de
University Medicine Greifswald, Institute for Community Medicine, Germany
(ORCiD: 0000-0001-6965-0544)

(4) Wolfgang Hoffmann; wolfgang.hoffmann@uni-greifswald.de
University Medicine Greifswald, Institute for Community Medicine, Germany
(ORCiD: 0000-0002-6359-8797)

(5) Oliver Ritter; o.ritter@klinikum-brandenburg.de
Brandenburg City Hospital, University Clinic for Cardiology and Pulmonology, Medical University, Germany (ORCiD: 0000-0003-2069-4364)

(6) Michael Oeff; oeff@klinikum-brandenburg.de
Brandenburg City Hospital, Germany

(7) Georg Schomerus; georg.schomerus@medizin.uni-leipzig.de
University of Leipzig Medical Center, Clinic of Psychiatry and Psychotherapy, Germany
(ORCiD: 0000-0002-6752-463X)

(8) Silke Schmidt; silke.schmidt@uni-greifswald.de
University of Greifswald, Department Health and Prevention, Germany
(ORCiD: 0000-0002-4194-1937)

*(*Shared first authorship)*

Corresponding author:

Holger Muehlan
University of Greifswald
Department Health & Prevention
Robert-Blum-Str. 13
17487 Greifswald
Germany

Phone: +49 (0)3834-420-3802
Fax: +49 (0)3834-420-3812
Email: holger.muehlan@uni-greifswald.de

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Abstract

Background: Although quality of life (QoL) is discussed as key patient-reported outcome (PRO) in telemedical (TM) applications, it was neither explored in this context nor assessable in a setting-sensitive manner. Therefore, we aimed to explore and conceptualize QoL in TM care as well as develop and test a content-valid "add-on" instrument to measure specific aspects of QoL in TM contexts. The aim of this paper was to describe the derivation of an initial item pool and the testing and refining of a first Tele-QoL questionnaire version.

Methods: An initial item pool was derived from a qualitative study. We used cognitive debriefings to test how relevant, plausible, and comprehensible the items were for patients (*n* = 32). Next, an initial questionnaire was applied to patients with depression or heart failure, with or without TM care (*n* = 200), to explore the dimensionality of the item pool. In parallel, an online expert survey amongst TM professionals (*n* = 15) was conducted.

Results: The initial item pool comprised 227 items and was further refined by cognitive debriefings, excluding 122 items. The expert survey rated the remaining 105 items of the provisional instrument. An average of about 20 items were assessed to be an optimal questionnaire length. Results of the pilot testing indicate a multidimensional structure of the Tele-QoL item pool.

Conclusions: Analyses of data from the pilot study confirmed the multidimensional structure of the item pool. Most of the specific factors represent different facets within the domains of our conceptual model. In a next step, we will evaluate the psychometric performance of the final Tele-QoL instruments using an independent validation sample.

Key Words: Quality of Life, Telemedicine, Cognitive Debriefing, Expert Survey, Piloting, instrument development

Key Points: (1) A preliminary version of a patient-reported measure assessing quality of life in telemedical settings was tested. (2) Initial analysis confirmed the multidimensional structure of the item pool. (3) The initial questionnaire was revised based on the study findings.

Background

Quality of Life (QoL) is discussed as a key patient-reported outcome (PRO) in telemedical (TM) applications (1,2). To test whether TM care has an impact on patients' QoL, the construct can be assessed on a generic, health-related, or disease-specific level, based on established measures (3,4). However, approaches for conceptual definitions of QoL in the context of TM healthcare were missing (1) In addition, reviews showed that no TM-related QoL measure is available (5). This research gap carries considerable practical relevance, as inadequate evaluation of TM applications has consequences for its accessibility, quality, and funding. The Tele-QoL project (6) was initiated to fill this gap in research. The project aimed to explore QoL in TM settings as well as to develop and test a content-valid "add-on" assessment to measure specific aspects of QoL in TM contexts. To address these objectives, we applied a mixed-methods design (7) and followed the recommended steps for PRO development (8,9).

First, we underwent a systematic literature review (5) and a qualitative study for concept elicitation (10). Within the systematic literature reviews on the purpose of intended use of TM solutions, concepts, and measurements used to evaluate TM applications from a patient's perspective (5) we learned that there are no setting-sensitive instruments to assess QoL in the context of TM healthcare. Besides, we analyzed the most commonly used QoL questionnaires to derive a general working model of QoL, consisting of a biological, psychological, social, functional, and disease-specific domain of QoL. Afterwards, we conducted interviews and focus groups with patients and TM professionals, aiming to understand the impact of TM care on QoL (10). The results of the qualitative data analyses were mapped on the prior identified general working model of QoL. The majority of aspects influencing the QoL of TM patients could be assigned to pre-existing facets of the derived working model. However, there were related to specific QoL issues in TM contexts, which could not be mapped onto the pre-existing QoL concept. As a consequence of our exploratory studies, we extended the working model of QoL by adding another domain, referred to as the *healthcare-related domain* (10). The newly designed domain consists of four facets called (a-b) needs-oriented care - aspects primarily from the healthcare side of the patient, (c) information and activation, and (d) perceived control and safety. A detailed description can be found in (10). However, it is important to note that only three of the four facets of the healthcare-related domain can be assessed from the patient's perspective. For this reason, the facet "needs-oriented care - aspects primarily from the healthcare side" shall not be taken into consideration in the PRO to be developed.

The objective of this paper is to describe the development and initial testing of the Tele-QoL instrument. The steps reported include (a) identifying the initial item pool, (b) pre-testing the questionnaire using the cognitive debriefing method “think aloud”, (c) conducting an online expert survey to assess the relevance, applicability, and scope of the extended concept and derived item pool, and (d) the initial testing of the instrument to explore the dimensionality of the item pool as well as psychometric performance on the item and scale level.

Methods

Study Participants

Patients. The samples for both cognitive debriefings and the pilot survey were planned similarly to each other. In both study sections, complementary patient groups with regard to their primary disease (mental vs. chronic physical condition) should be included. At the same time, it was important that the disease groups are often treated with TM care. For this reason, we included patients with depression or heart failure in these study sections (11–14). Furthermore, only half of the respective patient groups were treated with an active (regular phone calls) or passive (monitoring) TM application, while the other half were recruited among care-as-usual patients. With this sample selection, we wanted to represent as much heterogeneity as possible in terms of diseases and treatments and to contrast experiences with TM treatments with care-as-usual.

The recruitment of patients within the project was undertaken by three clinics in North-eastern Germany that were the project’s consortium partners. Depressive patients were recruited at University Medicine Greifswald and University Medicine Leipzig, while patients with heart failure were recruited at Brandenburg City Hospital. Respective study nurses identified eligible patients from hospital records and contacted them to inform them about the study. If patients were interested in participating, they were invited to the corresponding clinic. There they were informed a second time both verbally and in writing, were able to ask questions, and subsequently gave their written informed consent to the study. For participation, all patients were required to be of legal age. Furthermore, an equal distribution of sexes was aimed for. Exclusion criteria were moderate to severe impairment of cognitive functions (e.g., comorbid neurological diseases) and non-proficient knowledge of the German language. All patients received a compensation of €40 for the pre-testing or €20 for the pilot study to cover expenses.

Professionals. The main groups of TM healthcare professionals were recruited in order to include as diverse a sample of TM professionals as possible in the study section. These included members from science and industry, development and IT, clinics, start-ups, health policy, and health insurance companies as well as outpatient doctors, psychologists, and TM nurses. With this, we wanted to integrate as many different perspectives as possible in our study. The respective experts were identified based on recommendations, network contacts, literature research, and contributions at relevant conferences. They were recruited for the online expert survey via email.

Sample Sizes

Cognitive Debriefing. For the pre-testing of the initial items, a sample size of $n = 32$ patients was aimed for, which is in line with the recommendations by Perneger et al. (2015) (15). To balance both, the distribution of disease type and treatment approach, the sample should include $n = 16$ patients each with depression or heart failure, half of which ($n = 8$ each) was treated with or without TM care.

Online Expert Survey. The link to the online survey was sent directly or via snowball system to experts i.e., professionals working in the TM context. The number of participants was not determined in advance, but according to the study protocol, the aim was to include at least 10 respondents - the more, the better.

Pilot study. It was aimed for a sample size of $n = 200$ to confirm the assumptions of the more complex psychometric procedures like exploratory and confirmatory factor analysis. As described in the study protocol (6), the size of the item pool, the communalities of the items, and the number, item sizes, and eigenvalues of the factors were still unknown (16,17). For approximating the necessary case numbers, reference was made to simulation studies and reviews (18–20). For pilot testing of the instrument, an estimated item size of about 50+/-10 items was assumed. In summary, the sample sizes within the study sections reported here are displayed in Table 1.

Data collection and analyses

Ethics & Open Science. The project was approved by the Ethics Committee at the University Medicine Greifswald (BB 023/18) and the State Medical Association of Brandenburg (AS466 (bB)/2018). All participants provided written informed consent in compliance with the Helsinki Declaration and the DSGVO. In line with the Open Science Initiative, a research protocol was published in order to increase the transparency of study planning (6).

Table 1

Sample sizes per study section

Project task	Patients	Professionals
Pretesting of item pool	$n = 32$ Cognitive debriefings (face-to-face interviews) n=16 patients with depression/heart failure, thereof n=8 patients with/without TM care	$n = 15$ Expert-Ratings (online survey)
Pilot testing of preliminary instrument	$n = 200$ $n = 100$ patients with heart failure (50 each with or without TM care) $n = 100$ patients with depression (50 each with or without TM care)	---

Cognitive debriefings. Pretesting of the initial pool of 227 items was conducted to assess how relevant, plausible, and comprehensible the items were from the patient's perspective (*n* = 32). After explaining the study to the patients and obtaining their written informed consent, they were given a questionnaire containing the pre-test items. In a personal interview situation, the first or second author of this study went through the items with the patients. Using the think-aloud method (21), the participants were asked to read one item at a time and spontaneously express any thoughts that came to mind. If they did not comment, the interviewer asked them about the relevance, plausibility, and comprehensibility of the respective item. The interviews took about 45-60 minutes, but not every patient had all items discussed within that time. Every interview was voice-recorded and protocolled. The recorded comments were transferred to a Microsoft Excel list so that the patients' statements were grouped accordingly to the corresponding items. Afterwards, concrete improvements for rephrasing or deleting items were derived in discussion with the responsible working group.

Online expert survey. Similar to the extended concept of quality of life, which was discussed in an expert “validation” workshop (10), the items should also be validated by experts. For this reason, an online expert survey was conducted amongst TM professionals (*n* = 15) using the Unipark survey platform (https://www.unipark.com). At the beginning of the anonymous online study, the experts were informed about the survey and were then asked to give their consent to participate. Afterwards, the 105 items of the revised item pool were displayed. The experts were asked to rate the items on the criteria of relevance, applicability, and scope. Then they were asked about the optimal extent of the newly developed questionnaire. Finally, questions were asked regarding the TM experience of the experts. Following the survey period, the data was downloaded and stored on a designated file server provided by University of Greifswald. The descriptive analysis of the answers was performed using the programs Microsoft Excel and SPSS (22).

