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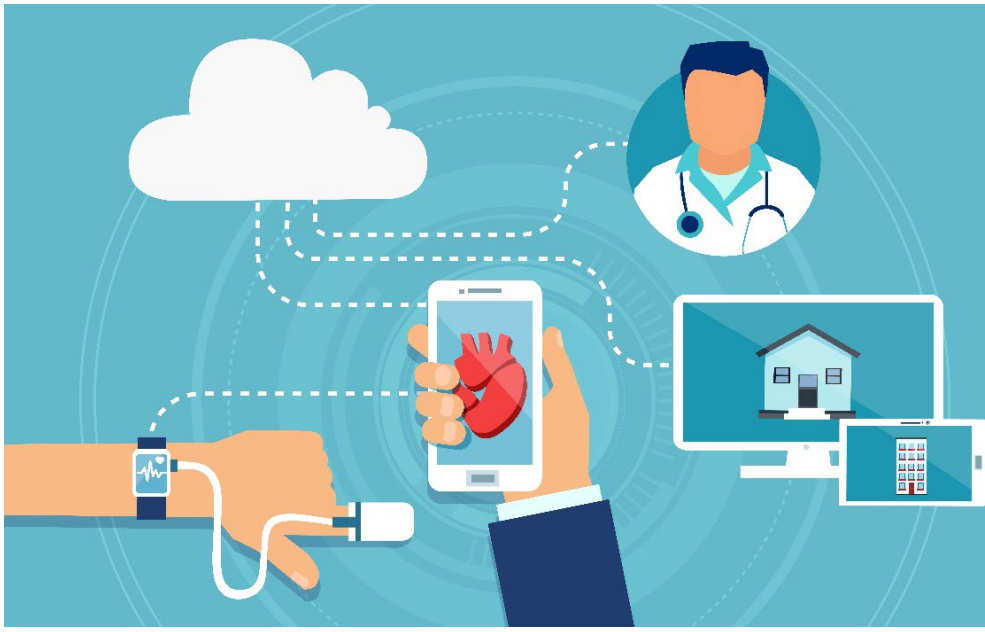
Telecardiology for heart failure patients: Benefit assessment and evaluation concept for telemedicine-supported care programs in Austria

Systematic Review



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Vienna, October 2025

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Content

List of figures

List of tables

List of abbreviations

AdHF .....advanced heart failure
AHF.....acute heart failure
ASSESS-DHT.....assess digital health technology
CG .....control group
BNP.....brain natriuretic peptide
CVD .....cardiovascular disease
CI.....confidence interval
DHT.....digital health technology
DiGA.....Digitale Gesundheitsanwendung
DMP.....disease management program
DMS .....data management system
ED .....emergency department
EUnetHTA .....European Network for Health Technology Assessment
ESC .....European Society for Cardiology
G-BA.....Gemeinsamer Bundesausschuss
GP.....general practitioner
GRADE.....Grading of Recommendations Assessment, Development and Evaluation
HDS-R .....HDS-R – Hasegawa's Dementia Scale Revised
HF .....heart failure
HRQoL .....health-related quality of life
ICD .....International Classification of Diseases
IG.....intervention group
IQWiG.....Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
INAHTA .....International Network of Agencies for Health Technology Assessment
LOS .....length of stay
LVEF.....left ventricular ejection fraction
MDR .....Medical Device Regulation
mITT.....modified intention to treat
MLWHFQ .....Minnesota Living with Heart Failure Questionnaire
NA .....not available
NTproBNP .....N-terminal pro-B-type natriuretic peptide
NYHA .....New York Heart Association
PHQ-9 .....Patient Health Questionnaire
Pts.....patients
RCT.....randomised controlled trial
RoB.....risk of bias
SMG .....self-management group
SR.....systematic review
TG .....telephone group
TMG.....telemonitoring group
UCG .....usual care group

Executive Summary

Background

Heart failure (HF) is the most common cause for hospitalisation in patients over 65; disease management programs (DMPs) are in use in Austria with non-invasive telemonitoring

Heart failure (HF) is a disease characterised by reduced capacity of the heart to pump enough blood and oxygen to supply the organs of the body. It is the most common cause of hospitalisation in patients over 65 years of age. In Austria, disease management programs (DMPs) for HF patients have been in use for over a decade. They are based on nurse-led home visits and non-invasive telemonitoring, where patients record their data on body weight, blood pressure, heart rate, and subjective well-being via mobile applications.

aim was to assess added benefit of telemonitoring to DMPs and provide an evaluation concept

The aim of this study was to systematically assess the evidence on clinical effectiveness and safety of non-invasive telemonitoring as an add-on to DMPs compared to DMPs without telemonitoring in HF patients. A further objective was to develop an evaluation concept for the systematic assessment of clinical and organizational care effects of digital health technologies (DHTs) in DMPs for Austria.

Methods

systematic review was conducted, EUnetHTA and ASSESS-DHT manual were used

To assess the evidence on clinical effectiveness and safety, a systematic literature search was conducted in four databases and supplemented by a manual search (1,351 hits). Randomized controlled trials (RCTs) published from 2010 onwards were included. EUnetHTA methodology together with the interim version of the ASSESS-DHT manual were applied, and the risk of bias and certainty of evidence were assessed. For the evaluation concept, we integrated findings from the technology assessment, targeted manual search, methodological approaches from the ASSESS-DHT manual, and input from the external reviewer.

Results

Clinical effectiveness and safety

3 randomised controlled trials (RCTs) found with 189 patients receiving telemonitoring with DMPs

Three relevant RCTs found were conducted between 2007 and 2015, identifying the total of 527 patients (189 HF patients in telemonitoring with DMPs). The certainty of the evidence was predominantly moderate, primarily due to wide confidence intervals (CIs) and small sample sizes. The follow-up period ranged from three to 24 months. The primary outcomes were rehospitalization for all causes (2 studies) and health-related quality of life (HRQoL) (1 study). Further outcomes include:

primary outcomes and further outcomes

- All-cause mortality rate,
- Rehospitalisation due to HF,
- Hospital length of stay (LOS),
- Emergency department (ED) visits,
- Compliance, and
- Depression.

improvement in rehospitalisation due to HF and health related quality of life (HRQoL)

Two outcomes were found to be improved in the intervention group (IG). Rehospitalisation due to HF improved by 40 percentage points in one study in favour of IG (CI overlapping: 5.7-43.7 in IG vs 33.5-79.7 in control group (CG). HRQoL was reported in one study and it was measured via Minnesota Living

with Heart Failure Questionnaire (MLWHFQ) that found a statistically significant 12-point improvement in IG compared to no improvement in CG (p=0.039).

The rest of the outcomes were either inconclusive or not reported on. Reported in all three studies, results on rehospitalisation for all causes were inconclusive and ranged from 6 percentage points improvement in CG to 8.4 percentage points improvement in IG with wide and overlapping CIs. ED visits were reported in one study with 7 percentage points in favour of CG (CIs overlapping: 10.6-26.4 in IG vs 3.8-14.8 in CG). In terms of compliance, 70% of patients were at least 70.0% compliant with daily data transmission. There was no difference reported on all-cause mortality, hospital LOS, health rating, or depression score. No endpoints were reported regarding safety.

inconclusive evidence or no data on the rest of the outcomes

Evaluation concept

An evaluation concept was developed to systematically assess the clinical, organizational, and economic care effects. Recognising the value of clinical and economic studies already conducted in Austria, the authors, nonetheless, suggest a need for a controlled study to be conducted. That is because a Class IIb medical device is at stake and the added clinical benefit has not yet been sufficiently demonstrated by controlled studies. A cluster RCT could be applied in the Austrian context as different programs in place are in different points in their lifecycle. Alternatively, other types of trials could be conducted such as a stepped-wedge controlled trial, target trial emulation study, or a regional RCT comparing telemonitoring with the DMP against the DMP alone. A follow-up of 12 months of intervention plus 12 months of post-intervention is recommended. Primary clinical outcomes should include HF-related mortality, HRQoL, and compliance. Organizational aspects (time expenditure, changes in workflows, communication, satisfaction) should be assessed using a mixed-methods approach and economic modelling based on controlled data from the payer's perspective should be considered. Equal opportunities for vulnerable groups (older patients, rural areas, low digital competence) as well as implementation and monitoring structures for DHT development are further key aspects.

evaluation concept needed for systematic assessment of clinical, organisation and economic care effects

various types of RCTs could be applied as a Class IIb medical device is at stake

organisational aspects could be measured by mixed methods approach

economic, ethical, and implementation-related aspects are also to be considered

Discussion and Conclusion

This is the first systematic review of non-invasive telemonitoring as an add-on to nurse-led DMPs for HF patients. We found evidence of moderate strength for reduced HF-related rehospitalizations and clinically important improvement in HRQoL. Compliance was relatively high at 70% compared to the literature (55-98.5%), however, Austrian specific data show very high compliance (97.6%). No concerns were raised regarding safety with respect to device function, but it remains unclear what role might errors in data transmission play.

first systematic review on this topic

moderate strength of evidence found for improvement in 2 outcomes, safety unclear

The expected added benefit of telemonitoring is based on four core assumptions. First is that early detection enables early response and the evidence as to whether early detection actually leads to reduced hospital stays is inconsistent. Second concerns self-monitoring, which can, on the one hand, improve self-management, but on the other hand, it can increase patients' anxiety and stress. Third concerns a life-line to health professionals, which can make patients feel more secure, but there is a risk of excessive dependence. Fourth concerns the claim that telemonitoring helps with better distribution of resources and thus reduces costs, but that is not sufficiently substantiated.

four assumptions behind benefit of telemonitoring: 1) early detection leads to early response, 2) self-monitoring improves self-management, 3) life-line to nurse means security, 4) telemonitoring is cost saving

Interoperability, ethics, and ELGA to be considered

Regarding interoperability, harmonization of different telemonitoring systems and their integration into the Austrian electronic health record (ELGA) is necessary. From an ethical perspective, patients have expressed concerns about data protection and social isolation.

heterogeneity of interventions
applicability of summarised evidence is limited, no ongoing trials were found,
cost-effectiveness is a significant gap

Devices in the clinical trials analysed were very heterogeneous in nature and their success seems to depend on a number of clinical, technical, and human factors. Also, because the results on the effects of telemonitoring interventions are equally very heterogeneous and the applicability of the data that drive this recommendation is limited, it is expected that new study results could potentially influence the effect estimate considerably. However, no ongoing RCT was found that could answer the research question of this assessment. Also, no data of sufficient quality on cost-effectiveness were found, which represents a key evidence gap. It is recommended to conduct a cost-effectiveness analysis from the perspective of Austrian payers, as well as a budget impact analysis for long-term sustainability based on data from a controlled study.

Zusammenfassung

Hintergrund

Herzinsuffizienz (HI) ist eine chronische Erkrankung, bei der das Herz nicht ausreichend Blut und Sauerstoff pumpen kann, um die Organe des Körpers zu versorgen. HI ist kein einzelnes pathologisches Krankheitsbild, sondern ein klinisches Syndrom mit Hauptsymptomen wie Müdigkeit, Knöchelschwellungen oder Atemnot. In Österreich waren 2024 rund 34 % aller Todesfälle kardiovaskulär bedingt. HI ist die häufigste Ursache für Krankenhausaufenthalte bei Patient:innen über 65 Jahren, was angesichts der österreichischen Demografie einen wesentlichen Anteil der Bevölkerung betrifft. Der Anteil der über 65-Jährigen stieg von 15,2 % (2011) auf 19,4 % (2021) und wird voraussichtlich bis 2040 auf 26,7 % ansteigen.

Herzinsuffizienz (HI): chronische Erkrankung des Herzens

2024: 34 % der Todesfälle in Ö durch Herzkreislauferkrankungen

In Österreich sind seit über einem Jahrzehnt Disease-Management-Programme (DMPs) für HI-Patient:innen im Einsatz, darunter HerzMobil (Tirol, Steiermark, Kärnten, Niederösterreich) und drei hybride Programme. KardioMobil Salzburg existiert seit 2004, während KardioMobil PLUS (mit Telemonitoring) erst kürzlich eingeführt wurde. Die DMPs basieren auf pflegegeleiteten Hausbesuchen mit Telemonitoring. Die Zielgruppe sind Patient:innen nach Krankenhausaufenthalt wegen akuter HI oder mit fortgeschrittener HI.

Disease-Management-Programme (DMPs) in Ö schon seit mehr als 10 Jahren eingesetzt

u. a. HerzMobil und Kardiomobil

Nicht-invasives Telemonitoring erfasst Patient:innendaten wie Körpergewicht, Blutdruck, Herzfrequenz und subjektives Wohlbefinden über mobile Anwendungen oder eigenständige Geräte. Der erwartete Nutzen liegt in der Prävention von Rehospitalisierungen, Reduktion der Mortalität sowie Kosteneinsparungen. Durch höhere Monitoring-Frequenz bei reduziertem Aufwand für das Gesundheitssystem sollen zeitnahe Reaktionen auf Gesundheitsveränderungen ermöglicht werden. Es besteht jedoch Unsicherheit über den nachweisbaren Zusatznutzen von Telemonitoring gegenüber etablierten DMPs.

DMPs: Hausbesuche mit Telemonitoring (TM)

Monitoring von u. a. Blutdruck und Herzfrequenz

Ziel dieser Arbeit war die systematische Bewertung der Wirksamkeit und Sicherheit von nicht-invasivem Telemonitoring als Ergänzung zu DMPs im Vergleich zu DMPs ohne Telemonitoring bei HI-Patient:innen nach Krankenhausentlassung. Im Fokus standen klinische Endpunkte (Mortalität, Rehospitalisierung, Lebensqualität) sowie organisatorische Aspekte (Inanspruchnahme, Nutzen für medizinisches Fachpersonal, Zusammenarbeit). Ein weiteres Ziel war die Entwicklung eines Evaluationskonzepts für die systematische Bewertung klinischer und organisatorischer Effekte von digitalen Gesundheitstechnologien in DMPs.

