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Ergebnisbericht

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Konsortialführung:	Universität Greifswald
Förderkennzeichen:	01VSF16027
Akronym:	TELE-QOL
Projekttitel:	Settingsensitive Konzeptualisierung und Erfassung der Lebensqualität in der telemedizinischen Versorgung
Autoren:	Silke Schmidt, Holger Muehlan & Klara Greffin für den Tele-QoL-Verbund
Förderzeitraum:	1. Oktober 2017 – 30. September 2021

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I. Abkürzungsverzeichnis

LQ	*Lebensqualität*
PREM	*Patient-reported experience measure*
PRO	*Patient-reported outcome*
PROM	*Patient-reported outcome measure*
TM	*Telemedizin*
Tele-QoL	*Fragebogen zur Erfassung der Lebensqualität im Kontext von Telemedizin*

II. Tabellenverzeichnis

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1. Zusammenfassung

Hintergrund. Lebensqualität (LQ) ist neben primär klinischen Outcomes ein zentrales patient*innen-bezogenes Outcome in der Gesundheitsforschung. Eine konzeptionelle, operationale und psychometrische Ausarbeitung des Konstrukts LQ im Kontext von telemedizinischen Anwendungen (TM) ist erforderlich, da bislang standardisierte Instrumente zur Bewertung der Lebensqualität wesentliche Aspekte des Einsatzes von TM nicht ausreichend abbilden. Das übergeordnete Ziel war es daher, ein Instrument zu entwickeln, das die LQ im Bereich TM adäquat erfassen kann. Zu diesem Zweck sollte zunächst ein erweitertes Arbeits-Modell der LQ abgeleitet werden. Anschließend sollte ein Instrument entwickelt und validiert werden, welches diejenigen Aspekte der Lebensqualität erfasst, die durch TM beeinflusst werden.

Methodik. Die Erweiterung des Konzepts der LQ basiert auf zwei systematischen Literatur-Reviews (*n*=293 & *n*=38) sowie auf Interviews (*n*=63) und Fokusgruppen (*n*=68) mit chronisch physisch oder psychisch erkrankten Patient*innen und TM-Expert*innen, auf deren Basis ein Arbeitsmodell der LQ im TM-Kontext abgeleitet wurde. Das qualitative Material wurde inhaltsanalytisch ausgewertet. Das resultierende Kategorien-System wurde in einem Expert*innen-Workshop (*n*=6) validiert und diente als Grundlage für die Itemgenerierung. Mit Hilfe kognitiver Prä-Testungen wurde geprüft, wie relevant, plausibel und verständlich die Items für Patient*innen (*n*=32) waren. Zusätzlich wurde eine Online-Umfrage unter TM-Expert*innen durchgeführt (*n*=15), um Relevanz, Anwendbarkeit und Umfang des Item-Pools zu bewerten. Schließlich wurde der initiale Itempool in einem Sample aus Patient*innen mit Depression oder Herzinsuffizienz, mit oder ohne TM-Erfahrung (*n*=200) getestet, um die psychometrische Performanz auf Item- und Skalenebene zu analysieren sowie die Dimensionalität des Item-Pools zu explorieren. Die abschließende Validierung des Instruments erfolgte in einem unabhängigen Sample von *n*=200 Patient*innen.

Ergebnisse. Das finale Kategoriensystem umfasst drei patient*innen-bezogene und eine system-bezogene Domäne. Der ursprüngliche Item-Pool mit 227 Items wurde durch die Prä-Testung weiter verfeinert, wobei 122 Items ausgeschlossen wurden. In der Expert*innenbefragung wurden 105 Items des vorläufigen Instruments bewertet, etwa 20 Items wurden als optimaler Umfang für ein entsprechendes „Add-on“-Instrument eingeschätzt. Faktorenanalytische Auswertungen der Pilotierungsdaten identifizierten die dimensionale Struktur des Instruments. Mit zwei Skalen pro Domäne umfasst das endgültige Instrument sechs Outcome-Skalen, die einem Faktor höherer Ordnung zugeordnet sind sowie zwei zusätzlichen Impact-Skalen, die unintendierte Auswirkungen der TM-Anwendung erfassen. Alle Skalen werden mit jeweils vier Items erfasst, das multidimensionale Tele-QoL Instrument umfasst damit insgesamt 32 Items. Parallel wurde ein Kurzindex mit sechs semantisch aggregierten Items der jeweiligen Outcome-Skalen entwickelt und validiert, der als ökonomische Alternative eingesetzt werden kann. Beide Instrumente weisen überzeugende psychometrische Eigenschaften auf.

Diskussion. Das resultierende modulare Verfahren erfasst zentrale Erfahrungen von Patient*innen mit TM-Anwendungen und deren Auswirkungen auf die LQ. Der Einsatz als ergänzendes Instrument wird zu einer angemesseneren Bewertung von TM führen, zur Verbesserung einer auf die individuellen Bedürfnisse der Patient*innen zugeschnittenen Versorgung beitragen und eine verbesserte Evaluation von digitalen Gesundheits-Anwendungen ermöglichen.

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2. Beteiligte Projektpartner*innen

Name	Institution	Verantwortlichkeit/ Rolle
Prof. Dr. Silke Schmidt	Universität Greifswald	Konsortialführung/ Projektkoordination
Dr. Holger Muehlan		Methodenverantwortung/ Stellvertretende Leitung
Dipl.-Psych. Klara Greffin		Wissenschaftliche Mitarbeiterin
Prof. Dr. Wolfgang Hoffmann PD Dr. Neeltje van den Berg	Universitätsmedizin Greifswald	Konsortialpartner: Rekrutierungszentrum – Telemedizinische Forschung & Versorgung im Integrierten Funktionsbereich Telemedizin
Prof. Dr. Michael Oeff Prof. Dr. Oliver Ritter	Telemedizin Zentrum Brandenburg	Konsortialpartner: Rekrutierungszentrum – Telemedizinische Versorgung
Prof. Dr. Georg Schomerus	Universitätsmedizin Leipzig	Kooperationspartner: Rekrutierungszentrum – Psychiatrische Versorgung

Fachlicher Ansprechpartner für Rückfragen nach Projektende:

Dr. Holger Muehlan
Universität Greifswald
Lehrstuhl Gesundheit und Prävention
Tel.: 03834/420 3802
Fax: 03834/420 3812
E-Mail: holger.muehlan@uni-greifswald.de

3. Projektziele

Gegenstand des Tele-QoL Projektes war die konzeptuelle, operationale und psychometrische Analyse und Fundierung der patient*innenberichteten Lebensqualität (LQ) im Kontext telemedizinischer Anwendungen (TM-Anwendungen), die zur mittel- und langfristigen Versorgung von chronisch physischen oder psychischen Erkrankungen im Erwachsenenalter eingesetzt werden. Hierbei waren vor allem solche Anwendungen von Interesse, die einen Kontakt zwischen Patient*innen und Versorgenden herstellen und nicht ausschließlich zu diagnostischen Zwecken eingesetzt werden. Typische Anwendungen sind beispielsweise das Telemonitoring im Bereich kardiologischer Erkrankungen. Allgemein wurde sich im Projekt an folgendem Begriffsverständnis der Bundesärztekammer (2015) orientiert:

> Telemedizin ist ein Sammelbegriff für verschiedenartige ärztliche Versorgungskonzepte, die als Gemeinsamkeit den prinzipiellen Ansatz aufweisen, dass medizinische Leistungen der Gesundheitsversorgung der Bevölkerung in den Bereichen Diagnostik, Therapie und Rehabilitation sowie bei der ärztlichen Entscheidungsberatung über räumliche Entfernungen (oder zeitlichen Versatz) hinweg erbracht werden. Hierbei werden Informations- und Kommunikationstechnologien eingesetzt. (Bundesärztekammer, 2015, S. 334)

Ausgangspunkt des Projektes war die Beobachtung, dass sich für die Evidenzlage bzgl. der Wirksamkeit von TM-Anwendungen zur Verbesserung der LQ ein gemischtes Bild ergibt: Obwohl Hinweise vorlagen, dass der Einsatz von TM-Anwendungen die LQ in den Interventionsgruppen gegenüber den Kontrollgruppen verbessern kann, sind diese Effekte sehr uneinheitlich. Die Unterschiede sind nicht immer klinisch relevant bzw. statistisch signifikant und unterscheiden sich zudem auch im Hinblick auf die untersuchten Erkrankungsgruppen (Muehlan & Schmidt, 2012, 2013). Zusätzlich sind Wirkungen auf die LQ oft auf eine Auswahl von Skalen begrenzt und Langzeitwirkungen werden i.d.R. nicht evaluiert (Muehlan & Schmidt, 2012, 2013).

Dies indizierte potenzielle Defizite im Hinblick auf einen patient*innenzentrierten Messansatz, welcher den Erwartungen an die Wirksamkeit von TM (Johnson et al., 2008) angemessen ist. Probleme bestehen u.a. darin, dass die Messungen häufig durch jeweils anwendungsspezifische Itemformulierungen der Patient Reported Outcome Measures (PROMs) und Patient Reported Experience Measures (PREMs) erfolgen. Zudem ergeben sich Herausforderungen in der Vergleichbarkeit aufgrund der Heterogenität der TM-Anwendungen und Versorgungsmodelle sowie den unterschiedlichen Bedürfnissen der jeweiligen Zielgruppen. Eine solide Beurteilung der Evidenz sollte sich daher (i) auf häufig verwendete TM-Anwendungen beziehen und (ii) auf Grundlage oft untersuchter Erkrankungsgruppen erfolgen. Dieser Forderung kann etwa für TM-Anwendungen für Patient*innen mit Herzinsuffizienz entsprochen werden und dokumentiert sich in vielzähligen Reviews (Clarke et al., 2011; Inglis et al., 2010; Polisena et al., 2010; Schmidt et al., 2010). Im Gegensatz zu den uneinheitlichen Befunden zu den Auswirkungen von TM-Anwendungen auf die LQ, scheint die Zufriedenheit der Patient*innen hoch zu sein (Schmidt, 2007).

Im Rahmen der Versorgungsforschung hat sich *LQ als zentrales patient*innen-berichtetes Outcome (PRO)* neben primär klinischen Zielkriterien etabliert. Im Hinblick auf die Wirksamkeit von TM-Anwendungen, die auf eine Verbesserung der (gesundheitsbezogenen) LQ abzielen, zeigen Reviews inkonsistente Befunde. In methodischer Hinsicht werden zwar immer öfter standardisierte Instrumente zur Erfassung der LQ eingesetzt. Allerdings bilden diese Instrumente nicht hinreichend die wichtigsten Aspekte der eigentlich intendierten Ergebnisse von TM-Anwendungen ab. So werden etwa Monitoring-Anwendungen vor allem eingesetzt, um die häusliche Überwachung durch medizinisches Personal zu verbessern sowie um das krankheitsbezogene Sicherheits- und Kontrollerleben der Patient*innen in ihrer häuslichen Umgebung bzw. ihrem persönlichen Umfeld zu erhöhen. Somit besteht eine Diskrepanz zwischen der primären Implementierungsintention und der entsprechenden Implementierungsevaluation im Bereich TM-Anwendungen, insbesondere für Monitoring-Verfahren. Darüber hinaus verweisen empirische Studien auf die subjektive Bedeutung der oben genannten Aspekte aus der Sicht der Patient*innen (wahrgenommenes Sicherheitserleben und Kontrollerfahrung), insbesondere im Hinblick auf die Akzeptanz dieser Versorgungsformen. Ähnliche Ergebnisse sind auch für andere Anwendungen aus dem Bereich der ambulanten Gesundheitsüberwachung bekannt, z.B. für assistive Monitoringsysteme im Rahmen der ambulanten Pflege und dem häuslichen Monitoring von älteren Menschen (Essén, 2008).

Daher bestand ein *Bedarf* an einer elaborierteren konzeptuellen, operationalen und psychometrischen Fundierung des Konstrukts der LQ im Rahmen von TM-Anwendungen, da es für die meisten TM-Anwendungen als das zentrale PRO definiert wird. Auf einer allgemeineren Ebene richtet sich dieser Ansatz aber auch auf die Notwendigkeit einer Reflexion psychischer Prozesse und sozialer Kontextfaktoren, die mit TM assoziiert sind bzw. damit im Zusammenhang stehen. Um solche Facetten mit zu integrieren, die aus Perspektive der Patient*innen auch einen großen Stellenwert einnehmen, muss ein Arbeitsmodell generiert und ein entsprechendes Erhebungsinstrument daraus abgeleitet werden.

Die *Ziele* des Tele-QoL Projekts waren daher (a) die Analyse und Fundierung des Konzepts der LQ im Kontext von TM-Anwendungen und (b) die Entwicklung und Testung eines Instruments zur Setting-sensitiven Erfassung von LQ im Kontext von TM.

4. Projektdurchführung

Eine ausführliche *Beschreibung des Projekts* ist in einem entsprechenden *Studienprotokoll* festgehalten (Greffin, Muehlan, et al., 2021).

Ziel dies Projekts war die Exploration des Konstrukts *Lebensqualität* im Kontext von TM-Anwendungen sowie die Entwicklung und Testung eines Fragebogens, mit dessen Hilfe LQ bei Patient*innen mit TM-Versorgung sensitiv erfasst werden kann.

Zur konkreten Ausführung des Projektes und zur Erreichung der im Antrag formulierten spezifischen Projektziele wurden entsprechende Teilstudien durchgeführt, die im Rahmen der Projektlaufzeit abgeschlossen werden konnten:

- Erstellung einer *Gap-Analyse* auf Basis eines systematischen Literaturreviews zur Beantwortung der Frage, wie LQ in TM-Studien erfasst wird.
- *Durchführung von qualitativen Studien* (Interviews, Fokusgruppen) zur Konzeptualisierung der LQ im Kontext der TM-Versorgung und Generierung eines Itempools für die Entwicklung des Fragebogens.
- *Entwicklung und Testung eines Fragebogens* zur Erfassung von LQ im Kontext von TM-Anwendungen auf Basis von umfassenden *quantitativen Studien*. Dieser Fragebogen liegt sowohl als Lang- als auch als Index-Version vor.
- *Erstellung und Dissemination* der Projektergebnisse über die Bereitstellung eines *Manuals und einer Projekthomepage sowie die Fertigstellung und Veröffentlichung projektbezogener Publikationen.*

5. Methodik

Ethikvotum und Einwilligung zur Teilnahme

Das Projekt wurde von der Ethikkommission der Universitätsmedizin Greifswald (BB 023/18, Datum: 27.02.2018) und der Landesärztekammer Brandenburg (AS466 (bB)/2018, Datum: 09.04.2018) genehmigt. Von allen Teilnehmer*innen wurde eine schriftliche Einwilligungserklärung eingeholt.

Art der Studie: Instrumentenentwicklungsstudie

Ziele der Studie:

(i) *Gap-Analyse:* Untersuchung möglicher Diskrepanzen zwischen dem definierten Ziel von TM-Interventionen, gewählten Konzepten und Messmethoden in Durchführbarkeits- und Wirksamkeitsstudien als Erklärung uneinheitlicher Ergebnisse hinsichtlich PROs in TM-Studien.

(ii) *Exploration des Konzepts*: Erweiterung des Konzepts der Lebensqualität im Kontext von Telemedizin-Anwendungen.

(iii) *Entwicklung des Instruments*: Entwicklung eines Instruments zur Erfassung der LQ in TM-Kontexten.

(iv) *Testung:* Psychometrische Testung des neu entwickelten Instruments.

Aufbau und Methoden

Das Design umfasste einen *explorativen Studienteil*, der aus einer systematischen Literaturübersicht (Gap-Analyse) und einer qualitativen Befragung (Exploration des Konzepts) bestand. Ein zweiter *quantitativer Ansatz* diente der strukturierten Bewertung (Prä-Testung der Items, Pilotierung und Validierung des Instruments) des entwickelten Fragebogens.

- **Systematischer Literaturreview:** Im Vorfeld der empirischen Untersuchungen wurde ein systematischer Literaturreview zur Fragestellung durchgeführt, ob auch mögliche Diskrepanzen zwischen dem definierten Ziel von Telemedizin-Interventionen, den gewählten Konzepten und den Messmethoden, die in Durchführbarkeits- und Wirksamkeitsstudien verwendet werden, mit ursächlich für uneinheitliche Ergebnisse in Telemedizin-Studien zu PROs sein könnten. Im Rahmen des systematischen Literaturreviews wurde zunächst ein geeigneter Suchstring definiert, um eine umfassende und systematische Recherche in Fachdatenbanken durchführen zu können (Greffin et al., subm.). Zusätzlich wurden eine manuelle Suche und eine Suche in Referenzlisten geeigneter Studien durchgeführt. Identifizierte Studien wurden im Rahmen von zwei Screenings und basierend auf im Vorfeld definierte Ein- und Ausschlusskriterien auf Ihre Eignung geprüft. In den Review eingeschlossene, also geeignete Studien wurden ausgewertet und die identifizierten Informationen zu Befunden aggregiert (Greffin et al., subm.).
- **Qualitative Studien (Exploration des Konzepts):** Es wurden Interviews und Fokusgruppen mit halbstrukturierten Leitfäden durchgeführt, um Erwartungen an, Erfahrungen mit und Bewertungen von TM-Anwendungen zu erfassen. Zusätzlich wurden die wahrgenommenen Auswirkungen von TM-Anwendungen auf die LQ diskutiert. Die intensive Nutzung qualitativer Erhebungsmethoden steht im Einklang mit bestehenden Empfehlungen der internationalen PROM/PREM-Forschung (Cheng & Clark, 2017).

- **Quantitative Studien (Prüfung des Instruments):** Zuerst wurde ein Prä-Test des neu entwickelten Fragebogens mit der kognitiven Debriefing-Methode "think aloud" durchgeführt. Anschließend erfolgten eine Online-Umfrage unter TM-Expert*innen sowie die Pilotierung und Validierung des Instruments zur psychometrischen Prüfung in zwei unabhängigen Patient*innen-Stichproben. Die Daten aus der Pilotierung wurden analysiert, um die Dimensionalität des Item-Pools und die psychometrische Performanz auf Item- und Skalenebene zu untersuchen. Dafür wurde u.a. eine Hauptachsenanalyse mit Promax-Rotation durchgeführt.

  Die Analysen der Validierungsdaten umfassten deskriptive Statistiken und Schätzungen der psychometrischen Eigenschaften auf der Ebene einzelner Items, zusammengesetzter Skalen sowie des Gesamtinstruments nach klassischer und moderner Testtheorie.

  Die faktorielle Validität wurde mittels konfirmatorischer Faktorenanalyse untersucht. Für eine hinreichende Modellpassung wurden für ausgewählte Fit-Indizes Cut-Off-Werte vorgegeben, etwa einen RMSEA nahe .06 und einen CFI nahe .95. Die konvergente und diskriminante Validität wurden durch die Berechnung von Pearson-Korrelationskoeffizienten für die Assoziationen zwischen Tele-QoL-Scores und verschiedenen Indikatoren der allgemeinen, gesundheitsbezogenen und krankheitsspezifischen LQ sowie weiteren Skalenwerten von Instrumenten zur Erfassung der Zufriedenheit mit der Versorgung, der Patient*innenaktivierung und der Gesundheitskompetenz untersucht, die alle als gering oder mäßig mit den Tele-QoL-Scores assoziiert angenommen wurden. Im Hinblick auf die konvergente Validität wurde eine hohe Assoziation mit den Subskalen eines Setting-spezifischen Maßes für Patient*innenerfahrungen in der Telemedizin (SeCu) angenommen. Schließlich analysierten wir die Korrelationen mit weiteren assoziierten Konstrukten, darunter Selbstmonitoring und Kontrollüberzeugung. Um die hypothesengeleitete „known-groups“ Validität in Bezug auf verschiedene klinische Variablen zu untersuchen, für die Unterschiede in der LQ durch die bestehende Forschungsliteratur belegt sind, wurden standardisierte Effektgrößen für Unterschiede zwischen zwei unabhängigen Mittelwerten mit Cohen's d berechnet. Es wurde angenommen, dass Patient*innen mit einer stärkeren Krankheitsschwere niedrigere Tele-QoL-Outcome-Scores und höhere Impact-Scores aufweisen.

  Die Rasch-Analyse wurde angewendet, um eine mögliche Fehlanpassung auf Item-Ebene zu erkennen. Die Analysen erfolgte auf Grundlage des partial credit model, wobei die Q-Index-Statistiken (Item Fit/Misfit) und die Schätzung der Schwellenwertparameter (Modellpassung/Verteilung) berücksichtigt wurden.

  Schließlich wurden auch Reliabilitätsprüfungen vorgenommen. Die Homogenität der Subskalen wurde durch Berechnung des Koeffizienten Cronbach‘s Alpha untersucht. Die Split-Half-Reliabilität wurde mit Hilfe des Split-Half-Koeffizienten von Guttman untersucht. Der Pearson-Korrelationskoeffizient (r) wurde zur Schätzung der Test-Retest-Reliabilität der Tele-QoL-Werte verwendet.

Stichprobe

Allgemein

Die Stichprobe wurde so konzipiert, dass sie eine gewisse Heterogenität der TM-Anwendungen und der Patient*innenpopulationen repräsentiert, um eine bessere Verallgemeinerbarkeit der Ergebnisse zu erzielen. Daher haben wir die wichtigsten Gruppen von TM-Expert*innen einbezogen und Patient*innengruppen auswählt, die hinsichtlich ihrer Grunderkrankung komplementär zueinander sind (psychische vs. chronisch physische Erkrankung), aber häufig in TM-Studien untersucht werden (Herzinsuffizienz vs. Depression). Darüber hinaus unterschieden sich die Patient*innengruppen hinsichtlich des Aktivitätsgrads im Rahmen der TM-Anwendung (aktiv (regelmäßige Telefonate) vs. passiv (Telemonitoring)). Damit sollten eine Vielzahl von TM-Erfahrungen von Patient*innen mit unterschiedlichen Erkrankungen, einem unterschiedlichen Versorgungsspektrum und mit unterschiedlichem soziodemographischem Hintergrund (Geschlecht, Alter) sowie von verschiedenen TM-Expert*innen erfasst werden.

Qualitative Studien (Exploration des Konzepts): Die Anzahl der Fokusgruppen und Interviews wurde so geplant, dass eine inhaltliche Sättigung erreicht werden kann (Guest et al., 2006; Nyumba et al., 2018):

Geplante Stichprobengröße

- **Fokusgruppen** mit einer Gesamtzahl von *n*=32 Patient*innen
- **Fokusgruppen** mit einer Gesamtzahl von *n*=30 Telemedizin-Expert*innen
- **Einzelinterviews** mit *n*=32 Patient*innen
- **Einzelinterviews** mit *n*=30 Telemedizin-Expert*innen.

Quantitative Studien (Prüfung des Instruments): Wir haben 32 Patient*innen (kognitives Debriefing) und sechs Expert*innnen (Expert*innen-Workshop) für die Prä-Testung des initialen Instruments erhoben.

Die Schätzung der für die *Pilotierung* und *Validierung* benötigten Stichprobengröße basierte auf den Voraussetzungen der komplexeren psychometrischen Verfahren (explorative sowie konfirmatorische Faktorenanalyse und differentielle Itemfunktionalität). Allerdings waren die Größe des Item-Pools, die Kommunalitäten der Items sowie die Anzahl, Itemgrößen und Eigenwerte der Faktoren im Vorfeld noch unbekannt (Costello & Osborne, 2005). Für die Annäherung an die erforderlichen Fallzahlen bezogen wir uns daher auf Simulationsstudien und Reviews (Anthoine et al., 2014). Für die Pilotierung gingen wir von einer geschätzten Itemgröße von etwa 50+/-10 Items aus, für die Validierung von etwa 25+/-10 Items. Bei Gruppenvergleichen mit zwei Vergleichsgruppen pro Merkmal (Versorgungsform, Krankheitsgruppe) im abschließenden Validierungsschritt entspricht das geschätzte Verhältnis von Fallzahl : Items für die Pilotierung und Validierung etwa 4:1 (3:1 bis 5:1) und damit der etablierten Praxis im PRO-Bereich (Anthoine et al., 2014). Unter Berücksichtigung eines vertretbaren Aufwandes und Nutzens ergab sich eine Fallzahl von *n*=200, die jeweils für die Pilotierungs- und Validierungsstudie als ausreichende Zahl für die durchzuführenden Analysen zugrunde gelegt werden sollte. Diese Fallzahl wurde jeweils erreicht.

Zusammenfassend kann festgehalten werden, dass alle beantragten Fallzahlen im Projekt umgesetzt wurden.

Tabelle 2

Stichprobengrößen pro Studienabschnitt (gesamt n=562)

Projektaufgabe	Patient*innen	Expert*innen
Interviews	*n*=33 Patient*innen	*n*=30 Telemedizin-Expert*innen
Fokusgruppen	*n*=38 Patient*innen	*n*=31 Telemedizin-Expert*innen (Arbeitsgruppen)
Expert*innen-Validierung des konzeptionellen Modells		Expert*innen-Workshop (*n*=6)
Prä-Testung der Items	Cognitive Debriefings n=32	Expert*innen-Befragung (*n*=15)
Pilotierung des Fragebogens	*n*=200 Patient*innen (gesamt) *n*=100 Patient*innen mit chronischen Erkrankungen (*n*=50 jeweils mit oder ohne Telemedizin) *n*=100 Patient*innen mit psychischen Erkrankungen (*n*=50 jeweils mit oder ohne Telemedizin)	
Validierung des Fragebogens	*n*=200 Patient*innen (gesamt) *n*=100 Patient*innen mit chronischen Erkrankungen (*n*=50 jeweils mit oder ohne Telemedizin) *n*=100 Patient*innen mit psychischen Erkrankungen (*n*=50 jeweils mit oder ohne Telemedizin)	

Rekrutierung

Die Rekrutierung der Patient*innen wurde von Konsortial- und Kooperationspartner*innen in Greifswald, Brandenburg und Leipzig realisiert. Die Studienpopulation wurde dabei aus Patient*innen rekrutiert, die eine a) TM-Behandlung erhalten oder erhalten haben oder b) mit „care-as-ususal“ aufgrund einer Depression oder Herzinsuffizienz behandelt werden bzw. wurden. Die Auswahl der Patient*innen erfolgte nach standardisierten Kriterien (z. B. Art der Erkrankung und Versorgung). Alle Teilnehmenden mussten mindestens 18 Jahre alt sein. Eine mäßige bis schwere Beeinträchtigung der kognitiven Funktionen (z. B. komorbide neurologische Erkrankungen) und nicht ausreichende Deutschkenntnisse waren Ausschlusskriterien. Die TM-Expert*innen wurden von der wissenschaftlichen Mitarbeiterin des Projekts identifiziert und per E-Mail, persönlich oder telefonisch rekrutiert. Sie mussten in TM-Bereichen wie Forschung, Entwicklung, Implementierung, Evaluation oder Finanzierung tätig sein.