Generating an initial item pool. The initial item pool of *n* = 227 items was derived from statements of patients and professionals from a previous qualitative study that were linked to the original working model on QoL in TM care settings (10). Only those statements were considered for item generation that were mapped to the additional domain of our conceptual model, referring to setting-related quality of life, which covers those aspects linked to the provision of healthcare services.

Pilot study. For the pilot study, patients (*n* = 200) were asked to fill in the initial version of the Tele-QoL questionnaire A (TM group) or B (care-as-usual group) consisting of *n* = 105 items. It was complemented by further validated questionnaires. Table 2 lists the assessments used in the pilot study. A detailed description of these instruments can be found in the Tele-QoL study protocol (6). The *study materials* were prepared by the University of Greifswald and subsequently sent to the recruiting partners. Depending on the recruitment center, the questionnaire was completed in the clinic/outpatient department or at home. In all cases, the patient was informed about the study and asked to give written consent to study participation. After completing the questionnaire, it was handed to the staff of the recruitment center or anonymously returned to the University of Greifswald in a pre-stamped envelope. After the questionnaires arrived at University of Greifswald, they were entered into an Excel spreadsheet and stored on the project server. The original questionnaires were filed and stored in lockable cabinets. This process was in accordance with the procedure proposed in the study protocol (6). Data from the pilot testing was analyzed to explore the dimensionality of the item pool and the psychometric performance on item and scale level. Therefore, we conducted a principal axis analysis with Promax rotation to initially determine the dimensionality of the item pool using IBM SPSS Version 28.0 (22).

Table 2

Instruments used within the pilot study

Study Assessments & Measures	Number of Items
General information	
• Sociodemographic characteristics	7
• Perceived relative health status	1
• Disease- & health-related information	8
Psychological instruments	
• Depressive symptoms (PHQ-9)	10
• Quality of life in the context of telemedical care (Tele-QoL-A)	105
• Quality of life in the context of standard care (Tele-QoL B)	105
• Perceived security in telemedicine (SeCu-20)	20
• Patient satisfaction (ZUF-8)	8
• Disease-specific quality of life – Heart Insufficiency (MLHFQ)	21
• Health status (VR-12)	12
• General quality of life (WHOQOL-BREF)	26

Results

Cognitive Debriefing

Cognitive debriefings with *n* = 32 patients led to a substantial reduction of the initial item pool and revision of item wordings. In sum, 122 items were excluded, ending up with 105 items for the preliminary pilot version of the Tele-QoL questionnaire. The majority of the remaining items were revised according to the statements resulting from the cognitive debriefings. Most frequently stated recommendations (Table 3a) referred to inappropriate phrasing or wording (104 items affected), difficulties in understanding the respective item (84 items affected), or an unclear reference within an item (31 items affected). As shown in Table 3b, for the majority of the items, only a few codes were assigned that categorized the patients' respective comments. If criticism or requests for change were expressed with regard to an item, this was mostly done by several people (Table 3b).

Table 3a

Results of cognitive debriefings with patients, listed according to frequency of respective comments

Category	Total (*n* = 32)	Patients with telemedical care (*n* = 16)	Patients with standard care (*n* = 16)
	(number/percentage of items affected out of 227, including multiple codings)		
● Inappropriate phrasing/wording	**104 / 46.85%**	65 / 29.28%	39 / 17.57%
● Item understanding	**84 / 37.84%**	49 / 22.07%	35 / 15.77%
● Unclear reference	**31 / 13.96%**	13 / 5.86%	18 / 8.11%
● Redundant content	**25 / 11.26%**	21 / 9.46%	8 / 3.60%
● Irrelevant content	**22 / 9.91%**	6 / 2.70%	16 / 7.21%
● Unanswerable item	**20 / 9.01%**	9 / 4.05%	11 / 4.95%
● Missing fit	**19 / 8.56%**	9 / 4.05%	10 / 4.50%
● Too imprecise	**19 / 8.56%**	9 / 4.05%	10 / 4.50%
● Rephrase positively	**16 / 7.21%**	11 / 4.95%	5 / 2.25%
● Includes insinuation	**16 / 7.21%**	8 / 3.60%	8 / 3.60%
● Too general	**14 / 6.31%**	4 / 1.80%	10 / 4.50%
● Too difficult	**11 / 4.95%**	10 / 4.50%	1 / 0.45%
● Too long	**11 / 4.95%**	7 / 3.15%	4 / 1.80%
● Ambiguous wording	**6 / 2.70%**	4 / 1.80%	2 / 0.90%
● Doesn’t apply for all	**4 / 1.80%**	0 / 0.00%	4 / 1.80%
● Wording structure	**3 / 1.35%**	1 / 0.45%	2 / 0.90%
● Miscellaneous quotes	**13 / 5.86%**	8 / 3.60%	5 / 2.25%
● *Multiple reading**	***10* / 4.50%**	*10* / 4.50%	*0* / 0.00%
● *Long reflection**	***9* / 4.05%**	*8* / 3.60%	*1* / 0.45%

*Notes: * Observed behaviour.*

Table 3b

Results of cognitive debriefings with patients, listed according to number of codes or commenting person

Frequencies	**Total (*n* = 32)**	**Patients with telemedical care (*n* = 16)**	**Patients with standard care (*n* = 16)**
	(number / percentage of items affected out of 227)		
● 5 codes per item	**2 / 0.91%**	---	---
● 4 codes per item	**20 / 9.01%**	---	1 / 0.45%
● 3 codes per item	**42 / 18.92%**	1 / 0.45%	9 / 4.05%
● 2 codes per item	**98 / 44.14%**	24 / 10.81%	51 / 22.97%
● 1 codes per item	**48 / 21.62%**	139 / 62.61%	123 / 55.41%
● 0 codes per item	**12 / 5.41%**	58 / 26.13%	38 / 17.12%
● 10 or more persons per item	**4 / 1.80%**	---	---
● 9 persons per item	**7 / 3.15%**	---	---
● 8 persons per item	**9 / 4.05%**	---	2 / 0.90%
● 7 persons per item	**12 / 5.41%**	---	2 / 0.90%
● 6 persons per item	**16 / 7.21%**	1 / 0.45%	8 / 3.60%
● 5 persons per item	**22 / 9.91%**	3 / 1.35%	13 / 5.86%
● 4 persons per item	**34 / 15.32%**	19 / 8.56%	22 / 9.91%
● 3 persons per item	**50 /22.52%**	29 / 13.06%	34 / 15.32%
● 2 persons per item	**41 / 18.47%**	59 / 26.56%	53 / 23.87%
● 1 person per item	**15 / 6.76%**	74 / 33.33 %	54 / 24.32%
● 0 persons per item	**12 / 5.41%**	37 / 16.67%	34 / 15.32%

Note. *“x persons per items” refers to the number of participating patients in the cognitive debriefing sessions whose comments were related to criticism of a respective item and a corresponding request for revision/elimination of the item.*

Online Expert Survey

An online expert survey amongst TM professionals (*n* = 15) was conducted to assess the relevance, applicability, and scope of the initial Tele-QoL questionnaire version. To begin with, the results regarding the relevance of the items, the content validity index (CVI, (23)) was on average .75. There were 50 items with a CVI > .79, indicating a high relevance of these items. In contrast, 20 items had an index of .70 < CVI <.79, indicating that revision of the items is needed. Finally, 35 items had a CVI value below .70, which indicates that these items should be eliminated. All 15 items related to the assessment of the potential negative impact were among the low CVI item group. We kept these 15 items but excluded the remaining 20 items. With regard to the possible length of a settings-sensitive add-on instrument, the mean value was 19 (*SD* = 11.29) with a mode of exactly 20 items (*n* = 5). Besides individual preferences, *n* = 3 respondents stated that the final instrument should contain 10 items, whereas *n* = 2 respondents argued for 40 items.

Table 4

Results of the online expert survey regarding content validity (n = 15)

I-CVI	**Proportion of positive ratings***	**Number of items**	**“Not applicable” rating**	**“Impact”-related items**
1.00	12 / 12	10	0	0
0.92	11 / 12	21	1	0
0.83	10 / 12	19	1	0
0.75	9 / 12	20	7	0
0.67	8 / 12	11	5	0
Lower	0-7 / 12	24	5	15

Note. Data sets for *n* = 3 survey particpants are incomplete.

Pilot Testing

The analysis of the initial Tele-QoL item pool (KMO =.77) resulted in a solution including one strong first factor with an eigenvalue of about 48.40, which accounts for almost 46% of the explained variance. Six additional factors have eigenvalues of at least 2 (2.08 to 4.99), explaining approximately an additional 18% of the variance. There are 11 factors with eigenvalues of at least 1.0 (1.05 to 1.75), accounting for a further 14% of explained variance. Table 5 provides detailed information. Further inspection indicates that a large proportion of items with high factor loadings on the first-factor display secondary factor loadings on various other factors.

Table 5

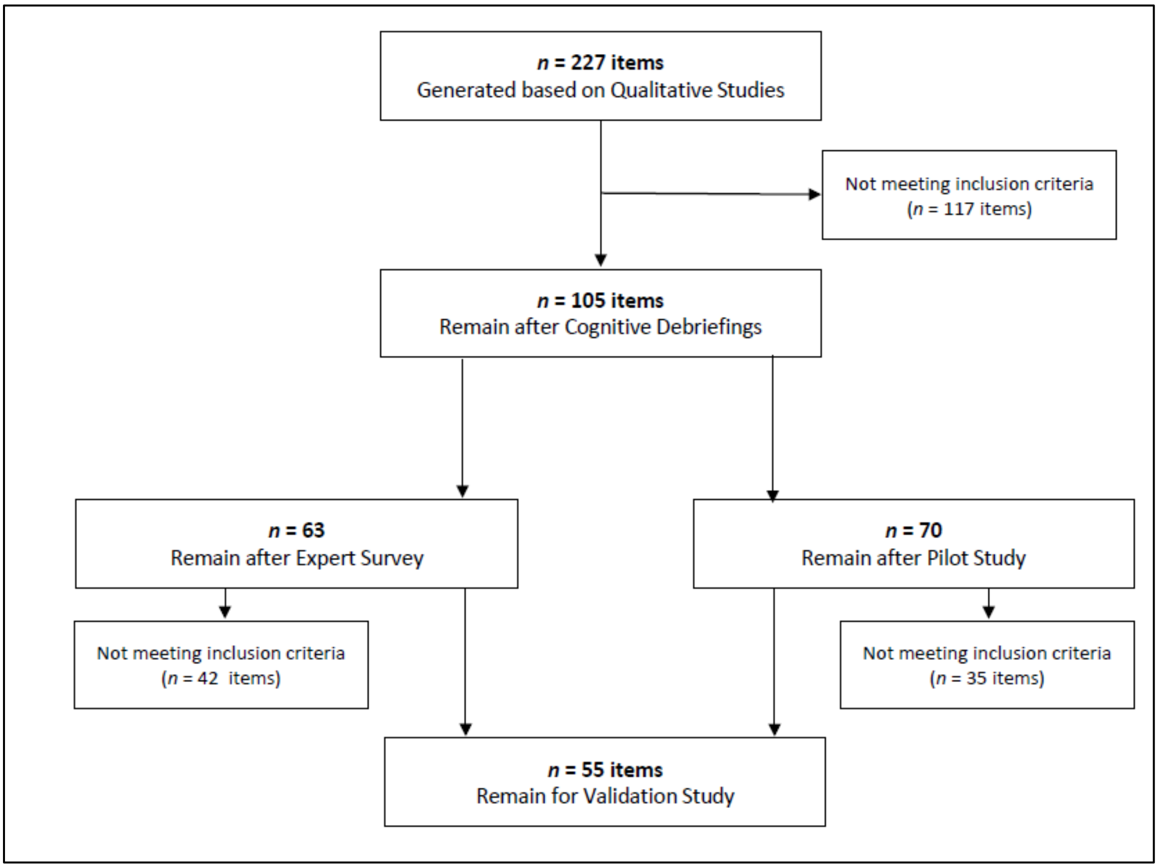
Results of principal axis analysis with Promax rotation of initial Tele-Qol pilot study item pool