Ziel: systematische Bewertung von TM als Ergänzung zu DMPs und Entwicklung eines Evaluationskonzepts

Methoden

Eine systematische Literatursuche wurde in vier Datenbanken (Medline, Embase, Cochrane Library, HTA-Datenbanken) durchgeführt und durch eine Handsuche ergänzt (1.351 Treffer). Eingeschlossen wurden randomisierte kontrollierte Studien (RCTs) ab 2010, die nicht-invasives Telemonitoring zusätzlich zu DMPs (Intervention) mit DMPs ohne Telemonitoring (Kontrolle) bei HI-Patient:innen nach Krankenhausentlassung verglichen.

systematische Literatursuche ergänzt mit einer Handsuche

Zwei Wissenschaftler:innen führten unabhängig voneinander die Studienauswahl und Qualitätsbewertung durch. Die interne Validität wurde mittels Cochrane Risk of Bias Tool v2, die Vertrauenswürdigkeit der Evidenz anhand des GRADE-Schemas (Grading of Recommendations Assessment, Develop-

Studienauswahl und Qualitätsbewertung mittels RoB v2 von 2 Wissenschaftler:innen

ment und Evaluation) bewertet. Die Ergebnisse wurden narrativ zusammengefasst. Das ASSESS-DHT-Manual wurde für die Bewertung herangezogen.

Beantwortung von Forschungsfrage 1 und 2

Die erste Forschungsfrage zur klinischen Wirksamkeit und Sicherheit wurde auf Basis der systematischen Literatursuche beantwortet, wobei das EUnet-HTA Core Model und ergänzende Fragestellungen aus dem ASSESS-DHT-Manual zur Anwendung kamen. Zur Beantwortung der zweiten Forschungsfrage wurde mittels Literatur aus der systematischen Suche, sowie den Erkenntnissen aus der Technologiebewertung und den methodischen Ansätzen des ASSESS-DHT-Manuals ein Evaluationskonzept entwickelt.

Ergebnisse

Klinische Wirksamkeit und Sicherheit

3 randomisiert kontrollierte Studien (RCTs) mit 189 HI Patient:innen in TM+DMP-Gruppen

Drei randomisiert kontrollierte Studien (RCTs), durchgeführt zwischen 2007 und 2015, wurden identifiziert. Insgesamt wurden 527 Patient:innen (ca. 189 HI-Patient:innen in Telemonitoring + DMP-Gruppen) eingeschlossen, die nicht-invasives Telemonitoring zusätzlich zu DMPs mit DMPs ohne Telemonitoring bei HI-Patient:innen nach Krankenhausentlassung verglichen. Die Vertrauenswürdigkeit der Evidenz war vorwiegend moderat, primär wegen breiten Konfidenzintervallen und kleinen Stichprobengrößen.

primäre Endpunkte der Studien

Die primären Endpunkte waren Rehospitalisierung (2 Studien) und gesundheitsbezogene Lebensqualität (1 Studie). Die Nachbeobachtungsdauer reichte von drei bis 24 Monate.

relevante Endpunkte: u. a. Gesamtmortalität, Rehospitalisierung, Notaufnahmebesuche

Folgende Endpunkte wurden als relevant definiert:

- Gesamtmortalität und HI-bedingte Mortalität
- Rehospitalisierung (alle Ursachen und HI-bedingt)
- Krankenhausaufenthaltsdauer
- Notaufnahmebesuche
- Lebensqualität
- Compliance
- Unerwünschte und schwerwiegende unerwünschte Ereignisse

Gesamtmortalität/ Krankenhausaufenthalte und Rehospitalisierungen: kein statistisch signifikanter Unterschied

HI-bedingte Rehospitalisierung: statistisch signifikanter Unterschied zugunsten der Interventionsgruppe (IG)

Eine Studie berichtete die Gesamtmortalität nach 24 Monaten ohne statistisch signifikanten Unterschied (15 % vs. 15,8 %, p=0,859). Die Rehospitalisierung für alle Ursachen wurde in allen drei Studien ohne statistisch signifikanten Unterschied berichtet, wobei die Konfidenzintervalle der Effektschätzer breit und überlappend waren (16-60 % in Telemonitoring + DMP vs. 10-68% in DMP). Die HI-bedingte Rehospitalisierung wurde in einer Studie mit einer statistisch signifikanten Reduktion um 40 Prozentpunkte zugunsten der Intervention berichtet (20 % vs. 57,9 %, p=0,048), jedoch mit marginal überlappenden Konfidenzintervallen (5,7-43,7 vs. 33,5-79,7). Eine Studie berichtete die Krankenhausaufenthaltsdauer ohne signifikanten Unterschied (4,9 vs. 4,8 Tage). Notaufnahmebesuche wurden in einer Studie mit 7 Prozentpunkten zugunsten der Kontrolle ohne statistische Signifikanz berichtet (17 % vs. 10 %).

Lebensqualität: statistisch signifikante Verbesserung in 1 Studie zugunsten IG

Bezüglich der Lebensqualität verwendete eine Studie den Minnesota Living with Heart Failure Questionnaire (MLWHFQ) und berichtete eine statistisch signifikante 12-Punkte-Verbesserung in der Telemonitoring + DMP-Gruppe gegenüber keiner Verbesserung in der DMP-Gruppe (p=0,039). Die Compliance wurde in einer Studie für die Interventionsgruppe berichtet, wobei 70 % der Patient:innen an mindestens 70% der Tage ihre Daten übermittelten.

Es wurden keine Daten zu unerwünschten Ereignissen oder schwerwiegenden unerwünschten Ereignissen in den eingeschlossenen Studien berichtet.

keine Sicherheitsdaten

Evaluationskonzept

Basierend auf den Studien sowie dem ASSESS-DHT-Manual wurde ein Evaluationskonzept mit dem Ziel erstellt, klinische, organisatorische und ökonomische Versorgungseffekte telemedizinisch unterstützter DMPs für HI-Patient:innen systematisch zu bewerten. Die Technologie befindet sich in österreichischen Regionen in unterschiedlichen Lifecycle-Stadien (Vergleichsstudienstadium in Tirol/Steiermark/Kärnten vs. frühes klinisches Stadium in OÖ/Vorarlberg/Wien). Da es sich um ein Klasse-IIb-Medizinprodukt handelt und der klinische Zusatznutzen noch nicht durch kontrollierte Studien ausreichend belegt ist, wird eine kontrollierte Studie empfohlen.

Evaluationskonzept basierend auf ASSESS-DHT Manual

DMPs in unterschiedlichen Stadien in Ö

Als Studiendesign eignet sich ein Cluster-RCT, das neue Programme (OÖ, Vorarlberg, Wien) mit etablierten HerzMobil-Programmen vergleicht. Alternativ könnten eine kontrollierte Studie mit Stepped-Wedge-Design, eine Target-Trial-Emulation oder ein regionales RCT, das Telemonitoring + DMP mit DMP allein vergleicht, durchgeführt werden. Ein Follow-up von 12 Monaten Intervention plus 12 Monaten Nachbeobachtung wird empfohlen.

Studiendesigns: RCT, Cluster RCT oder kontrollierte Studie mit Stepped-Wedge-Design

Als klinische Endpunkte eignen sich die HI-bedingte Mortalität, die gesundheitsbezogene Lebensqualität sowie die Compliance. Für die Erfassung organisatorischer Aspekte wie Zeitaufwand, Arbeitsablaufänderungen, Kommunikation und Zufriedenheit empfiehlt sich ein Mixed-Methods-Ansatz. Ergänzend ist eine ökonomische Modellierung aus Kostenträgerperspektive sinnvoll, die auf kontrollierten Studiendaten basiert. Weitere Aspekte umfassen die Gewährleistung von Chancengleichheit für vulnerable Gruppen (ältere Patient:innen, ländliche Regionen, geringe digitale Kompetenz) sowie den Aufbau von Implementierungs- und Monitoring-Strukturen zur Überwachung der DHT-Entwicklung.

Endpunkte: Mortalität, Lebensqualität, Compliance

organisatorische Aspekte (z. B. Zeitaufwand)

ökonomische Aspekte

Diskussion

Dies ist der erste systematische Review zu Telemonitoring als Ergänzung zu pflegegeleiteten DMPs. Es wurde moderate Evidenz für reduzierte HI-bedingte Rehospitalisierungen und verbesserte Lebensqualität gefunden. Die 12-Punkte-Verbesserung im MLWHFQ ist klinisch relevant (Schwellenwert 5 Punkte). Die HI-bedingte Rehospitalisierung zeigte eine Reduktion um 40 Prozentpunkte, konsistent mit einer österreichischen retrospektiven Studie (46 % Reduktion).

moderate Evidenz für Rehospitalisierung und Lebensqualität zugunsten TM + DMP

Österreichische Daten zeigen eine sehr hohe Akzeptanz: nur 8 % verweigerten die Programmteilnahme, und nur 2,4 % waren nachlässig bei der Datenübertragung. Zur Sicherheit wurden keine Endpunkte berichtet und keine Bedenken bezüglich Gerätefunktion oder Messgenauigkeit erhoben. Offen bleibt, welche Rolle Fehler bei der Datenübertragung spielen könnten, etwa durch verzögerte Reaktionen auf Gesundheitsverschlechterungen oder Fehlalarme.

hohe Akzeptanz in Ö

unklare Rolle von Fehlern in der Datenübertragung

Der erwartete Zusatznutzen von Telemonitoring basiert auf vier Kernannahmen: (1) Früherkennung: ermöglicht frühzeitige Reaktion: Die Evidenz ist inkonsistent, ob Früherkennung tatsächlich zu reduzierten Krankenhausaufenthalten führt. (2) Selbstmonitoring: kann einerseits Selbstmanagement verbessern, andererseits Angst und Stress erhöhen (relevant bei erhöhten Prävalenzen von Depressionen 20-45 % und Angst 20-50 %. (3) Kontinuierliche

4 Kernannahmen zu erwartetem Nutzen

Anbindung: Patient:innen fühlen sich sicherer, aber die Gefahr übermäßiger Abhängigkeit besteht. Geografische und sozioökonomische Faktoren können zu ungleichem Zugang führen. (4) Ressourcenverteilung: eine Studie berichtete Hinweise auf Kosteneinsparungen. Eine österreichische Analyse zeigte € 4.773 pro QALY, allerdings im Vergleich zu Standardversorgung ohne DMP.

Integration in bestehende Systeme

Hinsichtlich der Interoperabilität ist eine Harmonisierung verschiedener Telemonitoring-Systeme und deren Integration in die elektronische Gesundheitsakte (ELGA) erforderlich. Auch die EU-Kommission geht dabei auf die Notwendigkeit von Interoperabilität auf rechtlicher, organisatorischer und technischer Ebene ein.

Limitationen:

Die Limitationen dieser Arbeit betreffen zeitliche (ab 2010) und sprachliche Einschränkungen (Englisch/Deutsch) der Literatursuche, den Einschluss von Diabetes-Patient:innen in einer Studie sowie die Verwendung von Geräten aus den Jahren 2007 bis 2015.

Schlussfolgerung

potenzieller Nutzen auf moderater Evidenzbasis

Es wurde Evidenz mit moderater Vertrauenswürdigkeit gefunden, die auf einen Zusatznutzen von Telemonitoring in Kombination mit DMPs hinsichtlich HI-bedingter Rehospitalisierung und Lebensqualität hindeutet. Weist jedoch Limitationen auf, insbesondere hinsichtlich fehlender statistischer Präzision.

Klasse IIb Medizinprodukt

Evaluationskonzept als Maßstab für eine Studie

Da die evaluierten digitalen Gesundheitstechnologien als Klasse-IIb-Medizinprodukte einzustufen sind, wird ein RCT im österreichischen Kontext empfohlen, die sich auf kritische klinische und organisatorische Endpunkte sowie die kontextabhängige Compliance konzentriert. Das vorgeschlagene Evaluationskonzept soll als Maßstab für die Vorbereitung einer solchen Studie dienen.

Evidenzlücke: Kosteneffektivität

Es wurden keine Daten ausreichender Qualität zur Kosteneffektivität gefunden, was eine zentrale Evidenzlücke darstellt. Es wird empfohlen, eine Kosteneffektivitätsanalyse aus der Perspektive österreichischer Kostenträger durchzuführen, die Kosten für informelle Pflegepersonen einschließt, sowie eine Budget-Impact-Analyse zur langfristigen Nachhaltigkeit vorzunehmen.

1 Background

Overview of the disease[1]

Telemonitoring (TM) nach Krankenhausaufenthalt bei HI

While non-invasive telemonitoring devices can be used in various indications, the subject of this present systematic review (SR) is their use in patients with heart failure (HF) post-hospital discharge. HF is a disease characterised by reduced capacity of the heart to pump enough blood and oxygen to supply the organs of the body, which is associated with deterioration in physical performance [1].

Herzinsuffizienz (HI) als klinisches Syndrom mit mehreren Symptomen

According to the European Society for Cardiology (ESC), HF is not a single pathological diagnosis. It is a clinical syndrome that consists of main symptoms such as fatigue, ankle swelling, or breathlessness and may be further accompanied by signs such as peripheral oedema, elevated jugular venous pressure, and pulmonary crackles [2]. HF is caused by the functional and/or structural abnormality of the heart that results in inadequate cardiac output at rest and/or during exercise and is corroborated by elevated natriuretic peptide levels and/or objective evidence of pulmonary or systemic congestion [3].

Risikofaktoren u. a. Bluthochdruck, Herzmuskelerkrankungen und Diabetes Mellitus

HF is a multifactorial condition that is influenced by a variety of etiological factors including genetic predispositions, the presence of systemic hypertension, coronary artery disease, valvular heart disease, myocarditis and cardiomyopathies, or diabetes mellitus [4]. Furthermore, proper diet, regular exercise, and smoking cessation are some of the lifestyle risk factors that have an impact on the HF diagnosis [4].