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Auswertung der Daten

Datenerhebung und -verwaltung

Allgemein. Für das Projekt wurde ein Datenschutzkonzept erstellt, das geltenden Vorschriften entspricht. Dieses umfasst die Information und Einwilligung in die Studie, die Datenerhebung, den Datentransport, die Auswertung, die Verarbeitung und die Speicherung der Daten. Darüber hinaus stellte die Universität Greifswald einen geschützten Projektserverordner zur Verfügung und vergab entsprechende Zugriffsrechte an ausgewählte Mitglieder des Forschungsteams. Der Projektserver wurde für die sichere Speicherung der Projektdaten genutzt. Dessen Nutzung erfolgte im Einklang mit den geltenden Datenschutzgesetzen.

Qualitative Daten wurden mit einem Diktiergerät aufgezeichnet, nachdem alle Teilnehmer*innen ihr schriftliches Einverständnis gegeben haben. Nach der Aufzeichnung wurden die Audiodateien auf dem Projektserver gespeichert, bis eine Transkription der Interviews erstellt wurde. Die Audiodatei wurde anschließend gelöscht, während das Transkript auf dem Server gespeichert wurde.

Quantitative Daten wurden mit Hilfe von zumeist standardisierten Fragebögen erhoben. Das Studienmaterial wurde von der Universität Greifswald erstellt und anschließend an die rekrutierenden klinischen Partnereinrichtungen verschickt. Die Teilnehmer*innen wurden gebeten, die ausgefüllten Fragebögen in einem vorfrankierten Umschlag anonym an die Universität Greifswald zurückzusenden. Nach Eingang der Fragebögen wurden diese in eine Excel-Tabelle eingegeben und auf dem Projektserver gespeichert. Die Originalfragebögen werden in verschlossenen Schränken in Räumen, zu denen nur ein begrenzter Personenkreis Zugang hat, aufbewahrt.

Auswertung der Daten

Qualitative Daten. Die qualitativen Daten wurden mit der Software f4 transkript (dr. dresing & pehl GmbH, 2005) transkribiert und anschließend mit Hilfe der Software MAXQDA (VERBI Software, 2017) ausgewertet. Für die Kodierung des Datenmaterials wurde der inhaltsanalytische Ansatz von Mayring (2000) angewendet. Die Analyse und Kodierung der Transkripte wurden von zwei Personen (wissenschaftliche Mitarbeiterin, studentische Hilfskraft) unabhängig voneinander durchgeführt und iterativ verfeinert. Mögliche abweichende Kodierungen und widersprüchliche Interpretationen wurden in einem konsensualen Verfahren mit dem Methodenverantwortlichen besprochen. Die Analyse war darauf ausgerichtet, alle Textsequenzen/Einheiten zu identifizieren, die sich auf persönliche Erfahrungen im Zusammenhang mit der Anwendung von TM und deren Auswirkungen auf die LQ beziehen. Aus diesen Inhalten wurden iterativ Kategorien abgeleitet bzw. bestehenden Kategorien zugeordnet. Das resultierende Kategoriensystem und die strukturierten Inhalte sind das Ergebnis der Analysen, die aus dem Dateninput der qualitativen Studien generiert wurden. Zur externen Validierung der Ergebnisse wurde ein Expert*innen-Workshop mit Fachleuten aus dem Bereich der TM-Anwendungen und der LQ-Forschung durchgeführt.

Quantitative Daten. Nach der Generierung und Auswahl eines Item-Pools auf Basis des konzeptionellen Rahmenmodells erfolgte eine Prä-Testung der Items durch kognitive Debriefings. Die Pilottestung des initialen Fragebogens erfolgte in einer umfassenden Stichprobe. Analysen zu deskriptiven und psychometrischen Eigenschaften als auch zur multidimensionalen Struktur (explorative Faktorenanalyse) wurden durchgeführt. Die Validierung umfasste die Auswahl und Festlegung des endgültigen Item-Pools, einschließlich der Skalenzuordnung auf der Grundlage der Pilotergebnisse, die finale Testung auf Basis einer unabhängigen Stichprobe sowie Analysen der deskriptiven und psychometrischen Performanz auf Item-, Subskalen- und Instrumentenebene (u. a. konfirmatorische Faktorenanalyse und Rasch-Analyse).

6. Projektergebnisse

Alle im Antrag formulierten Projektziele wurden im Rahmen der Projektlaufzeit realisiert. Es gab diesbezüglich keine Anpassungen mit dem Förderer. Alle Projektergebnisse sind in den Publikationen des Tele-QoL Projekts dargestellt und können im Anhang eingesehen werden.

Gap-Analyse – Wie wird LQ aktuell in TM-Studien erfasst? Die Ergebnisse der Literaturreviews wurden zur Publikation eingereicht (Greffin et al., subm.)

- 293 Studien wurden in die *Review-Arbeit* eingeschlossen.
- Insgesamt wurden in den analysierten Studien nur wenige TM-spezifische *Messinstrumente* verwendet, keines davon erfasst die LQ.
- Es konnten zwei *Diskrepanzen* identifiziert werden: Die erste besteht zwischen den definierten Zielen des TM-Einsatzes und den für ihre Bewertung verwendeten Patient*innen-berichteten Outcomes (PROs), die zweite zwischen der Passung des PRO-Konstrukts und den jeweiligen patient*innen-bezogenen Messinstrumenten (PROMs).
- Ergänzend konnte ein *Mangel an Dokumentation* in TM-Studien festgestellt werden.

Qualitative Studie zur Konzeptualisierung der LQ im TM-Kontext (Greffin et al., 2021) und Generierung eines Itempools zur Fragebogen-Entwicklung (Muehlan et al., subm.)

- Die Mehrzahl der Aspekte, die die LQ von Patient*innen mit chronischen oder psychischen Erkrankungen beeinflussen, konnte einem gängigen *Arbeitsmodell* der LQ zugeordnet werden. Einige Aspekte, die als wichtig erachtet wurden (z. B. die wahrgenommene Sicherheit), wurden jedoch von den bereits vorhandenen Domänen nicht abgedeckt. Aus diesem Grund wurde das Arbeitsmodell der LQ erweitert und um eine sechste Domäne ergänzt, die als versorgungsbezogene Domäne bezeichnet wird.

Entwicklung und Testung eines modularen Selbstberichtsverfahrens zur Erfassung der LQ im Kontext von TM-Anwendungen (Greffin et al., subm.).

- Der ursprüngliche *Item-Pool* umfasste 227 Items und wurde durch kognitive Debriefings weiter verfeinert, wobei 122 Items ausgeschlossen wurden. In der Expert*innenbefragung wurden die verbleibenden 105 Items des vorläufigen Instruments bewertet. Ein Durchschnitt von etwa 20 Items wurde als optimale Fragebogenlänge bewertet. Die Ergebnisse der Pilotierung deuten auf eine multidimensionale Struktur des Tele-QoL-Itempools hin.
- Die angenommene *Faktorenstruktur* des multidimensionalen Tele-QoL-Instruments wurde bestätigt ($\chi^2(df=436)=696.53$, $p<0.001$, CFI=.94, TLI=0.93, RMSEA=0.056 [0.048; 0.064]). Die sechs „Outcome“-Subskalen des multi-dimensionalen Tele-QoL-Verfahrens korrelieren untereinander moderat bis (sehr) hoch (r=.39-.81), die beiden „Impact“-Subskalen mit .44. Die durchschnittlich hohen Interkorrelationen der Outcome-Subskalen lassen auch auf die mögliche Existenz eines gemeinsamen latenten Faktors höherer Ordnung schließen.
- Die *Reliabilitätskoeffizienten* für die interne Konsistenz (.83<.95), Split-Half- (.81<.91) und Retest-Reliabilität (.65<.77) der Subskalen und des Index erreichten ausreichende bis sehr gute Werte. Die Tele-QoL-Subskalen und der Index zeigten Rasch-Skalierbarkeit, keines der Items wies Infit auf und alle Schwellenparameter entsprachen den Modellannahmen.
- Die *Validität* beider Instrumente kann angenommen werden. Die Gesamtscores beider Verfahren korrelieren sehr hoch miteinander (*r*=.89), ebenso die Outcome-Subskalen des multidimensionalen Instruments mit dem Indexwert (*r*=.59<.83). Daraus ergibt

sich eine *hohe konvergente Validität* beider Verfahren. Alle sechs „Outcome-“ Subskalen des Tele-QoL-Instruments und der Indexwert korrelieren hoch mit drei der vier Subskalen des SeCu-Instruments zur Erfassung des Sicherheitserlebens in der TM (r=.36-.89). Dagegen verweisen vergleichbar niedrige bis moderate Korrelationen mit unterschiedlichen Indices der allgemeinen, gesundheitsbezogenen und krankheitsspezifischen Lebensqualität (WHOQOL-BREF, VR-12, MLHFI, WHO-5) auf eine hinreichende *divergente Validität* der Tele-QoL-Instrumente. Die „known groups“ Validität (Hypothesentests) wurde durch entsprechende Unterschiede in den Skalenwerten für Gruppen mit verschiedenen Krankheitsschweregraden aufgezeigt, mit jeweils kleinen bis moderaten Effektstärken (d =. 01<.44).

- Beide Fragebögen zeigen überzeugende *psychometrische Eigenschaften.* Der multidimensionale Tele-QoL besteht final aus sechs Outcome-Skalen und zwei Impact-Skalen, die (un-)beabsichtigte Auswirkungen von TM auf die LQ erfassen. Darüber hinaus bietet der Tele-QoL-Index eine kurze Alternative für ein allgemeines Screening der LQ im Kontext von TM-Anwendungen mit Hilfe von sechs Items, da der Kurzindex des Tele-QoL die primären Inhalte der Langform sehr gut auch in der Breite repräsentiert, jedoch keine multidimensionale Profildarstellung erlaubt.
- **Die Tele-QoL-Fragebögen können als ergänzende Module zu bestehenden LQ-Instrumenten verwendet werden, um versorgungsbezogene Aspekte der LQ aus der Sicht von Patient*innen zu erfassen.**

Manual & Projekt-bezogene Publikationen (vgl. Anhang und Projekthomepage).

Basierend auf unseren *Projektergebnissen* wurde das Konzept der LQ im Kontext von TM-Anwendungen um eine Domäne – die versorgungsbezogene Domäne – erweitert (Greffin et al., 2021). Um die Inhalte der Domäne zusätzlich zu bestehenden Fragebögen zur Erfassung der Lebensqualität messbar zu machen, wurde das modulare Tele-QoL Verfahren entwickelt und getestet (Muehlan et al., subm.; Greffin et al., subm.). Alle Informationen zu den Instrumenten sind frei verfügbar:

https://teleqol.psychologie.uni-greifswald.de/

Der finale *Fragebogen* ist sowohl als Langform (32 Items) als auch als Index-Version (6 Items) verfügbar. Beide Fragebögen liegen in einer Telemedizin-Version (A) und einer Vergleichsversion für Patient*innen ohne telemedizinische Betreuung (B) vor. Der Fragebogen kann *digital oder per Paper-and-Pencil* ausgefüllt werden. Die finalen Fragebögen befinden sich in den Anlagen.

7. Diskussion der Projektergebnisse

Diskussion

Die wichtigsten Ergebnisse

Ziel des Projekts war es, eine mögliche Erweiterung bestehender LQ-Konzepte zu explorieren, um darauf aufbauend ein Setting-sensitives Instrument zu entwickeln, zu pilotieren und zu validieren, das sich zur Bewertung der LQ im Kontext von TM-Anwendungen eignet (Greffin et al., 2021). Die Befragung von Patient*innen und TM-Expert*innen im Rahmen der qualitativen Studie förderte spezifische Aspekte der LQ im TM-Kontext zutage, die von bestehenden LQ-Konzepten noch nicht berücksichtigt wurden (Greffin et al., 2021). Deshalb wurden bestehende LQ-Konzepte um eine versorgungsbezogene Domäne erweitert. Eine umfangreiche systematische Literaturrecherche ergab, dass bisher kein Instrument zur

Bewertung der TM-spezifischen Aspekte der LQ vorlag (Greffin, et al., n.d.). Wir haben daher einen modularen kontextspezifischen Fragebogen entwickelt und getestet, der zur Bewertung der LQ bei TM-Anwendungen eingesetzt werden kann (Greffin et al., n.d.; Muehlan et al., n.d.).

Implikationen für die Evaluation von TM-Anwendungen

Der Tele-QoL-Fragebogen kann als ergänzendes Instrument zur Bewertung spezifischer Aspekte der LQ eingesetzt werden, die im Zusammenhang mit TM-Anwendungen als bedeutsam angesehen werden (Greffin, Schmidt, et al., 2021). Neben den positiven Effekten, die mit Hilfe von sechs Skalen gemessen werden können, stehen zwei weitere Skalen zur Verfügung, mit denen die möglichen negativen Auswirkungen von TM auf die LQ erfasst werden können. Der Fragebogen kann somit im Rahmen von Evaluationen eingesetzt werden, um sowohl erwünschte als auch unerwünschte Effekte von TM nachzuweisen (Gogia et al., 2016).

Der Inhalt des Fragebogens wurde direkt aus den im Rahmen der qualitativen Studie gesammelten Verbatims der Patient*innen abgeleitet (Greffin, Schmidt, et al., 2021; Tsang et al., 2017). Darüber hinaus wurde die Entwicklung der Items bis zu einem gewissen Grad durch einen bedürfnisorientierten Ansatz der LQ inspiriert (McKenna & Doward, 2004). Dieser Ansatz wurde berücksichtigt, da die Patient*innen die Auswirkungen von TM auf die LQ teilweise als das Ausmaß beschrieben, in dem die Nutzung digitaler Gesundheitslösungen ihren versorgungsbezogenen Bedürfnissen nachkommt. Infolgedessen ergänzt der Tele-QoL-Fragebogen auch solche LQ-Instrumente, die eher auf funktionalen Lebensqualität-Definitionen beruhen, um diese bedürfnisbezogene Perspektive.

*Relevanz für die Stimme der Patient*innen in der Telemedizin*

Durch den Tele-QoL-Fragebogen können die Auswirkungen von TM auf die LQ in geeigneter Weise aus Sicht der Patient*innen erfasst werden. Die erweiterte Konzeptualisierung der LQ in TM-Settings kann auch zu potenziellen Verbesserungen von TM-Anwendungen und einer individualisierten TM-Versorgung für Patient*innen mit chronisch physischen oder psychischen Erkrankungen beitragen. Dies ist möglich, weil die Tele-QoL Fragebögen den beteiligten Fachleuten Informationen darüber zur Verfügung stellen, wie eine TM-Anwendung entwickelt, implementiert und evaluiert werden sollte, um sich (besser) an die (Versorgungs-bezogenen) Bedürfnisse der einzelnen Patient*innen anzupassen.

Relevanz für digitale Versorgungslösungen

Die Verwendung eines Setting-spezifischen Fragebogens ist entscheidend, da er eine validere Bewertung der LQ in TM-Studien ermöglicht. Darüber hinaus hat die breitere Berücksichtigung der Patient*innenperspektive das Potenzial, als formative Evaluation im Rahmen einer kontinuierlichen Bewertung von TM-Leistungen zu fungieren und damit die partizipativen Anteile der Versorgungsforschung zu stärken. Die beteiligten Fachkräfte erhalten auf diese Weise ein direktes, informatives Feedback zu den psychosozialen Auswirkungen von TM-Anwendungen und können auf dieser Basis notwendige Anpassungen einleiten.

Stärken und Grenzen

Mixed-Methods-Ansatz. Wie von Rothrock et al. (2011) empfohlen, wurde für die Entwicklung des Tele-QoL-Fragebogens ein umfangreiches Mixed-Methods-Design gewählt. Im Rahmen der qualitativen Studie wurden 63 halbstrukturierte Einzelinterviews und 15 halbstrukturierte Fokusgruppen mit *n*=68 Teilnehmern durchgeführt, um die Auswirkungen der TM-Versorgung auf die LQ zu ermitteln (Greffin, Schmidt, et al., 2021). Anschließend wurde ein Expert*innen-

Workshop organisiert, um das erweiterte Setting-spezifische Konzept der LQ zu validieren. Nach der Ableitung eines ersten Item-Pools aus dem qualitativen Material erfolgte der Prä-Test des vorläufigen Instruments. Zum einen aus der Patient*innenperspektive mittels der Technik des "lauten Denkens" (Willis, 2005) im Rahmen kognitiver Debriefings (*n*=32) und zum anderen im Rahmen einer strukturierten Online-Befragung unter Expert*innen (*n*=15) unter Verwendung einer Kombination aus offenen und geschlossenen Fragen. Der quantitative Teil des Projekts bestand aus zwei Fragebogenstudien, die jeweils der Pilotierung oder Validierung des entwickelten Instruments dienten (Greffin, Muehlan, van den Berg, et al., n.d.; Muehlan et al., n.d.). Zu diesem Zweck wurden jeweils *n*=200 Patient*innen gebeten, den entwickelten Fragebogen und andere etablierte, standardisierte Instrumente auszufüllen. Zusammenfassend kann gesagt werden, dass bewährte qualitative und quantitative Methoden der Datenerhebung und -analyse kombiniert wurden, um das Tele-QoL-Instrument zu entwickeln.

*Anwender*inzentrierung.* Patient*innen und Stakeholder wurden konsequent in dieses Projekt einbezogen, was den Empfehlungen für die PROM-Entwicklung entspricht (Cheng & Clark, 2017; Rothrock et al., 2011). Insbesondere die qualitative Studie zeichnet sich durch die Einbeziehung einer großen Gruppe von zukünftigen Nutzer*innen des Fragebogens aus, d. h. sowohl derjenigen, die ihn zukünftig ausfüllen, als auch derjenigen, die ihn auswerten werden (Greffin, Schmidt, et al., 2021). In den Interviews und Fokusgruppen wurden zunächst Daten bei den relevanten Zielgruppen erhoben. Nach der Analyse der qualitativen Daten wurden erste Items abgeleitet, die dann sowohl von Expert*innen als auch von Patient*innen bewertet wurden. Neben der Überprüfung der Verständlichkeit und Relevanz der Items reflektierten einige der Befragten, ob die Validität der Interpretation ihrer Daten angenommen werden kann. Mit insgesamt *n*=400 Teilnehmer*innen an der quantitativen Studie kann man auch in diesem Projektabschnitt von einer hohen Patient*-innenbeteiligung an der Instrumentenprüfung sprechen. In diesem Zusammenhang ist ausdrücklich zu betonen, dass diese Art der Forschung nicht nur für, sondern mit betroffenen Patient*innen durchgeführt wurde.

Zusammensetzung der Stichprobe. Der allgemeine Stichprobenansatz, der in allen Phasen des Projekts berücksichtigt wurde, zielte darauf ab, konträre Patient*innengruppen im Hinblick auf ihre Grunderkrankung (psychische vs. chronische physische Erkrankung) einzubeziehen. Gleichzeitig war es wichtig, dass die ausgewählten Krankheitsgruppen häufig mit TM behandelt werden. Aus diesem Grund wurden für unsere empirischen qualitativen und quantitativen Studien Patient*innen mit Depression oder Herzinsuffizienz rekrutiert . Darüber hinaus wurde nur die Hälfte der jeweiligen Patient*innengruppen mit einer aktiven (regelmäßigen Telefonanrufe) oder passiven (Monitoring) TM-Anwendung versorgt, während die andere Hälfte aus der Gruppe der „care-as-usual"-Patient*innen rekrutiert wurde. Mit dieser Stichprobenauswahl wollten wir eine möglichst große Heterogenität in Bezug auf Krankheiten und Behandlungen abbilden, Erfahrungen mit und ohne TM-Behandlungen gegenüberstellen und somit verallgemeinerbarere Ergebnisse erzielen. Im Wesentlichen zielten wir darauf ab, eine Vielzahl von TM-Erfahrungen von Patient*innen mit unterschiedlichen Erkrankungen, aus verschiedenen Versorgungsspektren und mit unterschiedlichem soziodemografischem Hintergrund sowie von verschiedenen TM-Expert*innen als informative Datenbasis zu erfassen. Im Rahmen der Forschung zu TM-Anwendungen ist dieser Stichprobenansatz ein sehr elaborierter Ausgangspunkt. In Folgeprojekten ist es jedoch notwendig, weitere chronisch körperliche und psychische Erkrankungen sowie unterschiedliche Formen von TM-Anwendungen in den Fokus zu nehmen, um zu überprüfen, ob der Tele-QoL-Fragebogen eine adäquate Bewertung für die Erfassung unterschiedlicher Erkrankungen und TM-Anwendungen darstellt.

Lebensqualität. Einige der von Patient*innen und TM-Expert*innen beschriebenen Aspekte, die wir als zusätzliche versorgungsbezogene Domäne zusammengefasst haben, sind bereits aus früheren Diskussionen und anderen Gesundheitskontexten bekannt. Beispiele hierfür sind die Patient*innenzufriedenheit, das Empowerment von Patient*innen und die wahrgenommene Sicherheit. Daher kann es fraglich sein, weshalb es legitim ist, die identifizierten Konzepte zu einem gesonderten und ergänzenden LQ-Bereich zusammenzufassen. Man könnte argumentieren, dass dieser die Interaktion der Umgebung mit krankheitsspezifischen Aspekten wie Symptomen und dem Funktionsstatus des Patient*innen beschreibt (Bakas et al., 2012; Wilson, 1995). Sicherlich interagiert die versorgungsbezogene Domäne mit den etablierten Domänen der gesundheitsbezogenen und krankheitsspezifischen LQ. Diese decken jedoch die von unseren Studienteilnehmer*innen berichteten Aspekte nicht ausreichend ab. Die qualitative Studie des Tele-QoL-Projekts liefert Belege dafür, dass die Aspekte des versorgungsbezogenen Bereichs einen deutlichen Einfluss auf die LQ der Patient*innen haben, da sie unabhängig voneinander genannt wurden, als nach dem individuellen Verständnis von LQ gefragt wurde und danach, ob die Telemedizin-Behandlung diese beeinflusst oder nicht. Im Hinblick auf die Patient*innenorientierung sollten wir der Tatsache, dass die Patient*innen diese Aspekte als zu ihrer LQ gehörend bezeichnen, mehr Aufmerksamkeit schenken, als dass wir uns auf bereits bestehende konzeptionelle Denkmuster verlassen. Folglich sollten wir unsere traditionellen Konzepte generell vor dem Hintergrund des bedingten Gesundheitszustands eines Patient*innen sowie innovativer Behandlungsanwendungen überdenken - unser Vorschlag zur Erweiterung des LQ-Konzepts im Kontext der TM-Versorgung aus bedürfnisorientierter Perspektive ist ein erster Schritt in diese Richtung.

Open Science. Schließlich haben sich die Bemühungen der Open-Science-Initiative im Laufe des Projekts in ganz Deutschland weiterverbreitet und etabliert. Daher wurde versucht, den Open-Science-Gedanken auch in diesem Forschungsprojekt bestmöglich umzusetzen. So wurden ein Studienprotokoll erstellt (Greffin, Muehlan, et al., 2021) und die Studienergebnisse, der Fragebogen, das Handbuch und der Datenanalysecode als Open-Access-Material veröffentlicht. Die Daten des Projekts sind ebenfalls auf Anfrage erhältlich. Auf diese Weise möchten wir einen Beitrag zu einer nachhaltigeren und transparenteren Forschungskultur leisten. In zukünftigen Studien möchten wir den Open Science-Ansatz weiterverfolgen, z. B. durch die Präregistrierung von Studien und, insbesondere im Kontext qualitativer Forschung, durch das Führen offener Forschungstagebücher.

Fazit

Der Tele-QoL ist der erste Fragebogen überhaupt, der TM-spezifische Auswirkungen einer Versorgung auf die LQ von Patient*innen mit chronischen körperlichen und/oder psychischen Erkrankungen erfasst. Dies ist ein wichtiger und notwendiger Beitrag zur Entwicklung, Implementierung und Evaluierung von digitalen Gesundheitsanwendungen.

Gefördert durch:
Gemeinsamer Bundesausschuss
Innovationsausschuss

8. Verwendung der Ergebnisse nach Ende der Förderung

Der Tele-QoL Fragebogen ist das *Hauptergebnis* dieses Projekts. Es handelt sich hierbei um ein modulares Selbstberichtsverfahren, das die LQ von chronisch physisch oder psychisch erkrankten erwachsenen Personen ohne kognitive Einschränkungen erfasst, die mit Hilfe von TM-Anwendungen versorgt werden.

Durch die Tele-QoL-Fragebögen ist es möglich, die *Auswirkungen von TM auf die LQ* von Patient*innen verbessert zu erfassen. Die erweiterte Konzeptualisierung der LQ in TM-Settings kann auch zu potenziellen Verbesserungen von TM-Anwendungen und einer individualisierten TM-Versorgung für Patient*innen mit chronischen physischen und/oder psychischen Erkrankungen beitragen. Dies ist möglich, weil der Tele-QoL Fragebogen den beteiligten Fachleuten Informationen darüber zur Verfügung stellen kann, wie eine TM-Anwendung entwickelt, implementiert und evaluiert werden sollte, um sich besser an die (Versorgungs-bezogenen) Bedürfnisse der einzelnen Patient*innen anzupassen.

Die Tele-QoL-Fragebögen können als *ergänzendes Instrument* eingesetzt werden, um spezifische Aspekte der LQ zu erfassen, die im Zusammenhang mit TM-Anwendungen als bedeutsam angesehen werden (Greffin, Schmidt, et al., 2021). Neben den positiven Effekten, die mit Hilfe von sechs Skalen gemessen werden können, stehen zwei weitere Skalen zur Verfügung, die die möglichen negativen Auswirkungen von TM auf die LQ erfassen. Die Fragebögen können somit im Rahmen von Evaluationen eingesetzt werden, um sowohl erwünschte als auch unerwünschte Effekte von TM zu erfassen (Gogia et al., 2016). Damit bietet sich deren Einsatz gleichermaßen im Kontext von Health Outcome Assessment als auch Health Technology Assessment zur Erfassung der Patient*innenperspektive an.

Der Einsatz solcher *Setting-sensitiven Fragebögen* ist von entscheidender Bedeutung, da sie eine validere Bewertung der LQ in TM-Studien ermöglichen. So wurde ein verbessertes Wirksamkeitsmaß entwickelt, das im Bereich der Evaluation von TM-Anwendungen eingesetzt werden kann.

Schließlich hat die breitere Berücksichtigung der Patient*innenperspektive das Potenzial, als *formative Evaluation* im Rahmen einer kontinuierlichen Bewertung von TM-Versorgung zu fungieren und damit die partizipativen Anteile der Versorgungsforschung zu stärken. Das beteiligte Fachpersonal kann auf diese Weise ein direktes, informatives Feedback zu den psychosozialen Auswirkungen von TM-Anwendungen erhalten und gegebenenfalls entsprechende Anpassungen einleiten.

Der Tele-QoL Fragebogen kann sowohl *als Paper-Pencil Verfahren als auch als digitale Version* (z. B. via Tablets) eingesetzt werden. Damit sind die in der Versorgung notwendigen Investitionskosten für die Implementierung als gering einzuschätzen.