Factor No.	Eigen-value	Explained variance (%)	Cumulative explained variance (%)	Content of items with primary loadings on the respective factor
1	48.40	46.10	46.10	• Healthcare-related QoL & Well-Being
2	4.99	4.75	50.85	• Patient Needs, Safety & Trust
3	4.25	4.05	54.90	• Information & Patient Education
4	2.95	2.81	57.71	• Patient Burden & Impairment
5	2.43	2.31	60.02	• Patient Relief & Autonomy
6	2.21	2.10	62.13	• Surveillance & Obtrusiveness
7	2.08	1.98	64.11	• Negative Interactions
8	1.75	1.67	65.77	• Indifference & Critical Thoughts
9	1.67	1.59	67.36	• Patient Burden & Alienation
10	1.55	1.48	68.84	• Treatment Coordination
11	1.43	1.36	70.21	• Patient Motivation
12	1.41	1.34	71.55	• Lacking Support
13	1.38	1.31	72.86	• *(Diverse Content)*
14	1.24	1.18	74.04	• Decision Making
15	1.20	1.14	75.18	• Self-Disclosure
16	1.14	1.08	76.27	• Coordination
17	1.06	1.01	77.28	• Doubts
18	1.05	1.00	78.28	• Control

Item selection overview

Taken together, we depicted the complete item selection procedure in Figure 1. Within each of the main steps, the initial item pool was roughly shortened by about 50%, ending up with 55 items for the preliminary version of the instrument, representing appr. 25% of items from the initial item pool.

Figure 1 *Item selection flow chart of procedure from initial pool of items to preliminary version of measure*



Discussion

Main result

We aimed to develop and test a content-valid "add-on" assessment to measure specific aspects of QoL in TM contexts, which are not sufficiently covered by established instruments yet. Therefore, an initial item pool (*n* = 227) was derived from an extensive qualitative study and subsequently refined by cognitive debriefings with patients, excluding 122 items. Initial psychometric analysis of the pilot study data confirmed the multidimensional structure of the item pool. Moreover, in an online expert survey, the remaining 105 items of the provisional instrument were rated, and an average of about 20 items was assessed to be an optimal length. Additionally, several items were excluded after an online expert survey due to insufficient relevance.

Specific results

The results of the cognitive debriefings and the online expert survey provided extensive information on the selection and revision of the initial item pool. The cognitive debriefings indicated that many items are relevant and already applicable in the later target group of the questionnaire. However, it also became evident that wording needed to be adopted in about half of the item pool and that there are still redundant items in the item pool. Moreover, some items could not be answered by both groups (TM-care vs care-as-usual), as they referred to aspects that are only relevant within one of the groups. Since we aimed to develop two instruments that allow a comparison between TM-care and care-as-usual, these items were consequently excluded. The interviews within the later target group of the questionnaire implementation provided valuable landmarks for revising or excluding items. Pretesting is thus a further step in the development of the later questionnaire with extensive patient and stakeholder involvement (8,9,24).

Comparing the patients' interviews with the TM-experts' survey, it is interesting to see that the patients considered items that were supposed to assess potential negative impacts of TM care on QoL to be relevant. In contrast, all "impact" items were rated to be of low relevance by the TM professionals in the online expert survey. However, their assessment of relevance was related to their evaluation of applicability, with less relevant items being more frequently evaluated as not applicable. The question now is whether the items were assessed as not applicable due to their content or whether there is no interest in applying them. It can be assumed that the items that are supposed to capture the negative impact are considered less relevant, as legal regulations focus on the evaluation of positive outcomes of TM applications in terms of intended benefits (25). Nevertheless, due to our derived contents from the qualitative study that highlights the importance of also assessing the unintended effects of TM care, we decided to include a selection of revised impact items in the final Tele-QoL instrument, even though their relevance ranking was low.

Results from the pilot testing of the initial item pool indicate a diversified multidimensional structure that comprises a strong first factor, which accounts for nearly half of the explained variance. This factor covers healthcare-related QoL and well-being on a generic level, which is also evident by numerous secondary factor loadings of items with primary loadings on other factors. In addition to this “general” factor, we detected a couple of specific factors that represent different facets within the domains of our working model. However, the lower the eigenvalues get, the narrower the scopes of the respective factors are.

After conducting cognitive debriefings, the pilot study, and an online expert survey, we subsequently excluded 50 items. The item pool for the validation study now comprises 55 partly revised items. These items are represented by six outcome scales and two impact scales, which are intended to measure the positive and negative effects of TM care on the patients' QoL. The item pool for the validation study includes items for the later Tele-QoL extended version as well as the Tele-QoL index.

What the study / the measure adds to previous research

When treating chronic conditions or mental illnesses, the focus is more on managing, not necessarily on curing the condition. In order to support patients in the best possible way and to realize complex treatment (26), TM applications are increasingly used as a complement to face-to-face treatment. In addition to stabilizing or improving symptoms, these mainly aim to improve the patient's QoL. With the help of the Tele-QoL questionnaire, patients can now better illustrate how TM use affects their QoL. It is intended to be used as a supplement to existing QoL instruments in order to enhance setting-sensitivity. In addition to already validated, standardized assessments, the Tele-QoL items also cover the areas of needs-oriented care, information, and activation as well as perceived control and safety. Based on the setting-sensitive assessment, caregivers can adjust the treatment and pay more attention to its impact on the patient's daily life. By using the Tele-QoL questionnaire, health insurance companies will also have the opportunity to base the evaluation of TM applications - and the associated funding decisions - more on the insured person.

Strengths & Limitations

With respect to our study approach, several strengths and limitations must be considered. To begin with, developing the instrument was based on an extensive qualitative study (10), thus under the inclusion of the respective patient groups. Additionally, the perspective of experts was also taken into consideration by including experts in interviews, focus groups, and an expert online survey. This approach is in line with current guidelines for PROM development (8,9,24,27). Moreover, we expect a high content validity as well as good applicability of the later questionnaire, both on the patients' and the healthcare professionals' side.

Including patients aimed to identify broad experiences of contrasting disease groups and treatment approaches. Although this approach should help to extend the generalization of the data, the results remain limited to this sample for now. Because of this, the instrument is to be tested in further samples of patients with chronic conditions and mental illnesses in the future. The inclusion of different TM approaches will also be considered. The situation is similar regarding the experts. Although we tried to recruit a group as heterogeneous as possible, it was only possible to interview a selection of professionals who are involved in the design, application, and evaluation of TM care.

Conclusions

The preliminary version of the Tele-QoL instrument was comprehensively (pre-)tested by applying a rigorous, established approach (8). Initial psychometric analysis of the pilot study data confirmed the multidimensional structure of the item pool. In a next step, the refined and shortened questionnaire will be validated in another sample of n = 200 patients. After validating the instrument, the Tele-QoL will be the first measure assessing aspects of QoL specific to TM settings.

Declarations

Ethics approval and consent to participate

The Tele-Qol project was approved by the Ethics Committee at the University Medicine Greifswald (BB 023/18) and the partner department (AS466 (bB)/2018).

Consent to Publish

All participants provided their informed consent in written format.

Availability of data and materials

The datasets analysed during the current study are available from the corresponding author on reasonable request. A study protocol was published (6).

Competing interests

The authors declare that they have no competing interests.

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The study was jointly conducted by University of Greifswald, University Medicine Greifswald, Brandenburg City Hospital, and University of Leipzig Medical Center.

Author's contribution

SiS, HM and KG made contributions to the conceptualization and methodology of the project. HM and KG were responsible for the writing of the original draft. Investigations as well as review and editing were conducted by HM, KG, NB, WH, OR, MO, SiS and GS. Project administration and resources of the project were the responsibility of SiS and HM. All authors have read and agreed to the published version of the manuscript.

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List of abbreviations

QoL	Quality of Life
PRO	Patient-Reported Outcome
TM	Telemedical

Tables & Figures

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Paper V

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Measuring context that matters:

Validation of the modular Tele-QoL patient-reported outcome and experience measure

Authors:

(1) Klara Greffin; klara.greffin@uni-greifswald.de
University of Greifswald, Department Health and Prevention, Germany*

(2) Holger Muehlan; holger.muehlan@uni-greifswald.de;
University of Greifswald, Department Health and Prevention, Germany*

(3) Neeltje van den Berg; neeltje.vandenberg@uni-greifswald.de
University Medicine Greifswald, Institute for Community Medicine, Germany

(4) Wolfgang Hoffmann; wolfgang.hoffmann@uni-greifswald.de
University Medicine Greifswald, Institute for Community Medicine, Germany

(5) Oliver Ritter; o.ritter@klinikum-brandenburg.de
Brandenburg City Hospital, University Clinic for Cardiology and Pulmonology,
Medical University, Germany

(6) Michael Oeff; oeff@klinikum-brandenburg.de
Brandenburg City Hospital, Germany

(7) Sven Speerfork; sven.speerfork@medizin.uni-leipzig.de
University of Leipzig Medical Center, Clinic of Psychiatry and Psychotherapy, Germany

(8) Georg Schomerus; georg.schomerus@medizin.uni-leipzig.de
University of Leipzig Medical Center, Clinic of Psychiatry and Psychotherapy, Germany

(9) Silke Schmidt; silke.schmidt@uni-greifswald.de
University of Greifswald, Department Health and Prevention, Germany

*(*Shared first authorship)*

Corresponding author:

Klara Greffin

University of Greifswald

Department Health & Prevention

Robert-Blum-Str. 13

17487 Greifswald

Germany

Phone: +49 (0)3834-420-3808

Fax: +49 (0)3834-420-3812

Email: klara.greffin@uni-greifswald.de

Abstract

Objectives: A setting-sensitive instrument for assessing Quality of Life (QoL) in Telemedicine (TM) was unavailable. To close this gap, a content-valid "add-on" measure was developed. In parallel, a brief index was derived featuring six items that summarise the main content of the multidimensional assessment. After pre- and pilot-testing, the psychometric performance of the final measures was investigated in an independent study.

Methods: The questionnaires were applied along with other standardised instruments of similar concepts as well as associated, yet disparate concepts for validation purposes. The sample consisted of patients with depression or heart failure, with or without TM (*n*=200). Data analyses were aimed at calculating descriptive statistics and testing the psychometric performance on item, scale, and instrument level, including different types of validity and reliability.