Natural cause and burden of disease[2]

unheilbare Krankheit – mit möglichen stabilen Phasen

The natural course of heart failure is an irreversible and progressive worsening of the condition that is eventually fatal [5]. Progression of the disease is, however, individual and unpredictable. While some patients may remain stable for years, others may get worse quickly. Currently, there exists no cure for HF and hence the primary goal of treatment is slowing the progression of HF and symptom management.

kardiovaskuläre Erkrankungen: 40 % der Todesfälle von Erwachsenen in Europa (2024)

Cardiovascular diseases (CVDs) at large are one of the leading causes of premature death worldwide [6]. The WHO 2024 report states that in the European region alone, more than 40% of all deaths were due to CVDs [6]. In Austria in 2024, 34.3% of deaths were due to a cardiovascular cause [7]. For patients with advanced HF (where symptoms persist despite maximum therapy), 1-year mortality ranges from 25% to 75% [2].

HI: Hauptursache für Hospitalisierungen bei >65-Jährigen

HF is the most common cause of hospitalisation in patients over 65 years of age [8], which is of particular importance in the context of the Austrian demographics. In Austria, the proportion of population of 65 and over rose from 15.2% in 2011 to 19.4% in 2021. It is expected that by 2040, 26.7% of all Austrians could be 65 and over [9]. Adequate management and treatment options for this growing target group of patients is, hence, of high priority.

[1] A0002, A0003

[2] A0004, A0005, A0006

Current clinical diagnosis and management of the HF[3]

Diagnosis of heart failure

Ätiologie: myokardiale Dysfunktion

Because HF is not a single pathological diagnosis, its diagnosis is driven by identification of the right aetiology that underlies the observed cardiac dysfunction. HF is, for the most part, caused by myocardial dysfunction that can be either systolic, diastolic, or both, however, other causes such as pathology of the valves, pericardium, and endocardium, and abnormalities of heart rhythm and conduction may also contribute to HF [2].

Terminologie

The terminology used to describe HF is manifold and hence requires clarification. HF is typically categorised and diagnosed in the following ways [2, 3]:

- Based on the measurements of left ventricular ejection fraction (LVEF), which is a measure of the percentage of blood pumped out of the left ventricle with each heartbeat. Based on LVEF, HF can be categorised as preserved (≥50%), mildly reduced (41% and 49%), reduced (≤40%), and HF with improved ejection fraction.

  Auswurfleistung des Herzens

  - The diagnosis of HF with reduced LVEF requires the presence of symptoms and/or signs of HF and a reduced ejection fraction measured by echocardiography.

    Diagnose mit Echokardiographie

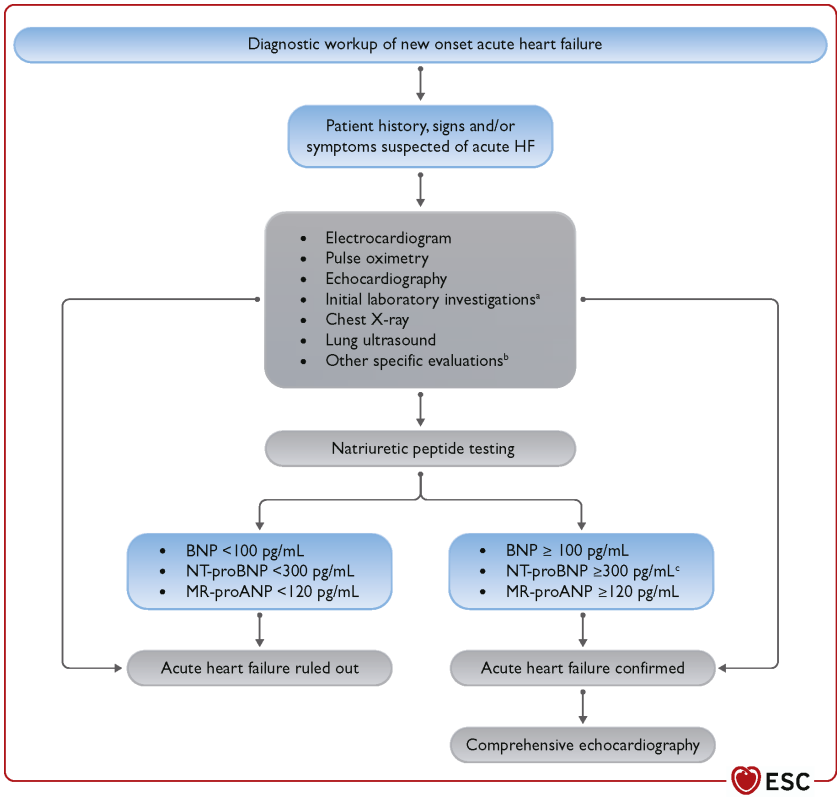
  - The diagnosis of HF with mildly reduced LVEF requires the presence of symptoms and/or signs, the presence of elevated natriuretic peptides (BNP ≥35 pg/mL or NT-proBNP ≥125 pg/mL) and further evidence of structural heart disease such as increased left atrial size, left-ventricular hypertrophy or echocardiographic measures of left ventricular filling.
  - The diagnosis of HF with preserved LVEF remains challenging. A variety of measures/scores is in tested, yet the best approach is currently not clear.
  - The diagnosis of HF with improved LVEF is diagnosed over against the measurement of baseline LVEF (≤40%) as a ≥10 point increase from baseline, as well as a second measurement of LVEF >40%.
- Based on severity of HF classified by the New York Heart Association (NYHA) functional classification. Diagnosis by NYHA classification relies solely on symptoms where Class I represents no limitation to physical activity and Class IV represents inability to carry on physical activity without discomfort.

  NYHA-Klassifizierung
- Based on chronic and acute states of the disease. While chronic HF describes those patients who have had an established diagnosis of HF or who have a more gradual onset of symptoms, acute HF refers to a more rapid onset.

  akute und chronische Form

  - If chronic HF patient deteriorates, either suddenly or slowly, the episode may be described as ‘decompensated’ HF. This can result in a hospital admission or treatment with intravenous diuretic therapy in the outpatient setting.
  - Severe acute HF episode may lead the patient to seek urgent medical attention, leading to an unplanned hospital admission or an emergency department visit. The diagnostic workup of AHF is outlined in Figure 1-1.

[3] A0024, A0025



Abbreviations: BNP ... B-type natriuretic peptide; MR-proANP ... mid-regional pro-atrial natriuretic peptide; NT-proBNP ... N-terminal pro-B-type natriuretic peptide

Figure 1-1: Diagnostic workup of new onset acute heart failure [2].

Management of heart failure

Zielgruppe der vorliegenden Arbeit: Patient:innen (Pat.) mit chronischer HI

With respect to management of HF, it is important to focus on the target population of the present SR, which are chronic HF patients post-acute HF episode, regardless of their LVEF or NYHA status. In terms of their management, the recommendations for chronic HF patients post-hospital discharge are based on multidisciplinary management that is active along the whole HF trajectory, enabling patients to have the correct investigations, an accurate diagnosis, appropriate evidence-based therapy, education, and suitable follow-up [2].

reduzierte Mortalität durch Disease Management Programme (DMPs)

Disease-management clinics and home visits by nurses are recommended based on the evidence of reduced all-cause mortality compared to usual care, with home visits being most effective [2]. HF management and telemonitoring are recommended to be patient-centred, taking a holistic approach to the patient rather than focussing solely on HF, including management of comorbid conditions, such as arrhythmias, hypertension, diabetes, renal dysfunction, and depression, in order to improve patient well-being and self-management [2].

Target population[4]

HI Pat. inkludiert nach Krankenhausaufenthalt

The target population of the present SR are chronic HF patients post-acute episode (hospitalisation) with no explicit limit to the measurement of their LVEF nor NYHA class.

steigende Inzidenz von kardiovaskulären Erkrankungen

While the age-adjusted incidence of HF is falling in developed countries, presumably due to better management of CVDs, overall incidence is increasing, presumably due to ageing of the population [2]. The incidence of HF in adults in Europe is 5/1.000 person-years and the prevalence appears to be 1-2% [2].

7.000 Pat. nehmen TM in Ö in Anspruch

The expected annual utilisation of telemonitoring in Austria is 7000 patients. This number is derived from yearly expected number of patients included in the telemonitoring disease management program (DMP) in HerzMobil Tyrol (adjusted for the Austrian population), which is the first Austrian DMP program for HF patients that has been in place for more than a decade [10].

DMPs in the Austrian setting[5]

DMPs für HI schon in einigen Regionen in Ö implementiert

The present SR is set in the Austrian context where DMPs for HF patients have been in use in specific regions for more than a decade [10]. Individual regions approach DMPs for HF differently, yet they all strive to provide comprehensive patient education, monitor HF symptoms, and optimise treatment based on up-to-date HF guidelines [10]. The regions that currently offer a DMP for HF patients are the following (see Table 1-1 for more detail) [10, 11]:

- HerzMobil Tyrol,
- HerzMobil Styria,
- HerzMobil Carinthia,
- HerzMobil Lower Austria (started in 2025), and
- KardioMobil (PLUS) Salzburg.

3 hybride Programme in Ö

Furthermore, there are three hybrid programs (Krems Model, KardioStabil Braunau, and IVH-OÖ-Pilot) that combine clinic and telecare-based approaches when caring for HF patients [10]. Also, as stated on the 4. HerzMobil Land meeting in June 2025, three more programs are potentially starting in 2025, including Upper Austria [12] and Vorarlberg, and a telemonitoring program in Vienna [13].

DMP: Hausbesuche von Pflegekräften und TM

The DMP is always primarily home-based with nurse-led home visits and telemonitoring. The target group are predominantly patients post hospitalisation with acute HF or patients with advanced HF (which refers to patients with persistent symptoms despite maximal therapy). The intervention is delivered via HF trained nursing staff in collaboration with registered network physicians, hospital-based cardiologists, and/or specialists for internal medicine. Some projects include a coordinator, and the means of communication is primarily face-to-face as well as via a telemonitoring intervention. Most of the projects last for 6 months, some for 3 months [10].

[4] A0007, A0023, A0011

[5] B0001, ASSESS-DHT Manual questions: The function(s) the DHT performs (e.g. data collection, assessment, monitoring, etc.) The features of the DHT (e.g. reminders, health warnings, advice, recording, etc.)

Table 1-1: Current DMPs in Austria [10]

	HerzMobil Lower Austria[6] [14]	Herzmobil Carinthia	Krems Model	Kardiomobil PLUS Slazburg	HerzMobil Styria	HerzMobil Tyrol	KardioStabil Braunau	IVH-OÖ-Pilot
Model and form of intervention	Nurse-based home visiting program		Clinic based and telehealth care	Nurse-based home visiting and telehealth program			Clinic based and telehealth care	Nurse-based home and office program
	Transitional care intervention (from acute to primary care)							
Digital health technology used	HerzMobil application by Telbiomed	HerzMobil application by Telbiomed	Telephone contact	HerzMobil application by Telbiomed	HerzMobil application by Telbiomed	HerzMobil application by Telbiomed	Telephone contact	No DHT used
Patient population	Hospitalisation for AHF			Hospitalisation for AHF, Non-hospitalised pts with AdHF, NYHA II and non-adherence/difficulties with treatment optimization	Hospitalisation for HF, Non-hospitalised pts with AdHF, NTproBNP >1,500 pg/ml	Hospitalisation for AHF, Non-hospitalised pts with AdHF, NTproBNP >1,500 pg/ml	Hospitalisation for AHF, Non-hospitalised pts with AdHF	Hospitalisation for HF/AdHF, AdHF pts. hospitalised for AHF within the last 6 months
Exclusion criteria	Life expectancy <6 months, mulltimorbidity (Charlson Index >6), Dementia, Lack of willingness to participate		Dementia, Non-mobile pts, Lack of willingness to participate	Life expectancy <6 months, Multimorbidity (Charlson Index >6), Dementia, Lack of willingness to participate				Pts. refractory to therapy, Nursing home residents, Dementia, Lack of willingness to participate
Intervention content	Patient and family education		Patient education	Patient and family education				Patient education
	Development of individual patient care plans		Monitoring of disease symptoms via telephone contacts	Development of individual patient care plans	Development of individual patient care plans	Development of individual patient care plans	Monitoring of disease symptoms via telephone contacts	Monitoring of disease symptoms
	Optimization of treatment based on prevailing guidelines							
	Home telemonitoring of disease symptoms, body weight, blood pressure, heart rate, and subjective well-being		NA	Home telemonitoring of disease symptoms, body weight, blood pressure and heart rate	Home telemonitoring of disease symptoms, body weight, blood pressure, heart rate, and subjective well-being	Home telemonitoring of disease symptoms, body weight, blood pressure, heart rate, and subjective well-being	NA	NA

[6] Start of the project in 2nd half of 2025, pilot region Wiener Neustadt.