9. Erfolgte bzw. geplante Veröffentlichungen

Internetseiten

- *Projekt-bezogene Homepage:*

  https://teleqol.psychologie.uni-greifswald.de/

Wissenschaftliche Artikel

Studienprotokoll

1. Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., … 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

Review-Artikel

2. Greffin, K., Muehlan, H., Rosenkranz, E., van den Berg, N., Hoffmann, W., Ritter, O., … Schmidt, S. (n.d.). Telemedicine and patient-reported outcomes in chronic conditions: concordance and discrepancy of purpose, concepts, and methods of measurement – a systematic literature review (submitted). *Journal of Medical Internet Research*.

Qualitative Artikel

3. Greffin, K., Schmidt, S., Berg, N. Van Den, Hoffmann, W., Ritter, O., Oeff, M., 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,* 19(1): 175. https://doi.org/10.1186/s12955-021-01807-8

Quantitative Artikel

4. Muehlan, H., Greffin, K., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., … Schmidt, S. (n.d.). Towards adjunct setting-related quality of life assessment in telemedicine – cognitive debriefing, expert rating and pilot testing of the Tele-QoL instrument (submitted). *BMC Health Services Research*.
5. Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., … Schmidt, S. (n.d.). Measuring context that matters: Validation of the modular Tele-QoL patient-reported outcome and experience measure (submitted). *Quality of Life Research*.

Konferenzbeiträge

Publizierte Konferenzbeiträge

- Greffin, K., Muehlan, H., Berg, N. v. d., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (2022). 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. *Quality of Life Research, 31 (Suppl.)*, S4-S5.
- Greffin, K., Schmidt, S., Berg, N. v. d., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., Speerforck, S. & Muehlan, H. (2021). Towards setting-sensitive quality of life assessment in telemedicine – validation of the modular Tele-QoL patient-reported outcome measure. *Quality of Life Research, 30* (Suppl.), S149-150.
- Greffin, K., Schmidt, S., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G. & 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. *Quality of Life Research, 29 (Suppl. 1),* S172-S173.
- Greffin, K., Schmidt, S., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G. & Muehlan, H. (2020). Towards adjunct setting-related quality of life assessment in telemedical care: concept elicitation, item generation and initial testing. *Quality of Life Research, 29 (Suppl. 1),* S173.

Sonstige Konferenzbeiträge

- 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.
- 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 Versorgungs-forschung (DKVF 2020), Berlin (online), Germany.
- Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Schomerus, G., Oeff, M., Ritter, O., Schmidt, S. (2019). Settingsensitive Konzeptualisierung der Lebensqualität im Kontext der telemedizinischen Versorgung – Ergebnisse einer qualitativen Befragung chronisch physisch oder psychisch erkrankter Personen. 14. Kongress der Fachgruppe Gesundheitspsychologie, Greifswald, Germany.
- 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 Versorgungs-forschung (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.

10. Literaturverzeichnis

Anthoine, E., Moret, L., Regnault, A., Sébille, V., & Hardouin, J.-B. (2014). Sample size used to validate a scale: a review of publications on newly-developed patient reported outcomes measures. *Health and Quality of Life Outcomes*, *12*(1), 2. https://doi.org/10.1186/s12955-014-0176-2

Bakas, T., McLennon, S. M., Carpenter, J. S., Buelow, J. M., Otte, J. L., Hanna, K. M., Ellett, M. L., Hadler, K. A., & Welch, J. L. (2012). Systematic review of health-related quality of life models. *Health and Quality of Life Outcomes*, *10*(1), 134. https://doi.org/10.1186/1477-7525-10-134

Bundesärztekammer. (2015). Ärztliche Positionen zu Einsatzgebieten telemedizinischer Patientenversorgung. *Tätigkeitsbericht Der Bundesärztekammer*, 334–335. http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/Telemedizin_Telematik/Telemedizin/118-DAET_EVI07_Einsatzgebiete_Telemedizin.pdf

Cheng, K. K. F., & Clark, A. M. (2017). Qualitative Methods and Patient-Reported Outcomes: Measures Development and Adaptation. *International Journal of Qualitative Methods*, *16*(1), 1–3. https://doi.org/10.1177/1609406917702983

Clarke, M., Shah, A., & Sharma, U. (2011). Systematic review of studies on telemonitoring of patients with congestive heart failure: a meta-analysis. *Journal of Telemedicine and Telecare*, *17*(1), 7–14. https://doi.org/10.1258/jtt.2010.100113

Costello, A. B., & Osborne, J. W. (2005). Best practices in exploratory factor analysis: Four recommendations for getting the most from your analysis. *Practical Assessment, Research and Evaluation*.

dr. dresing & pehl GmbH. (2005). *f4transkript* (7.0.6 USB).

Essén, A. (2008). The two facets of electronic care surveillance: an exploration of the views of older people who live with monitoring devices. *Social Science & Medicine (1982)*, *67*(1), 128–136. https://doi.org/10.1016/j.socscimed.2008.03.005

Gogia, S. B., Maeder, A., Mars, M., Hartvigsen, G., Basu, A., & Abbott, P. (2016). Unintended Consequences of Tele Health and their Possible Solutions. Contribution of the IMIA Working Group on Telehealth. *Yearbook of Medical Informatics*, *1*, 41–46. https://doi.org/10.15265/iy-2016-012

Greffin, K., Muehlan, H., Rosenkranz, E., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (n.d.). Telemedicine and patient-reported outcomes in chronic conditions: concordance and discrepancy of purpose, concepts, and methods of measurement – a systematic literature review (submitted). *Journal of Medical Internet Research*.

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

Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Speerforck, S., Schomerus, G., & Schmidt, S. (n.d.). Measuring context that matters: Validation of the modular Tele-QoL patient-reported outcome and experience measure (submitted). *Value in Health*.

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

Guest, G., Bunce, A., & Johnson, L. (2006). How Many Interviews Are Enough? *Field Methods*, *18*(1), 59–82. https://doi.org/10.1177/1525822X05279903

Inglis, S. C., Clark, R. A., McAlister, F. A., Ball, J., Lewinter, C., Cullington, D., Stewart, S., & Cleland, J. G. (2010). Structured telephone support or telemonitoring programmes for patients with chronic heart failure. *The Cochrane Database of Systematic Reviews*, *8*, CD007228. https://doi.org/10.1002/14651858.CD007228.pub2

Johnson, S. E., Fedor, M. A., & Hoban, M. B. (2008). Telemonitoring: a positive impact on patient outcomes. *Caring : National Association for Home Care Magazine*, *27*(7), 20–25. http://www.ncbi.nlm.nih.gov/pubmed/18683435

Lal, S., & Adair, C. E. (2014). E-mental health: A rapid review of the literature. *Psychiatric Services*, *65*(1), 24–32. https://doi.org/10.1176/appi.ps.201300009

Mayring, P. (2000). Qualitative Inhaltsanalyse. *Forum Qualitative Sozialforschung*, *1*(2), 1–10. http://www.springerlink.com/index/Q74U418433VJ0941.pdf

McKenna, S. P., & Doward, L. C. (2004). The needs-based approach to quality of life assessment. *Value in Health*, *7*(SUPPL. 1), S1–S3. https://doi.org/10.1111/j.1524-4733.2004.7s101.x

Muehlan, H., Greffin, K., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (n.d.). Towards adjunct setting-related quality of life assessment in telemedicine – cognitive debriefing, expert rating and pilot testing of the Tele-QoL instrument (submitted). *Quality of Life Research*.

Muehlan, H., & Schmidt, S. (2012). Telemonitoring und Lebensqualität. In F.-J. Bartmann, M. Blettner, & P. U. Heuschmann (Eds.), *Telemedizinische Methoden in der Patientenversorgung: Anwendungsspektrum, Chancen, Risiken* (pp. 95–106). Deutscher Ärzte-Verlag.

Muehlan, H., & Schmidt, S. (2013). Versorgungsbezogene E-Health-Anwendungen und Lebensqualität: Empirische Befunde und konzeptuelle Perspektiven. *Psychiatrische Praxis*, *40*(6), 307–312. https://doi.org/10.1055/s-0033-1349489

Nyumba, T., Wilson, K., Derrick, C. J., & Mukherjee, N. (2018). The use of focus group discussion methodology: Insights from two decades of application in conservation. *Methods in Ecology and Evolution*, *9*(1), 20–32. https://doi.org/10.1111/2041-210X.12860

Oeff, M., Müller, A., Neuzner, J., Sack, S., Schwab, J. O., Pfeiffer, D., & Zugck, C. (2008). EKG-telemonitoring. In *Herzschrittmachertherapie und Elektrophysiologie* (Vol. 19, Issue 3, pp. 137–145). https://doi.org/10.1007/s00399-008-0012-7

Polisena, J., Tran, K., Cimon, K., Hutton, B., McGill, S., Palmer, K., & Scott, R. E. (2010). Home telemonitoring for congestive heart failure: a systematic review and meta-analysis.

Journal of Telemedicine and Telecare, *16*(2), 68–76. https://doi.org/10.1258/jtt.2009.090406

Rothrock, N. E., Kaiser, K. A., & Cella, D. (2011). Developing a valid patient-reported outcome measure. *Clinical Pharmacology and Therapeutics*, *90*(5), 737–742. https://doi.org/10.1038/clpt.2011.195

Ryu, S. (2010). History of Telemedicine: Evolution, Context, and Transformation. *Healthcare Informatics Research*, *16*(1), 65. https://doi.org/10.4258/hir.2010.16.1.65

Schmidt, S. (2007). Telemedizin und Lebensqualität. *DMW - Deutsche Medizinische Wochenschrift*, *132*(9), 442–447. https://doi.org/10.1055/s-2007-970355

Schmidt, S., Schuchert, A., Krieg, T., & Oeff, M. (2010). Home Telemonitoring in Patients With Chronic Heart Failure A Chance to Improve Patient Care? *Deutsches Arzteblatt*, *107*(8), 131–138. https://doi.org/10.3238/arztebl.2010.0131

Tsang, S., Royse, C. F., & Terkawi, A. S. (2017). Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine. *Saudi Journal of Anaesthesia*, *11*(5), S80–S89. https://doi.org/10.4103/sja.SJA_203_17

VERBI Software. (2017). *MAXQDA - Software for qualitative data analyses* (No. 22).

Willis, G. (2005). *Cognitive interviewing*. SAGE Publications, Inc. https://doi.org/10.4135/9781412983655

Wilson, I. B. (1995). Linking Clinical Variables With Health-Related Quality of Life. *JAMA*, *273*(1), 59–65. https://doi.org/10.1001/jama.1995.03520250075037

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11. Anhang

Wissenschaftliche Artikel

Studienprotokoll

1. Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., … 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

Review-Artikel

2. Greffin, K., Muehlan, H., Rosenkranz, E., van den Berg, N., Hoffmann, W., Ritter, O., … Schmidt, S. (n.d.). Telemedicine and patient-reported outcomes in chronic conditions: concordance and discrepancy of purpose, concepts, and methods of measurement – a systematic literature review (submitted). *Journal of Medical Internet Research*.

Qualitativer Artikel

3. Greffin, K., Schmidt, S., Berg, N. Van Den, Hoffmann, W., Ritter, O., Oeff, M., 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,* 19(1): 175. https://doi.org/10.1186/s12955-021-01807-8

Quantitative Artikel

4. Muehlan, H., Greffin, K., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., … Schmidt, S. (n.d.). Towards adjunct setting-related quality of life assessment in telemedicine – cognitive debriefing, expert rating and pilot testing of the Tele-QoL instrument (submitted). *BMC Health Services Research*.

5. Greffin, K., Muehlan, H., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., … Schmidt, S. (n.d.). Measuring context that matters: Validation of the modular Tele-QoL patient-reported outcome and experience measure (submitted). *Quality of Life Research*.

12. Anlagen

A. Tele-QoL Fragebögen

- Langversion (A & B Version)
- Kurzversion (A & B Version)
- Index (A & B Version)

B. Ergänzende Dokumente

- Manual
- Kurzbeschreibung für die Praxis
- Auswertungssyntax

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Study Protocol

Setting-Sensitive Conceptualization and Assessment of Quality of Life in Telemedical Care—Study Protocol of the Tele-QoL Project

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

[1] Department of Psychology, University of Greifswald, 17489 Greifswald, Germany; holger.muehlan@uni-greifswald.de (H.M.); silke.schmidt@uni-greifswald.de (S.S.)
[2] Department of Health Care Epidemiology and Community Health, Institute of Community Medicine, University Medicine Greifswald, 17489 Greifswald, Germany; nberg@uni-greifswald.de (N.v.d.B.); wolfgang.hoffmann@uni-greifswald.de (W.H.)
[3] Brandenburg Medical School Theodor Fontane, 16816 Neuruppin, Germany; o.ritter@klinikum-brandenburg.de
[4] Department of Cardiology, Brandenburg City Hospital, 14770 Brandenburg an der Havel, Germany; michael@oeff.eu
[5] Department of Psychiatry and Psychotherapy, University Medicine Leipzig, 04103 Leipzig, Germany; Georg.Schomerus@medizin.uni-leipzig.de
* Correspondence: Klara.Greffin@uni-greifswald.de; Tel.: +49-3834-420-3808

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Abstract: Quality of life (QoL) is a core patient-reported outcome in healthcare 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 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 derived. 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-testings 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 assess 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 (PROs). Quality of life (QoL) is one of the central PROs in the context of TM evaluation 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 effectiveness 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 PROs 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-centered measurement approach that can capture the expected overall impact of TM [19]. An assessment of 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 instrument 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 the 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, such as chronic heart failure, QoL has been defined as a primary outcome indicator from patients' perspective. Reviews [12,25] have shown 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 psychosocial 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 outcome 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 outcome 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:* Identification of potential gaps between defined purpose, chosen constructs, and methods of measurement used within TM feasibility and effectiveness studies.
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 effectiveness studies.
- *Qualitative studies (concept elicitation)*: Interviews and focus groups will be conducted by 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 will be conducted, using the cognitive debriefing method "think aloud". 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 rationale: 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 choose 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 receive regular phone calls, while patients in the passive TM application group are 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 sociodemographic backgrounds, 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 the following:

- 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 (depression/heart failure) and type of care (TM/care as usual).
- Focus groups with a total number of 30 TM professionals.
- Thirty-two 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 (depression/heart failure) and type of care (TM/care as usual).
- Thirty single interviews with TM professionals.

Quantitative studies (testing): Thirty-two patients (cognitive debriefing; see [33]) and at least five 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 sample sizes, we reference simulation studies and reviews [36–38]. For piloting, we assume an estimated item size of about 50 ± 10 items, for validation of 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 to 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.

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 depression (50 each with or without TM care) $n = 100$ patients with heart failure (50 each with or without TM care)	
Validation of final instrument	$n = 200$ total patients $n = 100$ patients with depression (50 each with or without TM care) $n = 100$ patients with heart failure (50 each with or without TM care)	

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/mental condition or depression/heart failure. 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.

3.4.3. Study Assessment and Measures

Qualitative studies: The interviews and focus groups will be conducted by using 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).

Table 2. Questionnaires and items employed at the different study assessments.

Study Assessments and 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- and 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 (PAM13-D)	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	

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).

Sociodemographic characteristics will be assessed based on the "Demographic Standards", a joint recommendation of the Arbeitskreis Deutscher Markt- und Sozialforschungsinstitute e.V. (ADM), the Arbeitsgemeinschaft Sozialwissenschaftlicher 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, and 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 by 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", and 5 = "strongly agree". Internal consistency of the subscales "technology acceptance" and "technology competence" was excellent (α = 0.84); for the subscale "technology control", reliability was good (α = 0.74).

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 following response options: 1 = “not at all”, 2 = “several days”, 3 = “more than half the days”, and 4 = “nearly every day”. Internal reliability ($\alpha = 0.89$) and test–retest reliability after 48 h ($r = 0.84$) 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”, and 4 = “strongly agree”. Our study is primarily directed at generating initial evidence for the psychometric performance of the Tele-Qol measure.

With the “SeCu-20” 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”, and 4 = “strongly agree”. The internal reliability of the four scales “technology anxiety”, “perceived security”, “physician–patient relation”, and “perceived autonomy” is good to excellent ($\alpha = 0.70$–0.89).

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 ($\alpha = 0.92$). 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 healthcare provision in general?”). Response options were 1 = “not satisfied”, 2 = “partly satisfied”, 3 = “satisfied”, 4 = “very satisfied”, and 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”, and 4 = “agree strongly”. Internal reliability is excellent ($\alpha = 0.84$).

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”, and 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”, and 5 = “agree strongly”. The internal reliability range is between $\alpha = 0.76$ und $\alpha = 0.79$.

The “European Health Literacy Survey (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”, and 4 = “very easy”. Internal reliability is good (α = 0.80).

Correspondingly, we will implement a newly adapted version of HLS-EU-Q6 for digital healthcare, 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 = 0.89).

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”, and 6 = “at no instant”. Internal reliability is excellent (α = 0.92).

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. An example question is, “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, and 5 = “very strong”; and “no” = not applicable. Internal reliability is excellent (α = 0.92; see [60]).

To assess the subjective health status 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 have the following response options: 1 = “excellent”, 2 = “very good”, 3 = “good”, 4 = “not so good”, and 5 = “bad”. Questions include, how much they feel currently restricted in the stated tasks (response options: 1 = “yes, strongly restricted”, 2 = “yes, a little restricted”, and 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”, and 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”, and 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”, and 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”, and 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”, and 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, and it will be in line with current regulations. This covers information and consent to the study, data collection, data transport, as well as 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 by 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 test theory and item response 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, and 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 and the validation of the measure with an independent sample, as well as analyses of the descriptive and psychometric performance on the 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 from the patient's perspective.

(ii) *Setting-sensitive assessment:* The specific items will assess 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 QoL due to increased setting sensitivity.

(iii) *Care-relevant evaluation*: Such a conceptual framework and a corresponding instrument also provide 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 PROMs/PREMs in general or TM applications on QoL in particular. As a result, evaluations of the influence of TM applications on QoL 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. Conclusions

TM 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 February 2018) and the State Medical Association of Brandenburg (AS466 (bB)/2018, date: 9 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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References

1. Alvandi, M. Telemedicine and Its Role in Revolutionizing Healthcare Delivery. *Am. J. Acc. Care* **2017**, *5*, e1–e5.
2. Williams, O.E.; Elghenzai, S.; Subbe, C.; Wyatt, J.C.; Williams, J. The Use of Telemedicine to Enhance Secondary Care: Some Lessons from the Front Line. *Futur. Hosp. J.* **2017**, *4*, 109–114. [CrossRef] [PubMed]
3. Riva, S.; Mazzocco, K.; Pravettoni, G. Better Outcomes for Cancer Patients Using Telemedicine: Health-Related Quality of Life (HrQoL) and Empowerment. In *Tele-Oncology*; Gatti, G., Pravettoni, G., Capello, F., Eds.; Springer: Cham, Switzerland, 2015; pp. 23–37.
4. Totten, A.M.; Womack, D.M.; Eden, K.B.; McDonagh, M.S.; Griffin, J.C.; Grusing, S.; Hersh, W.R. *Telehealth: Mapping the Evidence for Patient Outcomes from Systematic Reviews*; Agency for Healthcare Research and Quality: Rockville, MD, USA, 2016.
5. Damant, J.; Knapp, M.; Freddolino, P.; Lombard, D. Effects of Digital Engagement on the Quality of Life of Older People. *Health Soc. Care Community* **2017**, *25*, 1679–1703. [CrossRef]
6. Eurlings, C.G.M.J.; Boyne, J.J.; de Boer, R.A.; Brunner-La Rocca, H.P. Telemedicine in Heart Failure—More than Nice to Have? *Netherlands Heart J.* **2019**, *27*, 5–15. [CrossRef]
7. Faruque, L.I.; Wiebe, N.; Ehteshami-Afshar, A.; Liu, Y.; Dianati-Maleki, N.; Hemmelgarn, B.R.; Manns, B.J.; Tonelli, M. Effect of Telemedicine on Glycated Hemoglobin in Diabetes: A Systematic Review and Meta-Analysis of Randomized Trials. *CMAJ* **2017**, *189*, E341–E364. [CrossRef] [PubMed]
8. Inglis, S.C.; Clark, R.A.; McAlister, F.A.; Stewart, S.; Cleland, J.G.F. Which Components of Heart Failure Programmes Are Effective? A Systematic Review and Meta-Analysis of the Outcomes of Structured Telephone Support or Telemonitoring as the Primary Component of Chronic Heart Failure Management in 8323 Patients: Abridged Coc. *Eur. J. Heart Fail.* **2011**, *13*, 1028–1040. [CrossRef]
9. Maric, B.; Kaan, A.; Ignaszewski, A.; Lear, S.A. A Systematic Review of Telemonitoring Technologies in Heart Failure. *Eur. J. Heart Fail.* **2009**, *11*, 506–517. [CrossRef]
10. Pandor, A.; Gomersall, T.; Stevens, J.W.; Wang, J.; Al-Mohammad, A.; Bakhai, A.; Cleland, J.G.F.; Cowie, M.R.; Wong, R. Remote Monitoring after Recent Hospital Discharge in Patients with Heart Failure: A Systematic Review and Network Meta-Analysis. *Heart* **2013**, *99*, 1717–1726. [CrossRef]
11. Pang, L.; Liu, Z.; Lin, S.; Liu, Z.; Liu, H.; Mai, Z.; Liu, Z.; Chen, C.; Zhao, Q. The Effects of Telemedicine on the Quality of Life of Patients with Lung Cancer: A Systematic Review and Meta-Analysis. *Ther. Adv. Chronic Dis.* **2020**, *11*, 1–12. [CrossRef]
12. Schmidt, S. Telemedicine and Quality of Life. *Dtsch. Med. Wochenschr.* **2007**, *132*, 442–447. [CrossRef]
13. Muehlan, H.; Schmidt, S. Telemonitoring und Lebensqualität. In *Telemedizinische Methoden in der Patientenversorgung: Anwendungsspektrum, Chancen, Risiken*; Bartmann, F.-J., Blettner, M., Heuschmann, P.U., Eds.; Deutscher Ärzte-Verlag: Köln, Germany, 2012; pp. 95–106.
14. Muehlan, H.; Schmidt, S. Versorgungsbezogene E-Health-Anwendungen Und Lebensqualität: Empirische Befunde Und Konzeptuelle Perspektiven. *Psychiatr. Prax.* **2013**, *40*, 307–312. [CrossRef]
15. Oeff, M.; Kotsch, P.; Gößwald, A.; Wolf, U. Überwachung Multipler Herzkreislaufparameter Mittels Telemonitoring Bei Patienten Mit Chronischer Herzinsuffizienz. *Herzschrittmacherther. Elektrophysiol.* **2005**, *16*, 150–158. [CrossRef] [PubMed]
16. Ritter, O.; Bauer, W.R. Use of "IEGM Online" in ICD Patients—Early Detection of Inappropriate Classified Ventricular Tachycardia via Home Monitoring. *Clin. Res. Cardiol.* **2006**, *95*, 368–372. [CrossRef] [PubMed]
17. Kidholm, K.; Clemensen, J.; Caffery, L.J.; Smith, A.C. The Model for Assessment of Telemedicine (MAST): A Scoping Review of Empirical Studies. *J. Telemed. Telecare* **2017**, *23*, 803–813. [CrossRef]
18. Langbecker, D.; Caffery, L.J.; Gillespie, N.; Smith, A.C. Using Survey Methods in Telehealth Research: A Practical Guide. *J. Telemed. Telecare* **2017**, *23*, 770–779. [CrossRef] [PubMed]
19. Johnson, S.E.; Fedor, M.A.; Hoban, M.B. Telemonitoring: A Positive Impact on Patient Outcomes. *Caring* **2008**, *27*, 20–25. [PubMed]
20. World Health Organisation. *World Health Statistics 2020: Monitoring Health for the SDGs, Sustainable Development Goals*; World Health Organisation: Geneva, Switzerland, 2020.
21. Fendrich, K.; Hoffmann, W. More than Just Aging Societies: The Demographic Change Has an Impact on Actual Numbers of Patients. *J. Public Health* **2007**, *15*, 345–351. [CrossRef]
22. Kopetsch, T. *Studie Zur Altersstruktur- Und Arztzahlentwicklung: Dem Deutschen Gesundheitswesen Gehen Die Ärzte Aus!* 5. Auflage; Bundesärztekammer und Kassenärztliche Bundesvereinigung: Berlin, Germany, 2010; ISBN 9783000309571.
23. Siewert, U.; Fendrich, K.; Doblhammer-Reiter, G.; Scholz, R.D.; Schuff-Werner, P.; Hoffmann, W. Versorgungsepidemiologische Auswirkungen Des Demografischen Wandels in Mecklenburg-Vorpommern: Hochrechnung Der Fallzahlen Altersassoziierter Erkrankungen Bis 2020 Auf Der Basis Der Study of Health in Pomerania (SHIP). *Dtsch. Arztebl.* **2010**, *107*, 328–334. [CrossRef]
24. van den Berg, N.; Schmidt, S.; Stentzel, U.; Mühlan, H.; Hoffmann, W. Telemedizinische Versorgungskonzepte in Der Regionalen Versorgung Ländlicher Gebiete: Möglichkeiten, Einschränkungen, Perspektiven. *Bundesgesundheitsblatt Gesundheitsforsch. Gesundh.* **2015**, *58*, 367–373. [CrossRef]