Results: The proposed factor structure of the multidimensional Tele-QoL measure has been confirmed. Reliability coefficients for internal consistency, split-half, and retest reliability of the subscales and index reached sufficient values. The Tele-QoL subscales and the index demonstrated Rasch scalability. Validity of both instruments can be assumed. Evidence for discriminant construct validity was provided. Known-groups validity was indicated by respective score differences for various classes of disease severity.

Conclusion: Both measures show convincing psychometric properties. The final Tele-QoL consists of six outcome scales and two impact scales assessing (un-)intended effects of TM on QoL. In addition, the Tele-QoL index provides a short alternative for economic assessment. The Tele-QoL measures can be used as complementary modules to existing QoL instruments capturing healthcare-related aspects of QoL from the patients’ perspective.

Key Words: Patient-Reported Outcome Measure, Quality of Life, Digital Health, Telemedicine, Validation

Background

Existing health-related or disease-specific quality of life (QoL) questionnaires assess the patient-reported impact of diseases or treatments on the construct (Haraldstad et al., 2019; Patrick & Deyo, 1989). Any aspects related to the context of healthcare, that might influence QoL beyond treatment, were hardly considered so far (Greffin et al., n.d.; Knapp et al., 2021). As part of the digitalization of healthcare, medical procedures and therapeutic treatment strategies are made available within the context of telemedicine (TM; Muehlan & Schmidt, 2013). Furthermore, additional health services are provided through innovative solutions, like telemonitoring (Johnson et al., 2008; Oeff et al., 2008; Ritter & Bauer, 2006; Schmidt, 2007b; van den Berg et al., 2015). This digital transformation has led to a change in healthcare contexts which is widely neglected in TM evaluations (Greffin, Schmidt, et al., 2021). In an extensive review including 293 TM studies (Greffin et al., n.d.), results indicated that TM-sensitive instruments were used in only about 5% of the ariticles included. Moreover, these instruments were only available for a limited range of concepts, as the majority was solely directed to assess satisfaction (Greffin et al., n.d.; Hajesmaeel-Gohari & Bahaadinbeigy, 2021). Thus, TM-specific aspects of care are not sufficiently covered by existing instruments, yet. Moreover, even though QoL is frequently considered as a core patient-reported outcome (Bullinger & Quitmann, 2014) in TM (Knapp et al., 2021; Riva et al., 2015; Schmidt, 2007a), there is no QoL instrument available for telehealth in particular. For this reason, we emphasize that more attention should be paid to contextual factors of healthcare, their influence on patients' experiences and health outcomes (Deng et al., 2010; Greffin, Schmidt, et al., 2021; Ng & Luk, 2019).

The aim of the "Tele-QoL" project was to close this gap by developing a suitable “add-on” QoL instrument to enable a setting-sensitive evaluation of TM applications (Greffin, Muehlan, et al., 2021). As such, this modular questionnaire shall asses QoL of patients with chronic conditions or mental illnesses in context of telemedical care.

Developing the Tele-QoL instrument was based on current recommendations for patient-reported outcome measures (Cheng & Clark, 2017; Rothrock et al., 2011) and to some extent inspired by a needs-based approach of QoL assessment (McKenna & Doward, 2004). The items of the Tele-QoL questionnaires were directly derived from qualitative interviews and focus groups and assess various facets of the healthcare-related domain of QoL (Greffin, Schmidt, et al., 2021). After developing the initial version, an expert workshop for external validation (*n*=6), an online expert survey to test the instrument's content validity (*n*=15), and a pretesting of the initial items with a sample of patients (*n*=32) were conducted. Subsequently, the revised version of the questionnaire was piloted. Therefore, a sample of patients with depression or heart failure with or without telemedical care (*n*=200) was recruited. As a result, we identified an appropriate measurement model comprising a superordinate factor with six sub-factors related to patient-relevant “outcomes”, and two factors related to unintended “impact” of telehealth on patients (Muehlan et al., n.d.).

The objective of this paper is to document the evaluation of performance and psychometric properties of the modular Tele-QoL instrument, including the multidimensional Tele-QoL measure with six outcome scales and two impact scales as well as the brief Tele-QoL index with six items. Both measures are equivalent in terms of conceptual approach and main content but differ in respect of their attributional primer. Thus, the alternative short version represents the main content of the outcome subscales as closely as possible with one item per dimension, excluding the content of the impact dimensions. This validation paper aims to document the psychometric performance of the Tele-QoL measures in terms of different forms of reliability and validity.

Methods

Data sample

For the validation study, patients with chronic heart failure or depression (*n*=200), with (version A) or without (version B) telemedical care were recruited. The recruitment was implemented in several hospitals of the project's consortium partners (Brandenburg, Greifswald, Leipzig) as well as at ambulatory healthcare facilities, all located in Northeastern Germany. In addition to the disease and treatment criteria mentioned above, a minimum age of 18 was an inclusion criterion, cognitive impairment and severe cognitive comorbidities as well as non-proficient knowledge of the German language were considered as exclusion criteria (Greffin, Muehlan, et al., 2021).

Treatment providers or study nurses in the recruitment centers informed interested patients according to pre-defined criteria in person or via telephone about purpose of the study, voluntariness, dropout options, and compensations. In addition, the patients received the information in written form along with phone and e-mail contact details of the recruiting centers and the scientific research assisstant. After the patients had given informed consent for the study, the questionnaires were handed out with the request to fill them in. Personal codes were generated for pseudonymous assignment of the follow-up survey, that were scheduled four weeks later. Personal assistance during the completion of the survey was available upon request. Completed questionnaires were mailed or dropped off in a prepaid envelope. After the questionnaires have been received , data were entered into an Excel spreadsheet and stored on a secured file server. Finally, the original questionnaires were stored in lockable cabinets.

Applied measures

Whereas all measures were applied to the first wave of the validation study, only some of them were also used within the second wave after four weeks to detect retest reliability, stability over time and sensitivity to change. All instruments included in the validation study are described in detail in the study protocol (Greffin, Muehlan, et al., 2021). Therefore, Table 1 shall provide a short overview, only.

Data analyses

Analyses were conducted including descriptive statistics and estimations of psychometric properties on the level of single items, composite scales as well as overall instrument according to classical and modern test theory. These analyses included reliability testing and validity exploration: *Factorial validity* was investigated applying confirmatory factor analysis. We assumed an appropiate model fit with the best fit statistics regarding a RMSEA close to .06, and a CFI close to .95 as cut-off criteria (Hu & Bentler, 1999).

Discriminant validity was investigated by calculating Pearson correlation coefficients for association between Tele-QoL scores and various indicators of general, health-related and disease-specific quality of life as well as measures related to the assessment of satistaction with care, patient activiation and health literacy, all assumed to be low or moderately associated with the Tele-QoL scores.

Concerning *convergent validity*, we assumed high associations with the subscales of a setting-sensitive measure for patient experiences in telemedicine. Finally, we tested for correlations with further associated constructs, including self-monitoring and locus of control.

To examine *known-groups validity* with respect to different clinical variables known for differences in quality of life, standardized effect sizes for differences of two independent means were estimated using Cohen’s d (Cohen, 1992). We excepted that patients with stronger disease severity show lower Tele-QoL outcome and higher impact scores.

Rasch analysis was used to detect possible misfit on item level. The partial credit model was applied to the data, using Q index statistics and threshold ordering estimation for detecting item misfit (Rost & von Davier, 1994).

For *reliability* testing, homogeneity of the subscales was investigated by computing Cronbach's alpha coefficient α. Split-half reliability was determined by the correlation between both test-halves. Pearson correlation coefficient (r) was used to estimate test-retest reliability of the Tele-QoL scores.

Table 1

Assessment of general information and psychological instruments included the Tele-QoL validation study

Study Assessments & Measures	Numbe rof Items	Validation study (I)	Validation study (II)
General information			
● Sociodemographic characteristics	7	X	
● Perceived relative health status	1	X	X
● Disease- & health-related information	8	X	X
Psychological instruments			
● Technology commitment (TB)	12	X	
● Heart failure severity (Goldman scale & NYHA)	6	X	X
● Depressive symptoms (PHQ-9)	10	X	X
● Quality of life in the context of telemedical care (Tele-QoL-A)	58	X	X
● Quality of life in the context of standard care (Tele-QoL B)	58	X	X
● Perceived security in telemedicine (SeCu-20)	20	X	X
● Patient satisfaction (ZUF-8)	8	X	
● Healthcare satisfaction – general item (YHC-SUN)	1	X	
● Patient activation (PAM-13)	13	X	
● Body-related self-consciousness – subscale “private” (KSA)	6	X	
● Body-related locus of control – subscale "health" (KLC)	5	X	
● Health literacy (HLS-6)	6	X	X
● Digital health literacy (D-HLS-6)	6	X	X
● Disease-specific quality of life - Depression (WHO-5)	5	X	X
● Disease-specific quality of life – Heart Insufficiency (MLHFQ)	21	X	X
● Health status (VR-12)	12	X	X
● Health-related quality of life (EQ-5D)	6	X	
● General quality of life (WHOQOL-BREF)	26	X	

Note. The selection of questionnaires within a study phase further depends on the group to which the patient belongs (heart failure or depression, with or without telemedical treatment).

Statistical software

Descriptive statistics and item-scaling analysis were performed using the IBM SPSS Version 28.0 (IBM Corp., 2021) Confirmatory factor analysis was processed using IBM AMOS Version 28 (Arbuckle, 2021). For Rasch analysis, the WINMIRA software package was used (von Davier, 2001).

Results

Sample characteristics

In total, *n*=200 patients aged 19 to 88 years participated in the Tele-QoL validation study (Table 2). Of these, 51.5% (*n*=103) reported being male, 48.0% (*n*=96) female, and 0.5% (*n*=1) diverse, respectively. Patients included were being treated for chronic heart failure (52.0%, *n*=104) or mental disorders (48.0%, *n*=96), depression in particular. Sociodemographic characteristics for each patient group is provided in Table 2.

Table 2

Sociodemographic characteristics of the Tele-QoL validation study sample (n=200)

Characteristics *		**Patients with heart failure**		**Patients with mental disorders**	
		Standard Care	*Telemedical Care*	*Standard Care*	*Telemedical Care*
Age Group	*< 35 years*	---	---	22 (48.0%)	7 (13.7%)
	36 - 50 years	1 (1.8%)	1 (2.0%)	12 (26.7%)	11 (21.6%)
	51 - 65 years	20 (36.4%)	9 (18.4%)	9 (20.0%)	29 (56.9%)
	66 - 80 years	23 (41.8%)	26 (53.1%)	2 (4.4%)	4 (7.8%)
	> 80 years	8 (14.5%)	9 (18.4%)	---	---
Gender	*Female*	18 (32.7%)	16 (32.7%)	27 (60.0%)	35 (68.6%)
	Male	37 (67.3%)	33 (67.3%)	17 (37.8%)	16 (31.4%)
	Diverse	---	---	1 (2.2%)	---
Education (Highest Degree)	*Primary school (8th/9th class)*	3 (5.5%)	10 (20.4%)	3 (6.7%)	2 (3.9%)
	Secondary School (10th class)	27 (49.1%)	25 (51.0%)	14 (31.1%)	29 (56.9%)
	High School (12th/13th class)	15 (27.3%)	9 (18.4%)	26 (57.8%)	15 (29.4%)
	Other Degree	7 (12.7%)	2 (4.1%)	2 (4.4%)	2 (3.9%)
	No Formal Degree	2 (3.6%)	1 (2.0%)	---	---

Notes: * Data referring to frequencies and percent. Absolute frequencies vary as a function of the amount of missing data for each variable. ** Sum of percent value may vary resulting from rounding of single percent rates.