	HerzMobil Lower Austria[6] [14]	Herzmobil Carinthia	Krems Model	Kardiomobil PLUS Slazburg	HerzMobil Styria	HerzMobil Tyrol	KardioStabil Braunau	IVH-OÖ-Pilot
Delivery personnel	Hospital-based cardiologists and specialists for internal medicine							
	Specialty-trained HF nurses							
	Networks of resident physicians: specialists for internal medicine and general practitioners	Registered network doctors play a minor role; this function is largely taken over by hospitals	NA	Networks of resident physicians: specialists for internal medicine and general practitioners	Networks of resident physicians: specialists for internal medicine only	Networks of resident physicians: specialists for internal medicine and general practitioners		
	Program coordinator							Local mobile support/social service
Intensity and complexity	3-6 months *Frequency of contact:* Minimum 3 visits, more detail unclear	6 months *Frequency of contact:* Nurse meets patient within 1 week after discharge Follow-up visits are individually scheduled telephone contacts when needed	6 months *Frequency of contact:* Every 4 weeks at the heart failure outpatient clinic and every 4 weeks telephone-based nurse contact	3-6 months *Frequency of contact:* 1-3 nurse visits In selected cases and 3 more visits if prolongation of project possible	3-6 months *Frequency of contact* 3 face-to-face nurse visits in first three months and telemonitoring	3-6 months *Frequency of contact:* 3 face-to-face nurse visits in and 3 visits form the network resident physician, Telemedical transmissions daily. Telephone and internet contacts when needed	3-6 months *Frequency of contact:* At a minimum, before discharge and telephone contact at week 1-2. Telephone contacts when needed	12 months *Frequency of contact:* Network physician meeting min. once per quarter. Final visit at the HF outpatient clinic at the end of the program. Nurse meets patient according to the network physicians' advice

Abbreviations: AdHF … advanced heart failure, AHF … Acute heart failure, GP … general practitioner, HF … heart failure, NTproBNP … N-terminal pro-B-type natriuretic peptide,
NYHA- New York Heart functional class

Claimed benefit of telemonitoring with DMPs[7]

angeblicher Nutzen der DMPs u.a. durch Prävention von Rehospitalisierungen

Claimed benefit of DMPs that are based on a nurse-led home visits post-hospital discharge program lies in prevention of rehospitalisation and reduction of mortality as well as healthcare costs [15, 16][8]. The addition of a telemedical component measuring patient's body functions and transmitting them to trained nursing personnel claims improvement in the same outcomes [17]. That is because, potentially, even more timely reactions to changes in patient's health state can be made, which is thanks to higher frequency of monitoring (via a telemonitoring device) with reduced friction for the healthcare system (no need of additional in-person visits). Furthermore, telemonitoring may improve rehospitalisation rates via the improvement of patient's self-management and medication adherence [18].

Phase of development, supplies needed, and administration[9]

Technologie für die DMPs von Telbiomed

The HerzMobil projects as well as the KardioMobil PLUS Salzburg project use the same digital solution that comes from a spin off company of the Austrian Institute of Technology called Telbiomed [19]. Figure 1-2 below shows the regions in Austria that use the HerzMobil application as of 2025.

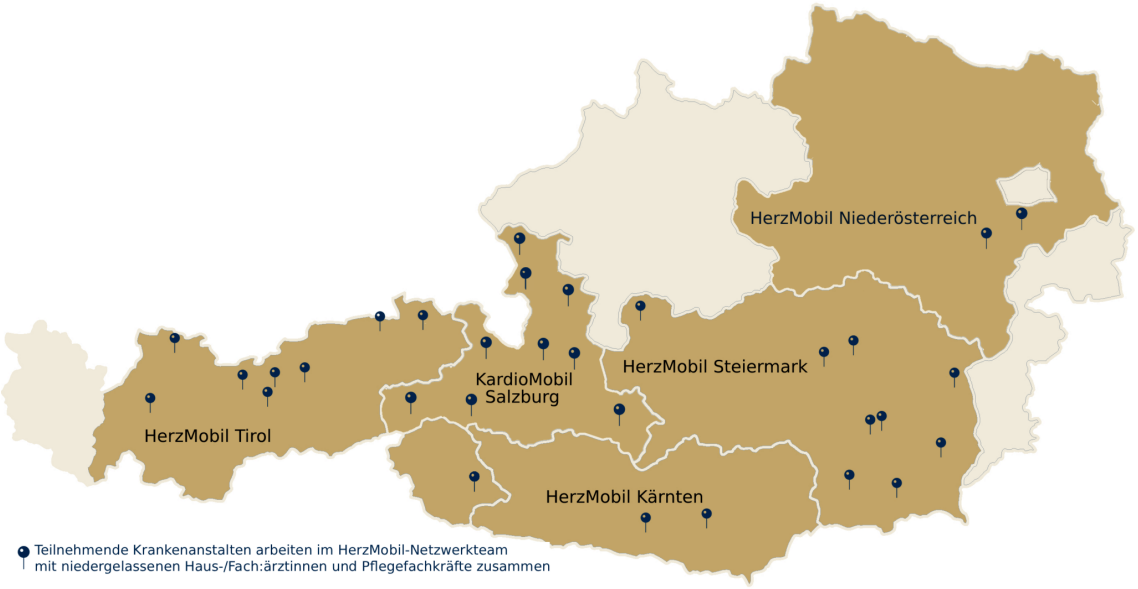


Figure 1-2: Map of HerzMobil application in Austria [19]

tägliches Monitoring mit dem Smartphone

The HerzMobil project uses medical devices for monitoring of patients with HF based on a mobile phone application that can be paired via Bluetooth with a blood pressure cuff, weight scale, glucometer, or pulse oximeter [19]. The application logs the above data on patient's physical functions as well as other health diary data such as medication, subjective health status, and pain perception [20]. Video conferencing is in-built in the mobile phone as is standard

[7] B0002, ASSESS-DHT Manual question: What is the place of the DHT in the care pathway?

[8] ASSESS-DHT Manual question: What is the medical focus of the DHT?

[9] B0003, B0004, B0008, and B0009

in conventional use. The daily measurements last a few minutes and the mobile application allows the patients to perform measurements in different places, however, the additional complementary measurement devices, such as weight scale or a blood pressure cuff, need to be accessible as well [19].

4 Komponenten im Telbiomed-System

The architecture of the Telbiomed system consists of four components. The central data management system (DMS), the mobile data collection application for smartphones and tablets (HerzMobil application), the KITMed analysis software for automatic, rule-based data analysis (medical device Class IIa) and the KITGuideMe decision support tool (medical device Class IIa) for guideline-compliant dosing [20]. The telehealth software is operated in the IT environment of the respective application partner or in a cloud service. The DMS enables access to patient data for different user roles via web dashboards and supports professional users in various processes such as patient registration, documentation of notes, documentation of health data, documentation of feedback information, and communication with patients via the linked application.

Datenaustausch über ein Datenmanagementsystem

In addition, the application is used to receive feedback information from HerzMobil Team (nurses, physicians) sent via the DMS [20]. All data is exchanged between the application and the data management system via an internet protocol. The system enables joint documentation by healthcare providers involved in the treatment network and patients, the embedding of documentation in elektronische Gesundheitsakte (ELGA) (telemonitoring episode report) [21] and the standardised integration of sensor devices.

Klasse IIb nach MDR (unterstützend in Diagnostik und Therapie)

keine Informationen zur CE-Kennzeichnung

As mentioned above, the devices used in the Austrian context fall in the category of Class IIb, medium to high risk devices according to the Medical Device Regulation (MDR) that are intended to aid in diagnostic or therapeutic decisions [22]. No information was found on CE mark of the interventions used in the studies, while the HerzMobil intervention used in the majority of the Austrian DMPs was found to be Class IIb medical device[23]. Also, information on CE marking of an analogous non-invasive telemonitoring intervention for HF patients was found, confirming the Class IIb classification [24].

Selbstmonitoring für 3-6 Monate, kontrolliert von Pflegekräften

With respect to administration, telemonitoring supported DMPs currently used in Austria start with a nurse-led training for patients with HF upon discharge from hospital (or within one week of discharge) on topics of self-care and the use the monitoring devices. Over the period of three to six months, it is the patient who performs daily measurements of their health functions in their home setting. These measurements are in turn controlled by the HF nurse also on daily basis and reviewed by the responsible physician (cardiologist, or specialists for internal medicine and general practitioners in some cases) [25]. If necessary, medication adjustments are made or patients are alerted to make a visit to hospital or their treating physician. Monitoring then continues for response and revised intervention [26].

Reimbursement status[10]

Refundierung in einigen Regionen in Ö möglich

In the Austrian context, the addition of telemonitoring to DMPs for HF patients post-hospital discharge is already inconsistently in use across the regions. There is reimbursement in Tyrol, Styria, Carinthia, Lower Austria, and Salzburg, and a pilot project in Upper Austria.

[10] A0021

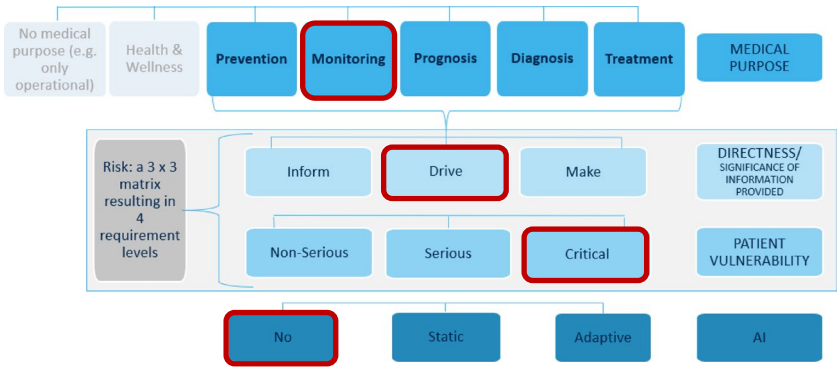
ASSESS-DHT Taxonomy

ASSESS-DHT-Taxonomie

With respect to the devices used in the Austrian context, the following ASSESS-DHT taxonomy applies (see Figure 1-3) [27]. Role of the devices at stake is monitoring with the purpose of informing healthcare professionals about the health state of a patient in a critical condition as well as driving change in the care pathway of the patient. Patient-generated data are collected by the device and with the aim of informing the healthcare professionals about patient's current health state and providing information that is to drive change in clinical management of the patient. Further features of the telemonitoring device include reminders prompting measurement and alerts if patients' data deviates from the expected thresholds. With respect to lifecycle of the technology and the ASSESS-DHT flowchart classification algorithm, the technologies under assessment are in their comparative study stage.

Aufnahme von Pat.-Daten für das Management

Verständigung des med. Fachpersonals bei Verschlechterung



Vulnerability of patients (state of healthcare situation/ condition)	'Directness' Intention of using DHT-collected or -produced information for health care decisions (by health care provider or patient)		
	Make (treat or diagnose)	Drive (clinical) management	Inform (clinical) management
Critical	IV Provides information to treat or diagnose a disease or conditions in a critical situation or condition → very high impact on patient or public health	III Provides information to drive clinical management of a disease or conditions in a critical situation or condition → high impact on patient or public health	II Provides information to inform clinical management of a disease or conditions in a critical situation or condition → medium impact on patient or public health
Serious	III Provides information to treat or diagnose a disease or conditions in a serious situation or condition → high impact on patient or public health	II Provides information to drive clinical management of a disease or conditions in a serious situation or condition → medium impact on patient or public health	I Provides information to inform clinical management for a disease or conditions in a serious situation or condition → low impact on patient or public health
Non-serious	II Provides information to treat or diagnose a disease or conditions in a non-serious situation or condition → medium impact on patient or public health t	I Provides information to drive clinical management of a disease or conditions in a non-serious situation or condition → low impact on patient or public health	I Provides information to inform clinical management for a disease or condition in a non-serious situation or condition → low impact on patient or public health

Figure 1-3: Categorisation of the device by the ASSESS-DHT taxonomy [27]

2 Scope

2.1 Research questions

The following research questions will be answered:

RQ1:

Is non-invasive telemonitoring together with a disease management program in comparison to the DMP alone in patients with heart failure post-hospitalisation more effective and safe concerning clinical outcomes (mortality, re-hospitalisation rate, or quality of life) and organisational outcomes (utilisation, benefits to healthcare professionals and their quality of collaboration)?

Forschungsfrage 1: Wirksamkeit und Sicherheit von DMP + TM

RQ2:

How can the clinical and organizational care effects of digital health technologies in DMPs be assessed? (for chapter 5: Evaluation concept)

Forschungsfrage 2: Evaluierungskonzept

2.2 Inclusion criteria

Inclusion criteria for relevant studies are summarised in Table 2-1.

Einschlusskriterien für relevante Studien

Table 2-1: Inclusion criteria

Population	Post-hospitalisation monitoring of HF patients regardless of their left-ventricular ejection fraction or New York Heart Association status ICD-10: ■ I50.22 for Chronic systolic (congestive) heart failure, ■ I50.32 for Chronic diastolic (congestive) heart failure, Mesh-term: Heart failure
Intervention	Non-invasive telemonitoring self-standing device or mobile phone app that monitors patients' body functions in addition to a face-to-face DMP. Mesh-term: Telemedicne, Disease management
Control	DMP without a telemontoring compoment[11] Mesh-term: Disease management
Outcomes	
Efficacy and Safety	Clinical ■ All-cause mortality and HF mortality, ■ All cause rehospitalisation and HF rehospitalisation, ■ Length of stay, ■ Quality of life, ■ Compliance.

[11] DMPs a are current standard of care for chronic HF patients post-discharge in the Austrian setting.

Efficacy and Safety *(continuation)*	Organisational ■ Utilisation, ■ Benefits for healthcare professionals, ■ Quality of collaboration between professional groups (physicians, nurses, etc.).
Study design	
Efficacy and Safety	Prospective randomised controlled trials, Systematic reviews, HTA reports, all published from 2010 onwards

Abbreviations: HTA … health technology assessment, ICD … international classification of diseases, HF … heart failure

3 Methods

EUnetHTA, ASSESS-DHT Taxonomie

The European Network for Health Technology Assessment (EUnetHTA) Core Model® [28] was used as reporting standards. Also, interim version of methods manual [29] and taxonomy [27] documents of the ongoing European project for the assessment of digital health technologies (DHTs), called ASSESS-DHT, was piloted in the present SR [30].

Registrierung

The SR was pre-registered on the Open Science Framework platform where the AIHTA protocol was published [31]. There were no protocol deviations.

Forschungsfragen basierend auf EUnetHTA Core Model

Assessment elements from the EUnetHTA Core Model® for the production of Rapid Relative Effectiveness Assessments (Version 4.2) were customised to the specific objectives of the present SR. Please refer to Appendix (Table A-5) for the detailed research questions.