25. Muehlan, H.; Schmidt, S. Psycho-Social Aspects of Personal Health Monitoring: A Descriptive Literature Review. *Stud. Health Technol. Inform.* **2013**, *187*, 41–53.
26. Schmidt, S.; Rienhoff, O. *Ethical and Legal Aspects of Personal Health Monitoring*; IOS Press: Amsterdam, The Netherlands, 2013.
27. Maresova, P.; Javanmardi, E.; Barakovic, S.; Barakovic Husic, J.; Tomsone, S.; Krejcar, O.; Kuca, K. Consequences of Chronic Diseases and Other Limitations Associated with Old Age—A Scoping Review. *BMC Public Health* **2019**, *19*, 1431. [CrossRef] [PubMed]
28. Megari, K. Quality of Life in Chronic Disease Patients. *Health Psychol. Res.* **2013**, *1*, e27. [CrossRef]
29. Lasch, K.E.; Marquis, P.; Vigneux, M.; Abetz, L.; Arnould, B.; Bayliss, M.; Crawford, B.; Rosa, K. PRO Development: Rigorous Qualitative Research as the Crucial Foundation. *Qual. Life Res.* **2010**, *19*, 1087–1096. [CrossRef] [PubMed]
30. Krueger, R.A.; Casey, M.A. Participants in a Focus Groups. In *Focus Groups. A Practical Guide for Applied Research*; Sage Publications, Inc.: Thousand Oaks, CA, USA, 2014; pp. 77–102. ISBN 9781483365244.
31. Saunders, B.; Sim, J.; Kingstone, T.; Baker, S.; Waterfield, J.; Bartlam, B.; Burroughs, H.; Jinks, C. Saturation in Qualitative Research: Exploring Its Conceptualization and Operationalization. *Qual. Quant.* **2018**, *52*, 1893–1907. [CrossRef]
32. Vasileiou, K.; Barnett, J.; Thorpe, S.; Young, T. Characterising and Justifying Sample Size Sufficiency in Interview-Based Studies: Systematic Analysis of Qualitative Health Research over a 15-Year Period. *BMC Med. Res. Methodol.* **2018**, *18*, 148. [CrossRef]
33. Perneger, T.V.; Courvoisier, D.S.; Hudelson, P.M.; Gayet-Ageron, A. Sample Size for Pre-Tests of Questionnaires. *Qual. Life Res.* **2015**, *24*, 147–151. [CrossRef]
34. Costello, A.B.; Osborne, J.W. Best Practices in Exploratory Factor Analysis: Four Recommendations for Getting the Most from Your Analysis. *Pract. Assess. Res. Eval.* **2005**, *10*, 1–9.
35. Osborne, J. *Best Practices in Exploratory Factor Analysis*; CreateSpace: Scotts Valley, CA, USA, 2014.
36. Anthoine, E.; Moret, L.; Regnault, A.; Sbille, V.; Hardouin, J.B. Sample Size Used to Validate a Scale: A Review of Publications on Newly-Developed Patient Reported Outcomes Measures. *Health Qual. Life Outcomes* **2014**, *12*, 1–10. [CrossRef]
37. Hogarty, K.Y.; Hines, C.V.; Kromrey, J.D.; Ferron, J.M.; Mumford, K.R. The Quality of Factor Solutions in Exploratory Factor Analysis: The Influence of Sample Size, Communality, and Overdetermination. *Educ. Psychol. Meas.* **2005**, *65*, 202–226. [CrossRef]
38. Wolf, E.J.; Harrington, K.M.; Clark, S.L.; Miller, M.W. Sample Size Requirements for Structural Equation Models: An Evaluation of Power, Bias, and Solution Propriety. *Educ. Psychol. Meas.* **2013**, *73*, 913–934. [CrossRef] [PubMed]
39. Beckmann, K.; Glemser, A.; Heckel, C.; Al:, E. *Demographische Standards*; 6. Auflage; Federal Statistical Office: Wiesbaden, Germany, 2016; ISBN 9783824609031.
40. Renner, B.; Hahn, A.; Schwarzer, R. *Risiko und Gesundheitsverhalten*; Dokumentation der Messinstrumente des Forschungsprojekts „Berlin Risk Appraisal and Health Motivation Study" (BRAHMS); Freie Universität Berlin: Berlin, Germany, 1996; ISBN 3-00-000631-1.
41. Neyer, F.J.; Felber, J.; Gebhardt, C. Entwicklung und Validierung einer Kurzskala zur Erfassung von Technikbereitschaft. *Diagnostica* **2012**, *58*, 87–99. [CrossRef]
42. Goldman, L.; Hashimoto, B.; Cook, E.F.; Loscalzo, A. Comparative Reproducibility and Validity of Systems for Assessing Cardiovascular Functional Class: Advantages of a New Specific Activity Scale. *Circulation* **1981**, *64*, 1227–1234. [CrossRef] [PubMed]
43. The Criteria Committee of the New York Heart Association. *Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels*, 9th ed.; Little Brown & Co, Ed.; American Heart Association: Dallas, TX, USA, 1994.
44. Hoppe, U.C.; Böhm, M.; Dietz, R.; Hanrath, P.; Kroemer, H.K.; Osterspey, A.; Schmaltz, A.A.; Erdmann, E. Leitlinien Zur Therapie Der Chronischen Herzinsuffizienz. *Z. Kardiol.* **2005**, *94*, 488–509. [CrossRef]
45. Kroenke, K.; Spitzer, R.L.; Williams, J.B.W.; Löwe, B. The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: A Systematic Review. *Gen. Hosp. Psychiatry* **2010**, *32*, 345–359. [CrossRef]
46. Karg, O.; Weber, M.; Bubulj, C.; Esche, B.; Weber, N.; Geiseler, J.; Bachl, C.; Schellhorn, H. Akzeptanz einer telemedizinischen Intervention bei Patienten mit chronisch-obstruktiver Lungenerkrankung TT—Acceptance of a telemonitoring device in patients with chronic obstructive pulmonary disease. *Dtsch Med. Wochenschr.* **2012**, *137*, 574–579.
47. Attkisson, C.C.; Zwick, R. The Client Satisfaction Questionnaire: Psychometric Properties and Correlations with Service Utilization and Psychotherapy Outcome. *Eval. Program Plann.* **1982**, *5*, 233–237. [CrossRef]
48. Schmidt, J.; Lamprecht, F.; Wittmann, W.W. Zufriedenheit Mit Der Stationären Versorgung. Entwicklung Eines Fragebogens Und Erste Validitätsuntersuchungen. *Psychother. Psychosom. Medizinische Psychol.* **1989**, *39*, 248–255.
49. Schmidt, S.; Thyen, U.; Herrmann-Garitz, C.; Bomba, F.; Muehlan, H. The Youth Health Care Measure-Satisfaction, Utilization, and Needs (YHC-SUN)-Development of a Self-Report Version of the Child Health Care (CHC-SUN) Proxy-Measure. *BMC Health Serv. Res.* **2016**, *16*, 1–12. [CrossRef]
50. Hibbard, J.H.; Mahoney, E.R.; Stockard, J.; Tusler, M. Development and Testing of a Short Form of the Patient Activation Measure. *Health Serv. Res.* **2005**, *40*, 1918–1930. [CrossRef]
51. Brenk-Franz, K.; Hibbard, J.H.; Herrmann, W.J.; Freund, T.; Szecsenyi, J.; Djalali, S.; Steurer-Stey, C.; Sönnichsen, A.; Tiesler, F.; Storch, M.; et al. Validation of the German Version of the Patient Activation Measure 13 (PAM13-D) in an International Multicentre Study of Primary Care Patients. *PLoS ONE* **2013**, *8*, e74786. [CrossRef]

52. Bohner, G.; Harlacher, U.; Rudolf, C.; Sieger, H.; Schwarz, N. Selbstaufmerksamkeit und Körperaufmerksamkeit. In *Bericht über den 33. Kongreß der Deutschen Gesellschaft für Psychologie in Mainz 1982*; Lüer, G., Ed.; Hogrefe: Göttingen, Germany, 1982; pp. 649–652.
53. Mrazek, J. Die Erfassung körperbezogener Kontrollüberzeugungen. In *Diagnostik von Attributionen und Kontrollüberzeugungen*; Krampen, G., Ed.; Hogrefe: Göttingen, Germany, 1989; pp. 112–118.
54. Albani, C.; Blaser, G.; Geyer, M.; Schmutzer, G.; Hinz, A.; Bailer, H.; Grulke, N.; Brähler, E. Psychometrische Überprüfung Und Normierung Des Fragebogens Körperbezogener Locus of Control (KLC) an Einer Repräsentativen Deutschen Bevölkerungsstichprobe. *Z. Med. Psychol.* **2007**, *16*, 83–91.
55. Pelikan, J.M.; Ganahl, K. Measuring Health Literacy in General Populations: Primary Findings from the HLS-EU Consortium's Health Literacy Assessment Effort. *Stud. Health Technol. Inform.* **2017**, *240*, 34–59. [PubMed]
56. Brähler, E.; Mühlan, H.; Albani, C.; Schmidt, S. Teststatistische Prüfung Und Normierung Der Deutschen Versionen Des EUROHIS-QOL Lebensqualität-Index Und Des WHO-5 Wohlbefindens-Index. *Diagnostica* **2007**, *53*, 83–96. [CrossRef]
57. Topp, C.W.; Østergaard, S.D.; Søndergaard, S.; Bech, P. The WHO-5 Well-Being Index: A Systematic Review of the Literature. *Psychother. Psychosom.* **2015**, *84*, 167–176. [CrossRef] [PubMed]
58. Quittan, M.; Wiesinger, G.F.; Crevenna, R.; Nuhr, M.J.; Posch, M.; Hülsmann, M.; Müller, D.; Pacher, R.; Fialka-Moser, V. Cross-Cultural Adaptation of the Minnesota Living with Heart Failure Questionnaire for German-Speaking Patients. *J. Rehabil. Med.* **2001**, *33*, 182–186. [CrossRef]
59. Rector, T.S.; Cohn, J.N. Assessment of Patient Outcome with the Minnesota Living with Heart Failure Questionnaire: Reliability and Validity during a Randomized, Double-Blind, Placebo-Controlled Trial of Pimobendan. *Am. Heart J.* **1992**, *124*, 1017–1025. [CrossRef]
60. Garin, O.; Ferrer, M.; Pont, A.; Wiklund, I.; Ganse, E.; Vilagut, G.; Almansa, J.; Ribera, A.; Alonso, J. Evidence on the Global Measurement Model of the Minnesota Living with Heart Failure Questionnaire. *Qual. Life Res.* **2013**, *22*, 2675–2684. [CrossRef]
61. Jones, D.; Kazis, L.; Lee, A.; Rogers, W.; Skinner, K.; Cassar, L.; Wilson, N.; Hendricks, A. Health Status Assessments Using the Veterans SF-12 and SF-36: Methods for Evaluating Outcomes in the Veterans Health Administration. *J. Ambul. Care Manag.* **2001**, *24*, 68–86. [CrossRef] [PubMed]
62. Buchholz, I.; Feng, Y.-S.; Buchholz, M.; Kazis, L.E.; Kohlmann, T. The German Version of the Veterans Rand—36/12 Item Health Survey: Translation and Adaptation of a Generic Health Assessment Instrument in a Sample of Inpatient Rehabilitation Patients. Available online: https://www.researchsquare.com/article/rs-98587/v1 (accessed on 3 October 2021).
63. Devlin, N.J.; Brooks, R. EQ-5D and the EuroQol Group: Past, Present and Future. *Appl. Health Econ. Health Policy* **2017**, *15*, 127–137. [CrossRef]
64. Herdman, M.; Gudex, C.; Lloyd, A.; Janssen, M.; Kind, P.; Parkin, D.; Bonsel, G.; Badia, X. Development and Preliminary Testing of the New Five-Level Version of EQ-5D (EQ-5D-5L). *Qual. Life Res.* **2011**, *20*, 1727–1736. [CrossRef]
65. Skevington, S.M.; Sartorius, N.; Amir, M.; Sartorius, N.; Orley, J.; Kuyken, W.; Power, M.; Herrman, H.; Schofield, H.; Murphy, B.; et al. Developing Methods for Assessing Quality of Life in Different Cultural Settings—The History of the WHOQOL Instruments. *Soc. Psychiatry Psychiatr. Epidemiol.* **2004**, *39*, 1–8. [CrossRef] [PubMed]
66. dr. Dresing & pehl GmbH F4transkript 2019. Available online: https://www.audiotranskription.de/f4transkript/ (accessed on 3 October 2021).
67. *VERBI Software MAXQDA—Software for Qualitative Data Analyses*; VERBI Software: Berlin, Germany, 2017.
68. Mayring, P. *Qualitative Content Analysis: Theoretical Foundation, Basic Procedures and Software Solution (Free Download via Social Science Open Access Repository SSOAR)*; GESIS: Mannheim, Germany, 2014.
69. Federal Institute for Drugs and Medical Devices. *The Fast-Track Process for Digital Health Applications (DiGA) According to Section 139e SGB V*; Federal Institute for Drugs and Medical Devices: Bonn, Germany, 2019; pp. 1–124.

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 pre-requisites 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

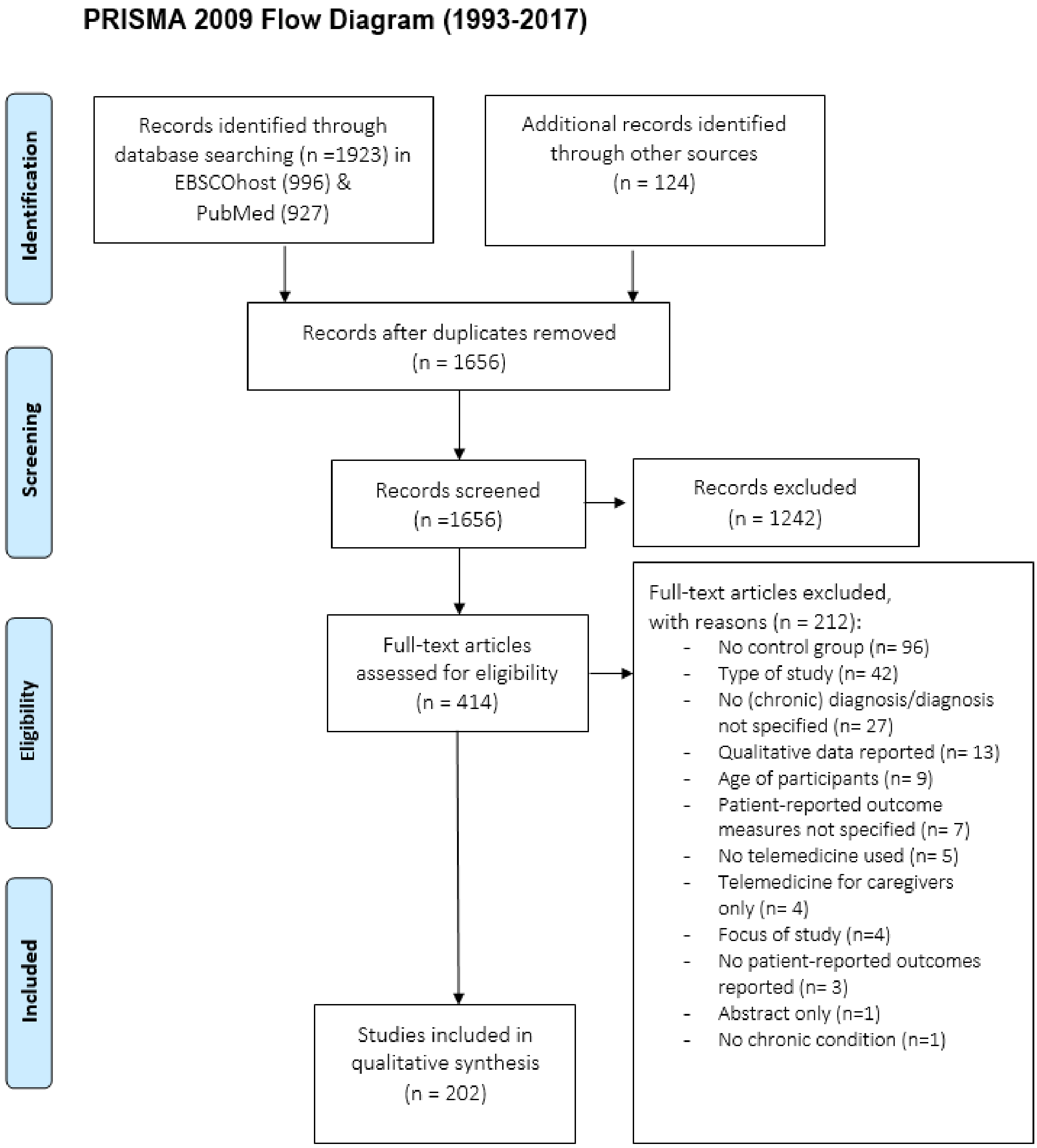

Figure 2

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

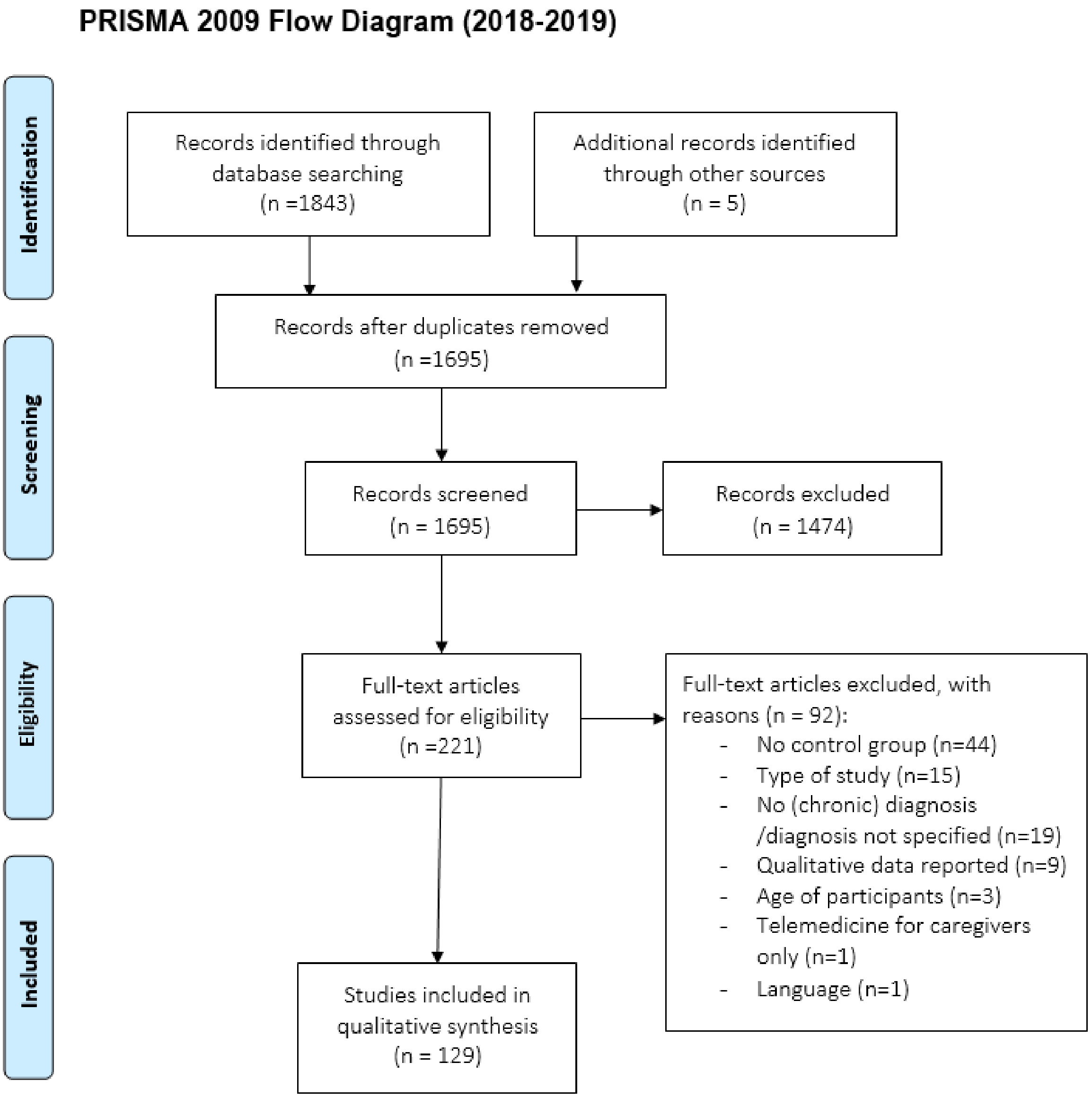

Table 4

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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References

Arora, S., Peters, A. L., Burner, E., Lam, C. N., & Menchine, M. (2014). Trial to examine text message-based mhealth in emergency department patients with diabetes (TExT-MED): A randomized controlled trial. *Annals of Emergency Medicine*, *63*(6), 745–754.e6. https://doi.org/10.1016/j.annemergmed.2013.10.012

Atella, V., Piano Mortari, A., Kopinska, J., Belotti, F., Lapi, F., Cricelli, C., & Fontana, L. (2019). Trends in age-related disease burden and healthcare utilization. *Aging Cell*, *18*(1), e12861. https://doi.org/10.1111/acel.12861

Brennan, P., Perola, M., van Ommen, G. J., & Riboli, E. (2017). Chronic disease research in Europe and the need for integrated population cohorts. *European Journal of Epidemiology*, *32*(9), 741–749. https://doi.org/10.1007/s10654-017-0315-2

Bunz, U. K. (2004). The Computer-Email-Web (CEW) Fluency Scale-Development and Validation. *International Journal of Human_Computer Interaction*, *17*, 479–506.

Calvert, M., Blazeby, J., Altman, D. G., Revicki, D. A., Moher, D., & Brundage, M. D. (2013). Reporting of patient-reported outcomes in randomized trials: The CONSORT PRO extension. *JAMA - Journal of the American Medical Association*, *309*(8), 814–822. https://doi.org/10.1001/jama.2013.879

Chan, R. J., Crichton, M., Crawford-Williams, F., Agbejule, O. A., Yu, K., Hart, N. H., de Abreu Alves, F., Ashbury, F. D., Eng, L., Fitch, M., Jain, H., Jefford, M., Klemanski, D., Koczwara, B., Loh, K., Prasad, M., Rugo, H., Soto-Perez-de-Celis, E., van den Hurk, C., & Chan, A. (2021). The efficacy, challenges, and facilitators of telemedicine in post-treatment cancer survivorship care: an overview of systematic reviews. *Annals of Oncology*, *32*(12), 1552–1570. https://doi.org/10.1016/j.annonc.2021.09.001

Chen, J., Jin, W., Zhang, X. X., Xu, W., Liu, X. N., & Ren, C. C. (2015). Telerehabilitation Approaches for Stroke Patients: Systematic Review and Meta-analysis of Randomized Controlled Trials. *Journal of Stroke and Cerebrovascular Diseases*, *24*(12), 2660–2668. https://doi.org/10.1016/j.jstrokecerebrovasdis.2015.09.014

Cheng, K. K. F., & Clark, A. M. (2017). Qualitative Methods and Patient-Reported Outcomes: Measures Development and Adaptation. *International Journal of Qualitative Methods*, *16*(1), 1–3. https://doi.org/10.1177/1609406917702983

Christensen, K., Doblhammer, G., Rau, R., & Vaupel, J. W. (2009). Ageing populations: the challenges ahead. *The Lancet*, *374*(9696), 1196–1208. https://doi.org/10.1016/S0140-6736(09)61460-4

Corbett, J. A., Opladen, J. M., & Bisognano, J. D. (2020). Telemedicine can revolutionize the treatment of chronic disease. *International Journal of Cardiology: Hypertension*, *7*(September), 100051. https://doi.org/10.1016/j.ijchy.2020.100051

Demirci, S., Kauffeld-Monz, M., & Schaat, S. (2021). Perspektiven für die Telemedizin - Voraussetzungen der Skalierung und Marktpotential. In *Bundesministeriums für Wirtschaft und Energie*.

Dierks, C. (2006). Gesundheits-Telematik — Rechtliche Antworten. *Datenschutz und Datensicherheit - DuD*, *30*(3), 142–147. https://doi.org/10.1007/s02045-006-0042-5

Dinesen, B., Nonnecke, B., Lindeman, D., Toft, E., Kidholm, K., Jethwani, K., Young, H. M., Spindler, H., Oestergaard, C. U., Southard, J. A., Gutierrez, M., Anderson, N., Albert, N. M., Han, J. J., & Nesbitt, T. (2016). Personalized Telehealth in the Future: A Global Research Agenda. *Journal of Medical Internet Research*, *18*(3), e53. https://doi.org/10.2196/jmir.5257

Dunagan, W. C., Littenberg, B., Ewald, G. A., Jones, C. A., Emery, V. B., Waterman, B. M., Silverman, D. C., & Rogers, J. G. (2005). Randomized trial of a nurse-administered, telephone-based disease management program for patients with heart failure. *Journal of Cardiac Failure*, *11*(5 SPEC. ISS.), 358–365. https://doi.org/10.1016/j.cardfail.2004.12.004

Ebrahim, S. (1995). Clinical and public health perspectives and applications of health-related quality of life measurement. *Social Science and Medicine*, *41*(10), 1383–1394. https://doi.org/10.1016/0277-9536(95)00116-O

Editors, T. Pl. M. (2011). Best Practice in Systematic Reviews: The Importance of Protocols and Registration. *PLoS Medicine*, *8*(2), e1001009. https://doi.org/10.1371/journal.pmed.1001009

Eurlings, C. G. M. J., Boyne, J. J., de Boer, R. A., & Brunner-La Rocca, H. P. (2019). Telemedicine in heart failure—more than nice to have? *Netherlands Heart Journal*, *27*(1), 5–15. https://doi.org/10.1007/s12471-018-1202-5

European Commission. (2020). *European Commission Report on the Impact of Demographic Change*. 1–30. https://ec.europa.eu/info/sites/info/files/demography_report_2020_n.pdf

Eze, N. D., Mateus, C., & Hashiguchi, T. C. O. (2020). Telemedicine in the OECD: An umbrella review of clinical and cost-effectiveness, patient experience and implementation. *PLoS ONE*, *15*(8 August). https://doi.org/10.1371/journal.pone.0237585

Faruque, L. I., Wiebe, N., Ehteshami-Afshar, A., Liu, Y., Dianati-Maleki, N., Hemmelgarn, B. R., Manns, B. J., & Tonelli, M. (2017). Effect of telemedicine on glycated hemoglobin in diabetes: a systematic review and meta-analysis of randomized trials. *Canadian Medical Association Journal*, *189*(9), E341–E364. https://doi.org/10.1503/cmaj.150885

Federal Institute for Drugs, & Devices, M. (2019). *The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V* (pp. 1–124). https://www.bfarm.de/EN/MedicalDevices/DiGA/_node.html

Gellis, Z. D., Kenaley, B., McGinty, J., Bardelli, E., Davitt, J., & Have, T. Ten. (2012). Outcomes of a telehealth intervention for homebound older adults with heart or chronic respiratory failure: A randomized controlled trial. *Gerontologist*, *52*(4), 541–552. https://doi.org/10.1093/geront/gnr134

Greffin, K., Schmidt, S., Berg, N. Van Den, 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

Gregersen, T. L., Green, A., Frausing, E., Ringbæk, T., Brøndum, E., & Ulrik, C. S. (2016). Do telemedical interventions improve quality of life in patients with COPD? A systematic review. *International Journal of COPD*, *11*(1), 809–822. https://doi.org/10.2147/COPD.S96079

Hajesmaeel-Gohari, S., & Bahaadinbeigy, K. (2021). The most used questionnaires for evaluating telemedicine services. *BMC Medical Informatics and Decision Making*, *21*(1), 36. https://doi.org/10.1186/s12911-021-01407-y

Han, L., Hazlewood, G. S., Barnabe, C., & Barber, C. E. H. (2021). Systematic Review of Outcomes and Patient Experience with Virtual Care in Rheumatoid Arthritis. *Arthritis Care & Research*, 0–3. https://doi.org/10.1002/acr.24586

Höhne, P. (2012). *Die Erfassung der Lebensqualität in Studien zu Telemonitoring bei ausgewählten Erkrankungen – Eine systematische Literaturrecherche und –analyse*. University of Greifswald.