Factorial validity was explored by applying confirmatory factor analysis (CFA). We used Maximum-likelihood parameter estimation for testing the model. Despite impaired normal distribution of items, this method can be applied as it is assumed to be robust even if the data violates the assumption of normal distribution. The model did fit the data well (χ^2(df=436)=696.53, p< 0.001, CFI=.94, TLI=0.93, RMSEA=0.056 [0.048; 0.064]).

The six "outcome" subscale scores of the multidimensional Tele-QoL instrument correlate moderately to highly with each other (r =.39-.81), the two "impact" subscales moderately with r=.44 (see Table 3). The high average *intercorrelation coefficients* of the outcome subscales also support the assumption of a common underlying factor, as determined by the higher-order factor within the CFA. The Tele-QoL index score correlates moderately to highly with all outcome scales of the muldimensional Tele-QoL (r =.59-.83), but slightly negatively with both impact scales (r =.12 and r.=-16).

Rasch analysis (Partial Credit Model) with emphasis on the operational characteristics of the items showed that none of the items in any of the Tele-QoL subscales or the Tele-QoL index displays infit, indicating no substantial deviation from the model. The range of item locations for the majority of the scales is moderate (< 2 logits), but the effective range carried by threshold distributions along the latent traits varies between >4 and <11 logits. Ordering of thresholds is in accordance with the model assumptions for all items in any of the sub-scales and the index as well (Table 4).

For reliability testing, the *internal consistency* was calculated using Cronbach's alpha (α) coefficient for all subscales and the index score. For the Tele-QoL-PRO index, a value of *α*=.90 and for the Tele-QoL-PRO subscales values between *α*=.84 and .95 were obtained. Thus, the internal consistencies for all scales of the Tele-QoL instruments can be judged as very good. All subscales of the Tele-QoL measure as well as the Tele-QoL index also yielded very good values for the *split-half-reliability*, which varied between .81 and .91*. Retest reliability* was determined over a period of approximately four weeks, controlling for the course of the disease. The corresponding coefficients vary between .65 and .77 and are thus sufficient to good. All reliability coefficients for the subscales of the Tele-QoL and the Tele-QoL index are also depicted in Table 4.

Table 3

Intercorrelations of the Tele-QoL sub-scale scores (n=200)

Tele-QoL instruments	*Number of items*	**Tel-QoL outcome scales**						**Tel-QoL impact scales**		**Tele-QoL index**
Multidimensional Tele-QoL measure		Patient Needs & Trust	Patient Relief & Autonomy	Information & Patient Education	Interaction & Patient Motivation	Control & Self-Monitoring	Safety & Well-Being	Surveillance & Data Processing	Patient Burden & Impairment	Total score
• Patient Needs & Trust	4	**---**	**.44**	**.50**	**.40**	**.52**	**.51**	-.24	-.25	**.59**
• Patient Relief & Autonomy	4	**.44**	**---**	**.69**	**.63**	**.47**	**.39**	-.07	-.07	**.63**
• Information & Patient Education	4	**.50**	**.69**	**---**	**.80**	**.63**	**.49**	-.12	-.13	**.76**
• Interaction & Patient Motivation	4	**.40**	**.63**	**.80**	**---**	**.60**	**.53**	-.06	-.14	**.73**
• Control & Self-Monitoring	4	**.52**	**.47**	**.63**	**.60**	**---**	**.81**	-.12	-.28	**.83**
• Safety & Well-Being	4	**.51**	**.39**	**.49**	**.53**	**.81**	---	-.20	-.26	**.74**
• Surveillance & Data Processing	4	-.24	-.07	-.12	-.06	-.12	-.20	**---**	**.44**	-.12
• Patient Burden & Impairment	4	-.25	-.07	-.13	-.14	-.28	-.26	**.44**	**---**	-.16
• ***Tele-QoL index***	6	**.59**	**.63**	**.76**	**.73**	**.83**	**.74**	-.12	-.16	---

*Notes: Interpretation of correlation coefficients: r < 0.30: low; r = 0.30 - 0.60: moderate; r > 0.60: high. In **bold** print: r > 0.30.*

Table 4

Rasch analysis and reliabilities of the multidimensional Tele-QoL sub-scales and the Tele-QoL index (n=200)

Tele-QoL instruments	**Number of items**	**Range of item locations**	**Range of threshold parameters**	**Non-ordered tresholds**	**Item fit (Q index)**	**Internal consistency**	**Spilt-half reliability**	**Retest reliability**
Multidimensional Tele-QoL measure		*($n_{min-max}$ = 178-185)*	*($n_{min-max}$ = 178-185)*	*($n_{min-max}$ = 178-185)*	*($n_{min-max}$ = 178-185)*	*($n_{min-max}$ = 178-185)*	*($n_{min-max}$ = 178-185)*	*($n_{min-max}$ = 77-79)*
• Patient Needs & Trust	4	- 0.84 < 0.75	- 3.90 < 3.10	---	.025 < .048	.90	.89	.75
• Patient Relief & Autonomy	4	- 0.13 < 0.23	- 2.39 < 2.92	---	.034 < .069	.87	.83	.75
• Information & Patient Education	4	- 0.43 < 0.03	- 2.34 < 2.47	---	.030 < .092	.83	.83	.70
• Interaction & Patient Motivation	4	- 1.16 < 0.69	- 4.35 < 3.49	---	.028 < .082	.90	.84	.70
• Control & Self-Monitoring	4	- 0.82 < 0.80	- 2.28 < 2.24	---	.038 < .071	.84	.91	.77
• Safety & Well-Being	4	- 1.17 < 0.96	- 6.27 < 4.46	---		.87	.84	.72
• Surveillance & Data Processing	4	- 0.95 < 0.88	- 3.20 < 3.00	---	.019 < .050	.93	.81	.71
• Patient Burden & Impairment	4	- 0.84 < 0.84	- 2.60 < 5.63	---	.021 < .038	.95	.91	.65
Tele-QoL index	6	- 0.26 < 0.74	- 2.71 < 3.05	---	.046 < .075	.90	.84	.70

Evidence for *known-groups validity* of the Tele-QoL measure is displayed by expected group differences (d=.01<.44) in the Tele-QoL scores for patients with different disease severity (Table 5).

Table 5

Known-groups validity of the Tele-QoL subscales and Tele-QoL index (n=200)

Tele-QoL instruments	**Patients with heart failure** *(NYHA =1 vs. NYHA > 1)*		**Patients with mental disorders** *(PHQ < 15 vs. PHQ > 14)*	
Multidimensional Tele-QoL measure	*Mean Difference*	*Effect Size Cohen's d*	*Mean Difference*	*Effect Size Cohen's d*
• Patient Needs & Trust	0.93	**0.28**	0.42	0.16
• Patient Relief & Autonomy	0.33	0.12	1.09	**0.41**
• Information & Patient Education	0.52	0.17	1.09	**0.38**
• Interaction & Patient Motivation	1.21	**0.33**	1.29	**0.41**
• Control & Self-Monitoring	1.51	**0.44**	0.02	0.01
• Safety & Well-Being	0.63	0.19	0.78	**0.33**
• Surveillance & Data Processing	-0.79	**-0.27**	-0.46	-0.18
• Patient Burden & Impairment	-0.93	**-0.37**	-0.80	**-0.34**
Tele-QoL index	0.84	0.17	0.94	**0.40**

With regard to *discriminant construct validity related to quality of life* results show low to moderate correlations with different indices of general quality of life (WHOQOL-BREF), health-related quality of life (EQ-5D, VR-12), disease-specific quality of life, and well-being (MLHFQ, WHO-5) indicate a sufficient *divergent validity* of the Tele-QoL instruments, since they capture different aspects of quality of life than previous instruments on already established concepts of quality of life (Table 6). Most coefficients for correlations between the six Tele-QoL outcome subscales with scores from other quality of life measures are notably higher for those domains related to mental issues (WHOQOL-BREF: Mental/Psychological Domain, VR-12 Mental Health Status) than domains related to physical issues (WHOQOL-BREF: Physical Domain, VR-12 Physical Health Status). Also, domains related to social or environmental issues show higher correlations than domains related to physical issues, but not as high as the "mental" domains. Correlation coeffients with physical domains of quality of lfie are generally weak or low (r =-.17 to .27). Both impact scales of the multidimensional Tele-QoL measure show low negative correlations with almost all quality of lfie scores (r=-.25 to .02).

Discriminant construct validity related to patient's experiences with healthcare provision was also investigated using other measures of related concepts assessing satisfaction with healthcare (YHC-SUN), patient satisfaction (ZUF-8) as well as patient activation (PAM13-D). For almost all correlations between Tele-QoL outcome subscale scores and index score, coefficients indicate moderate associations (*r*=.22-.61). In addition, discriminant construct validity was also investigated to some selected patient's experiences covered by the Tele-QoL scales. Considering "information & patient activiation", health-literacy (HLS-EU-Q6) as well as digital health literacy (D-HLS-EU-Q6) were assessed. Correlations coefficients indicate low associations (*r<.10*). With respect to "control and self-monitoring" was investigated by applying intruments assessing related concepts such as private body-related self-monitoring (KSA) as well as internal and external health-related locis o control (KLC). Again, correlations coefficients also indicate low associations (*r<.10*).

All six outcome subscales of the Tele-QoL instrument and the index score correlate moderately to highly with the three subscales of the SeCu-instrument assessing patient experiences in telemedicine (*r*=.36-.90). This supports the assumption of *convergent validity*. Missing substantial correlations (*r*=-.06<.07) with the SeCu subscale assessing negative experiences in telemedicine ("technology anxiety") indicate *divergent validity*. Correspondingly, the "Surveillance & Data Processing" subscale of the Tele-QoL instrument shows moderate correlation coefficients with "technology anxiety" (*r*= .31), but both impact subscales correlate slightly negative with the three "positive" SeCu subscales (*r*=-.30<-.08).