3.1 Systematic literature search

systematische Literatursuche in 4 Datenbanken

The systematic literature search was conducted on the 18 of July in the following databases:

- Medline via Ovid
- Embase
- The Cochrane Library
- HTA (INAHTA)

1.291 Treffer bei syst. Suche identifiziert

The systematic search was limited to the years 2010 to 2025 and to articles published in English or German. After deduplication, overall 1291 citations were included. The specific search strategy employed can be found in the Appendix.

52 Referenzen durch Handsuche identifiziert

By hand-search, an additional 60 citations were found, resulting in overall 1,351 hits.

Literatur für Technologiebeschreibung durch syst. Suche identifiziert

Literature for the description of the technology and literature concerning health problem and current use of the technology was identified through the systematic search.

3.2 Flow chart of study selection

Literaturauswahl

Overall, 1,343 hits were identified. The references were screened by two independent researchers and in case of disagreement a third researcher was involved to solve the differences. The selection process is displayed in Figure 3-1.

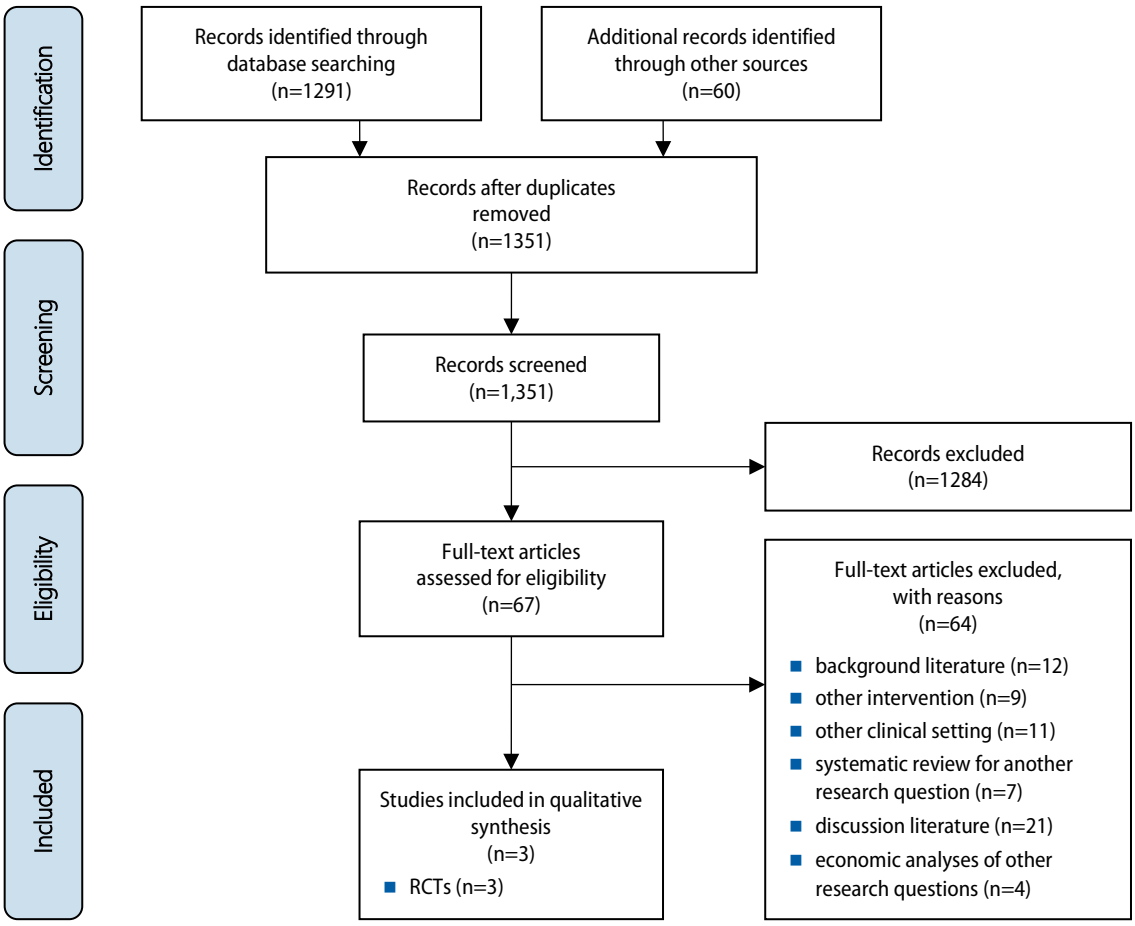


Figure 3-1: Flow chart of study selection (PRISMA Flow Diagram)

3.3 Analysis and synthesis of evidence

Verzerrungspotenzial mit Cochrane RoB v2 bewertet

Certainty of evidence was assessed using Cochrane Risk of Bias tool 2 [32] for all three RCTs found (see Table A-2). One reviewer (MS) systematically extracted relevant data from the included studies into extraction tables. A second reviewer (MR) cross-checked the data extraction tables with the data source and validated them for accuracy. Risk of bias was conducted by independent researchers (MS, MR) and differences were settled via consensus.

Vertrauenswürdigkeit der Evidenz nach GRADE

Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool was used to assess the certainty of evidence [33] (MS, MR). Based on the data extraction tables (see Appendix, Table A-1), data on each selected outcome category were, if applicable, synthesised across studies according to GRADE [33]. The research questions were answered in plain text format with reference to GRADE evidence tables (Table A-3).

3.4 Evaluation concept

Evaluationskonzept zur Beurteilung des Zusatznutzens

The aim of the evaluation concept (answering research question two) is to conceptualise methods for the assessment of added benefit of DHTs as part of DMPs for patients with HF. Its goal is to enable comparability between regions, support evidence-based decisions on Austria-wide implementation, and identify good practices for the sustainable integration of telemonitoring.

Literatur, ASSESS-DHT-Framework und Expert:inneninput als Basis für das Evaluationskonzept

The evaluation concept was developed based on the experience with the present SR, the global as well as the local Austrian published literature analysed, and the questions from the ASSESS-DHT Life-cycle framework [29]. Also, input from the external reviewer (RW) was considered. Besides the clinical questions analysed in the literature, the evaluation concept focuses also on those questions that the literature does not give answers to, especially questions pertaining to health professionals and the organisation of care. The criteria for the evaluation concept were documented in a narrative form.

4 Results: Benefit Assessment

4.1 Outcomes

entscheidende Endpunkte für Wirksamkeit

The following outcomes were defined as *critical* to derive a recommendation:

- Clinical:
  - All-cause mortality,
  - Rehospitalisation for all causes/due to HF,
  - Health-related quality of life (HRQoL),
  - Depression.
- Organisational:
  - Utilisation,
  - Benefits for healthcare professionals,
  - Quality of collaboration between professional groups (physicians, nurses, etc.).

Informationen zu klin. Endpunkten in der syst. Suche gefunden

The above listed clinical outcomes were selected because they report on the critical patient-relevant endpoints that were defined at PICO formation. Also, relevant information for all the clinical outcomes was found in the systematic literature search.

Gesamtmortalität und HI-bedingte Mortalität

Lebensqualität (MLWHFQ)

Depression (PHQ-9)

In terms of definitions of the clinical outcomes, all-cause mortality refers to mortality results from any cause, not just mortality caused by HF. Rehospitalisation refers to the rate of readmission of patients to hospital, which is reported both for all causes as well as due to HF alone. With respect to the outcome of HRQoL, the Minnesota Living with Heart Failure Questionnaire (MLWHFQ) was used to assess patient's quality of life in one study [34] and subjective health ratings were used in another study [35]. MLWHFQ is a self-administered 21-item questionnaire, where scores range from 0 to 105, with higher scores indicating poorer quality of life. Depression is assessed by a Patient Health Questionnaire (PHQ-9), which measures the severity of depression and the total scores of 5, 10, 15, and 20 represent cut-points for mild, moderate, moderately severe and severe depression, respectively [36].

keine Sicherheitsdaten

There were no safety-related outcomes found in the literature and assessed in the present SR.

Inanspruchnahme von med. Leistungen

Endpunkte für med. Fachpersonal

In terms of definitions of organisational outcomes, utilisation is defined as the quantification of the use of health-related services [37]. In terms of the setting of the present SR, on top of the clinical outcomes described above (which partly also refer to the use of healthcare services), utilisation refers to the consumption of also other services such as outpatient visits or additional consultations with specialists. Benefits to healthcare professionals are defined as any quantification of the added value for the practice of healthcare professionals such as reduction in working hours allocated to a task or ease of work.

4.2 Included studies

3 RCTs inkludiert

There were three randomised controlled trials (RCTs) included in the analysis[12]. Two were conducted in the USA, while the third was conducted in Japan. All were funded by public bodies and while the study period was unclear in one study [35], the other two studies were conducted between 2007 and 2009 [38] and between 2013 and 2013 [34]. The total number of HF patients in the intervention groups receiving care via DMP with telemonitoring were 189.

Pat. mit HI und vorhergehendem Krankenhausaufenthalt

In terms of inclusion criteria, all included patients were diagnosed with HF and were post-hospitalisation, transferring to home care. Their age varied from 57,2-90 (in means: 70.5 to 83) and their NYHA class was II-IV at registration in one study [34], and not defined in the other two [35, 38]. In one study [35], patients also had to be cognitively intact, able to hear and see well enough to use the equipment, English speaking, and have a fixed telephone line.

Ausschlusskriterien u.a. wenn Umgang mit Telefon nicht möglich

Exclusion criteria were not defined in one study [38] and while in another study [35], patients were excluded if followed by other programs, in the third study [34], exclusion criteria were severe comorbidity, inability to stand or communicate by telephone, cognitive impairment scores of ≤20 out of 30 on Hierarchic Dementia Scale Revised, and physical difficulty undergoing the trial.

primärer Endpunkte Rehospitalisierung (2 Studien), Lebensqualität (1 Studie)

Primary outcome was rehospitalisation in two studies [35, 38] and in the third study [34], it was HRQoL. Out of the total of 528 patients included in the studies analysed, 316 were female. Ethnicity was primarily Caucasian in both studies conducted in the USA [35, 38] and presumably East Asian ethnic group in the study conducted in Japan [34]. Data on life expectancy of more than six months at baseline was reported only in one study [38] and it was 50% for IG and 42.9% in CG. Primary HF diagnosis was present in 63.5-77.1% of patients in two studies [35, 38] and unclear in the third [34]. MLWHFQ score was measured only in one study [34] and it varied from 32.2-47.6 points. Follow-up ranged from 3 to 24 months and loss to follow-up was unclear in one study [38] and in the other two studies it ranged from 10.4% [35] to 22% [34].

Study characteristics and results of included studies are displayed in Table A-1 and Table A-2 and in the evidence profile in Table A-3.

4.3 Interventions used in the included studies[13]

Vergleich DMP mit Hausbesuchen + TM vs. DMP mit Hausbesuchen ohne TM

The model of intervention in all three studies analysed had a nurse-let home-visiting program as a comparator to nurse-based home-visiting programs with daily telemedical monitoring (see Table 4-1). All three studies included patient education and a form of self-monitoring of body functions with a videoconferencing screen in two studies [35, 38]. Two studies aimed at treatment optimisation, while it was unclear in the third study [38]. All three studies were primarily carried out by trained HF nurses, who were in consultation

[12] ASSESS-DHT Life-cycle framework questions number 33 and 118

[13] B0001

with clinicians in [34, 35]. Frequency of communication with patients varied from monthly visits and daily telemonitoring contact in [34] to 1.4 face to face visits per week in [35] and in [38], there were 0.35 telemonitoring data transmissions per patient per week.

The devices used in the studies analysed most presumably fall in the category of Class IIb, as do the devices used in the Austria context outlined above. Two studies analysed in this review were conducted in early 2010s [34, 38]. There is hence a generational difference between the devices used in some studies included in the analysis and the devices used in the current practice in Austria.

verwendete Produkte: Klasse IIb nach MDR

Table 4-1: Overview of DMPs used in the studies analysed

	Bowles et al. (2009) [35]	Mizukawa et al. 2019 [34]	Pekmezaris et al. (2012) [38]
Model and form of intervention	Home visiting program		
	Nurse-based		
	Transitional care intervention (from acute to primary care)		
Patient population	Hospitalisation for HF or diabetes	Hospitalisation for HF	
Intervention content	Patient education		
	Self-monitoring of disease symptoms via a telemonitoring device with functions such as blood pressure cuff, weight scale, glucometer and pulse oximeter, alternatively a digital stethoscope and videoconferencing screen[14]	Self-monitoring of disease symptoms via a telemonitoring device such as weight, blood pressure, and pulse catalogued by a pt in a notebook[15]	Self-monitoring of disease symptoms via a telemonitoring device with functions such as blood pressure cuff, bodyweight scale, pulse oximeter, digital stethoscope and videoconferencing screen[16]
	Frequent face to face visits	Monthly face to face behavioural modification counselling	1 live nursing visit and 2 telemonitoring visits for the first 2 weeks, followed by an increased frequency of telemonitoring and reduction in live visits
	Optimization of treatment based on guidelines in cooperation with the physician	Close follow-up of treatment ahderence and optimization of care if needed in cooperation with the cardiologist	Role of treatment optimisation was unclear
Delivery personnel	Specialty-trained nurses		
	Patient's physician (diabetologist, cardiologist)	Hospital-based cardiologists	Unclear role of physicians
Means of communication	*Patient to caregiver:* face to face & telehealth monitors	*Patient to caregiver:* face to face & telephone	*Patient to caregiver:* face to face & telehealth monitors
Intensity and complexity	3 months (1-2 months intervention, 1 month follow-up) *Frequency of contact:* Average 11 face to face visits and average 0.35 data transmissions per patient.	24 months (12 months intervention, 12 months follow-up) *Frequency of contact:* Face-to-face nurse counselling every 4 weeks and daily telemonitoring. Physician visit ever 2-4 weeks depending on the patient's health state.	3 months (2 months intervention, 1 month follow-up) *Frequency of contact:* Average 11 face to face visits and 5 telemonitoring visits per patient.