Hsiao, B., & Fraenkel, L. (2017). Incorporating the Patient's perspective in outcomes research. *Current Opinion in Rheumatology*, *29*(2), 144–149. https://doi.org/10.1097/BOR.0000000000000372

Hung, W. W., Ross, J. S., Boockvar, K. S., & Siu, A. L. (2011). Recent trends in chronic disease, impairment and disability among older adults in the United States. *BMC Geriatrics*, *11*(1), 47. https://doi.org/10.1186/1471-2318-11-47

Inglis, S. C., Clark, R. A., McAlister, F. A., Stewart, S., & Cleland, J. G. F. (2011). Which components of heart failure programmes are effective? A systematic review and meta-analysis of the outcomes of structured telephone support or telemonitoring as the primary component of chronic heart failure management in 8323 patients: Abridged Coc. *European Journal of Heart Failure*, *13*(9), 1028–1040. https://doi.org/10.1093/eurjhf/hfr039

Izquierdo, R. E., Knudson, P. E., Meyer, S., Kearns, J., Ploutz-Snyder, R., & Weinstock, R. S. (2003). A comparison of diabetes education administered through telemedicine versus in person. *Diabetes Care*, *26*(4), 1002–1007. https://doi.org/10.2337/diacare.26.4.1002

Jansà, M., Vidal, M., Viaplana, J., Levy, I., Conget, I., Gomis, R., & Esmatjes, E. (2006). Telecare in a structured therapeutic education programme addressed to patients with type 1 diabetes and poor metabolic control. *Diabetes Research and Clinical Practice*, *74*(1), 26–32. https://doi.org/10.1016/j.diabres.2006.03.005

Karimi, M., & Brazier, J. (2016). Health, Health-Related Quality of Life, and Quality of Life: What is the Difference? *PharmacoEconomics*, *34*(7), 645–649. https://doi.org/10.1007/s40273-016-0389-9

Knapp, A., Harst, L., Hager, S., Schmitt, J., & Scheibe, M. (2021). Use of Patient-Reported Outcome Measures and Patient-Reported Experience Measures Within Evaluation Studies of Telemedicine Applications: Systematic Review. *Journal of Medical Internet Research*, *23*(11), e30042. https://doi.org/10.2196/30042

Koff, P. B., Jones, R. H., Cashman, J. M., Voelkel, N. F., & Vandivier, R. W. (2009). Proactive integrated care improves quality of life in patients with COPD. *European Respiratory Journal*, *33*(5), 1031–1038. https://doi.org/10.1183/09031936.00063108

León, A., Cáceres, C., Fernández, E., Chausa, P., Martin, M., Codina, C., Rousaud, A., Blanch, J., Mallolas, J., Martinez, E., Blanco, J. L., Laguno, M., Larrousse, M., Milinkovic, A., Zamora, L., Canal, N., Miró, J. M., Gatell, J. M., Gómez, E. J., & García, F. (2011). A new multidisciplinary home care telemedicine system to monitor stable chronic human immunodeficiency virus-infected patients: A randomized study. *PLoS ONE*, *6*(1). https://doi.org/10.1371/journal.pone.0014515

Marcano Belisario, J. S., Huckvale, K., Greenfield, G., Car, J., & Gunn, L. H. (2013). Smartphone and tablet self management apps for asthma. *Cochrane Database of Systematic Reviews*, *2017*(12). https://doi.org/10.1002/14651858.CD010013.pub2

Maric, B., Kaan, A., Ignaszewski, A., & Lear, S. A. (2009). A systematic review of telemonitoring technologies in heart failure. *European Journal of Heart Failure*, *11*(5), 506–517. https://doi.org/10.1093/eurjhf/hfp036

McIlhenny, C. V, Guzic, B. L., Knee, D. R., Wendekier, C. M., Demuth, B. R., & Roberts, J. B. (2011). Using technology to deliver healthcare education to rural patients. *Rural and Remote Health*, *11*(4), 1798.

McKenna, S. P., & Doward, L. C. (2004). The needs-based approach to quality of life assessment. *Value in Health*, *7*(SUPPL. 1), S1–S3. https://doi.org/10.1111/j.1524-4733.2004.7s101.x

McLean, S., Chandler, D., Nurmatov, U., Liu, J., Pagliari, C., Car, J., & Sheikh, A. (2011). Telehealthcare for asthma: A Cochrane review. *Cmaj*, *183* (11). https://doi.org/10.1503/cmaj.101146

Mercieca-Bebber, R., King, M. T., Calvert, M. J., Stockler, M. R., & Friedlander, M. (2018). The importance of patient-reported outcomes in clinical trials and strategies for future optimization. *Patient Related Outcome Measures*, *9*, 353–367. https://doi.org/10.2147/prom.s156279

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & PRISMA Group. (2009). Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Medicine*, *6*(7), e1000097. https://doi.org/10.1371/journal.pmed.1000097

Moher, D., Shamseer, L., Clarke, M., Ghersi, D., Liberati, A., Petticrew, M., Shekelle, P., & Stewart, L. A. (2015). Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews*, *4*(1), 1. https://doi.org/10.1186/2046-4053-4-1

Oeff, M., Müller, A., Neuzner, J., Sack, S., Schwab, J. O., Pfeiffer, D., & Zugck, C. (2008). ECG Telemonitoring. *Herzschrittmachertherapie Und Elektrophysiologie*, *19*(3), 137–145. https://doi.org/10.1007/s00399-008-0012-7

Pan American Health Organization. (2016). Framework for the Implementation of a Telemedicine Service. In *Pan American Organization, World Health Organization* (Issue May). https://iris.paho.org/handle/10665.2/28414

Pandor, A., Gomersall, T., Stevens, J. W., Wang, J., Al-Mohammad, A., Bakhai, A., Cleland, J. G. F., Cowie, M. R., & Wong, R. (2013). Remote monitoring after recent hospital discharge in patients with heart failure: a systematic review and network meta-analysis. *Heart*, *99*(23), 1717–1726. https://doi.org/10.1136/heartjnl-2013-303811

Pang, L., Liu, Z., Lin, S., Liu, Z., Liu, H., Mai, Z., Liu, Z., Chen, C., & Zhao, Q. (2020). The effects of telemedicine on the quality of life of patients with lung cancer: a systematic review and meta-analysis. *Therapeutic Advances in Chronic Disease*, *11*, 204062232096159. https://doi.org/10.1177/2040622320961597

Pedersen, N., Elkjaer, M., Duricova, D., Burisch, J., Dobrzanski, C., Andersen, N. N., Jess, T., Bendtsen, F., Langholz, E., Leotta, S., Knudsen, T., Thorsgaard, N., & Munkholm, P. (2012). EHealth: Individualisation of infliximab treatment and disease course via a self-managed web-based solution in Crohn's disease. *Alimentary Pharmacology and Therapeutics*, *36*(9), 840–849. https://doi.org/10.1111/apt.12043

Pequeno, N. P. F., Cabral, N. L. de A., Marchioni, D. M., Lima, S. C. V. C., & Lyra, C. de O. (2020). Quality of life assessment instruments for adults: a systematic review of population-based studies. *Health and Quality of Life Outcomes*, *18*(1), 208. https://doi.org/10.1186/s12955-020-01347-7

Popay, J., Roberts, H., Sowden, A., Petticrew, M., Arai, L., Rodgers, M., & Britten, N. (2006). Narrative Synthesis in Systematic Reviews: A Product from the ESRC Methods Programme. *ESRC Methods Programme*, *2006*, 93. https://doi.org/10.13140/2.1.1018.4643

Poulsen, K. A., Millen, C. M., Lakshman, U. I., Buttner, P. G., & Roberts, L. J. (2015). Satisfaction with rural rheumatology telemedicine service. *International Journal of Rheumatic Diseases*, *18*(3), 304–314. https://doi.org/10.1111/1756-185X.12491

Ritter, O., & Bauer, W. R. (2006). Use of "IEGM Online" in ICD patients—. *Clinical Research in Cardiology*, *95*(7), 368–372. https://doi.org/10.1007/s00392-006-0390-y

Riva, S., Mazzocco, K., & Pravettoni, G. (2015). Better Outcomes for Cancer Patients Using Telemedicine: Health-Related Quality of Life (HrQoL) and Empowerment. In G. Gatti, G. Pravettoni, & F. Capello (Eds.), *Tele-Oncology* (pp. 23–37). Springer, Cham. https://doi.org/10.1007/978-3-319-16378-9_3

Roorda, L. D., Crins, M. H., & Terwee, C. B. (2019). Clinimetrics: Patient-Reported Outcomes Measurement Information System (PROMIS ®). *Journal of Physiotherapy*, *65*(2), 110. https://doi.org/10.1016/j.jphys.2018.11.009

Rothrock, N. E., Kaiser, K. A., & Cella, D. (2011). Developing a valid patient-reported outcome measure. *Clinical Pharmacology and Therapeutics*, *90*(5), 737–742. https://doi.org/10.1038/clpt.2011.195

Ryu, S. (2010). History of Telemedicine: Evolution, Context, and Transformation. *Healthcare Informatics Research*, *16*(1), 65. https://doi.org/10.4258/hir.2010.16.1.65

Schmidt, S. (2007a). Telemedicine and quality of life. *Deutsche Medizinische Wochenschrift*, *132*(9), 442–447. https://doi.org/10.1055/s-2007-970355

Schmidt, S. (2007b). Telemedizin und Lebensqualität. *DMW - Deutsche Medizinische Wochenschrift*, *132*(9), 442–447. https://doi.org/10.1055/s-2007-970355

Schmidt, S., Schuchert, A., Krieg, T., & Oeff, M. (2010). Home Telemonitoring in Patients With Chronic Heart Failure A Chance to Improve Patient Care? *Deutsches Arzteblatt*, *107*(8), 131–138. https://doi.org/10.3238/arztebl.2010.0131

Schmidt, S., Sheikzadeh, S., Beil, B., Patten, M., & Stettin, J. (2008). Acceptance of telemonitoring to enhance medication compliance in patients with chronic heart failure. *Telemedicine Journal and E-Health : The Official Journal of the American Telemedicine Association*, *14*(5), 426–433. https://doi.org/10.1089/tmj.2007.0076

Sicotte, C., Paré, G., Morin, S., Potvin, J., & Moreault, M. P. (2011). Effects of home telemonitoring to support improved care for chronic obstructive pulmonary diseases. *Telemedicine and E-Health*, *17*(2), 95–103. https://doi.org/10.1089/tmj.2010.0142

Spethmann, S., & Köhler, F. (2022). Telemedizin bei chronischer Herzinsuffizienz – von klinischen Studien zur Regelversorgung. *Der Internist*, *63*(3), 266–273. https://doi.org/10.1007/s00108-022-01268-1

Srikesavan, C., Bryer, C., Ali, U., & Williamson, E. (2019). Web-based rehabilitation interventions for people with rheumatoid arthritis: A systematic review. *Journal of Telemedicine and Telecare*, *25*(5), 263–275. https://doi.org/10.1177/1357633X18768400

Strode, S. W., Gustke, S., & Allen, A. (1999). Technical and clinical progress in telemedicine. *Journal of the American Medical Association*, *281*(12), 1066–1068. https://doi.org/10.1001/jama.281.12.1066

Swiss Academic Software GmbH. (2018). *Citavi 6* (No. 5 & 6). http://www.citavi.com

Tchero, H., Teguo, M. T., Lannuzel, A., & Rusch, E. (2018). Telerehabilitation for stroke survivors: Systematic review and meta-analysis. *Journal of Medical Internet Research*, *20*(10), 1–10. https://doi.org/10.2196/10867

Timmerberg, B. D., Wurst, J., Patterson, J., Spaulding, R. J., & Belz, N. E. (2009). Feasibility of using videoconferencing to provide diabetes education: a pilot study. *Journal of Telemedicine and Telecare*, *15*(2), 95–97. https://doi.org/10.1258/jtt.2008.080813

Totten, A. M., Womack, D. M., Eden, K. B., McDonagh, M. S., Griffin, J. C., Grusing, S., & Hersh, W. R. (2016). Telehealth: Mapping the evidence for patient outcomes from systematic reviews. *Technical Brief No 26*, *125 p*, Report No.: 16–EHC034–EF. Contract No.: 290–2015–0. http://www.ncbi.nlm.nih.gov/pubmed/27536752

U.S. Department of Health and Human Services Food and Drug Administration. (2009). Guidance for Industry Use in Medical Product Development to Support Labeling Claims Guidance for Industry. *Clinical/Medical Federal Register*, *December*, 1–39.

Weldring, T., & Smith, S. M. S. (2013). Article Commentary: Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs). *Health Services Insights*, *6*, HSI.S11093. https://doi.org/10.4137/HSI.S11093

WHO Global Observatory for eHealth. (2010). *Telemedicine: opportunities and developments in Member States: report on the second global survey on eHealth*. World Health Organization. https://apps.who.int/iris/handle/10665/44497

Wood, P. R., & Caplan, L. (2019). Outcomes, Satisfaction, and Costs of a Rheumatology Telemedicine Program: A Longitudinal Evaluation. *Journal of Clinical Rheumatology : Practical Reports on Rheumatic & Musculoskeletal Diseases*, *25*(1), 41–44. https://doi.org/10.1097/RHU.0000000000000778

Wootton, R. (2012). Twenty years of telemedicine in chronic disease management-an evidence synthesis. *Journal of Telemedicine and Telecare*, *18*(4), 211–220. https://doi.org/10.1258/jtt.2012.120219

Zhang, X., Xiao, H., & Chen, Y. (2019). Evaluation of a WeChat-based life review programme for cancer patients: A quasi-experimental study. *Journal of Advanced Nursing*, *75*(7), 1563–1574. https://doi.org/10.1111/jan.14018

Zhang, Y., Yang, N., Si, G., Zhang, Y., Dong, Z., Huang, Y., & Tan, X. (2019). What matters the adherence with BP 24-hr self-monitoring wearable device among hypertensive patients? A population-based survey. *Translational Behavioral Medicine*, *10*(4), 1053–1063. https://doi.org/10.1093/tbm/ibz069

Zissman, K., Lejbkowicz, I., & Miller, A. (2012). Telemedicine for multiple sclerosis patients: Assessment using Health Value Compass. *Multiple Sclerosis Journal*, *18*(4), 472–480. https://doi.org/10.1177/1352458511421918

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Health and Quality of Life Outcomes

RESEARCH

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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] and Holger Muehlan[1]

Abstract

Background: Although telemedical 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 chronic physical or mental illnesses, with or without telemedicine supported healthcare as well as telemedical professionals. Mayring's content analysis approach was used to encode the qualitative data 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.

Keywords: 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

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*Correspondence: klara.greffin@uni-greifswald.de
[1] Department of Psychology, Chair of Health and Prevention, University of Greifswald, Robert-Blum-Str. 13, 17489 Greifswald, Germany
Full list of author information is available at the end of the article

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, WHO-QOL-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 chronic physical disease), but often included in telemedical studies. In addition, we included active (regular phone calls) and passive (remote health 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) aiming at $n = 8$ for 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 (chronic physical or mental disease), 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.

Table 1 Recruited sample for focus groups and individual interviews consisting of patients and professionals

Patients	Focus groups		Interviews		Total
	TM	No TM	TM	No TM	
Mental disorder	10	10	9	8	37
Chronic physical disease	9	9	8	8	34
Total (Patients)	38		33		71
Professionals	31		30		131

TM, with telemedicine; no TM, without telemedicine

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 min. 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 min. 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 (Additional file 1: Supplementary A and Additional file 2: Supplementary 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. The inductive categories 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, WHOQOL-100/WHOQOL-BREF), health-related (SF-36/SF-12/ SF-8/ SF-6), or disease-specific (EORTC QOL-C30, MLHFQ, FACT) 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 eight 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 patients suffered from cardiological diseases (n=10 dilated cardiomyopathy, n=9 ischemic cardiomyopathy; n=9 each with or without telemedicine) and 20 patients had depression (n = 10 each with or without telemedical treatment). 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 chronic physical diseases (n = 16; thereof n = 9 dilated cardiomyopathy, n = 5 chronic kidney failure, n = 5 diabetes mellitus, n = 3 hypertension, n = 2 peripheral artery disease, and n = 1 rheumatoid arthritis - as most patients suffered from more than one disease. N = 8 patients each were with or without telemedical treatment). Additionally, 17 patients suffered from mental disorders (thereof n = 15 depression, n = 3 PTSD, n = 3 anxiety disorder, n = 2 schizophrenia, n = 1 panic disorder, n = 1 bipolar disorder, n = 1 substance use disorder, n = 1 personality disorder, n = 1 problem gamling, n = 1 somatic symptom disorder - as most patients suffered from more than one disease. N = 9 patients were with and n=8 patients were 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.

Treatment of patients in the telemedical group

Patients with mental disorders 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 30–50 min. 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 chronic physical illnesses 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 (Additional file 3: 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 to 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 even 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

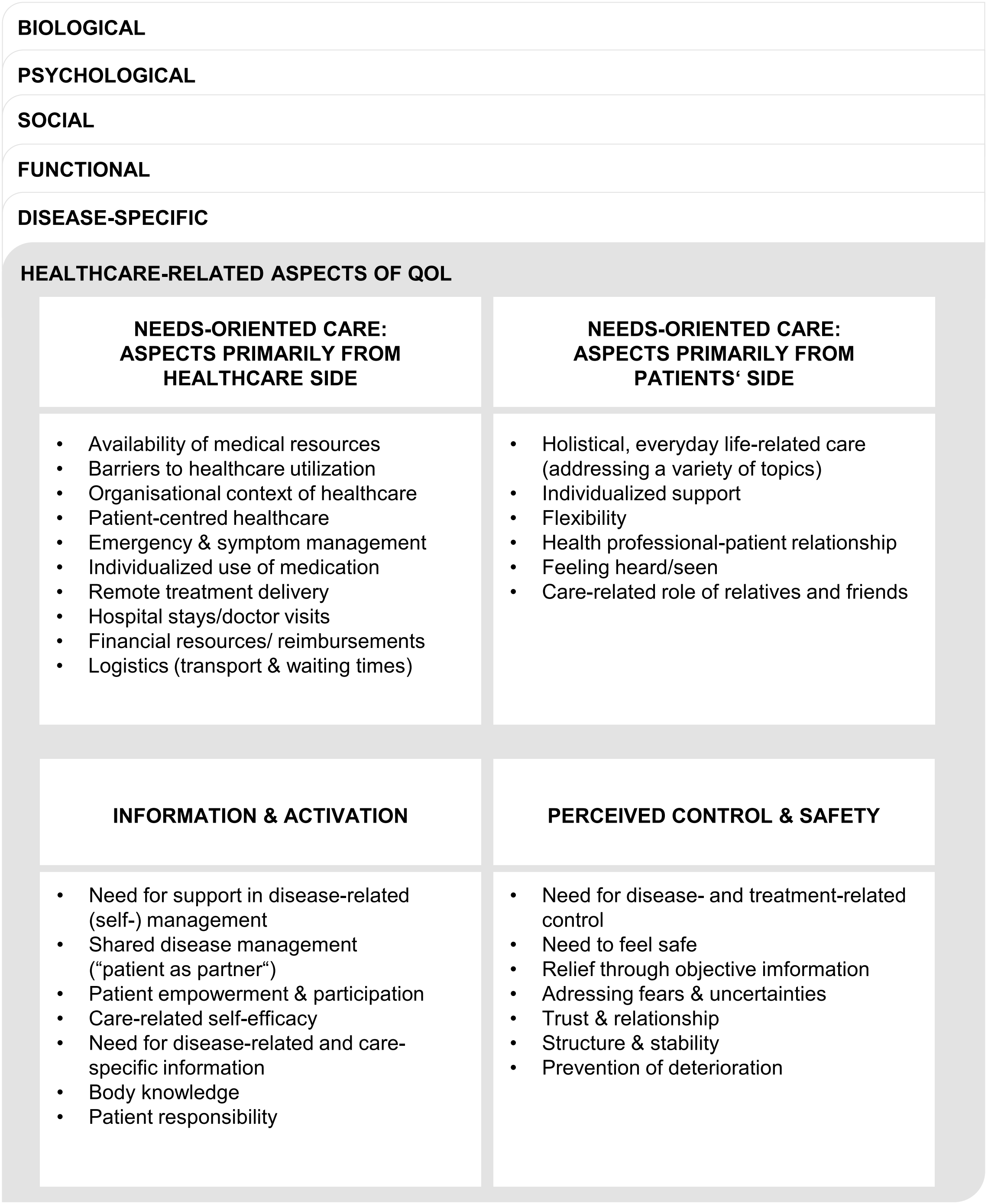
The majority of aspects that influence the QoL of patients dealing with chronic conditions or mental illnesses could be assigned to the identified working model. However, some aspects that were considered important were not covered by the pre-existing domains yet. For that reason, we extend the working 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) information and activation, and (d) perceived control and safety (Fig. 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 the 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



BIOLOGICAL

PSYCHOLOGICAL

SOCIAL

FUNCTIONAL

DISEASE-SPECIFIC

HEALTHCARE-RELATED ASPECTS OF QOL

NEEDS-ORIENTED CARE: ASPECTS PRIMARILY FROM HEALTHCARE 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)

NEEDS-ORIENTED CARE: ASPECTS PRIMARILY FROM PATIENTS‘ SIDE

- 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

- 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

PERCEIVED CONTROL & SAFETY

- 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

Fig. 1 Healthcare-related domain

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.

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 caregiving. 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.

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 safer, which is an essential component of improving the quality of life.")*.

Perceived control and safety

The fourth facet that influences QoL was named *perceived control and safety*. It is defined by statements from patients and professionals about how a disease can make the patient feel vulnerable in their daily life due to fears, lack of knowledge, uncertainty, or treatment intransparency. Primarily, patients describe to feel "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.

Perceived control and safety

Aspects relating to the facet perceived 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 perceived control and safety and can be linked to the privacy dimension of the obtrusiveness concept by Hensel et al. [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 perceived safety/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 their 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 and mental illness; active and passive telemedical approaches; patients and 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

Two 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, 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 generation. 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.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12955-021-01807-8.

Additional file 1. Supplementary A: Focus group guides.

Additional file 2. Supplementary B: Interview guides.

Additional file 3. Supplementary C: A quantitative summary of the data evaluation.

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Authors' contributions

KG, HM and SiS prepared the qualitative study, KG and HM developed the guidelines, NvdB, WH, KG, OR and 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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Availability of data and materials
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Declarations

Ethics approval and consent to participate
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.

Competing interests
The authors declare that they have no competing interests.

Author details
[1]Department of Psychology, Chair of Health and Prevention, University of Greifswald, Robert-Blum-Str. 13, 17489 Greifswald, Germany. [2]Institute of Community Medicine, Section Epidemiology of Health Care and Community Health, University Medicine Greifswald, 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]Department of Psychiatry and Psychotherapy, University Medicine Leipzig, Semmelweisstraße 10, 04103 Leipzig, Germany.

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References

1. Snyder CF, Wu AW, Miller RS, Jensen RE, Bantug ET, Wolff AC. The role of informatics in promoting patient-centered care. Cancer J. 2011;17(4):211–8.
2. Demiris G, Afrin LB, Courtney KL, Sondhi M, Vimarlund V, Lovis C, et al. Patient-centered applications: use of information technology to promote disease management and well ness. J Am Med Inform Assoc. 2008;15(206):8–13.
3. Federal Institute for Drugs and Medical Devices. The fast-track process for Digital Health Applications (DiGA) according to Section 139e SGB V; 2019. pp. 1–124.
4. Bashshur RL, Shannon GW, Smith BR, Alverson DC, Antoniotti N, Barsan WG, et al. The empirical foundations of telemedicine interventions for chronic disease management. Telemed e-Health. 2014;20(9):769–800.
5. Sood S, Mbarika V, Jugoo S, Dookhy R, Doarn CR, Prakash N, et al. What is telemedicine? A collection of 104 peer-reviewed perspectives and theoretical underpinnings. Telemed J E Health. 2007;13(5):573–90.
6. WHO. A health telematics policy in support of WHO's Health-For-All strategy for global health development: report of the WHO group consultation on health telematics, 11–16 December, Geneva, 1997. Geneva: World Health Organization; 1998.
7. Mercieca-Bebber R, King MT, Calvert MJ, Stockler MR, Friedlander M. The importance of patient-reported outcomes in clinical trials and strategies for future optimization. Patient Relat Outcome Meas. 2018;9:353–67.
8. Weldring T, Smith SMS. Article commentary: Patient-reported outcomes (PROs) and patient-reported outcome measures (PROMs). Heal Serv Insights. 2013;6:61–8.
9. Schmidt S, Schuchert A, Krieg T, Oeff M. Home telemonitoring in patients with chronic heart failure a chance to improve patient care? Dtsch Arztebl. 2010;107(8):131–8.
10. Bullinger M, Quitmann J. Quality of life as patient-reported outcomes: principles of assessment. Dialogues Clin Neurosci. 2014;16(2):137–45.
11. Tunder R, Martschinke B. The QALY approach—potentials and limits. Urologe. 2014;53(1):7–14.
12. Karimi M, Brazier J. Health, health-related quality of life, and quality of life: what is the difference? Pharmacoeconomics. 2016;34(7):645–9.
13. Haraldstad K, Wahl A, Andenæs R, Andersen JR, Andersen MH, Beisland E, et al. A systematic review of quality of life research in medicine and health sciences. Qual Life Res. 2019;28(10):2641–50.
14. Schmidt S. Telemedicine and quality of life. Dtsch Medizinische Wochenschrift. 2007;132(9):442–7.
15. Inglis SC, Clark RA, McAlister FA, Stewart S, Cleland JGF. Which components of heart failure programmes are effective? A systematic review and meta-analysis of the outcomes of structured telephone support or telemonitoring as the primary component of chronic heart failure management in 8323 patients: Abridged Coc. Eur J Heart Fail. 2011;13(9):1028–40.
16. Clark RA, Inglis SC, McAlister FA, Cleland JGF, Stewart S. Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis. Br Med J. 2007;334(7600):942–5.
17. Pandor A, Gomersall T, Stevens JW, Wang J, Al-Mohammad A, Bakhai A, et al. Remote monitoring after recent hospital discharge in patients with heart failure: a systematic review and network meta-analysis. Heart. 2013;99(23):1717–26.
18. Maric B, Kaan A, Ignaszewski A, Lear SA. A systematic review of telemonitoring technologies in heart failure. Eur J Heart Fail. 2009;11(5):506–17.
19. Hughes HA, Granger BB. Racial disparities and the use of technology for self-management in blacks with heart failure: a literature review. Curr Heart Fail Rep. 2014;11(3):281–9.
20. Eurlings CGMJ, Boyne JJ, de Boer RA, Brunner-La Rocca HP. Telemedicine in heart failure—more than nice to have? Netherlands Hear J. 2019;27(1):5–15.
21. Ritter O, Bauer WR. Use of "IEGM Online" in ICD patients—early detection of inappropriate classified ventricular tachycardia via Home Monitoring. Clin Res Cardiol. 2006;95(7):368–72.
22. Yang D, Hur JW, Bin Kwak Y, Choi SW. A systematic review and meta-analysis of applicability of web-based interventions for individuals with depression and quality of life impairment. Psychiatry Investig. 2018;15(8):759–66.
23. Königbauer J, Letsch J, Doebler P, Ebert D, Baumeister H. Internet- and mobile-based depression interventions for people with diagnosed depression: a systematic review and meta-analysis. J Affect Disord. 2017;223(April):28–40.
24. Greffin K, Schmidt S, van den Berg N, Hoffmann W, Ritter O, Oeff M, et al. Telemedicine and patient-reported outcomes: concordance and discrepancy of purpose, constructs and methods of measurement—a systematic literature review **(in preparation)**
25. Brunton L, Bower P, Sanders C. The contradictions of telehealth user experience in chronic obstructive pulmonary disease (COPD): a qualitative meta-synthesis. PLoS ONE. 2015;10(10):1–22.
26. Lee PA, Greenfield G, Pappas Y. Patients' perception of using telehealth for type 2 diabetes management: a phenomenological study. BMC Health Serv Res. 2018;18(1):1–9.
27. Morgan D, Koszeniuk J, Stewart N, O'Connell M, Karunanyake C, Beever R. The telehealth satisfaction scale: reliability, validity, and satisfaction with telehealth in a rural memory clinic population. Telemed J E Health. 2014;20(11):997–1003.
28. Yip MP, Chang AM, Chan J, MacKenzie AE. Development of the Telemedicine Satisfaction Questionnaire to evaluate patient satisfaction with telemedicine: a preliminary study. J Telemed Telecare. 2003;9(1):46–50.
29. Parmanto B, Lewis ANJ, Graham KM, Bertolet MH. Development of the Telehealth Usability Questionnaire (TUQ). Int J Telerehabilitation. 2016;8(1):3–10.
30. Demiris G, Speedie S, Finkelstein S. A questionnaire for the assessment of patients' impressions of the risks and benefits of home telecare. J Telemed Telecare. 2000;6(5):278–84.
31. Saunders B, Sim J, Kingstone T, Baker S, Waterfield J, Bartlam B, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. Qual Quant. 2018;52(4):1893–907.