Table 6

Intercorrelations of the Tele-QoL scores with subscale scores of other measures for convergent and discriminant validation (n=200)

Tele-Qol module	**(subscales)**	Patient Needs & Trust	Patient Relief & Autonomy	Information & Patient Education	Interaction & Patient Motivation	Control & Self-Monitoring	Safety & Well-Being	Surveillance & Data Processing	Patient Burden & Impairment	Tele-QoL index
Items		*4*	*4*	*4*	*4*	*4*	*4*	*4*	*4*	*6*
WHOQOL-BREF	Physical Domain	.10	.18	.21	.27	.10	.05	-.14	-.17	.10
	Mental Domain	.15	**.40**	**.36**	.28	.17	.09	-.18	-.07	.27
	Social Domain	.17	**.34**	.27	.21	.23	.19	-.16	-.04	**.30**
	Environmental Domain	.17	.29	.27	.25	.26	.13	-.25	-.22	.29
EQ-5D	Health-related QoL	.04	.06	.09	.19	.01	.04	-.21	-.11	.01
VR-12	Physical Health Status	.04	-.01	.01	.12	-.01	.05	-.13	-.11	-.02
	Mental Health Status	.18	**.43**	**.37**	**.31**	.20	.10	-.15	-.12	.26
MLHFQ *	Disease-specific QoL (Heart Failure)	.20	.26	**.33**	**.34**	**.34**	.27	-.14	-.15	**.30**
WHO-5**	Disease-specific QoL (Depression)	.14	**.37**	.29	**.36**	.17	.15	.02	-.04	.24
YHC-SUN-1	Satisfaction with Healthcare	**.39**	**.41**	**.46**	**.47**	**.47**	**.48**	-.10	-.12	**.52**
ZUF-8	Patient Satisfaction	**.46**	**.48**	**.56**	**.58**	**.59**	**.56**	-.19	-.17	**.61**
PAM-13-D	Patient Activation	.22	.28	**.33**	**.34**	.27	.22	-.14	-.01	**.33**
HLS-EU-Q6	Health Literacy	.16	.07	.07	.21	.17	.28	-.19	-.19	.15
D-HLS-EU-Q6	Digital Health Literacy	.13	.05	.04	.18	.10	.21	-.18	-.12	.08
KSA	Private body-related Self-Monitoring	.10	-.03	-.01	-.01	-.05	.03	.11	.10	.05
KLC	Health-related Locus of Control (internal)	.17	.01	.05	.02	.06	.10	.01	-.05	.04
KLC	Health-related Locus of Control (external)	-.08	.01	.05	-.03	-.01	-.09	.03	-.02	-.05
TBS	Technology Acceptance	.12	.12	.13	.16	-.03	-.00	-.12	-.05	.07
	Technology Competence	.12	-.09	-.11	.01	-.02	.06	-.19	-.18	-.04
	Technology Control	.02	-.05	.04	.15	.02	.02	-.08	-.09	-.00
SeCu***	Technology Anxiety	-.06	-.02	-.04	.05	.04	.07	**.31**	.20	.07
	Perceived Security	**.58**	**.57**	**.81**	**.74**	**.80**	**.80**	-.22	**-.30**	**.84**
	Perceived Autonomy	**.38**	**.63**	**.78**	**.90**	**.62**	**.66**	-.08	-.08	**.82**
	Physician- patient-relation	**.36**	**.59**	**.70**	**.66**	**.72**	**.71**	-.08	-.17	**.81**

*Notes: * For patients with chronic heart failure only; ** for patients with depression only, *** for patients with telemedical care only. Interpretation of correlation coefficients: r < 0.30: low; r = 0.30 - 0.60: moderate; r > 0.60: high. In* ***bold*** *print: r > 0.30. WHOQOL-BREF: World Health Organization Quality of Life measure (short version); EQ-5D: EuoQol Quality of Life measure; VR-12: Veterans RAND 12 Item Health Survey (short version); MLHFQ: Minnesota Living with Heart Failure Questionnaire; WHO-5: World Health Organization Well-Being Scale; YHC-SUN-1: Generic single-item measure of satisfaction with heathcare from the Satisfaction, Utilization & Needs Questionnaire (Youth version); ZUF-8: Patient Satisfaction Scale (8 item version); PAM-13-D: Patient Activation Measure; HLS-EU-Q6: Health Literacy Scale HLS-EU (6 item version); D-HLS-EU-Q6: (Adopted) Digital version of the Health Literacy Scale HLS-EU (6 item version); KSA: Body-related Self-Awareness Scale; KLC: Body-related Locus of Control Scale; TBS: Technology Commitment Scale; SeCu: Perceived Security in Telemedicine Scale.*

Discussion

Main results

With the Tele-QoL measures, we provide a quantitative instrument that assesses the impact of the TM healthcare context on QoL of patients, beyond the effects of the disease and the treatment (Greffin, Schmidt, et al., 2021).

Summarizing the results of this study, the Tele-QoL measures show a convincing psychometric performance. Our results confirm the factorial structure of the multidimensional measure. The reliabilities of all subscales and of the index measure are satisfying, with the internal consistencies and split-half reliability being very good and a retest-reliability with sufficient to good values. Also, operational characteristics of the items were in line with the model assumptions implied by the Rasch model. The correlations of the Tele-QoL outcome scales with each other indicate a common underlying factor, which is consistent with our model assumptions. Construct validity - assessed at the level of discriminant and convergent validity - can be considered as given on the basis of the results provided by the validation study. Moreover, there is reasonable evidence, that the concept of healthcare-related quality of life and the domains representing this construct in the measurement model are not identical with related constructs and are sufficiently distinguished from each other in terms of the discriminant validity. This also provides initial evidence for the incremental validity and added value of the Tele-QoL measures. Finally, a high content validity can be assumed, as the questionnaire was developed on the basis of extensive qualitative material, which was directly assessed in the project.

Getting to know the Tele-QoL

The Tele-QoL is used to assess healthcare-related aspects of QoL in the context of telemedical applications (version A) or standard care (comparison version B). It is used as an "add-on instrument" as a supplement to already existing QoL questionnaires. The target group of the Tele-QoL are patients aged 18 years and older who receive telemedical care (version A). It is irrelevant whether the patients are being treated for chronic physical or mental illnesses. At the moment, the Tele-QoL instruments are available in German (accessible via https://teleqol.psychologie.uni-greifswald.de/).

The questionnaire opens with a short instruction on the objective and how to carry it out; this is followed by the respective items. In addition, the temporal reference of four weeks is referred to again at the beginning of each page. Patients rate their healthcare-related experiences of the last four weeks on the basis of six (index), 24 (short form) or 32 (long form) items using a

4-point Likert scale with the ratings 1="Do not agree" to 4="Highly agree". Answering the questionnaire takes about 20 minutes (Tele-QoL instrument) or 5 minutes (Tele-QoL index).

The full version of the Tele-QoL consists of 24 items of six outcome scales and eight items of two impact scales; the short version of the Tele-QoL comprises six items that refer exclusively to the outcome scales. These 24 items are affiliated with six facets of a core module, which can be used to assess the intended outcomes of telemedical applications. The additional impact module can be used if negative effects of the applications shall be evaluated. It is available in the Tele-QoL long version.

The Tele-QoL instruments are available as A and B version. Version A contains all telemedicine-related items of the Tele-QoL, while version B was designed as a comparative instrument for patients with chronic conditions or mental illnesses who are currently undergoing care-as-usual.

How can the Tele-QoL measures benefit the evaluation of TM applications?

According to a modern understanding, the majority of patients are considered active protagonists who no longer want to be treated passively, but also want to make their own contribution to their health (Haslbeck et al., 2015; Kennedy et al., 2007). With a long-lasting illness, however, the needs and challenges in everyday life that a patient is confronted with also increase (McGilton et al., 2018). For this reason, it is the purpose of (TM) care for long-term illnesses to support patients in the management of their illness and the needs associated with it (Huygens et al., 2016). In order to assess whether and to what extent TM applications are able to provide this support, appropriate assessments are needed that reflect the patient's perspective (Federal Institute for Drugs and Medical Devices, 2019). Therefore, the development and implementation of a setting-sensitive questionnaires like the Tele-QoL measures are crucial as they allow for a more valid assessment in TM studies. In this way, the healthcare context is included in the evaluation of care components, in addition to the effects of the disease and respective treatment. As a result, for example, the demand for a valid and quantitative summative evaluation of the medical benefit can now be better met (Federal Institute for Drugs and Medical Devices, 2019).

The extended consideration of the patient perspective also has the potential to function as a formative evaluation in the context of a continuous assessment of TM care services. In this way, the professionals involved receive direct, informative feedback on the effects of TM applications on the patients' QoL and can initiate necessary adjustments accordingly.

In general, patients using telemedicine will have the opportunity to better represent the impact of TM on their QoL via the Tele-QoL questionnaire. The extended conceptualization of QoL in

TM settings may also lead to potential improvements in TM applications and individualized TM care for patients with chronic diseases and mental illnesses.

Strengths and limitations

The Tele-QoL is developed based on an extensive mixed-methods approach, which is a strength in terms of content validity (Cheng & Clark, 2017; Rothrock et al., 2011). Moreover, patients were included in all stages of the development and validation process. Another advantage is the sample composition for validation, consisting of respondents with complementary diseases and forms of treatment. Thus, half of the sample consisted of patients with telemedical or standard treatment, half of whom were chronically physically or mentally ill. Amongst patients with telemdical care, half of them were treated with an active TM approach (regular phone calls), the other half were treated with a passive TM approach (remote vital monitoring) TM application. The aim was to represent all potential user groups and to test whether the questionnaire can be used independently of the disease and the treatment.

However, our validation study also has limitations. First of all, in planning the project, a compromise had to be made between an adequate sample size and the feasibility of data collection. A sample of *n*=200 is considered fair (Tsang et al., 2017) and is therefore sufficient, but can be expanded. Future evaluation of the psychometric properties should be based on larger samples, including more disease groups and other TM settings. Moreover, other important properties of the measures need to be investigated, such as readability or responsiveness.

To assess retest reliability, patients were asked to complete a second questionnaire four weeks after the initial survey. The date for the second questionnaire was written on the instrument. In addition, after completing the second questionnaire, patients were asked to write the current date under the questionnaire’s items. Unfortunately, not all patients did so. Therefore, we cannot be sure in every case that the questionnaires were filled out exactly four weeks later.

The severity of the respective disease, which was used for calculating the known-groups validity, was based on patients’ self-reports, assessed via patient-reported outcome measures. The data may be biased, for example, by how someone feels on a particular day. In addition, the validation was conducted as a questionnaire study in which patients were asked to fill out different questionnaires one after the other. We arranged the order of the questionnaires in such a way that the questions on general health run towards specific health questions in order to cause as little priming as possible. Nevertheless, answering one questionnaire may have an impact on answering subsequent questionnaires.

It remains unclear what effect the SARS-CoV-2 pandemic outbreak had on our sample. The recruiting institutions had the impression that more severely burdened patients were less willing to participate in the study than before the pandemic, but this circumstance was not systematically recorded. Nevertheless, it should be reported that in this context there may have been a selection and nonresponse bias in our sample regarding the severity levels included. Besides, TM was suddenly used as a substitute, not as a complement.

In summary, this instrument development demonstrates that the psychometric properties of the Tele-QoL measures are convincing. However, it only remains the first step towards a fully validated questionnaire (Frost et al., 2007).

Conclusion & Outlook

The modular Tele-QoL instruments represent a methodologically sound measure to assess QoL in TM settings. They can be used as complementary modules to existing QoL instruments to assess healthcare-related aspects of QoL from the patients' perspective in telehealth contexts. It is an important and necessary contribution to developing, implementing, and evaluating digital health applications.

In the future, the Tele-QoL approach will be further adapted so that it can also be used for children and adolescents (new development of a Tele-QoL Kids) as well as in other countries (cultural adaptation and translation) facing similar healthcare challenges. Tele-QoL can also be further developed as a computer-adaptive method due to the lack of deviations from the Rasch model.

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Ethical Standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Ethics approval

The Tele-QoL project was approved by the Ethics Committee at the University Medicine Greifswald (BB 023/18) and the partner department (AS466 (bB)/2018).

Consent to participate

All participants consent in written format.