[14] The monitors used include: Sentry III, Honeywell HomMed, Inc., ViTelCare Turtle, Visual Telecommunications Network, Inc., and Aviva 1010, American TeleCare Inc.

[15] The monitors used include: CITIZEN SYSTEMS CO. LTD.,. The data were transmitted wirelessly via a Bluetooth connection to the server software application, Multihome gateway, which was developed by CYBERCROSS JAPAN CO. LTD.

[16] The monitor used was: TeleCare #1010

4.4 Results

4.4.1 Clinical outcomes

Mortality[17]

All-cause mortality was reported in one study [34] where three patients died in IG as well as in CG (15% in IG vs 15.8% in CG) with confidence intervals of 0.0-30.6 in IG and 0.0-32.2 in CG. HF related mortality was not reported in any study.

Mortalität: 3 Todesfälle in beiden Gruppen

Morbidity[18]

The following endpoints were found to answer the question regarding the impact of telemonitoring on the progression/recurrence of HF: rehospitalisation for all causes, rehospitalisation due to HF, hospital length of stay (LOS), and emergency department (ED) visits.

Endpunkte zur Morbidität

Rehospitalisation for all causes was reported in all three studies. The difference between the rehospitalisation rate of IG and CG ranged from -6 to 8.4 percentage points in favour of the intervention, with wide overlapping confidence intervals. In the IG, 16 to 60% of patients, while in CG, 10 to 68% of patients were rehospitalised for all causes.

Rehospitalisierung zugunsten der Interventionsgruppe (IG)

Rehospitalisation due to HF was reported in one study [34] where the difference between IG and CG was almost 40 percentage points in favour of the intervention, with the numerical difference being four versus eleven patients and wide overlapping confidence intervals (5.7-43.7 in IG vs 33.5-79.7 in CG).

HI-bedingte Rehospitalisierung zugunsten der IG

Hospital LOS was reported in one study [38] and was 4.9 days in IG (standard deviation ±8.2) and 4.8 days in CG (standard deviation ±10.2).

vergleichbare Krankenhausaufenthaltsdauer

ED visits were reported in one study [35] where the difference between IG and CG was seven percentage points in favour of the control, numerically 17 vs 10 patients, with confidence intervals overlapping (10.6-26.4 in IG vs 3.8-14.8 in CG).

weniger Besuche in der Notaufnahme in Kontrollgruppe

Function[19]

The assessed remote non-invasive telemonitoring devices require that the patient interacts with them on the daily basis through daily vital sign measurements. Either through the self-standing device, or in the updated form via a mobile phone application, the patient needs to perform daily measurements of blood pressure, weight, glucose, oxygen saturation, or auscultation.

tägliche Messung der Vitalfunktionen erforderlich

In terms of compliance, this endpoint was reported in one study individually for the IG [34] where 70.0% of patients were at least 70.0% compliant with daily data transmission, meaning no break in information transfer for >30 days (except during hospitalisation).

70 % der Pat. zeigten hohe Compliance

[17] D0001
[18] D0006
[19] D0016

Health-related quality of life and patient satisfaction[20]

HRQoL was analysed in two studies [34, 35] using different metrics. While subjective health status rating was performed in [35], MLWHFQ was used in [34]. There was no significant difference in health ratings with p value of 0.76 [35] and in terms of MPQHFQ, there was a 12-point improvement in IG compared to no improvement in CG [34] with p value 0.039.

Lebensqualität in 2 Studien berichtet, stat. signifikante (sign.) Verbesserung zugunsten der IG

A relevant patient reported outcome is depression rate in [35], where 24% of patients had moderate to severe depression at baseline and at last follow-up, there was no significant difference in depression scores after adjustments for HF and number of nursing visits.

keine Veränderung der Depressionsrate

4.4.2 Organisational outcomes

With respect to the organisational outcomes, no data was found on benefits to healthcare professionals. Apart from the clinical outcomes outlined above concerning rehospitalisation, ED visits, or hospital LOS (which are also in part organisational), no other utilisation related outcomes were reported, for instance on the difference in outpatient visits between patients in IG and CG[21].

begrenzte Daten zu organisatorischen Aspekten

Data to answer the key organisational questions with respect to organisational added value, such as staff workload and coordination, deployment of healthcare personnel, or the reduction of (future) use of healthcare services and other medical devices or pharmaceuticals were not found[22].

Endpunkte, die med. Fachpersonal betreffen nicht berichtet

Concerning quality of collaboration between professional groups, one of the studies analysed reported that there were inconsistencies in nurse-doctor interactions if changes were supposed to be instituted to the care plan and the nurses reported communication and collaboration barriers with the physicians [35].

1 Studie berichtet über die Pflegekräfte-Ärzt:innen Zusammenarbeit

Comprehensive cost data were also missing in the studies analysed.

keine umfassenden Kostendaten

[20] D0013, D0017

[21] ASSESS-DHT Life-cycle framework question number 111

[22] ASSESS-DHT Manual question: What is the organisational (added) value: deployment of healthcare personnel, or the reduction of (future) use of healthcare services and other medical devices or pharmaceuticals?

5 Evaluation concept

5.1 Position of the technology in the life cycle

unterschiedliche Implementierungsphasen in Ö

Currently, most of the DMPs for HF patients in Austria already have some degree of telemonitoring as part of the care pathway. Some regions have their telemonitoring programs already established (Tyrol, Styria, and Carinthia), while other regions are either in the process of implementing it (Upper Austria, Vorarlberg, and Vienna), or are transitioning from a DMP without to DMP with telemonitoring (Salzburg).

Produktlebenszyklus-Ansatz für die Klassifizierung

Based on these different stages of uptake of the technology, according to the ASSESS-DHT Life-cycle classification (see Figure 5-1) [29], it can be said that the technology is in different stages in its life-cycle in different regions in Austria. While it is in its comparative study, or even long-term study stage in Tyrol, Styria, Carinthia, and partly Salzburg, it is in its early clinal stage in Upper Austria, Vorarlberg, and Vienna. Naturally, learnings from one region can be translated to another, but because a Class IIb medical device is under assessment here, it is important to underline that with respect to MDR, insufficient evidence base was used for positive reimbursement decisions in regions where telemonitoring is established. That is because the added clinical benefit of telemonitoring has not yet been sufficiently established by a controlled trial.

Lifecycle Stage	Simplified Evaluation Focus
Preclinical	Is the technology safe and usable in lab or simulated settings?
Experimental / Local Validation	Can it work safely in a real clinical setting, and has it been developed to a stable optimised state?
Early Clinical	How does it perform in real use, including in specific sub-groups? Are there important user learning and trust issues to resolve? Can we achieve consensus on a trial protocol for a randomised controlled trial?
Comparative Study	Is it better or equivalent to current care? Is it effective and cost-effective?
Long-term Study	Does it remain safe and effective over time? Are there any rare problems or performance shifts?

Figure 5-1: Evaluation Focus at Each Lifecycle Stage from the ASSESS-DHT Manual [29]

5.2 Study design

med. Produkt der Klasse IIb – benötigt RCT

The DHT used in the telemedical care context is a software application considered as a Class IIb medical device compatible with other non-digital components. According to MDR as well as according to the ASSESS-DHT Manual and the LC approach [29], controlled trials (preferably RCTs) are the suitable study design to establish the added benefit considering the DHT's risk class.

mögliche Szenarien für Studien

The evidence gathered in the present SR does not clearly establish the benefit of telemonitoring as part of DMPs for HF patients with sufficient certainty. Hence, if possible, one of the following trial scenarios could be put in place in Austria.

Cluster-RCT oder kontrollierte Studie mit Stepped-Wedge-Design

Given that the responsibility for HF DMPs lies in the hands of the regions, a variety of approaches to DMPs are currently in use, and the fact that some regions are only now starting to pilot a HF DMP, a cluster RCT could be considered. Potentially, a stepped-wedge controlled trial could be considered where all clusters eventually receive telemonitoring with DMPs, but in a staggered, sequential manner over time [39].

RCT mit Vergleich TM + DMP vs. DMP

Equally, an RCT comparing an intervention group that includes telemonitoring added to a DMP with a control group of the DMP alone within a specific region could answer the research question of the present SR with sufficient clarity. In the absence of quality data supporting the use of telemonitoring and thanks to the relatively high safety profile of telemonitoring devices in use, such RCT could be conducted. It would, arguably, provide the best standard of care that is in line with the ESC guideline (as a face-to-face DMP would be provided) as well as examine the research question at stake without endangering patients' wellbeing. Alternatively, a target trial emulation study could be applied, mimicking the structure of an RCT to estimate a causal effect from observational data [40].

Verblindung nur bei Datenanalyse möglich

With respect to recruitment and blinding, the studies report the involvement of designated HF centres, which recruited the necessary number of patients in an open-label format and randomly assigned them into groups. As no sham devices were used, no blinding at patient level or at the point of care delivery were in place. The same design as applied in the international literature could be applied in Austria, however, blinding at the level of data analysis could be applied and clearer reporting of relevant outcomes (outlined below) and subgroup effects could be applied also. In terms of the primary outcomes, HRQoL, HF mortality, and compliance should be considered as these outcomes can provide most information with respect to the actual added value of telemonitoring (see more detailed reasoning in the discussion). Hence, as the study of the highest quality analysed in the present SR applied twelve months of the telemonitoring intervention and a twelve-month follow-up period [34], such a longer period of follow-up is also recommended.

5.3 Clinical care effects

Endpunkte zur Evaluierung klin. relevanter Verbesserungen

The crucial question that, hence, needs to be answered is whether telemonitoring in addition to DMPs leads to clinically important improvement in patient-relevant clinical outcomes and care processes. The relevant outcomes measured in the international literature and reported on in the present SR include:

- All-cause mortality and HF-related mortality rates,
- All cause rehospitalisation and HF-related rehospitalisation rates,
- Total hospital length of stay measured in days,
- Number of emergency department visits,
- Health-related quality of life, measured via the Minnesota Living with Heart Failure Questionnaire (MLWHFQ),
- Compliance measured via daily interaction with the DHT, and
- Depression, measured by Patient Health Questionnaire (PHQ-9).

weitere Endpunkte

Further relevant outcomes found in the general HF literature that were not reported on in the present SR, but were, nonetheless found relevant, include:

- Medication adherence, measured by patients' self-report in the application, and
- Number of false alerts evaluated by the HF nurse executing the DMP.

Messung von Lebensqualität und Depression

Considering the Austrian context, if there is an established tool measuring HRQoL of HF patients other than MLWHFQ, this one single tool should be applied for the sake of comparability between regions. The same applies to the outcome depression, as its prevalence is particularly high in HF patients and its measurement can be context specific. Except for these two outcomes, all the above outcomes are considered relevant for answering the crucial benefit assessment question. However, the outcomes of HF-related mortality, HRQoL, and compliance, in particular, should be considered as the primary outcomes.

Compliance geht mit Patient:innenzufriedenheit einher

A particular attention should be paid to the question of compliance and satisfaction, both with respect to patients as well as with respect to the service providers. That is because patients' compliance with the DHT very much reflects patients' satisfaction with the tool as well as satisfaction with the program in general. Compliance was measured in the studies analysed via digital outcome of interactions with the DHT. If information was not transferred from the patient to the health professional, the patient was considered non-compliant. This measure of compliance provides a valid approach, however, it needs to be noted that there may be reasons pertaining to patients' disadvantages highlighted below that may contribute to non-compliance. Such potential reasons such as lack of digital literacy should be accounted for in the face-to-face visits by the HF nursing staff.

Gründe für Non-Compliance sind vielfältig

Zufriedenheit von Pat. und med. Fachpersonal

Furthermore, a measurement of satisfaction should be applied both towards patients as well as the service providers. For patients, the measurement of satisfaction can be embedded in the application itself (as is currently the case), while for the care providers, the question on satisfaction could be incorporated in the provider survey outlined below.

5.4 Health economics

inkrementelles Kosten-effektivitätsverhältnis basierend auf RCT-Daten

Unless telemonitoring as part of a DMP is a clear case of a beneficial intervention that is also cost saving (no additional costs are incurred), a context specific economic modelling is necessary to establish the cost-effectiveness of the new intervention, compared to the established standard of care. There were health economic models developed in the Austrian context [41] with clinical data coming from a retrospective trial [25]. Calculating the incremental cost-effectiveness ratio based on data from a controlled trial (either one of the options outlined below) would greatly improve the certainty in the conclusions on cost-effectiveness of telemonitoring with DMPs for HF patients.

5.5 Organisational care effects

Mixed-Methods-Ansatz für organisatorische Aspekte (z. B. Umfrage)

Just like the question of added benefit, also the question of organisational and system aspects of telemonitoring and cooperation between healthcare professionals should be given adequate attention as that is where the current evidence gap lies. A mixed methods approach including surveys, interviews, or process evaluation approaches could be applied to elucidate this part of the research problem. For instance, a survey for healthcare professionals that focuses on factors related to the implementation of a telemonitoring HF DMP and the role of cooperation between healthcare professionals, could be put in place. The following aspects could be considered:

potenzielle Themen für Umfrage

- What is the time requirement needed for the delivery of the new telemonitoring care pathway?
- How does telemonitoring change the workflows change the workflows within the teams?
- What is the frequency of digital interactions that is on top of individual face-to-face interactions?
- How is the communication between healthcare professionals set up? How does it influence the delivery of care and if necessary, can it be improved?
- Does telemonitoring bring about a confusion in roles between HF nurses and the responsible physicians?
- Are healthcare professionals satisfied with the training provided for the new process of healthcare delivery via the use of telemonitoring?