32. Krueger RA, Casey MA. Participants in a focus groups. In: Krueger RA, editor. Focus groups a practical guide for applied research. Singapore: Sage; 2014.
33. Vasileiou K, Barnett J, Thorpe S, Young T. Characterising and justifying sample size sufficiency in interview-based studies: systematic analysis of qualitative health research over a 15-year period. BMC Med Res Methodol. 2018;18(1):1–18.
34. Cheng KKF, Clark AM. Qualitative methods and patient-reported outcomes: measures development and adaptation. Int J Qual Methods. 2017;16(1):1–3.
35. Husbands S, Mitchell PM, Coast J. A systematic review of the use and quality of qualitative methods in concept elicitation for measures with children and young people. Patient. 2020;13(3):257–88.
36. dr. dresing & pehl GmbH. f4transkript. Marburg; 2019.
37. Mayring P. Qualitative content analysis: theoretical background and procedures. In: Bikner-Ahsbahs A, Knipping C, Presmeg N, editors. Approaches to qualitative research in mathematics education advances in mathematics education. Dordrecht: Springer; 2015.
38. VERBI Software. MAXQDA—software for qualitative data analyses. Berlin, Germany; 2017.
39. Palcu P, Munce S, Jaglal SB, Allin S, Chishtie JA, Silverstein A, et al. Understanding patient experiences and challenges to osteoporosis care delivered virtually by telemedicine: a mixed methods study. Osteoporos Int. 2020;31(2):351–61.
40. Powell RE, Henstenburg JM, Cooper G, Hollander JE, Rising KL. Patient perceptions of telehealth primary care video visits. Ann Fam Med. 2017;15(3):225–9.
41. Jensen CM, Overgaard S, Wiil UK, Clemensen J. Can tele-health support self-care and empowerment? A qualitative study of hip fracture patients' experiences with testing an "App." SAGE Open Nurs. 2019;5:1–11.
42. Clemensen J, Rothmann MJ, Smith AC, Caffery LJ, Danbjorg DB. Participatory design methods in telemedicine research. J Telemed Telecare. 2017;23(9):780–5.
43. Hensel BK, Demiris G, Courtney KL. Defining obtrusiveness in home telehealth technologies: a conceptual framework. J Am Med Inform Assoc. 2006;13(4):428–31.
44. Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life: a conceptual model of patient outcomes. JAMA J Am Med Assoc. 1995;273(1):59–65.
45. Bakas T, McLennon SM, Carpenter JS, Buelow JM, Otte JL, Hanna KM, et al. Systematic review of health-related quality of life models. Health Qual Life Outcomes. 2012;10:1–12.
46. Terwee CB, Prinsen CAC, Chiarotto A, De Vet HCW, Westerman MJ, Patrick DL, et al. COSMIN standards and criteria for evaluating the content validity of health-related patient-reported outcome measures: a Delphi study. Qual Life Res. 2018;27:1159–70.
47. Mayring P. Einführung in die qualitative Sozialforschung. Eine Anleitung zu qualitativem Denken. 6. Aufl. Beltz Studium. Weinheim; Basel; 2016.

Publisher's Note

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

Purpose: 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 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 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. In the expert survey, the remaining 105 items of the provisional instrument were rated. 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.

Conclusion: 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

Background

Quality of Life (QoL) is discussed as a key patient-reported outcome in telemedical (TM) applications [1,2]. To test whether TM 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 were missing [1]. In addition, reviews showed that so far, no TM-related QoL measure is available [Greffin et al., submitted]. 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 [5] 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 [6] and followed the recommended steps for PRO development [7,8].

First, we underwent systematic literature reviews [Greffin et al., submitted] and a qualitative study for concept elicitation [9]. Within the systematic literature reviews on purpose of intended TM use, concepts, and measurements used to evaluate TM from a patient's perspective [Greffin et al., submitted], we learnt that there are no setting-sensitive instruments to assess QoL in the context of TM. Besides, we analysed 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 group with patients and TM professionals, aiming to understand the impact of TM on QoL [9]. The results of the qualitative data analyses were mapped on the prior identified general working mode of QoL. The majority of aspects influencing 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 *healthcare-related domain* [9]. The newly designed domain consists of four facets called (a-b) needs-oriented care - aspects primarily from the healthcare side or the patient, (c) information and activation, and (d) perceived control and safety. A detailed description can be found in [9]. However, it is important to note here 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 dimensionality of the item pool as well as psychometric performance on 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. For this reason, we included patients with depression or heart failure in these study sections [10–13]. 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 was 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 in University Medicine Greifswald and University Medicine Leipzig, while patients with heart failure were recruited in Brandenburg City Hospital. Respective study nurses identified eligible patients from hospital records and contacted them to inform 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 patient received a compensation of €40 for the pretesting 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 pretesting 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) [14]. 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.

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 conform the assumptions of the more complex psychometric procedures like exploratory and confirmatory factor analysis. As described in the study protocol [5], the size of the item pool, the communalities of the items, and the number, item sizes, and eigenvalues of the factors were still unknown [15,16]. For the approximation of the necessary case numbers, reference was made to simulation studies and reviews [17–19]. For pilot testing the instrument, an estimated item size of about 50+/-10 items was assumed. In summary, the sample sizes within the different 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 [5].

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	*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 [20], 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 [9], 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 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 programmes Microsoft Excel and SPSS [21].

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 [9]. 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, that are 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 *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 [5]. The *study materials* were prepared by the University of Greifswald and subsequently sent to the recruiting partners. Depending on the recruitment centre, 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 in to the staff of the recruitment centre or anonymously returned to 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 procedure proposed in the study protocol [5]. Data from the pilot testing was analysed to explore 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 [21].

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 an 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 the frequency of the respective comments (n=32)

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 the number of codes per items or commenting person per item (n=32)

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 relevance of the items, the content validity index (CVI, [22]) 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 is indicating 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, that accounts for almost 46% of the explained variance. Six additional factors have eigenvalues of at least 2 (2.08 to 4.99), explaining approximately additional 18% of variance. There are 11 factors with eigenvalues of at least 1.0 (1.05 to 1.75), accounting for further 14% of explained variance. Table 5 provides detailed information. Further inspection indicate 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 the principal axis analysis with Promax rotation of the initial Tele-Qol pilot study item pool (n=200)

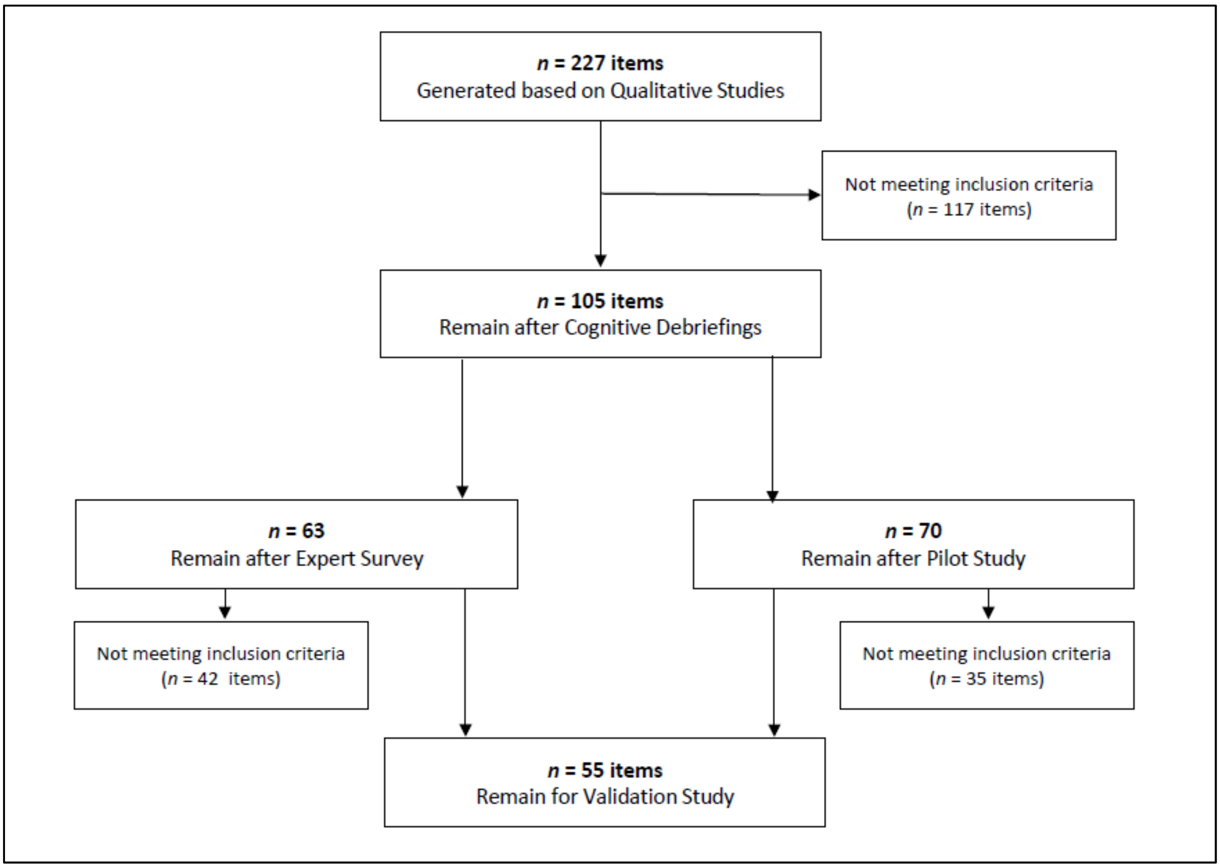
Factor No.	Eigen-value	Explained variance (%)	Cumulative explained variance (%)	Content of items with primary loadings on the respective factor
1	48.40	46.10	46.10	• Healthcare-related QoL & Well-Being
2	4.99	4.75	50.85	• Patient Needs, Safety & Trust
3	4.25	4.05	54.90	• Information & Patient Education
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 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

Flow chart of stepwise item selection 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. Additional, 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 of items. Pretesting is thus a further step in the development of the later questionnaire with extensive patient and stakeholder involvement [7,8,23].

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 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 application in terms of intended benefits [24]. Nevertheless, due to our derived contents from the qualitative study that highlight the importance of also assessing the unintended effects of TM, we decided to include a selection of revised impact items in the final Tele-QoL instrument, even though there relevance ranking was low.

Results from the pilot testing of the initial item pool indicate a diversified multidimensional structure that comprises of 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 represents different facets within the domains of our working model. However, the lower the eigenvalues gets, 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 on the patients' QoL. The item pool for the validation study includes items for the later Tele-QoL long 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 realise complex treatment [25], TM applications are increasingly used as a compliment of face-to-face treatment. In addition to stabilising or improving symptoms, these mostly 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, standardised 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 towards 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 [9], thus under 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 [7,8,23,26]. Moreover, we expect a high content validity as well as a 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 generalisation 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 of course only possible to interview a selection of professionals who are involved in the design, application, and evaluation of TM care.

Conclusion & Outlook

The preliminary version of the Tele-QoL instrument was comprehensively (pre-)tested applying a rigorous, established approach [7]. 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.

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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). All participants provided their informed consent in written format.

Protocol

A study protocol was publishes [5].

Declaration of interests

The authors declare no conflict of interest.

Author’s contribution

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

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

References

1. Schmidt, S. Telemedicine and Quality of Life. *Dtsch. Medizinische Wochenschrift* **2007**, *132*, 442–447, doi:10.1055/s-2007-970355.

2. Riva, S.; Mazzocco, K.; Pravettoni, G. Better Outcomes for Cancer Patients Using Telemedicine: Health-Related Quality of Life (HrQoL) and Empowerment. In *Tele-Oncology*; Gatti, G., Pravettoni, G., Capello, F., Eds.; Springer, Cham., 2015; pp. 23–37 ISBN 978-3-319-16378-9.

3. Knapp, A.; Harst, L.; Hager, S.; Schmitt, J.; Scheibe, M. Use of Patient-Reported Outcome Measures and Patient-Reported Experience Measures Within Evaluation Studies of Telemedicine Applications: Systematic Review. *J. Med. Internet Res.* **2021**, *23*, e30042, doi:10.2196/30042.

4. Pequeno, N.P.F.; Cabral, N.L. de A.; Marchioni, D.M.; Lima, S.C.V.C.; Lyra, C. de O. Quality of Life Assessment Instruments for Adults: A Systematic Review of Population-Based Studies. *Health Qual. Life Outcomes* **2020**, *18*, 208, doi:10.1186/s12955-020-01347-7.

5. Greffin, K.; Muehlan, H.; van den Berg, N.; Hoffmann, W.; Ritter, O.; Oeff, M.; Schomerus, G.; Schmidt, S. Setting-Sensitive Conceptualization and Assessment of Quality of Life in Telemedical Care - Study Protocol of the Tele-QoL Project. *Int. J. Environ. Res. Public Health* **2021**, *18*, doi:10.3390/ijerph181910454.

6. Lasch, K.E.; Marquis, P.; Vigneux, M.; Abetz, L.; Arnould, B.; Bayliss, M.; Crawford, B.; Rosa, K. PRO Development: Rigorous Qualitative Research as the Crucial Foundation. *Qual. Life Res.* **2010**, doi:10.1007/s11136-010-9677-6.

7. Rothrock, N.E.; Kaiser, K.A.; Cella, D. Developing a Valid Patient-Reported Outcome Measure. *Clin. Pharmacol. Ther.* **2011**, *90*, 737–742, doi:10.1038/clpt.2011.195.

8. Cheng, K.K.F.; Clark, A.M. Qualitative Methods and Patient-Reported Outcomes: Measures Development and Adaptation. *Int. J. Qual. Methods* **2017**, *16*, 1–3, doi:10.1177/1609406917702983.

9. Greffin, K.; Schmidt, S.; van den Berg, N.; Hoffmann, W.; Ritter, O.; Oeff, M.; Schomerus, G.; Muehlan, H. 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 Qual. Life Outcomes* **2021**, 1–14, doi:10.1186/s12955-021-01807-8.

10. Ryu, S. History of Telemedicine: Evolution, Context, and Transformation. *Healthc. Inform. Res.* **2010**, *16*, 65, doi:10.4258/hir.2010.16.1.65.

11. Schmidt, S.; Schuchert, A.; Krieg, T.; Oeff, M. Home Telemonitoring in Patients With Chronic Heart Failure A Chance to Improve Patient Care? *Dtsch. Arztebl.* **2010**, *107*, 131–138, doi:10.3238/arztebl.2010.0131.

12. Oeff, M.; Müller, A.; Neuzner, J.; Sack, S.; Schwab, J.O.; Pfeiffer, D.; Zugck, C. EKG-Telemonitoring. *Herzschrittmachertherapie und Elektrophysiologie* 2008, *19*, 137–145.

13. Lal, S.; Adair, C.E. E-Mental Health: A Rapid Review of the Literature. *Psychiatr. Serv.* **2014**, *65*, 24–32, doi:10.1176/appi.ps.201300009.

14. Perneger, T. V.; Courvoisier, D.S.; Hudelson, P.M.; Gayet-Ageron, A. Sample Size for Pre-Tests of Questionnaires. *Qual. Life Res.* **2015**, *24*, 147–151, doi:10.1007/s11136-014-0752-2.

15. Osborne, J.; Osborne, J.W.; Costello, A.B.; Kellow, J.T. *Best Practices in Exploratory Factor Analysis*; 2011; ISBN 9781500594343.

16. Costello, A.B.; Osborne, J.W. Best Practices in Exploratory Factor Analysis: Four Recommendations for Getting the Most from Your Analysis. *Pract. Assessment, Res. Eval.* **2005**.

17. Anthoine, E.; Moret, L.; Regnault, A.; Sébille, V.; Hardouin, J.-B. Sample Size Used to Validate a Scale: A Review of Publications on Newly-Developed Patient Reported Outcomes Measures. *Health Qual. Life Outcomes* **2014**, *12*, 2, doi:10.1186/s12955-014-0176-2.

18. Hogarty, K.Y.; Hines, C. V; Kromrey, J.D.; Ferron, J.M.; Mumford, K.R. The Quality of Factor Solutions in Exploratory Factor Analysis: The Influence of Sample Size, Communality, and Overdetermination. *Educ. Psychol. Meas.* **2005**, *65*, 202–226, doi:10.1177/0013164404267287.

19. Wolf, E.J.; Harrington, K.M.; Clark, S.L.; Miller, M.W. Sample Size Requirements for Structural Equation Models. *Educ. Psychol. Meas.* **2013**, *73*, 913–934, doi:10.1177/0013164413495237.

20. Willis, G. Cognitive Interviewing 2005.

21. IBM Corp. IBM SPSS Statistics for Windows 2021.

22. Zamanzadeh, V.; Ghahramanian, A.; Rassouli, M.; Abbaszadeh, A.; Alavi-Majd, H.; Nikanfar, A.-R. Design and Implementation Content Validity Study: Development of an Instrument for Measuring Patient-Centered Communication. *J. Caring Sci.* **2015**, *4*, 165–178, doi:10.15171/jcs.2015.017.

23. Carlton, J.; Peasgood, T.; Mukuria, C.; Johnson, J.; Ogden, M.; Tovey, W. The Role of Patient and Public Involvement and Engagement (PPIE) within the Development of the EQ Health and Wellbeing (EQ-HWB). *J. Patient-Reported Outcomes* **2022**, *6*, doi:10.1186/s41687-022-00437-y.

24. Federal Institute for Drugs and Medical Devices The Fast-Track Process for Digital Health Applications (DiGA) According to Section 139e SGB V 2019, 1–124.

25. Nolte, E.; Knai, C.; McKee, M. Managing Chronic Conditions. Experience in Eight Countries. *Obs. Stud. Ser. N˚15* **2008**, 202.

26. Clemensen, J.; Rothmann, M.J.; Smith, A.C.; Caffery, L.J.; Danbjorg, D.B. Participatory Design Methods in Telemedicine Research. *J. Telemed. Telecare* **2017**, *23*, 780–785, doi:10.1177/1357633X16686747.

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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).

Table 1

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

Study Assessments & Measures	Numbero f 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).

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.

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.

References

Arbuckle, J. L. (2021). *Amos 28.0 User's Guide.* IMB SPSS.

Bullinger, M., & Quitmann, J. (2014). Quality of life as patient-reported outcomes: principles of assessment. *Dialogues in Clinical Neuroscience*, *16*(2), 137–145. https://doi.org/10.31887/DCNS.2014.16.2/mbullinger

Cheng, K. K. F., & Clark, A. M. (2017). Qualitative Methods and Patient-Reported Outcomes: Measures Development and Adaptation. *International Journal of Qualitative Methods*, *16*(1), 1–3. https://doi.org/10.1177/1609406917702983

Cohen, J. (1992). A power primer. In *Psychological Bulletin* (Vol. 112, Issue 1, pp. 155–159). American Psychological Association. https://doi.org/10.1037/0033-2909.112.1.155

Deng, G., Weber, W., Sood, A., & Kemper, K. J. (2010). Research on integrative healthcare: context and priorities. *Explore (New York, N.Y.)*, *6*(3), 143–158. https://doi.org/10.1016/j.explore.2010.03.007

Federal Institute for Drugs and Medical Devices. (2019). *The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V* (pp. 1–124). https://www.bfarm.de/EN/MedicalDevices/DiGA/_node.html

Frost, M. H., Reeve, B. B., Liepa, A. M., Stauffer, J. W., Hays, R. D., & Sloan, J. A. (2007). What is sufficient evidence for the reliability and validity of patient-reported outcome measures? *Value in Health*, *10*(SUPPL. 2), 94–105. https://doi.org/10.1111/j.1524-4733.2007.00272.x

Greffin, K., Muehlan, H., Rosenkranz, E., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (n.d.). Telemedicine and patient-reported outcomes in chronic conditions: concordance and discrepancy of purpose, concepts, and methods of measurement – a systematic literature review (submitted). *Journal of Medical Internet Research*.

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

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

Hajesmaeel-Gohari, S., & Bahaadinbeigy, K. (2021). The most used questionnaires for evaluating telemedicine services. *BMC Medical Informatics and Decision Making*, *21*(1), 36. https://doi.org/10.1186/s12911-021-01407-y

Haraldstad, K., Wahl, A., Andenæs, R., Andersen, J. R., Andersen, M. H., Beisland, E., Borge, C. R., Engebretsen, E., Eisemann, M., Halvorsrud, L., Hanssen, T. A., Haugstvedt, A., Haugland, T., Johansen, V. A., Larsen, M. H., Løvereide, L., Løyland, B., Kvarme, L. G., Moons, P., … Helseth, S. (2019). A systematic review of quality of life research in medicine and health sciences. *Quality of Life Research*, *28*(10), 2641–2650. https://doi.org/10.1007/s11136-019-02214-9

Haslbeck, J., Klein, M., Bischofberger, I., & Sottas, B. (2015). Leben mit chronischer Krankheit. Die Perspektive von Patientinnen, Patienten und Angehörigen. In *Obsan Dossier* (Vol. 46).

Hu, L., & Bentler, P. M. (1999). Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Structural Equation Modeling: A Multidisciplinary Journal*, *6*(1), 1–55. https://doi.org/10.1080/10705519909540118

Huygens, M. W. J., Vermeulen, J., Swinkels, I. C. S., Friele, R. D., Van Schayck, O. C. P., & De Witte, L. P. (2016). Expectations and needs of patients with a chronic disease toward self-management and eHealth for self-management purposes. *BMC Health Services Research*, *16*(1), 1–11. https://doi.org/10.1186/s12913-016-1484-5

IBM Corp. (2021). *IBM SPSS Statistics for Windows* (28.0). IBM Corp.

Johnson, S. E., Fedor, M. A., & Hoban, M. B. (2008). Telemonitoring: a positive impact on patient outcomes. *Caring : National Association for Home Care Magazine*, *27*(7), 20–25. http://www.ncbi.nlm.nih.gov/pubmed/18683435

Kennedy, A., Rogers, A., & Bower, P. (2007). Support for self care for patients with chronic disease. *British Medical Journal*, *335*(7627), 968–970. https://doi.org/10.1136/bmj.39372.540903.94

Knapp, A., Harst, L., Hager, S., Schmitt, J., & Scheibe, M. (2021). Use of Patient-Reported Outcome Measures and Patient-Reported Experience Measures Within Evaluation Studies of Telemedicine Applications: Systematic Review. *Journal of Medical Internet Research*, *23*(11), e30042. https://doi.org/10.2196/30042

McGilton, K. S., Vellani, S., Yeung, L., Chishtie, J., Commisso, E., Ploeg, J., Andrew, M. K., Ayala, A. P., Gray, M., Morgan, D., Chow, A. F., Parrott, E., Stephens, D., Hale, L., Keatings, M., Walker, J., Wodchis, W. P., Dubé, V., McElhaney, J., & Puts, M. (2018). Identifying and understanding the health and social care needs of older adults with multiple chronic conditions and their caregivers: A scoping review. In *BMC Geriatrics* (Vol. 18, Issue 1). BMC Geriatrics. https://doi.org/10.1186/s12877-018-0925-x

McKenna, S. P., & Doward, L. C. (2004). The needs-based approach to quality of life assessment. *Value in Health*, *7*(SUPPL. 1), S1–S3. https://doi.org/10.1111/j.1524-4733.2004.7s101.x

Muehlan, H., Greffin, K., van den Berg, N., Hoffmann, W., Ritter, O., Oeff, M., Schomerus, G., & Schmidt, S. (n.d.). Towards adjunct setting-related quality of life assessment in telemedicine – cognitive debriefing, expert rating and pilot testing of the Tele-QoL instrument (submitted). *Quality of Life Research*.