Preregistration and study protocol

The study protocol was published in the journal IJERPH "Setting-sensitive conceptualization and assessment of quality of life in telemedical care – Study protocol of the Tele-QoL project" (Greffin, Muehlan, et al., 2021).

Conflict of interest

All authors declare that they have no conflict of interest.

Author's contribution

- Conceptualization: HM, SiS, NvdB & WH;
- Methodology: KG, HM;
- Software: HM;
- Investigation: KG, NvcB, WH, MO, OR, SvS, GS;
- Resources, SiS, HM;
- Data curation, KG, HM;;
- Writing—original draft preparation, KG, HM;
- Writing—review and editing: SiS, NB, WH, OR, MO, SvS & GS;
- Visualization: KG, HM;
- Supervision: SiS;
- Project administration: KG, SiS.

All authors have read and agreed to the published version of the manuscript.

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ii. Tele-QoL Questionnaires

The Tele-QoL questionnaires are included here in the long version and in the index version for TM (A) or care-as-usual (B). The questionnaires were developed, tested, refined and validated in this dissertation.

TELEQL

Seit einiger Zeit befinden Sie sich aufgrund einer chronischen oder psychischen Erkrankung in telemedizinischer Behandlung. Hierzu würden wir Sie im Folgenden gerne befragen. Bitte beantworten Sie jede der Fragen, indem Sie bei den Antwortmöglichkeiten denjenigen Ausprägungsgrad ankreuzen, der am besten auf Sie zutrifft. Bitte denken Sie bei der Beantwortung der Fragen daran, wie es Ihnen **in den letzten 4 Wochen** durchschnittlich ergangen ist. Falls Ihre telemedizinische Behandlung bereits abgeschlossen sein sollte, versuchen Sie sich bitte daran zu erinnern, wie Sie sich damals gefühlt haben.

		Stimmt nicht	Stimmt kaum	Stimmt eher	Stimmt genau
1.	Mir wurde erklärt wie meine telemedizinische Behandlung funktioniert.	①	②	③	④
2.	Ich habe verstanden was im Rahmen der telemedizinischen Behandlung mit mir passiert.	①	②	③	④
3.	Ich bin über die Grenzen meiner telemedizinischen Behandlung informiert.	①	②	③	④
4.	Im Rahmen meiner telemedizinischen Behandlung erhalte ich genau die Informationen, die wichtig für mich sind.	①	②	③	④
5.	Durch die telemedizinischen Kontrollen achte ich mehr auf die Signale meines Körpers.	①	②	③	④
6.	Durch die Telemedizin weiß ich, wie ich meine Beschwerden deuten kann.	①	②	③	④
7.	Durch die Telemedizin kann ich einschätzen, wann ich zusätzliche medizinische Hilfe in Anspruch nehmen sollte.	①	②	③	④
8.	Die telemedizinischen Maßnahmen geben mir ein Gefühl von Kontrolle.	①	②	③	④

		Stimmt nicht	Stimmt kaum	Stimmt eher	Stimmt genau
9.	Ich mache mir Sorgen, dass meine Gesundheitsdaten missbraucht werden könnten.	①	②	③	④
10.	Ich befürchte, dass auch fremde Personen ohne Erlaubnis auf meine Gesundheitsdaten zugreifen können.	①	②	③	④
11.	Ich habe Angst, dass durch die telemedizinischen Kontrollen meine Privatsphäre verletzt werden könnte.	①	②	③	④
12.	Durch die telemedizinische Behandlung fühle ich mich fremdbestimmt.	①	②	③	④
13.	Durch die Telemedizin fühle ich mich auch zu Hause gut versorgt.	①	②	③	④
14.	Durch die telemedizinische Behandlung fühle ich mich innerlich ruhiger.	①	②	③	④
15.	Dank der Telemedizin fühle ich mich im Umgang mit meiner Erkrankung sicherer.	①	②	③	④
16.	Die telemedizinische Erfassung meiner Gesundheitsdaten gibt mir ein Gefühl von Sicherheit.	①	②	③	④
17.	Ich fühle mich durch die telemedizinischen Maßnahmen im Alltag unterstützt.	①	②	③	④
18.	Ich kann durch die Telemedizin in meinem Alltag aktiver sein.	①	②	③	④
19.	Durch die telemedizinische Behandlung bin ich im Alltag unabhängiger.	①	②	③	④
20.	Durch die Telemedizin komme ich besser mit schwierigen Situationen zurecht.	①	②	③	④

		Stimmt nicht	Stimmt kaum	Stimmt eher	Stimmt genau
21.	Meine telemedizinische Behandlung ist mit hohem bürokratischem Aufwand für mich verbunden.	①	②	③	④
22.	Die telemedizinischen Behandlungsmaßnahmen belasten mich.	①	②	③	④
23.	Die telemedizinischen Behandlungsmaßnahmen überfordern mich.	①	②	③	④
24.	Meine telemedizinische Behandlung schränkt mich im Alltag ein.	①	②	③	④
25.	Meine persönlichen Bedürfnisse werden bei der telemedizinischen Behandlung berücksichtigt.	①	②	③	④
26.	Die telemedizinische Behandlung ist genau auf meine Bedürfnisse abgestimmt.	①	②	③	④
27.	Ich habe Vertrauen in meine telemedizinischen Behandlungsmaßnahmen.	①	②	③	④
28.	Ich kann mich auf meine telemedizinische Behandlung verlassen.	①	②	③	④
29.	Ich habe die Möglichkeit, auch kurzfristig Auskunft zu meiner Behandlung zu bekommen.	①	②	③	④
30.	Ich fühle mich von meiner telemedizinischen Ansprechperson verstanden.	①	②	③	④
31.	Meine telemedizinische Ansprechperson und ich unterhalten uns auf Augenhöhe.	①	②	③	④
32.	Meine telemedizinische Ansprechperson motiviert mich, Absprachen auch wirklich umzusetzen.	①	②	③	④

TELEQoL

Seit einiger Zeit befinden Sie sich aufgrund einer chronischen oder psychischen Erkrankung in telemedizinischer Behandlung. Hierzu würden wir Sie im Folgenden gerne befragen. Bitte beantworten Sie jede der Fragen, indem Sie bei den Antwortmöglichkeiten denjenigen Ausprägungsgrad ankreuzen, der am besten auf Sie zutrifft. Bitte denken Sie bei der Beantwortung der Fragen daran, wie es Ihnen **in den letzten 4 Wochen** durchschnittlich ergangen ist. Falls Ihre telemedizinische Behandlung bereits abgeschlossen sein sollte, versuchen Sie sich bitte daran zu erinnern, wie Sie sich damals gefühlt haben.

		Stimmt nicht	Stimmt kaum	Stimmt eher	Stimmt genau
1.	Ich fühle mich durch die Telemedizin sicherer.	①	②	③	④
2.	Ich kann mein alltägliches Leben durch die Telemedizin freier gestalten.	①	②	③	④
3.	Ich weiß durch die telemedizinischen Kontrollen, wie es um meine Gesundheit steht.	①	②	③	④
4.	Ich werde durch die telemedizinischen Maßnahmen stets im Umgang mit meiner Erkrankung begleitet.	①	②	③	④
5.	Ich empfinde meine telemedizinische Behandlung als genau auf mich abgestimmt.	①	②	③	④
6.	Ich bin über meine telemedizinische Behandlung informiert.	①	②	③	④

Index-Version A

TELEQ L

Seit einiger Zeit befinden Sie sich aufgrund einer chronischen oder psychischen Erkrankung in medizinischer oder therapeutischer Behandlung. Hierzu würden wir Sie im Folgenden gerne befragen. Bitte beantworten Sie jede der Fragen, indem Sie bei den Antwortmöglichkeiten denjenigen Ausprägungsgrad ankreuzen, der am besten auf Sie zutrifft. Bitte denken Sie bei der Beantwortung der Fragen daran, wie es Ihnen **in den letzten 4 Wochen** durchschnittlich ergangen ist. Falls Ihre Behandlung bereits abgeschlossen sein sollte, versuchen Sie sich bitte daran zu erinnern, wie Sie sich damals gefühlt haben.

		Stimmt nicht	Stimmt kaum	Stimmt eher	Stimmt genau
1.	Mir wurde erklärt wie meine Behandlung funktioniert.	①	②	③	④
2.	Ich habe verstanden was im Rahmen der Behandlung mit mir passiert.	①	②	③	④
3.	Ich bin über die Grenzen meiner Behandlung informiert.	①	②	③	④
4.	Im Rahmen meiner Behandlung erhalte ich genau die Informationen, die wichtig für mich sind.	①	②	③	④
5.	Durch die medizinischen Kontrollen achte ich mehr auf die Signale meines Körpers.	①	②	③	④
6.	Durch die Behandlung weiß ich, wie ich meine Beschwerden deuten kann.	①	②	③	④
7.	Durch die Behandlung kann ich einschätzen, wann ich zusätzliche medizinische Hilfe in Anspruch nehmen sollte.	①	②	③	④
8.	Die medizinischen Maßnahmen geben mir ein Gefühl von Kontrolle.	①	②	③	④

		Stimmt nicht	Stimmt kaum	Stimmt eher	Stimmt genau
9.	Ich mache mir Sorgen, dass meine Gesundheitsdaten missbraucht werden könnten.	①	②	③	④
10.	Ich befürchte, dass auch fremde Personen ohne Erlaubnis auf meine Gesundheitsdaten zugreifen können.	①	②	③	④
11.	Ich habe Angst, dass durch die medizinischen Kontrollen meine Privatsphäre verletzt werden könnte.	①	②	③	④
12.	Durch die medizinische Behandlung fühle ich mich fremdbestimmt.	①	②	③	④
13.	Durch die Behandlung fühle ich mich auch zu Hause gut versorgt.	①	②	③	④
14.	Durch die Behandlung fühle ich mich innerlich ruhiger.	①	②	③	④
15.	Dank der Behandlung fühle ich mich im Umgang mit meiner Erkrankung sicherer.	①	②	③	④
16.	Die medizinische Erfassung meiner Gesundheitsdaten gibt mir ein Gefühl von Sicherheit.	①	②	③	④
17.	Ich fühle mich durch die Behandlungsmaßnahmen im Alltag unterstützt.	①	②	③	④
18.	Ich kann durch die Behandlung in meinem Alltag aktiver sein.	①	②	③	④
19.	Durch die Behandlung bin ich im Alltag unabhängiger.	①	②	③	④
20.	Durch die Behandlung komme ich besser mit schwierigen Situationen zurecht.	①	②	③	④

		Stimmt nicht	Stimmt kaum	Stimmt eher	Stimmt genau
21.	Meine Behandlung ist mit hohem bürokratischem Aufwand für mich verbunden.	①	②	③	④
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23.	Die Behandlungsmaßnahmen überfordern mich.	①	②	③	④
24.	Meine Behandlung schränkt mich im Alltag ein.	①	②	③	④
25.	Meine persönlichen Bedürfnisse werden bei der Behandlung berücksichtigt.	①	②	③	④
26.	Die Behandlung ist genau auf meine Bedürfnisse abgestimmt.	①	②	③	④
27.	Ich habe Vertrauen in meine Behandlungsmaßnahmen.	①	②	③	④
28.	Ich kann mich auf meine medizinische Behandlung verlassen.	①	②	③	④
29.	Ich habe die Möglichkeit, auch kurzfristig Auskunft zu meiner Behandlung zu bekommen.	①	②	③	④
30.	Ich fühle mich von meiner medizinischen Ansprechperson verstanden.	①	②	③	④
31.	Meine medizinische Ansprechperson und ich unterhalten uns auf Augenhöhe.	①	②	③	④
32.	Meine medizinische Ansprechperson motiviert mich, Absprachen auch wirklich umzusetzen.	①	②	③	④