Frage der Refundierung

A further system relevant question that needs a context specific solution is related to digital health data, reimbursement, and interoperability. In particular, what needs to be resolved is the interconnectedness between the telemonitoring systems and reimbursement mechanisms, in the form of the Elektronische Gesundheitsakte, ELGA.

5.6 Equal opportunities

Pat. in kritischen Situationen

Gesundheitskompetenz

With respect equal opportunities, it is important to bear in mind that the intervention targets vulnerable groups and concerns the question of fairness on a number of levels. Its target are often frail elderly patients in a critical health state post-hospitalisation due to their HF. This increases the stakes for a timely access to care that can be limited for those patients who live in rural areas, where individual face-to-face visits are more complicated. Also, because telemonitoring requires patients' disciplined daily measurement of their vital signs and an active use of a mobile phone application, patients with lower digital literacy may be disadvantaged.

Einbeziehen ethischer Aspekte in die Studie

A successful study that would strive for the provision of equal opportunities would need to take these points into account. The potential measures applied could include: provision of support to patients with limited digital literacy, selection of patients regardless of their geographical location, or analysis of dropout rates by subgroups.

5.7 Implementation and monitoring

Implementierung und Überwachung

What needs to be further considered are aspects related to implementation and monitoring of the technology in use. As a mobile phone application is a DHT, it will require updates over time and its application in the care pathway needs to be coordinated. As suggested by the ASSESS-DHT Life-cycle framework [29], the following questions may need to be considered:

potenzielle Fragen aus dem ASSESS-DHT-Manual

- Is the developer actively implementing and monitoring a data quality framework?
- Is there evidence to show the robustness of the device against environmental and biological influences and its ability to maintain and produce accurate measurement?
- Has the system been integrated into the clinical workflow and tested in a real-world setting for technical and procedural compatibility?
- In case that artificial intelligence will be applied, are specific monitoring strategies in place and clearly described, including responsibility and timing?
- Are there tested processes to monitor, detect, and resolve interoperability issues (e.g., connection failures, changes in connected systems) in integrated digital healthcare environments, including incident-response and change-management procedures?

6 Certainty of evidence

Verzerrungspotenzial mit Cochrane RoB v2 bewertet

The risk of bias (RoB) for individual studies was assessed with the Cochrane Collaboration's tool for randomised trials [32] and is presented in Table A-3 in the Appendix.

hohes RoB in einer Studie

High RoB in [35] was caused by the absence of baseline and clarity in outcome data reporting, which lead to a risk of bias due to deviations from intended interventions, bias due to missing outcome data, measurement of the outcome, and selection of the reported result [35].

einige Bedenken in RoB bei 2 Studien

Some concerns regarding RoB in [38] were caused by bias in selection of the reported results and unclear reporting with respect to loss to follow-up. Also, there were some concerns regarding the outcome HRQoL in [34] with respect to bias inherent to measurement of the outcome.

Vertrauenswürdigkeit der Evidenz nach GRADE

The strength of evidence was rated according to GRADE (Grading of Recommendations Assessment, Development and Evaluation) Schema [33] for each endpoint individually. Each study was rated by two independent researchers. There were no cases of disagreement. A more detailed list of criteria applied can be found in the recommendations of the GRADE Working Group [33].

GRADE uses four categories to rank the strength of evidence:

- **High** = We are very confident that the true effect lies close to that of the estimate of the effect;
- **Moderate** = We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different;
- **Low** = Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect;
- **Very low** = Evidence either is unavailable or does not permit a conclusion.

The ranking according to the GRADE scheme for the research question can be found in the summary of findings Table 6-1 below and in the evidence profile in Appendix Table A-3.

moderate Vertrauenswürdigkeit der Evidenz

Overall, the strength of evidence for the effectiveness of telemedicine with DMPs in comparison to DMPs alone is mainly moderate, downgraded primarily for imprecision. For the safety of telemedicine with DMPs compared to DMPs alone, no evidence is available.

Table 6-1: Summary of findings table of telemonitoring as part of DMPs [32]

Outcome	Anticipated absolute effects (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality	Comments
	Risk with [comparison]	Risk with [intervention]				
All cause mortality rate	158 per 1000	150 per 1000	0.95	39	high ⊕⊕⊕⊕	-
Rehospitalisation for all causes in HF pts	519 per 1000	524 per 1000	1.01	207	high ⊕⊕⊕⊕	-
Rehospitalisation for all causes in HF and diabetes pts	80 per 1000	163 per 1000	2.03	210	moderate ⊕⊕⊕◯	-
Rehospitalisation due to HF	526 per 1000	200 per 1000	0.38	39	high ⊕⊕⊕⊕	-
HRQoL	NA	NA	NA	39	high ⊕⊕⊕⊕	Unit cannot be converted
Hospital LOS	NA	NA	NA	168	high ⊕⊕⊕⊕	Unit cannot be converted
ED visit at 60	750 per 1000	173 per 1000	2.16	210	moderate ⊕⊕⊕◯	-
Compliance	NA	NA	NA	NA	high ⊕⊕⊕⊕	Reported only for IG

Abbreviations: CI … confidence interval, ED … emergency department, HRQoL … health-related quality of life, LOS … length of stay, NA … not available

7 Discussion

moderate Vertrauenswürdigkeit der Evidenz für Rehospitalisierung und Lebensqualität

We found moderate strength of evidence for reduced heart failure (HF) rehospitalisations and improved health-related quality of life (HRQoL), but inconsistent evidence for other outcomes overall. To our knowledge, this is the first systematic review of the addition of non-invasive telemonitoring approaches to nurse-led face-to-face disease management programs (DMPs) for HF patients post-hospitalization when compared to such DMPs alone. In our systematic search, we found many systematic reviews (SRs) comparing non-invasive telemonitoring to usual care (no explicit face-to-face DMPs) (based on considerably heterogenous randomised controlled trials (RCTs), which examined the replacement of personal contact, not the addition of telemonitoring to face-to-face visits. As appropriate for a Class IIb medical device[23], three RCTs met our inclusion criteria for the analysis of clinical effectiveness, with 189 HF patients receiving care via DMPs combined with telemonitoring.

Clinical effectiveness and safety

Ergebnisse zur Wirksamkeit

Concerning clinical effectiveness, results from the RCTs report the following on clinically relevant outcomes (patient as well as system relevant):

- There was no difference reported on all-cause mortality [34], hospital length of stay (LOS) [38], health rating, or depression score [35],
- Rehospitalisation for all causes was inconclusive and ranged from six percentage points improvement in control group (CG) to 8.4 percentage points improvement in intervention group (IG) with wide and overlapping confidence intervals [34, 35, 38],
- Rehospitalisation due to HF improved by 40 percentage points in favour of IG statistically significantly (confidence intervals (CI) overlapping: 5.7-43.7 in IG vs 33.5-79.7 in CG) [34],
- Emergency department (ED) visits were seven percentage points in favour of CG without statistical significance (10.6-26.4 in IG vs 3.8-14.8 in CG) [35],
- HRQoL measured via Minnesota Living with Heart Failure Questionnaire (MLWHFQ) found a statistically significant 12-point improvement in IG compared to no improvement in CG (p=0.039) [34],
- 70% of patients were at least 70.0% compliant with daily data transmission, and
- The rest of the outcomes that we predominantly pertinent to answering questions on the organisational care effects (utilisation, benefits for healthcare professional, or quality of collaboration) were not reported on in the studies.

Interpretation of findings

persönliche Hausbesuche reduzieren Mortalität

As recommended by the European Society for Cardiology (ESC) guidelines for the management of patients with HF, face-to-face home visits are supported by evidence of reduced all-cause mortality [2]. Face-to-face visits are also included in the guideline on DMPs for HF patients by the Institut für Qualität

[23] ASSESS-DHT Manual question: What type of evidence is required and what evidence is available?

und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) [42]. The effectiveness of face-to-face DMPs is, therefore, not analysed in the present SR, but the addition of telemonitoring to established DMPs is. The present SR is approached as a single technology assessment primarily focusing on the narrow research question of added value of telemonitoring to HF DMPs. Based on moderate certainty of evidence found, the addition of telemonitoring is seen to have the potential to reduce rehospitalization due to HF and improve patients' HRQoL. The clinical benefit of telemonitoring is deemed relevant for informing the national procedures with regards to implementation of telemonitoring in HF DMPs[24].

unschlüssige Ergebnisse zur Rehospitalisierung

The outcome of rehospitalisation for all causes was inconclusive as results were found both for and against the intervention [34, 38]. In one study [35], it was assumed that rehospitalisation rate refers to all causes and not merely to HF mortality (as diabetes patients are also part of this cohort), however, categorically less patients (16% in IG and 10% in CG) were rehospitalised, compared to the two studies above. In none of the studies the result in this outcome reached statistical significance.

Verbesserung der Lebensqualität

The benefit was observed with respect to HRQoL and rehospitalizations due to HF[25]. The improvement in HRQoL measured via MLWHFQ was observed in a pilot study with small sample size, 20 patients in IG and 19 in CG [34]. Regardless, the effect was statistically significant ($p=0.039$). Also, because already a 5 point improvement in MLWHRQ is seen as clinically relevant, the improvement brought about by the telemonitoring intervention was also seen as clinically relevant for the HF patients [43].

stat. sign. Ergebnisse zur HI-bedingten Rehospitalisierung

Statistically significant results came out of the outcome rehospitalisation due to HF [8]. This result is also consistent with a retrospective non-randomised controlled study from the Austrian HerzMobil Tyrol program, where HF rehospitalisation was the primary outcome in which there was a 46% reduction between IG and CG (more detail on limitation of the study design in Studies in the Austrian setting) [25]. Although a decrease in HF-specific rehospitalisation was observed, its interpretation remains uncertain due to variability in reporting and possible confounding by intervention intensity.

hohe Compliance (Informationen nur zur IG vorhanden)

Compliance data found in the present SR were relatively high compared to other telemonitoring studies (where no DMPs are part of the intervention or control), the percentage ranged from 55% of participants using the telemonitoring system at least 3 times per week [44] to 75% to 98.5% [45]. Because of the trial setting, there was no information provided on the compliance of the patients in CG. Furthermore, a 2025 systematic review on factors influencing compliance to non-invasive telemonitoring interventions in HF found that compliance is a critical determinant of success and that there is a significant variation in compliance across different studies [46]. The SR underscores the importance of factors such as socioeconomic factors, patient education, and complexity of the telemonitoring intervention and highlights the need for standardised compliance metrics across studies. It also suggests the correlation between age, sex and compliance; indicating that women and older patients report higher rates of compliance. In terms of data on compliance from the Austrian context that report on the experiences with the HerzMobil

Einfluss von sozioökonomischen Faktoren, Alter und Geschlecht auf die Compliance

[24] ASSESS-DHT Manual question: Is the clinical benefit of the DHT relevant to the national procedure of implementing the DHT?

[25] ASSESS-DHT Manual question: On what level does the DHT provide a clinical benefit?

program, it was almost 8% (n=22) of patients that refused to enrol for the program, but once enrolled, only 2.4 (n=6) were negligent in daily data transfer (yet completed the 3-months long program nonetheless) [25]. Compared to the published literature, the Austrian results suggest a very high compliance.

unterschiedl. Interventionslänge in den Studien

The length of the intervention as such varied and it was one to two months long in [35, 38] and 6 months long in [34]. Loss to follow-up was sufficiently clarified in two studies [34, 35] and unclear in one [38].

keine Sicherheitsdaten

Concerning safety, no safety outcome was reported and no safety related concerns were raised in the literature analysed with respect to, for instance, device performance, technological stability or accuracy in data measurement. It remains, however, an open question what the role of errors with the digital health technology in the daily practice would be and what patient-relevant outcomes it could lead to[26]. For instance, an error in transmitting patient's body function measurements could lead to a delayed response on the side of the HF nurse, thus delaying the necessary early response to patient's health deterioration. Such concerns were raised in one study [47] with regards to false alerts caused by inappropriate measurement techniques on the side of patients as well as by inefficiencies of the telehealth system. In this case, the alert threshold that was set based on patient's discharge vital signs measurements kept sending wrong alerts once patient's measurements changed/stabilised in the home setting (and the threshold was not appropriately adjusted in the process).

unklarer Einfluss von Technikfehlern (z. B. Fehlalarmen)

Studies in the Austrian setting

1. HerzMobil-Programm in Tirol

The first Austrian study from Tyrol on the HerzMobil program was a prospective pilot, single-arm study including 35 patients assessing changes in health status, self-care behaviour, and satisfaction [17]. Health status was assessed via Kansas City Cardiomyopathy Questionnaire and patients' score improved from 46.2 to 69.8 after three months, where changes of around five points may be considered clinically meaningful [48]. Self-care behaviour was assessed via the European Heart Failure Self-Care Behaviour Scale (9 items) and reported a score 13 (range 9 to 22, with 9 being the best self-care behaviour). Patient satisfaction was 86% or higher in all dimensions (based on an Information System Success Model survey). This study was also not included in the present SR review as it did not meet the inclusion criteria for study design.

Verbesserung des Gesundheitszustands und der Pat.-Zufriedenheit

retrospektiv kontrollierte Studie in Tirol

A further clinical trial from the HerzMobil Tyrol program was published in 2022 [25]. As a retrospective non-randomised controlled study, it matches patients by age and sex, and studies outcomes such as HF rehospitalisation and all-cause mortality within six months. It concludes that telemonitoring supported DMPs for HF patients in Tyrol are feasible and effective in clinical practice as only 19.1% (48/251) of patients experienced HF rehospitalisation within six months, compared to 34.6% (89/257) of patients in the control group receiving standard discharge planning and an unstructured follow-up left to the respective family doctor or internist. The conclusions cannot be taken at face value due to the low evidence quality and comparator arm of usual care without a DMP applied, but they suggest improvement in rehospitalisation due to HF as well as mortality outcomes. This study was also not included in the present SR review as it did not meet the inclusion criteria both in terms of study design and in terms of not having a DMP in the control arm.