Muehlan, H., & Schmidt, S. (2013). Versorgungsbezogene E-Health-Anwendungen und Lebensqualität: Empirische Befunde und konzeptuelle Perspektiven. *Psychiatrische Praxis*, *40*(6), 307–312. https://doi.org/10.1055/s-0033-1349489

Ng, J. H. Y., & Luk, B. H. K. (2019). Patient satisfaction: Concept analysis in the healthcare context. *Patient Education and Counseling*, *102*(4), 790–796. https://doi.org/https://doi.org/10.1016/j.pec.2018.11.013

Oeff, M., Müller, A., Neuzner, J., Sack, S., Schwab, J. O., Pfeiffer, D., & Zugck, C. (2008). EKG-telemonitoring. In *Herzschrittmachertherapie und Elektrophysiologie* (Vol. 19, Issue 3, pp. 137–145). https://doi.org/10.1007/s00399-008-0012-7

Patrick, D. L., & Deyo, R. A. (1989). Generic and disease-specific measures in assessing health status and quality of life. *Medical Care*, *27*(3 Suppl), S217-32. https://doi.org/10.1097/00005650-198903001-00018

Ritter, O., & Bauer, W. R. (2006). Use of "IEGM Online" in ICD patients—. *Clinical Research in Cardiology*, *95*(7), 368–372. https://doi.org/10.1007/s00392-006-0390-y

Riva, S., Mazzocco, K., & Pravettoni, G. (2015). Better Outcomes for Cancer Patients Using Telemedicine: Health-Related Quality of Life (HrQoL) and Empowerment. In G. Gatti, G. Pravettoni, & F. Capello (Eds.), *Tele-Oncology* (pp. 23–37). Springer, Cham. https://doi.org/10.1007/978-3-319-16378-9_3

Rost, J., & von Davier, M. (1994). A Conditional Item-Fit Index for Rasch Models. *Applied Psychological Measurement*, *18*(2), 171–182. https://doi.org/10.1177/014662169401800206

Rothrock, N. E., Kaiser, K. A., & Cella, D. (2011). Developing a valid patient-reported outcome measure. *Clinical Pharmacology and Therapeutics*, *90*(5), 737–742. https://doi.org/10.1038/clpt.2011.195

Schmidt, S. (2007a). Telemedicine and quality of life. *Deutsche Medizinische Wochenschrift*, *132*(9), 442–447. https://doi.org/10.1055/s-2007-970355

Schmidt, S. (2007b). Telemedizin und Lebensqualität. *DMW - Deutsche Medizinische Wochenschrift*, *132*(09), 442–447. https://doi.org/10.1055/S-2007-970355

Tsang, S., Royse, C. F., & Terkawi, A. S. (2017). Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine. *Saudi Journal of Anaesthesia*, *11*(5), S80–S89. https://doi.org/10.4103/sja.SJA_203_17

van den Berg, N., Schmidt, S., Stentzel, U., Mühlan, H., & Hoffmann, W. (2015). Telemedizinische Versorgungskonzepte in der regionalen Versorgung ländlicher Gebiete. *Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz*, *58*(4–5), 367–373. https://doi.org/10.1007/s00103-015-2134-5

von Davier, M. (2001). *WINMIRA Users Manual. A program system for analyses with the Rasch Model, with Latent Class Analysis and with Mixed Rasch Model.*

Anlage A: Tele-QoL Fragebögen

TELE QoL

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 bürokratischen 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

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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 bürokratischen Aufwand für mich verbunden.	①	②	③	④
22.	Die Behandlungsmaßnahmen belasten mich.	①	②	③	④
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

TELEQ L

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		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.	Durch die Telemedizin fühle ich mich auch zu Hause gut versorgt.	①	②	③	④
10.	Durch die telemedizinische Behandlung fühle ich mich innerlich ruhiger.	①	②	③	④
11.	Dank der Telemedizin fühle ich mich im Umgang mit meiner Erkrankung sicherer.	①	②	③	④
12.	Die telemedizinische Erfassung meiner Gesundheitsdaten gibt mir ein Gefühl von Sicherheit.	①	②	③	④
13.	Ich fühle mich durch die telemedizinischen Maßnahmen im Alltag unterstützt.	①	②	③	④
14.	Ich kann durch die Telemedizin in meinem Alltag aktiver sein.	①	②	③	④
15.	Durch die telemedizinische Behandlung bin ich im Alltag unabhängiger.	①	②	③	④
16.	Durch die Telemedizin komme ich besser mit schwierigen Situationen zurecht.	①	②	③	④
17.	Meine persönlichen Bedürfnisse werden bei der telemedizinischen Behandlung berücksichtigt.	①	②	③	④
18.	Die telemedizinische Behandlung ist genau auf meine Bedürfnisse abgestimmt.	①	②	③	④
19.	Ich habe Vertrauen in meine telemedizinischen Behandlungsmaßnahmen.	①	②	③	④
20.	Ich kann mich auf meine telemedizinische Behandlung verlassen.	①	②	③	④

		Stimmt nicht	Stimmt kaum	Stimmt eher	Stimmt genau
21.	Ich habe die Möglichkeit, auch kurzfristig Auskunft zu meiner Behandlung zu bekommen.	①	②	③	④
22.	Ich fühle mich von meiner telemedizinischen Ansprechperson verstanden.	①	②	③	④
23.	Meine telemedizinische Ansprechperson und ich unterhalten uns auf Augenhöhe.	①	②	③	④
24.	Meine telemedizinische 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.	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
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10.	Durch die Behandlung fühle ich mich innerlich ruhiger.	①	②	③	④
11.	Dank der Behandlung fühle ich mich im Umgang mit meiner Erkrankung sicherer.	①	②	③	④
12.	Die medizinische Erfassung meiner Gesundheitsdaten gibt mir ein Gefühl von Sicherheit.	①	②	③	④
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TELEQ•L

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		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

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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
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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

TELE
Q L

MANUAL

MANUAL

VORWORT

Der *Tele-QoL* dient der Erfassung von versorgungsbezogenen Aspekten der Lebensqualität im Kontext telemedizinischer Anwendungen (*Version A*) oder der Standardversorgung (*Vergleichsversion B*).

Dieses Instrument wurde im Rahmen des „Tele-QoL“-Projektes, gefördert durch den Innovationsfonds des Gemeinsamen Bundesausschusses (01VSF16027), entwickelt. Die *Ziele* des Projektes waren die Prüfung einer potentiellen Erweiterung bestehender Lebensqualitätskonzepte und die darauf aufbauende Entwicklung, Pilotierung und Validierung eines Setting-sensitiven Instruments zur Erfassung von Lebensqualität im Kontext telemedizinischer Anwendungen.

In diesem Manual werden der Aufbau und die Anwendung des Tele-QoL beschrieben. Dafür werden zunächst das zugrundeliegende Verständnis des Konstruktes *Lebensqualität*, die Struktur sowie die Auswertung und Interpretation des modularen Tele-QoL Verfahrens vorgestellt. Es folgen die Ergebnisse der statistischen Analysen zu den psychometrischen Eigenschaften der Fragebögen.

INHALT

HINTERGRUND DES TELE-QOL

Die steigende Anzahl an chronisch physisch oder psychisch erkrankten Patient*innen als auch die sinkende Zahl an Hausärzt*innen in ländlichen Regionen erfordert flexible Konzepte der Gesundheitsversorgung, z.B. telemedizinischer Versorgungskonzepte.

Da besonders für Patient*innen mit chronischen Erkrankungen oft nicht die Heilung, sondern ein guter Umgang mit Symptomen und Einschränkungen und damit eine gute *Lebensqualität* trotz der Erkrankung(en) im Vordergrund der Behandlung steht, wird die Lebensqualität als patientenbezogenes Kriterium auch im Kontext telemedizinischer Versorgung als wichtiger Endpunkt für Therapien angesehen.

Existierende Verfahren zur Erfassung der Lebensqualität messen zwar gesundheitsbezogene Auswirkungen verschiedener Erkrankungen, berücksichtigen bisher aber kaum Aspekte der (telemedizinischen) Versorgungsangebote, die die Lebensqualität darüber hinaus beeinflussen.

Das übergeordnete Ziel des „Tele-QoL"-Projekts war es daher, diese Lücke durch die Entwicklung eines geeigneten Lebensqualitätsfragebogens zu schließen, um so die Setting-sensitive Evaluation von telemedizinischen Anwendungen zu ermöglichen.

Das modulare Tele-QoL Verfahren trägt damit dem Bedarf eines an patientenbezogenen Maßen orientierten Instruments zur Erfassung der Lebensqualität von Patient*innen mit chronisch physischen oder psychischen Erkrankungen im Rahmen telemedizinischer Anwendungen Rechnung.

DER BEGRIFF DER LEBENSQUALITÄT

Unter dem Konstrukt der *Lebensqualität* ist nach der Definition der Weltgesundheitsorganisation (WHO, 1997) die „subjektive Wahrnehmung einer Person über ihre Stellung im Leben in Relation zu Kultur und Wertesystemen […] und in Bezug auf ihre Ziele, Erwartungen, Maßstäbe und Anliegen" zu verstehen, welche durch die „körperliche Gesundheit […], den psychischen Zustand, die sozialen Beziehungen, die persönlichen Überzeugungen und ihre Stellung zu den […] Eigenschaften der Umwelt" (WHO, 1997, S. 1) bestimmt wird. Damit kann die Lebensqualität als multidimensionales Konstrukt verstanden werden, welches sich sowohl aus der subjektiven Bewertung physischer, psychischer sowie sozialer Aspekte zusammensetzt, als auch den kulturellen Rahmen, die Umwelt und das individuelle Wertesystem von Personen mit einbezieht. Die Lebensqualität ist somit sowohl ein Maß für die subjektive Bewertung der eigenen Gesundheit und des Wohlbefindens, als auch Abbild der allgemeinen Lebenssituation und der individuellen Einschätzung der Lebenszufriedenheit. Folglich stellt das Konstrukt als patientenberichtetes Outcome ein wichtiges Kriterium für die Umsetzung und Evaluation von gesundheitsbezogenen medizinischen Maßnahmen dar (Erhart, Wille & Ravens-Sieberer, 2006).

Da die Bewertung der individuellen Lebensqualität auf komplexen, nicht direkt beobachtbaren oder objektiven Prozessen beruht, bildet sie eine hochgradig subjektive Einschätzung ab, die sich nicht auf andere Menschen übertragen lässt. Es stehen eine Reihe von standardisierten Instrumenten zur Verfügung, die die generische oder krankheitsspezifische (gesundheitsbezogene) Lebensqualität von Patient*innengruppen im Selbstbericht erfassen (Freire Pequeno et al., 2020).

KONZEPTION DES TELE-QOL

Zunächst wurde *ein systematischer Literatur-review* durchgeführt (Greffin et al., in prep.) der die Passung von definierten Zielkriterien tele-medizinischer Anwendungen, den zur Evaluation ausgewählten patientenbezogenen Endpunkten und den dafür verwendeten Instrumenten (*PROM*) untersuchte. Die identifizierten Instrumente zur

Erfassung der Lebensqualität im Rahmen telemedizinischer Studien wurden zudem bzgl. der damit erfassten Domänen der Lebensqualität mit-einander verglichen. Dies ermöglichte die Erstellung eines *allgemeinen Arbeitsmodells der Lebensqualität* bestehend aus fünf etablierten Domänen (körperlich, psychologisch, sozial, funktionell, krankheits-bezogen). Im Anschluss erfolgte eine umfangreiche *qualitative Erhebung* zur Exploration des Konzepts der Lebensqualität im Kontext telemedizinischer Anwendungen. Durch semi-strukturierte Interviews und Fokusgruppen mit Patient*innen und Expert*innen aus dem Versorgungsspektrum Telemedizin wurden Erwartungen an, Erfahrungen mit und Bewertungen von telemedizinischen Anwendungen sowie wahrgenommene Auswirkungen von Telemedizin auf die Lebensqualität von Patient*innen diskutiert (Greffin et al., 2021). Die Ergebnisse deuten darauf hin, dass neben den Aspekten der bereits etablierten Domänen auch die Art der Versorgung einen Einfluss auf die Lebensqualität nimmt. Das Arbeitsmodell wurde daher um eine weitere Domäne ergänzt die solche versorgungsbezogene Aspekte abbildet, welche die Lebensqualität von Patient*innen mit chronisch physischen oder psychischen Erkrankungen positiv oder negativ beeinflussen (*versorgungsbezogene Domäne bzw. healthcare-related domain*). Sie besteht aus folgenden Facetten:

Bedürfnisorientierte Versorgung aus der Perspektive des Gesundheitswesens

Diese Facette umfasst versorgungsbezogene Aspekte, welche primär durch das Gesundheitswesen, zugrundeliegende ökonomische, politische und personelle Strukturen sowie bestimmt sind. Darunter zählen etwa die Verfügbarkeit medizinischer Ressourcen, die Anzahl und Art von Krankenhausaufenthalten bzw. Arztbesuche oder logistische Aspekte wie Anfahrtswege oder Wartezeiten. Diese Facette ist kein Bestandteil des im Anschluss entwickelten Tele-QoL Fragebogens, da sich die relevanten Aspekte nur schwer aus der Patient*innenperspektive einschätzen lassen.

Bedürfnisorientierte Versorgung aus der Perspektive der Patient*innen

Diese Facette umfasst versorgungsbezogene Aspekte, in die Patient*innen in stärkerem Maße involviert sind und zum Teil Einfluss nehmen z.B. durch aktive Mitgestaltung dieser oder der Wahrnehmung ihrer Auswirkungen. Hierzu zählen etwa eine ganzheitliche und alltagsbezogene Versorgung, die Arzt-Patienten-Beziehung oder das Gefühl, gesehen/gehört zu werden.

Information und Aktivierung

Unter diese Facette fallen etwa die versorgungsbezogene Selbstwirksamkeit, das Unterstützungsbedürfnis im krankheitsbezogenen (Selbst-)Management sowie das Empowerment von Patient*innen durch Information und Anleitung sowie das Bedürfnis nach Teilhabe.

Wahrgenommene Kontrolle und Sicherheit

Diese Facette umfasst die wahrgenommene Erleichterung durch objektive Informationen über den Erkrankungsverlauf, die Aspekte Vertrauen und Beziehung, Struktur und Stabilität sowie wahrgenommene Sicherheit.

KONSTRUKTION DES TELE-QOL

Die Konstruktion des Tele-QoL basiert auf aktuellen Empfehlungen zur Entwicklung von Patienten-berichteten Outcomes (Cheng & Clark, 2017). Die *Items* zu den verschiedenen Facetten der versorgungsbezogenen Domäne der Lebensqualität wurden auf Basis der qualitativen Interviews und Fokusgruppen abgeleitet. Im Anschluss erfolgten ein Expert*innenworkshop zur externen Validierung, ein Online-Expertensurvey zur Prüfung der Inhaltsvalidität, Relevanz, Vollständigkeit und zum geeigneten Umfang des Instruments (n=15), sowie eine Prätestung des initialen Instruments mit chronisch physisch oder psychisch erkrankten Personen (n=32).

Im Rahmen dieser *Prätestung (cognitive debriefings)* wurden 227 initial identifizierte Items zur Erfassung der versorgungsbezogenen Domäne mit der Methode des *Lauten Denkens* evaluiert. Die Proband*innen schätzten die Items hinsichtlich des Verständnisses, der Relevanz, der Formulierung, Genauigkeit, Schwierigkeit, Länge und Redundanz ein. Anschließend wurde der Studienabschnitt der *quantitativen Testung* in den Teilschritten der Pilottestung und der abschließenden Validierungstestung initiiert.

Im Zuge der *Pilottestung* (*n*=200) anhand der Zielpopulation von Patient*innen mit Depression oder Herzinsuffizienz mit bzw. ohne telemedizinischer Versorgung konnten faktorenanalytisch ein übergeordneter Faktor, sechs Teilfaktoren und ein Impact-Faktor identifiziert werden (siehe „Wie ist der Tele-QoL aufgebaut?"). Die anschließende *Validierungstestung* (*n*=200) diente der Reliabilitäts- und Validitätsüberprüfung sowie der finalen Itembearbeitung und Reduktion auf vier Items pro Faktor.

WAS ERFASST DER TELE-QOL?

Der Tele-QoL ist als ein Setting-sensitives „add-on-Instrument" zur Erfassung von versorgungsspezifischen Aspekten der Lebensqualität im Kontext telemedizinischer Anwendungen zu verstehen.

Bisher existierende Instrumente zur Erfassung der Lebensqualität (z.B. MOS 36-item Short Form Health Survey (SF-36)) sind meist in dem Maße standardisiert, dass relevante Aspekte der telemedizinischen Versorgung vernachlässigt werden (etwa Erhöhung der erlebten Sicherheit oder subjektive Kontrolle). Dies hat zur Folge, dass die Wirksamkeit telemedizinischer Anwendungen in Evaluationsstudien nicht vollumfassend evaluiert werden kann. Der *Tele-QoL* soll als ergänzendes Instrument die Wirksamkeit von Telemedizin/-monitoring aus Patient*-innenperspektive messbar zu machen.

Wie beschrieben erfasst der Tele-QoL eine das Arbeitsmodell der Lebensqualität ergänzende Domäne, die die Versorgung betreffende Einflüsse abbildet (*healthcare-related domain*). Die oben beschriebenen Facetten dieser neuen Domäne werden über sechs bis acht extrahierte Skalen erfasst:

- Information & Aufklärung
- Kontrolle & Selbstmonitoring
- Sicherheit & Wohlbefinden
- Entlastung & Unabhängigkeit
- Kooperation & Kommunikation
- Bedürfnisorientierung & Vertrauen
- Datenverarbeitung & Überwachung
- Belastung & Einschränkung

Da Lebensqualität in besonderer Weise subjektiven Bewertungsprozessen unterliegt, handelt es sich bei dem Tele-QoL um ein Patient*innen-berichtetes Instrument, d.h. Patient*innen stellen Ihre Antworten im Selbstbericht zur Verfügung.

WIE IST DER TELE-QOL AUFGEBAUT?

Die Langversion des Tele-QoL besteht aus 24 Items der Outcome-Skalen und 8 Items der Impact-Skalen, die Kurzversion des Tele-QoL umfasst ausschließlich die Outcome-Skalen. Diese 24 Items umfassen 6 Facetten eines *Kernmoduls*, welche zur Erfassung der intendierten Outcomes telemedizinischer Anwendungen eingesetzt werden können (siehe Abbildung 1). Acht weitere Items bilden ein *Zusatzmodul* bestehend aus den zwei Skalen

Abbildung 1

Struktur des modularen Tele-QoL Verfahrens

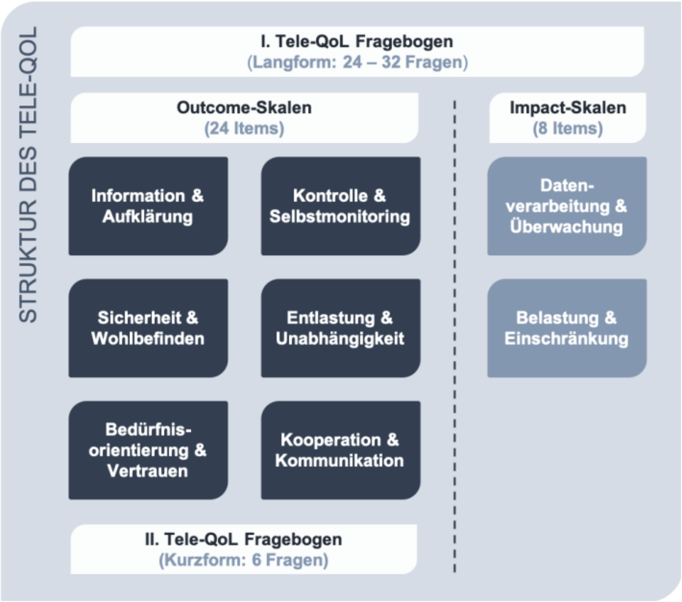

Tabelle 1

Item-Skalen-Zuordnungen des Tele-QoL

Skala	*Tele-QoL PRO-Instrument*	*Tele-QoL PRO-Index*
Information & Aufklärung	Item 01-04	„Ich bin über meine telemedizinische Behandlung informiert.“
Kontrolle & Selbstmonitoring	Item 05-08	„Ich weiß durch die telemedizinischen Kontrollen, wie es um meine Gesundheit steht.“
Datenverarbeitung & Überwachung	Item 09-12	-
Sicherheit & Wohlbefinden	Item 13-16	„Ich fühle mich durch die Telemedizin sicherer.“
Entlastung & Unabhängigkeit	Item 17-20	„Ich kann mein alltägliches Leben durch die Telemedizin freier gestalten.“
Belastung & Einschränkung	Item 21-24	-
Bedürfnisorientierung & Vertrauen	Item 25-28	„Ich empfinde meine telemedizinische Behandlung als genau auf mich abgestimmt.“

Belastung & Einschränkung sowie *Datenverarbeitung & Überwachung*. Das Zusatzmodul kann eingesetzt werden, wenn neben den intendierten Outcomes telemedizinischer Anwendungen auch negative Auswirkungen der Anwendungen evaluiert werden sollen. Es steht in der Langversion des Tele-QoL zur Verfügung,

Das *Tele-QoL PRO-Instrument* (Lang- und Kurzform) liegt als A- und B-Version vor. Version A beinhaltet alle Telemedizin-orientierten Items des Tele-QoL (*Tele-QoL PRO-Instrument*). Version B wurde als Vergleichsinstrument für Patient*innen mit chronisch physischen oder psychischen Erkrankungen konzipiert, die sich aktuell nicht in telemedizinischer Behandlung befinden.

Als ökonomische Alternative wurde der *Tele-QoL PRO-Index* extrahiert, welcher mithilfe von 6 Items die 6 Facetten des *Kernmoduls* (siehe Grafik 1, Tabelle 1) erfasst. Der Tele-QoL PRO-Index steht ebenfalls für die beiden Versorgungsgruppen „Telemedizin“ oder „Standardversorgung“ zur Verfügung.

WIE IST DER TELE-QOL ANZUWENDEN?

Zielgruppe des Tele-QoL sind Patient*innen ab 18 Jahren, welche telemedizinisch versorgt werden (Version A). Dabei ist unerheblich, ob sich die Proband*innen aufgrund physischer oder psychischer Erkrankungen in Behandlung befinden. Die Version B kann bei Patient*innen ohne telemedizinische Versorgung vergleichend oder im Vorfeld telemedizinischer Betreuung hinzugezogen werden.

Der Fragebogen beginnt mit einer kurzen Instruktion zu Zielstellung und Durchführung; es folgen die jeweiligen Items. Außerdem wird bei jedem Seitenbeginn erneut auf den temporalen Bezug von 4 Wochen verwiesen. Patient*innen schätzen anhand von 6 (index), 24 (Kurzform) oder 32 (Langform) Items ihre versorgungsbezogenen Erfahrungen der letzten 4 Wochen über eine 4-stufige Likertskala mit den Abstufungen 1=„Stimmt nicht“ bis 4=„Stimmt genau“ ein. Die Beantwortung erfolgt per Paper-Pencil-Verfahren und dauert etwa 20 Minuten (Tele-QoL PRO-Instrument) bzw. 5 Minuten (Tele-QoL PRO-Index).

AUSWERTUNG UND INTERPRETATION

Wie wird der Tele-QoL ausgewertet?

Zur Auswertung werden die Ziffern der angekreuzten Antworten jedes Items des Fragebogens pro Patient*in in eine Datentabelle übertragen (z.B. in Excel, SPSS). Zur Ermittlung der Skalenwerte wird jeweils der Mittelwert aller Items berechnet, die jeweils zu einer Skala gehören. Für den Tele-QoL können auf diese Weise die Werte für insgesamt 8 Subskalen mit jeweils 4 Items ermittelt werden. Davon werden 6 Subskalen als sog. „Outcome"-Skalen bezeichnet, die anderen 2 Subskalen als sog. „Impact"-Skalen. Neben diesen 8 Subskalen ist auch die Berechnung eines Tele-QoL-Gesamtwertes möglich, der die 24 Items der 6 „Outcome"-Skalen umfasst sowie die Berechnung eines Tele-QoL-Indexwertes, der die 6 Items des Tele-QoL-Index umfasst (vgl. „Wie ist der Tele-QoL aufgebaut?").

Hinweis. Uneindeutig beantwortete Items (z.B. mehrere Kreuze oder zwischen Antwortstufen gekreuzt) werden als „fehlend" gewertet. Bei Vorliegen von jeweils bis maximal 25% fehlender Werte ist der Mittelwert der anderen Items hinreichend für die Berechnung des Skalenwerts (bei allen Subskalen und dem Index also maximal 1 Item, für die Gesamtskala maximal 6 Items). Bei mehr als 25% fehlender Werte sollten keine Skalenwerte berechnet werden (siehe Anhang „SPSS Auswertungssyntax").

Wie interpretiere ich die Werte des Tele-QoL?

Ein Einsatz des Tele-QoL eignet sich vor allem **bei vergleichenden Studienansätzen**, hier lassen sich sowohl Gruppenunterschiede als auch Veränderungen über die Zeit als Differenzen zwischen den jeweiligen Werten zur Interpretation von Unterschieden in der Lebensqualität heranziehen. Es liegen keine Normwerte für die Tele-QoL-Instrumente vor. Referenzwerte aus bisherigen Studien können bei Bedarf bei den Autor*innen angefragt werden.

- Interpretation von Outcome-Skalen, Gesamt-Wert und Index-Score: Höhere Werte weisen auf eine positivere Auswirkung der (telemedizinischen) Versorgung auf die Lebensqualität von Patient*innen hin.
- Interpretation der Impact-Skalen: Höhere Score-Werte weisen auf einen negativeren Einfluss der (telemedizinischen) Versorgung auf die Patient*innen hin.

PSYCHOMETRISCHE ANALYSEN

REKRUTIERUNG

Für die Validierungsstudie (Greffin et al., 2021) wurden Patient*innen mit chronischer Herzinsuffizienz oder Depression (n = 200) jeweils mit oder ohne telemedizinische Versorgung rekrutiert. Neben den o.g. Erkrankungen war das Mindestalter von 18 Jahren ein Einschlusskriterium, kognitive Beeinträchtigungen sowie schwere kognitive Komorbiditäten galten als Ausschlussgrund (Greffin et al., 2020).

Die Behandler*innen bzw. Study Nurses in den Rekrutierungszentren klärten Interessierte persönlich oder telefonisch über Ablauf, Freiwilligkeit, Abbruchmöglichkeiten, Aufwandsentschädigung sowie den Studienzweck auf. Zusätzlich erhielten die Patient*innen diese Informationen in schriftlicher Form. Im Zuge der Instruktionen wurden zur anonymen Zuordnung der nach vier Wochen erfolgten Follow-Up-Erhebung persönliche Codes generiert. Außerdem waren für etwaige Fragen auch telefonische und E-Mail-Kontaktdaten angegeben. Eine persönliche Hilfestellung während der Bearbeitung war ebenfalls möglich. Vollständige ausgefüllte Fragebögen wurden in einem vorfrankierten und adressierten Umschlag versendet oder abgegeben (Greffin et al., 2020).

VALIDIERUNGSSTICHPROBE

An der Validierungsstudie nahmen *n*=200 Patient*innen im Alter von 19 bis 88 Jahren teil (*M*=58.3, *SD*=17.1; *n*=193). Von diesen gaben 51.5% (*n*=103) an, männlich, 48.0% (*n*=96) weiblich bzw. 0.5% (*n*=1) divers zu sein. 45.5% (*n*=91) der Patient*innen waren aufgrund von chronischer Herzinsuffizienz in Behandlung, chronische Depressionen hatten 45.0% (*n*=90) der Befragten, 9.5% (*n*=19) gaben keine oder keine eindeutige Diagnose an. Die Hälfte aller Patient*innen (50.0%, *n*=100) erhielten aufgrund dieser Diagnose telemedizinische Betreuung, 46.0% (*n*=92) hingegen nicht. Bei 4.0% (*n*=8) lag keine entsprechende Angabe vor.

Von den Patient*innen mit chronischer Herzinsuffizienz wurden 53.4% (*n*=47) tele-medizinisch betreut, 46.6% (*n*=41) nicht. Unter den Patient*innen mit chronischen Depressionen erhielten 53.9% (*n*=48) telemedizinische Betreuung und 46.1% (*n*=41) nicht. Bei 11.5% (*n*=23) fehlte mindestens eine dieser beiden Angaben.