TELEQoL

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		Stimmt nicht	Stimmt kaum	Stimmt eher	Stimmt genau
1.	Ich fühle mich durch die Behandlung sicherer.	①	②	③	④
2.	Ich kann mein alltägliches Leben durch die Behandlung freier gestalten.	①	②	③	④
3.	Ich weiß durch die medizinischen Kontrollen, wie es um meine Gesundheit steht.	①	②	③	④
4.	Ich werde durch die Behandlungsmaßnahmen stets im Umgang mit meiner Erkrankung begleitet.	①	②	③	④
5.	Ich empfinde meine Behandlung als genau auf mich abgestimmt.	①	②	③	④
6.	Ich bin über meine Behandlung informiert.	①	②	③	④

Index-Version B

iii. Declaration of the personal contribution

Overview of the author's personal contributions to the scientific papers submitted:

Paper I

Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2021). Setting-sensitive conceptualization and assessment of quality of life in telemedical care –study protocol of the Tele-QoL project. *International Journal of Environmental Research and Public Health*, *18*(19). https://doi.org/10.3390/ijerph181910454

Study concept/design	Schmidt, Muehlan
Development of the research question	Schmidt, Muehlan, Greffin
Data collection	Schmidt, Muehlan, Greffin
Data analysis	-
Interpretation of the data	-
Preparation of the manuscript	Greffin, Muehlan,
Revision of the manuscript	All authors

Paper II

Greffin, K., Muehlan, H., Rosenkranz, E., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2022). *Telemedicine and patient-reported outcomes in chronic conditions: concordance and discrepancy of purpose, concepts, and methods of measurement – a systematic literature review.* [Manuscript submitted for publication]. Department Health and Prevention, University of Greifswald.

Study concept/design	Greffin, Muehlan, Schmidt
Development of the research question	Greffin, Muehlan, Rosenkranz
Data collection	Greffin, Rosenkranz
Data analysis	Greffin, Rosenkranz
Interpretation of the data	Greffin, Rosenkranz
Preparation of the manuscript	Greffin, Rosenkranz
Revision of the manuscript	All authors

Paper III

Greffin, K., Schmidt, S., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Muehlan, H. (2021). Same same - but different: using qualitative studies to inform concept elicitation for quality of life assessment in telemedical care: a request for an extended working model. *Health and Quality of Life Outcomes*, 1-14. https://doi.org/10.1186/s12955-021-01807-8

Study concept/design	Greffin, Muehlan, Schmidt
Development of the research question	Greffin, Muehlan
Data collection	Greffin, Muehlan, van den Berg, Hoffmann, Ritter, Oeff
Data analysis	Greffin, Muehlan
Interpretation of the data	Greffin, Muehlan
Preparation of the manuscript	Greffin, Muehlan
Revision of the manuscript	All authors

Paper IV

Muehlan, H., **Greffin, K.**, van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2022). *Towards adjunct setting-related quality of life assessment in telemedicine – cognitive debriefing, expert rating and pilot testing of the Tele-QoL instrument.* [Manuscript submitted for publication]. Department Health and Prevention, University of Greifswald.

Study concept/design	Greffin, Muehlan, Schmidt
Development of the research question	Greffin, Muehlan, Schmidt
Data collection	Greffin, Muehlan, van den Berg, Hoffmann, Ritter, Oeff, Schomerus
Data analysis	Muehlan
Interpretation of the data	Muehlan, Greffin
Preparation of the manuscript	Greffin, Muehlan
Revision of the manuscript	All authors

Paper V

Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Speerforck, S., Schomerus, G., & Schmidt, S. (2022). *Measuring context that matters: Validation of the modular Tele-QoL patient-reported outcome and experience measure.* [Manuscript submitted for publication]. Department Health and Prevention, University of Greifswald.

Study concept/design	Greffin, Muehlan, Schmidt
Development of the research question	Greffin, Muehlan, Schmidt
Data collection	Greffin, Muehlan, van den Berg, Oeff, Hoffmann, Ritter, Speerforck, Schomerus
Data analysis	Muehlan
Interpretation of the data	Muehlan, Greffin
Preparation of the manuscript	Greffin, Muehlan
Revision of the manuscript	All authors

iv. List of Publications

JOURNAL ARTICLES

- **Greffin, K.**, Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Speerforck, S., Schomerus, G., & Schmidt, S. (2022). *Measuring context that matters: Validation of the modular Tele-QoL patient-reported outcome and experience measure.* [Manuscript submitted for publication]. Department Health and Prevention, University of Greifswald.
- Muehlan, H., **Greffin, K.**, van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2022). *Towards adjunct setting-related quality of life assessment in telemedicine – cognitive debriefing, expert rating and pilot testing of the Tele-QoL instrument.* [Manuscript submitted for publication]. Department Health and Prevention, University of Greifswald.
- **Greffin, K**., Schmidt, S., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Muehlan, H. (2021). Same same - but different: using qualitative studies to inform concept elicitation for quality of life assessment in telemedical care: a request for an extended working model. *Health and Quality of Life Outcomes*, 1–14. https://doi.org/10.1186/s12955-021-01807-8
- **Greffin, K.**, Muehlan, H., Rosenkranz, E., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2022). *Telemedicine and patient-reported outcomes in chronic conditions: concordance and discrepancy of purpose, concepts, and methods of measurement – a systematic literature review.* [Manuscript submitted for publication]. Department Health and Prevention, University of Greifswald.
- **Greffin, K.**, Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2021). Setting-sensitive conceptualization and assessment of quality of life in telemedical care—study protocol of the Tele-QoL project. *International Journal of Environmental Research and Public Health*, *18*(19). https://doi.org/10.3390/ijerph181910454
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- **Greffin, K.**, Schmidt, S., Schönborn, L., & Muehlan, H. (2021). “Blood for Blood”? Personal Motives and Deterrents for Blood Donation in the German Population. *International Journal of Environmental Research and Public Health*, 18(8). https://doi.org/10.3390/ijerph18084238

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- **Greffin, K**., Muehlan, H., Sümnig, A., Schmidt, S., & Greinacher, A. (2018). Psychologische Optionen zur Reaktivierung und Bindung von Blutspendern. *Transfusionsmedizin - Immunhämatologie, Hämotherapie, Immungenetik, Zell-therapie*, 8(1), 24–32. https://doi.org/10.1055/s-0043-121416
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- **Greffin, K.**, Schmidt, S., van den Berg, N., Hoffmann, W., Schomerus, G., Oeff, M., Ritter, O., Muehlan, H. (2021). Towards setting-sensitive quality of life assessment in telemedicine – validation of the modular Tele-QoL patient-reported outcome measure. 28th Annual Conference of the International Society for Quality of Life Research (ISOQOL 2021), online.
- **Greffin, K.**, Muehlan, H., van den Berg, N., Hoffmann, W., Oeff, M., Ritter, O., Schomerus, G., Speerforck, S., Schmidt, S. (2021). Tele-QoL – Finale Ergebnisse eines Projekts zur Entwicklung eines settingbezogenen Instruments zur Messung der Lebensqualität im Kontext telemedizinischer Anwendungen. Deutscher Kongress für Versorgungsforschung (DKVF 2020), Berlin (online), Germany.
- König, N., **Greffin, K.** (2021). Digitaler Deutschunterricht: Mehr als die bloße Übertragung der Arbeitsformen in ein anderes Medium. Jahrestagung der DGFE-Sektion Schulpädagogik, online.
- **Greffin, K.**, Schönborn, L., Schmidt, S., Muehlan, H. (2021). Donor career development – how past behaviour influences future blood donation intention. 35th Annual Conference of the European Health Psychology Society (EHPS 2021), online.
- **Greffin, K.,** Muehlan, H., van den Berg, N., Hoffmann, W., Schomerus, G., Oeff, M., Ritter, O., Schmidt, S. (2021). Concept elicitation for setting-sensitive patient-reported outcome measurement in telemedicine: A context-related approach to an extended working model for quality of life assessment. Patient Reported Outcome Measures (PROMs) Research Conference, Sheffield (online), England.
- **Greffin, K.,** Muehlan, H., van den Berg, N., Hoffmann, W., Schomerus, G., Oeff, M., Ritter, O., Schmidt, S. (2020). Settingsensitive Konzeptualisierung und Erfassung der Lebensqualität in der telemedizinischen Versorgung (Tele-QoL): Entwicklungsstand und Pilotierungsergebnisse. Deutscher Kongress für Versorgungsforschung (DKVF 2020), Berlin (online), Germany.
- **Greffin, K.,** Muehlan, H., Tomczyk, S., Suemnig, A., Schmidt, S., & Greinacher, A. (2020). Investigating how deferral affects momentary mood, satisfaction with the donation process, and subsequent return behaviour in first-time donors. International Society of Blood Transfusion (ISBT) – Virtual Congress 2020.

- **Greffin, K.,** Schmidt, S., van den Berg, N., Hoffmann, W., Schomerus, G., Oeff, M., Ritter, O., Muehlan, H. (2020). Subjective experiences in telemedicine and the call for setting-related quality of life: A qualitative study in telemedical professionals as well as patients with mental disorders and chronic conditions. 27th Annual Conference of the International Society for Quality of Life Research (ISOQOL 2020), online.
- **Greffin, K.,** Schmidt, S., van den Berg, N., Hoffmann, W., Schomerus, G., Oeff, M., Ritter, O., Muehlan, H. (2020). Towards adjunct setting-related quality of life assessment in telemedical care: concept elicitation, item generation and initial testing. 27th Annual Conference of the International Society for Quality of Life Research (ISOQOL 2020), online.
- **Greffin, K.** (2020). Patient-reported outcomes in passive monitoring. Virtual.MEDICA 2020 – Fields of innovation, online.
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- **Greffin, K.,** Muehlan, H., van den Berg, N., Hoffmann, W., Schomerus, G., Oeff, M., Ritter, O., Schmidt, S. (2018). Diskrepanzen zwischen patienten-berichteten Zielkriterien und Instrumenten im Kontext der telemedizinischen Versorgung – ein systematischer Literaturreview. Deutscher Kongress für Versorgungsforschung (DKVF 2018), Berlin, Germany.

- **Greffin, K.,** Muehlan, H., van den Berg, N., Hoffmann, W., Schomerus, G., Oeff, M., Ritter, O., Schmidt, S. (2017). Setting-sensitive Konzeptualisierung und Erfassung der Lebensqualität in der telemedizinischen Versorgung. Deutscher Kongress für Versorgungsforschung (DKVF 2017), Berlin, Germany.
- **Greffin, K.,** Muehlan, H., Sümnig, A., Schmidt, S. & Greinacher, A. (2017). Psychische Faktoren und praktische Implementierungsoptionen zum Aufbau von Spenderloyalität bei initial abgelehnten Neuspendern. *Health Psychology 2017*, 172-174.

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