RELIABILITÄT

Interne Konsistenz

Zur Bestimmung der internen Konsistenz wurde der Koeffizient Cronbach's Alpha (**α**) für alle Subskalen und den Gesamtscore sowie den Indexwert berechnet. Für den Tele-QoL-PRO-Index ergab sich ein Wert von **α**=.90 und für die Tele-QoL-PRO-Gesamtskala von **α**=.95. Die internen Konsistenzen für die Subskalen variieren zwischen .83 und .90. Damit sind die internen Konsistenzen für alle Skalen der Tele-QoL-Verfahren als sehr gut einzuschätzen. Die Werte sind auch der Tabelle 2 zu entnehmen.

Tabelle 2

Interne Konsistenzen für Gesamtskala und Subskalen des Tele-QoL-PRO-Instruments sowie den Tele-QoL-PRO-Index

Skala	Interne Konsistenz (α)
Information & Aufklärung	.90
Kontrolle & Selbstmonitoring	.84
Datenverarbeitung & Überwachung	.89
Sicherheit & Wohlbefinden	.86
Entlastung & Unabhängigkeit	.90
Belastung & Einschränkung	.85
Kooperation & Kommunikation	.83
Bedürfnisorientierung & Vertrauen	.92
Tele-QoL Gesamtskala	**.95**
Tele-QoL Index	**.90**

Split-Half-Reliabilität

Auch für die Testhalbierungsreliabilität erga-ben sich für alle Skalen der Tele-QoL-Verfahren sehr gut Werte, die zwischen **α**=.82 und **α**=..92 variieren (vgl. Tab. 3).

Tabelle 3

Testhalbierungs-Reliabilitäten für Gesamtskala und Subskalen des Tele-QoL-PRO-Instruments sowie für den Tele-QoL-PRO-Index

Skala	Retest-Reliabilität
Information & Aufklärung	.89
Kontrolle & Selbstmonitoring	.82
Datenverarbeitung & Überwachung	.88
Sicherheit & Wohlbefinden	.83
Entlastung & Unabhängigkeit	.92
Belastung & Einschränkung	.83
Kooperation & Kommunikation	.86
Bedürfnisorientierung & Vertrauen	.87
Tele-QoL Gesamtskala	**.86**
Tele-QoL Index	**.84**

Retestreliabilität

Die Retestreliabilität wurde über einen Messzeitraum von ca. 4 Wochen unter Kontrolle des Krankheitsverlaufs ermittelt. Die entsprechenden Werte variieren zwischen .60 und .78 und sind somit akzeptabel bis gut. Die genauen Werte für die jeweils einzelnen Skalen der Tele-QoL-Verfahren sind in Tabelle 4 zu finden.

Tabelle 4

Retest-Reliabilitäten für Gesamtskala und Subskalen des Tele-QoL-PRO-Instruments
sowie für den Tele-QoL-PRO-Index

Skala	Retest-Reliabilität
Information & Aufklärung	.77
Kontrolle & Selbstmonitoring	.72
Datenverarbeitung & Überwachung	.62
Sicherheit & Wohlbefinden	.74
Entlastung & Unabhängigkeit	.75
Belastung & Einschränkung	.66
Kooperation & Kommunikation	.61
Bedürfnisorientierung & Vertrauen	.60
Tele-QoL Gesamtskala	**.78**
Tele-QoL Index	**.65**

Rasch-Analyse

Eine ergänzende Rasch-Analyse (Partial Credit Model) mit Schwerpunkt auf den operationalen Merkmalen der Items zeigte, dass keines der Items in einer der Tele-QoL-Subskalen oder dem Tele-QoL-Index einen Infit aufweist, was auf keine wesentliche Abweichung vom Modell hinweist. Die Anordnung der Schwellenwerte stimmt mit den Modellannahmen für alle Items in allen Subskalen und auch für den Index überein. Die Spannweite der Item-Positionen ist für die Mehrheit der Skalen klein (<2 Logits), die effektive Spannweite, die von den Schwellenwertverteilungen abgebildet wird, variiert jedoch zwischen >4 und <11 Logits und repräsentiert somit einen relativen breiten Ausschnitt der latenten Merkmalsverteilung.

VALIDITÄT

Konstruktvalidität

Die sechs „Outcome"-Subskalen des multidimensionalen Tele-QoL-Verfahrens korrelieren untereinander moderat bis (sehr) hoch miteinander (*r*=.39-.81), die beiden „Impact"-Subskalen mit .44. Die durchschnittlich hohen *Interkorrelationen* der Outcome-Subskalen lassen auch auf die mögliche Existenz eines gemeinsamen latenten Faktors höherer Ordnung schließen.

Die faktorielle Validität wurde mit Hilfe einer *konfirmatorischen Faktorenanalyse* untersucht. Die Ergebnisse der Fitstatistik zeigen, dass das angenommene Modell gut durch die empirischen Daten bestätigt werden konnte ($\chi^2(df=436)=696.53$, $p < 0.001$, CFI=.94, TLI=0.93, RMSEA=0.056 [0.048; 0.064]).

Konvergente/divergente Validität

Die Gesamtscores beider Verfahren korrelieren sehr hoch miteinander (*r*=.89), ebenso die Outcome-Subskalen des multidimensionalen Instruments mit dem Indexwert (*r*=.59-.83). Daraus ergibt sich zum einen eine *hohe konvergente Validität* beider Verfahren, zum anderen lässt sich daraus schließen, dass der Kurzindex des Tele-QoL die primären Inhalte der Langform sehr gut auch in der Breite repräsentiert und der Index-wert einen geeignete Alternative für die Abbildung des Gesamtscores darstellt, die jedoch keine multidimensionale Profildarstellung erlaubt (vgl. Tab. 5).

Tabelle 5

Interkorrelationen für Gesamtskala und Subskalen des Tele-QoL-PRO-Instruments mit dem Tele-QoL-PRO-Index

Skala	Tele-QoL-Index
Information & Aufklärung	.59
Kontrolle & Selbstmonitoring	63
Datenverarbeitung & Überwachung	-.12
Sicherheit & Wohlbefinden	.76
Entlastung & Unabhängigkeit	.73
Belastung & Einschränkung	-.17
Kooperation & Kommunikation	.74
Bedürfnisorientierung & Vertrauen	.83
Tele-QoL Gesamtskala	**.89**

Alle sechs „Outcome-"Subskalen des Tele-QoL-Instruments sowie der Gesamtscore und der Indexwert korrelieren hoch mit drei der vier Subskalen des SECU-Instruments zur Erfassung des Sicherheitserlebens in der Telemedizin (*r*=.36-.89). Daraus lässt sich auf eine *konvergente Validität* der Verfahren schließen.

Dagegen verweisen vergleichbar niedrige bis moderate Korrelationen mit unterschiedlichen Indices der allgemeinen, gesundheitsbezogenen und krankheitsspezifischen Lebensqualität (WHOQOL-BREF, VR-12, MLHFI, WHO-5) auf eine hinreichende *divergente Validität* der der Tele-QoL-Instrumente, da diese somit andere Aspekte der Lebensqualität erfassen als bisherige Instrumente zu bereist etablierten Konzepten der Lebensqualität.

Aus den hohen Korrelationen mit der *Versorgungszufriedenheit* ergeben sich sowohl Hinweise auf die konvergente als auch divergente Validität der Tele-QoL-Verfahren. Einerseits bestätigt dies so den Zusammenhang mit dem Versorgungskontext i.S. der konvergenten Validität, andererseits aber auch, dass die Konzepte versorgungsbezogene Lebensqualität und Versorgungszufriedenheit nicht identisch und damit i.S. der divergenten Validität der Tele-QoL-Verfahren hinreichend abgrenzbar voneinander sind.

„Known-Groups“-Validität

Hinweise zur diskriminanten Validität der Tele-QoL-Verfahren ergeben sich z.B. durch statistisch signifikante Differenzen im Gesamtscore und Indexwert bei Gruppen mit unterschiedlicher Schwere der Erkrankungen (Patient*innen mit chronischer Herzinsuffizienz oder Depressionen), mit jeweils kleinen bis zu moderaten Effektstärken.

LITERATUR

1. Cheng, K.K.F.; Clark, A.M. Qualitative Methods and Patient-Reported Outcomes: Measures Development and Adaptation. *Int. J. Qual. Methods* 2017, *16*, 1–3, doi:10.1177/1609406917702983
2. Erhart, M.; Wille, N.; Ravens-Sieberer, U. Die Messung Der Subjektiven Gesundheit: Stand Der Forschung Und Herausforderungen. *Gesundheitliche Ungleichheit* 2009, 335–352, doi:10.1007/978-3-531-91643-9_19.
3. Greffin, K.; Schmidt, S.; van den Berg, N.; Hoffmann, W.; Ritter, O.; Oeff, M.; Schomerus, G.; Muehlan, H. Telemedicine and Patient-Reported Outcomes: Concordance and Discrepancy of Purpose, Constructs and Methods of Measurement - a Systematic Literature Review (in preparation).
4. Greffin, K.; Schmidt, S.; Berg, N. Van Den; Hoffmann, W.; Ritter, O.; Oeff, M.; Schomerus, G.; Muehlan, H. 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 Qual. Life Outcomes* 2021, 1–14, doi:10.1186/s12955-021-01807-8.
5. Pequeno, N.P.F.; Pequeno, N.P.F.; Cabral, N.L. de A.; Marchioni, D.M.; Lima, S.C.V.C.; Lyra, C. de O. Quality of Life Assessment Instruments for Adults: A Systematic Review of Population-Based Studies. *Health Qual. Life Outcomes* 2020, *18*, 1–13, doi:10.1186/s12955-020-01347-7.
6. World Health Organization. Division of Mental Health and Prevention of Substance Abuse (1997). WHOQOL: Measuring Quality of Life. World Health Organization. https://apps.who.int/iris/handle/10665/63482

TELE-QOL PROJEKTGRUPPE

Universität Greifswald
Institut für Psychologie
Lehrstuhl Gesundheit und Prävention
Robert-Blum-Straße 13
17493 Greifswald
E-Mail: Tele-QoL@uni-greifswald.de

TELE
Q📶L

KURZBESCHREIBUNG FÜR DIE PRAXIS

WAS MISST DER TELE-QOL?

Der Tele-QoL ist ein Setting-sensitives **„add-on-Instrument“ zur Erfassung versorgungsspezifischer Aspekte der Lebensqualität (LQ) im Kontext telemedizinischer Anwendungen**. Dieses Instrument kann ergänzend zu generischen, gesundheitsbezogenen und/oder krankheitsspezifischen LQ-Instrumenten verwendet werden.

FÜR WELCHE ZIELGRUPPE WURDE DER TELE-QOL ENTWICKELT?

Der Tele-QoL dient der Erhebung der Lebensqualität bei Patent*innen **ab 18 Jahren mit chronisch physischen oder psychischen Erkrankungen**, die sich in telemedizinischer oder Standardversorgung befinden. Als Ausschlusskriterium für die Anwendung des Fragebogens werden mittelschwere bis schwere Beeinträchtigungen kognitiver Funktionen (z.B. komorbide neurologische Erkrankungen) definiert.

WIE IST DER TELE-QOL AUFGEBAUT?

Die Struktur des Tele-QoL ergibt sich aus sechs Facetten im *Kernmodul* und zwei Facetten im *Zusatzmodul*:

AUFBAU DES TELE-QOL-FRAGEBOGENS

Information & Aufklärung	*Beispielitem:* *(4 Items)*	Ich bin über die Grenzen meiner telemedizinischen Behandlung informiert.	**Outcome-Skalen** (24 Items)
Kontrolle & Selbstmonitoring	*Beispielitem:* *(4 Items)*	Durch die Telemedizin weiß ich, wie ich meine Beschwerden deuten kann.	
Sicherheit & Wohlbefinden	*Beispielitem:* *(4 Items)*	Durch die telemedizinische Behandlung fühle ich mich innerlich ruhiger.	
Entlastung & Unabhängigkeit	*Beispielitem:* *(4 Items)*	Ich kann durch die Telemedizin in meinem Alltag aktiver sein.	
Bedürfnisorientierung & Vertrauen	*Beispielitem:* *(4 Items)*	Ich werde durch die telemedizinischen Maßnahmen stets im Umgang mit meiner Erkrankung begleitet.	
Kooperation & Kommunikation	*Beispielitem:* *(4 Items)*	Ich fühle mich von meiner telemedizinischen Ansprechperson verstanden.	
Datenverarbeitung & Überwachung	*Beispielitem:* *(4 Items)*	Ich mache mir Sorgen, dass meine Gesundheitsdaten missbraucht werden könnten.	**Impact-Skalen** (8 Items)
Belastung & Einschränkung	*Beispielitem:* *(4 Items)*	Meine telemedizinische Behandlung schränkt mich im Alltag ein.	

Tabelle 1.

Zuordnung der Items zu den Skalen und der Lang- bzw. Indexform

Skala	***Tele-QoL PRO-Instrument (lang)***	***Tele-QoL PRO-Index***
Information & Aufklärung	Item 01-04	„Ich bin über meine telemedizinische Behandlung informiert.“
Kontrolle & Selbstmonitoring	Item 05-08	„Ich weiß durch die telemedizinischen Kontrollen, wie es um meine Gesundheit steht.“
Datenverarbeitung & Überwachung	Item 09-12	-
Sicherheit & Wohlbefinden	Item 13-16	„Ich fühle mich durch die Telemedizin sicherer.“
Entlastung & Unabhängigkeit	Item 17-20	„Ich kann mein alltägliches Leben durch die Telemedizin freier gestalten.“
Belastung & Einschränkung	Item 21-24	-
Bedürfnisorientierung & Vertrauen	Item 25-28	„Ich empfinde meine telemedizinische Behandlung als genau auf mich abgestimmt.“
Kooperation & Kommunikation	Item 29-32	„Ich werde durch die telemedizinischen Maßnahmen stets im Umgang mit meiner Erkrankung begleitet.“

Welche Versionen des Tele-QoL sind verfügbar?

Der Tele-QoL liegt in **zwei Versionen für unterschiedliche Versorgungssettings** vor: Als *A-Version* (Anwendung im Kontext der Telemedizin) und als *B-Version* (Vergleichsinstrument für die Anwendung im Kontext der Standardversorgung). Für beide Versionen liegen jeweils eine multidimensionale **Langform** (Outcome- und Impact-Skalen), eine **Kurzform** (Outcome-Skalen) sowie eine kurze Indexform in deutscher Sprache vor (vgl. Tabelle 1).

Wie wird der Tele-QoL angewendet?

Der Tele-QoL ist ein Fragebogen zur **Selbstbeurteilung**, bei dem die Patient*innen gebeten werden, ihre behandlungsbezogenen Erfahrungen der letzten vier Wochen anhand einer vierstufigen Likertskala einzuschätzen. Die Beantwortung erfolgt per Paper-Pencil-Verfahren und dauert etwa 20 Minuten (Tele-QoL PRO-Instrument) bzw. 5 Minuten (Tele-QoL PRO-Index). Prinzipiell ist auch der Einsatz über das elektronische Erhebungsformat (ePRO) möglich, jedoch liegen bisher noch keine Studienerfahrungen damit vor.

Wie wird der Tele-QoL ausgewertet?

Zur Auswertung werden die Ziffern der angekreuzten Antworten jedes Items des Fragebogens pro Patient*in in eine Datentabelle übertragen (z.B. in Excel, SPSS). Zur Ermittlung der Skalenwerte wird jeweils der Mittelwert aller Items berechnet, die jeweils zu einer Skala gehören. Für den Tele-QoL können auf diese Weise die Werte für insgesamt 8 Subskalen mit jeweils 4 Items ermittelt werden. Davon werden 6 Subskalen als sog. „Outcome"-Skalen bezeichnet, die anderen 2 Subskalen als sog. „Impact"-Skalen. Neben diesen 8 Subskalen ist auch die Berechnung eines Tele-QoL-Gesamtwertes möglich, der die 24 Items der 6 „Outcome"-Skalen umfasst sowie die Berechnung eines Tele-QoL-Indexwertes, der die 6 Items des Tele-QoL-Index umfasst (vgl. „Wie ist der Tele-QoL aufgebaut?").

Hinweis. Uneindeutig beantwortete Items (z.B. mehrere Kreuze oder zwischen Antwortstufen gekreuzt) werden als „fehlend" gewertet. Bei Vorliegen von jeweils bis maximal 25% fehlender Werte ist der Mittelwert der anderen Items hinreichend für die Berechnung des Skalenwerts (bei allen Subskalen und dem Index also maximal 1 Item, für die Gesamtskala maximal 6 Items). Bei mehr als 25% fehlender Werte sollten keine Skalenwerte berechnet werden (siehe Anhang „SPSS Auswertungssyntax").

Wie interpretiere ich die Werte des Tele-QoL?

Ein Einsatz des Tele-QoL eignet sich vor allem **bei vergleichenden Studienansätzen**, hier lassen sich sowohl Gruppenunterschiede als auch Veränderungen über die Zeit als Differenzen zwischen den jeweiligen Werten zur Interpretation von Unterschieden in der Lebensqualität heranziehen. Es liegen keine Normwerte für die Tele-QoL-Instrumente vor. Referenzwerte aus bisherigen Studien können bei Bedarf bei den Autor*innen angefragt werden.

Interpretation von Outcome-Skalen, Gesamt-Wert und Index-Score: Höhere Werte weisen auf eine positivere Auswirkung der (telemedizinischen) Versorgung auf die Lebensqualität von Patient*innen hin.

Interpretation der Impact-Skalen: Höhere Score-Werte weisen auf einen negativeren Einfluss der (telemedizinischen) Versorgung auf die Patient*innen hin.

WO FINDE ICH AUSFÜHRLICHE INFORMATIONEN ZUM TELE-QOL?

Weitere Informationen finden Sie auf https://teleqol.psychologie.uni-greifswald.de/ Dort stehen Ihnen in einem Downloadbereich alle Versionen des Tele-QoL sowie ein ausführliches Manual zur Verfügung.

Zur Homepage des Tele-QoL gelangen Sie zudem über diesen QR-Code:

TELE QOL

SPSS-SYNTAX FÜR DAS MODULARE TELE-QOL VERFAHREN

TELE-QOL & INDEX

```
*** (Version 1.0: 07.11.2021) ***
* Die 32 Tele-QoL Items werden den folgenden 8 Subskalen zugeordnet, 6 Outcome Subskalen und 2 Impact Subskalen.
* Die 24 Items der 6 Outcome Subskalen können auch in einem Gesamtwert zusammengefasst werden.
* Die 6 Items des Tele-QoL Index werden zu einem Indexwert zusammengefasst.
* Für alle Skalenwerte (8 Subskalen, 1 Gesamtwert, 1 Indexwert) werden jeweils der Mittelwert und der linear transformierte Mittelwert berechnet.
```

*TELE-QOL-OUTCOME-SKALEN (6 SUBSKALEN MIT JEWEILS 4 ITEMS) *

*** Subskala 1 "INFORMATION & AUFKLÄRUNG" - Mittelwert (Range: 1-4) & Linear transformierter Mittelwert (Range: 0-100).**

```
COMPUTE TQ_IA_m=mean.3(TQ_01, TQ_02, TQ_03, TQ_04).
VARIABLE LABELS TQ_IA_m 'Tele-Qol - Information & Aufklärung (Mittelwert 1-4)'.
COMPUTE TQ_IA_t=(100/3)*((mean.3(TQ_01, TQ_02, TQ_03, TQ_04))-1).
VARIABLE LABELS TQ_IA_t 'Tele-Qol - Information & Aufklärung (Linear transformierter Mittelwert 0-100)'.
EXECUTE.
```

*** Subskala 2 "KONTROLLE & SELBSTMONITORING" - Mittelwert (Range: 1-4) & Linear transformierter Mittelwert (Range: 0-100).**

```
COMPUTE TQ_KS_m=mean.3(TQ_05, TQ_06, TQ_07, TQ_08).
VARIABLE LABELS TQ_KS_m 'Tele-Qol - Kontrolle & Selbstmonitoring (Mittelwert 1-4)'.
COMPUTE TQ_KS_t=(100/3)*((mean.3(TQ_05, TQ_06, TQ_07, TQ_08))-1).
VARIABLE LABELS TQ_KS_t 'Tele-Qol - Kontrolle & Selbstmonitoring (Linear transformierter Mittelwert 0-100)'.
EXECUTE.
```

*** Subskala 3 "SICHERHEIT & WOHLBEFINDEN" - Mittelwert (Range: 1-4) & Linear transformierter Mittelwert (Range: 0-100).**

```
COMPUTE TQ_SW_m=mean.3(TQ_13, TQ_14, TQ_15, TQ_16).
VARIABLE LABELS TQ_SW_m 'Tele-Qol - Sicherheit & Wohlbefinden (Mittelwert 1-4)'.
COMPUTE TQ_SW_t=(100/3)*((mean.3(TQ_13, TQ_14, TQ_15, TQ_16))-1).
VARIABLE LABELS TQ_SW_t 'Tele-Qol - Sicherheit & Wohlbefinden (Linear transformierter Mittelwert 0-100)'.
EXECUTE.
```

*** Subskala 4 "ENTLASTUNG & UNABHÄNGIGKEIT" - Mittelwert (Range: 1-4) & Linear transformierter Mittelwert (Range: 0-100).**

```
COMPUTE TQ_EU_m=mean.3(TQ_17, TQ_18, TQ_19, TQ_20).
VARIABLE LABELS TQ_EU_m 'Tele-Qol - Entlastung & Unabhängigkeit (Mittelwert 1-4)'.
COMPUTE TQ_EU_t=(100/3)*((mean.3(TQ_17, TQ_18, TQ_19, TQ_20))-1).
VARIABLE LABELS TQ_EU_t 'Tele-Qol - Entlastung & Unabhängigkeit (Linear transformierter Mittelwert 0-100)'.
EXECUTE.
```

*** Subskala 5 "BEDÜRFNISORIENTIERUNG & VERTRAUEN".- Mittelwert (Range: 1-4) & Linear transformierter Mittelwert (Range: 0-100).**

```
COMPUTE TQ_BV_m=mean.3(TQ_25, TQ_26, TQ_27, TQ_28).
VARIABLE LABELS TQ_BV_m 'Tele-Qol - Bedürfnisorientierung & Vertrauen (Mittelwert 1-4)'.
COMPUTE TQ_BV_t=(100/3)*((mean.3(TQ_25, TQ_26, TQ_27, TQ_28))-1).
VARIABLE LABELS TQ_BV_t 'Tele-Qol - Bedürfnisorientierung & Vertrauen (Mittelwert 1-4)'.
EXECUTE.
```

*** Subskala 6 "KOOPERATION & KOMMUNIKATION" - Mittelwert (Range: 1-4) & Linear transformierter Mittelwert (Range: 0-100).**

```
COMPUTE TQ_KK_m=mean.3(TQ_29, TQ_30, TQ_31, TQ_32).
VARIABLE LABELS TQ_KK_m 'Tele-Qol - Kooperation & Kommunikation (Mittelwert 1-4)'.
COMPUTE TQ_KK_t=(100/3)*((mean.3(TQ_29, TQ_30, TQ_31, TQ_32))-1).
VARIABLE LABELS TQ_KK_t 'Tele-Qol - Kooperation & Kommunikation (Linear transformierter Mittelwert 0-100)'.
EXECUTE.
```

* TELE-QOL-Impact-Skalen (2 Subskalen mit jeweils 4 Items) *

```
* Subskala 7 "DATENVERARBEITUNG & ÜBERWACHUNG" - Mittelwert (Range: 1-4) & Linear transformierter Mittelwert (Range: 0-100).
COMPUTE TQ_DÜ_m=mean.3(TQ_09, TQ_10, TQ_11, TQ_12).
VARIABLE LABELS TQ_DÜ_m 'Tele-Qol - Datenverarbeitung & Überwachung (Mittelwert 1-4)'.
COMPUTE TQ_DÜ_t=(100/3)*((mean.3(TQ_09, TQ_10, TQ_11, TQ_12))-1).
VARIABLE LABELS TQ_DÜ_t 'Tele-Qol - Datenverarbeitung & Überwachung (Linear transformierter Mittelwert 0-100)'.
EXECUTE.

* Subskala 8 "BELASTUNG & EINSCHRÄNKUNG" - Mittelwert (Range: 1-4) & Linear transformierter Mittelwert (Range: 0-100).
COMPUTE TQ_BE_m=mean.3(TQ_21, TQ_22, TQ_23, TQ_24).
VARIABLE LABELS TQ_BE_m 'Tele-Qol - Belastung & Einschränkung (Mittelwert 1-4)'.
COMPUTE TQ_BE_t=(100/3)*((mean.3(TQ_21, TQ_22, TQ_23, TQ_24))-1).
VARIABLE LABELS TQ_BE_t 'Tele-Qol - Belastung & Einschränkung (Linear transformierter Mittelwert 0-100)'.
EXECUTE.
```

* TELE-QOL-Gesamtwert (aller 6 Outcome-Skalen, insgesamt 24 Items).

```
* Gesamtskala "TELE-QOL TOTAL".- Mittelwert (Range: 1-4) & Linear transformierter Mittelwert (Range: 0-100).
COMPUTE TQ_GW_m=mean.18(TQ_01, TQ_02, TQ_03, TQ_04, TQ_05, TQ_06, TQ_07, TQ_08, TQ_13, TQ_14, TQ_15, TQ_16, TQ_17, TQ_18, TQ_19, TQ_20, TQ_25, TQ_26, TQ_27, TQ_28, TQ_29, TQ_30, TQ_31, TQ_32).
VARIABLE LABELS TQ_GW_m 'Tele-Qol - Gesamtwert (Mittelwert 1-4)'.
COMPUTE TQ_GW_t=(100/3)*((mean.18(TQ_01, TQ_02, TQ_03, TQ_04, TQ_05, TQ_06, TQ_07, TQ_08, TQ_13, TQ_14, TQ_15, TQ_16, TQ_17, TQ_18, TQ_19, TQ_20, TQ_25, TQ_26, TQ_27, TQ_28, TQ_29, TQ_30, TQ_31, TQ_32))-1).
VARIABLE LABELS TQ_GW_t 'Tele-Qol - Gesamtwert (Linear transformierter Mittelwert 0-100)'.
EXECUTE.
```

* TELE-QOL-Index-Wert (6 Items).

```
* Index "TELE-QOL INDEX" - Mittelwert (Range: 1-6) & Linear transformierter Mittelwert (Range: 0-100).
COMPUTE TQI_IW_m=mean.5(TQI_01, TQI_02, TQI_03, TQI_04, TQI_05, TQI_06).
VARIABLE LABELS TQI_IW_m 'Tele-Qol Index - Indexwert (Mittelwert 1-6)'.
COMPUTE TQI_IW_t=(100/5)*((mean.5(TQI_01, TQI_02, TQI_03, TQI_04, TQI_05, TQI_06))-1).
VARIABLE LABELS TQI_IW_t 'Tele-Qol Index - Indexwert (Linear transformierter Mittelwert 0-100)'.
EXECUTE.



EXECUTE.



**** (Prüfung: 07.11.2021) ***
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