Vergleich war Standardtherapie – keine direkte Übertragbarkeit der Ergebnisse

[26] ASSESS-DHT Manual question: What are the potential harms and risks of using DHTs?

unschlüssige Kosteneffektivität

A cost-effectiveness analysis based on the clinical data above is reported on below in the Underpinning assumptions, point 4. Due to the low quality of design of the clinical studies above, the evidence from both of the studies is supposed to be seen not as conclusive, but as hypothesis generating.

Commonalities and differences between programs and studies

Ähnlichkeiten der Disease Management Programme (DMPs) in den Studien zu den österreichischen DMPs

Compared to the list of programs in use in the Austrian context, the interventions from the three studies analysed resemble all six programs currently in use. What they have in common is that they all are nurse-based interventions aimed at transitional care (from acute to primary), they target patients with heart failure (primarily) post-hospitalisation, and provide patient education. Telemonitoring is set up on daily basis, similar body functions are measured, and optimisation of treatment follows if necessary. Information about the design and the ease of using the devices, in the studies assessed as well as in the concrete Austria contexts, was not found.

Unterschied der Zielgruppe: in Ö-Programmen auch Pat. in fortgeschrittenerem Stadium

The currently running programs and the studies analysed slightly differ in the target group in that the Austrian programs aim also at advanced heart failure patients, while the studies aimed at heart failure patients post-hospitalisation only. The programs educate patient relatives (not only patients alone as the studies do) and while all listed Austrian programs use mobile application for patient monitoring, the studies use specific devices for measurement and monitoring (and video transmission). Face to face visits vary from weekly to monthly and the length of the intervention also varies from tree to twelve months.

Internal and external validity

interne Validität: moderate Vertrauenswürdigkeit der Evidenz

Overall, the certainty of evidence was mainly moderate. The comparator in all three studies was the relevant gold standard of evidence in the form of a DMP. All three studies assessed were RCTs with risk of bias at the outcome level judged to be low, of some concerns, and high. High risk of bias was primarily due to one study [35] with low quality reporting standards (more detail in section 7) and some concerns were related to bias in the selection of the reported results and loss to follow-up in [38], to the measurement of the outcome HRQoL in one study, and to its small sample size [34]. The internal validity of the evidence base is thus judged as moderate.

vergleichsweise alte Technologien in den Studien (2007-2015)

sehr kleine Studienpopulation

The transmission technology used by patients in the studies may be partially obsolete (used between 2007 and 2015), however, its key aspects are well established and remain the same (weight scale, glucometer, pulse oximeter, or stethoscope) even in the newer versions that are based on mobile phone applications. Also, the study with moderate certainty of evidence and low risk of bias that drives the present SR (it suggests an added benefit in HRQoL and rehospitalisation due to HF) is the most up-to-date study as it recruited patients between 2013 and 2015 [34]. The study, however, was significantly underpowered and the sample sizes are too small to make confident statements about treatment effectiveness. Hence, the applicability of the technology used in the studies assessed is seen as pertinent to the present SR and thus the evidence base is, to some extent, seen as relevant to the scope of this present SR. That includes the relevance of the outcomes assessed, which report on most of the outcomes outlined in the project protocol. The external validity of the evidence base is thus also judged as moderate.

Evidenzlücken u. a. zu geeigneter Interventionslänge und Kosten

Conclusions of the present SR are seen as relevant to the clinical situation under assessment. Gaps in the evidence base are related to the appropriate length of the intervention, the relevance of the older versions of telemonitoring devices to the present updated ones, the question of how to interpret the results of hospital readmissions and ED visits, the impact of telemonitoring on patient's psychological wellbeing, and the question of cost-effectiveness of telemonitoring as such.

Underpinning assumptions

Kernannahmen zur Wirksamkeit von Telemonitoring (TM)

The expected effect of telemonitoring lies in the following four core assumptions: 1) early detection allows for early reaction, 2) self-monitoring fosters control, 3) a lifeline gives patients stability, and 4) telemonitoring helps with better distribution of resources and thus reduces costs.

1. Early detection, early reaction

Früherkennung einer Verschlechterung durch hohen Informationsfluss

First assumption is that the high frequency of information exchange between the patient and the specialised HF nurse allows for an early detection of deterioration of the patient's condition. That, in turn, should allow for an early intervention (for instance medication adjustment) and thus reduce hospital admission or ED visits and mortality.

unklares Zusammenspiel von Früherkennung und Reduktion der Besuche in der Notaufnahme

With respect to the first assumption, the evidence from clinical studies and further literature on telemonitoring in HF patients is inconclusive whether early detection actually translates into a reduction in hospital and ED visits [49]. It is also unclear whether these reduction in these outcomes reflects positively or negatively on the intervention. On the one hand, more hospitalisations and ED visits may reflect positively on telemonitoring as that may be a sign of timely alerts that triggered a hospital visit. On the other hand, more hospitalisations may reflect on unnecessary burdening of the system of healthcare in situations that could be resolved in patient's home environment by a HF nurse. Interpreting the results of this outcome in the absence of mortality and quality of life data is limited, i.e. whether timely monitoring leads to patient-relevant appropriate care provided and hence reduction in all-cause/HF mortality.

TM kann zu erhöhter Inanspruchnahme von ambulanten Leistungen führen (kein Notfall)

Such lack of conclusiveness regarding the value of reduction of hospital/ED visits was also highlighted a recent Dutch SR that assessed the effect of telemonitoring on the above outcomes in the context with no DMPs in the intervention and comparator arms [50]. What remains pertinent to the present SR's research questions, nonetheless, is that the authors highlight that telemonitoring in some instances leads to an increase in nonemergency outpatient department visits. That puts into question whether telemonitoring brings and added value to the patient as well as the system of healthcare after all, and whether it is a cost-effective intervention[27]. In present SR, in one study analysed [34], rehospitalisation due to HF was statistically significantly reduced by almost 40 percentage points between IG and CG, but the study does not report on the number of other nonemergency outpatient department visits. In other words, it remains unclear whether the prevention of hospitalisation due to HF creates an unwarranted side effect, i.e. an increased consumption of healthcare services through other means.

[27] ASSESS-DHT Life-cycle approach question number 111.

Voraussetzung für guten Ablauf: funktionierende Pflegekräfte-Ärzt:innen-Interaktion

Further challenges are potentially related to the aspect of early reactions, because a functional nurse-doctor interaction is a prerequisite for the delivery of appropriate care [34]. It is the HF nurses who are the point of contact for HF patients, yet it is the treating physicians (cardiologists, doctors of internal medicine, or general practitioners) who are responsible for adequate care delivery. Depending on the context and the power difference between doctors and nurses, there were concerns raised whether specialist nurse services will ever be welcomed by all doctors involved [51]. Furthermore, there were further concerns raised regarding the opposition from the healthcare professionals to telemonitoring interventions as such [52]. Part of the problem can be caused by the gap in digital skills and competencies of healthcare professionals, which is an individual topic that needs to be addressed for telemonitoring to be successfully applied [53].

2. Self-monitoring and control

Annahme: Auseinandersetzung mit Körperfunktionen führt zu gesunderem Lebensstil

Second assumption is that reviewing one's own body functions on a daily basis may help patients to gain more control over their health condition and thus stimulate better medication adherence and healthier lifestyle [35]. It is argued that for a patient to learn how to interpret body signals and hence change behaviour, at least a six-month long intervention is needed [34]. While some patients just need to be instructed and they follow the procedure straightaway, others need frequent reminders that a telemonitoring system may provide [34].

mögliche positive und negative Effekte

It is equally unclear whether active patient participation in the monitoring process brings positive, or even potentially negative, effects. In telemonitoring approaches that require active patient participation, such that are analysed in this SR, much responsibility is put on patients, who are required to measure the bodily function on daily basis. This might, on the one hand, positively foster more ownership and self-care [54][28], yet on the other hand, it may create unduly pressure resulting in increased stress and anxiety [55]. Even though it is generally suggested that telemonitoring in HF patients has positive effects [56], too much focus on the bodily functions may lead to a patient's increased anxiety, overdetection, and potential overdiagnosis and overtreatment [57, 58].

Zusammenspiel der Diagnose mit Angst

Being aware of the relationship between HF diagnosis and patients' anxiety and depression is particularly relevant as it is reported that patients with HF have significantly higher rates of depression and anxiety when compared to the general population. The prevalence of anxiety ranges from 20 to 50% and the prevalence of depression from 20 to 45% [56]. Also, there is a bidirectional relationship between HF and anxiety or depression as HF may worsen anxiety or depression, which in turn may worsen HF outcomes [56].

Integration in existierende Infrastruktur

Furthermore, it is important to mention behavioural aspects related to implementation. It is repeatedly argued that successful telemonitoring is not only based on the efficacy of the technology, but also on its integration in the existing work practices of those who interact with it daily, patients or healthcare professionals[29] [59, 60]. Henceforth, ease of use of telemonitoring interventions or those that do not require active patient participation could reduce the

[28] ASSESS-DHT Manual question: Does the DHT enhance patient engagement, improve access to care or adherence to therapy, or empower individuals to manage their health?

[29] ASSESS-DHT Manual question: Does the content or design of the DHT affect the clinical effectiveness of the DHT?

friction of daily body function measurements and thus improve compliance [61], reduce the number of false alerts caused by inappropriate measurement techniques [47], and reduce the potential risk of related anxiety and depression [62]. Such interventions that are in their early clinical stage (with respect to the ASSESS-DHT lifecycle classification algorithm) may include a smart toilet seat that measures patient's heart functions when using the toilet [63], remote speech analysis that can detect HF events [64], wireless stickers that can transmit physiological signals emanating from the skin and send them to a monitor stuck on clothing and then to a healthcare professional on the receiving end [65].

Reduktion der Anforderungen an digitale Kompetenz

Furthermore, such approaches could reduce the weight that is put on the requirement of patient to be digitally literate when performing the body function measurements, which was suggested to be an issue by HF patients [52] as well as in the population of patients with diabetes that tend to be in a similar age group [66].

3. A supportive lifeline

Gefühl von Sicherheit durch das Monitoring

Third assumption is that having a lifeline to a healthcare professional may prove essential to a patient at the time of need [34]. Patients may feel reassured as they perceive to be continuously under practitioner's surveillance [67]. Practitioners, to the contrary, expressed the concern in a qualitative study, regarding excessive patient dependence on practitioners for support [67]. Appropriate case selection and training regarding enabling self-management were suggested to be put in place to mitigate that patient-nurse/doctor dependence.

Disparitäten bzgl. Zugang zur med. Leistungen

Important to bear in mind, however, is also the aspect of geographical limitations of HF face-to-face DMPs and age-driven vulnerability of HF patients that may result in unequal access to care. As is often the case, models of care that are derived from practices in urban areas need adjustments for their application in remote areas [51]. A further obstruction to having a lifeline to a HF nurse may be caused by differences in education and potentially also social class where socioeconomic status was found to be a predictor of adverse outcomes in HF patients [68][30]. Less educated and less digitally skilled vulnerable elderly population may be limited in benefiting from the telemonitoring intervention [38].

Online-Gespräche als etablierte Alternative zu Hausbesuchen

With respect to individual contact with patients monitored from home, an established alternative to face-to-face visits found in the literature are telephone-based visits. This type of an intervention has the potential to, on the one hand, overcome geographical disparities, but, in the other hand, it relies even more heavily on patient's digital skills. In the present SR, we found nine RCTs that analysed non-invasive telemonitoring approaches added to telephone visits compared to telephone visits alone. However, because of the assumption that telephone visits and home face-to-face visits cannot be seen as the same intervention [38], we did not extract this data.

geringer Rehospitalisierung, verbesserte Lebensqualität, mögliche Kostenersparnis

Based on a brief analysis, the data on added value of telemonitoring to telephone visits seem to go in both directions. On the one hand, mortality benefit in two studies [69, 70], telemonitoring-driven reduction in HF-related visits/hospitalisations was observed in three studies [70-73], high rates of compliance were reported in two [71, 74], quality of life improvement was reported

[30] ASSESS-DHT Life-cycle framework, question number 112

in one [73], and overall lower costs for the home telemonitoring group were reported in another study [75]. On the other hand, three studies reported no added benefit of telemonitoring to telephone visit-based DMPs [76-78], no effect on specific endpoints of mortality, HF-related admissions, and HRQoL was reported in two studies [71, 76], and higher costs in the telemonitoring group were reported in one study [71]. One of the hypotheses for reduced effect of telephone visits on the outcome of rehospitalisation/ED visits is that the reporting of symptoms via telephone gives less room for the nurse to confirm or dispute the patient's concern. Furthermore, the patient's concern puts the nurse in the position of having to act on the information in the absence of more detail at hand, thus referring the patient to the hospital [35].

4. Better resource distribution, less costs

effektivere Ressourcenverteilung

Fourth assumption is that effective telemonitoring helps distributing healthcare resources more effectively (less hospitalisations, less ED visits, more patient satisfaction) and thus leads to more cost-effective care delivered to HF patients [52].

mögliche Kosteneinsparung durch TM (naiver Kostenvergleich)

Only one of the studies assessed reported data on costs [38][31]. A naïve comparison of direct costs for the payer would be in today's terms 6,756 (±12,398) EUR for IG, compared to the cost for CG being 7,483 (±14,055) EUR – implying that telemonitoring brought about a saving for the healthcare system [38]. In the absence of statistical power for sub-analyses, the authors nonetheless suggest a hint towards a relationship between NYHA class and telemonitoring, where telemonitoring is suggested to reduce hospital costs for patients in New York Heart Association (NYHA) classes 1 and 2, while it increases hospital costs for patients classes 3 and 4 [38]. The above data, however, ought not to be taken as conclusive as for the cost-effectiveness assessment of the intervention, a more comprehensive economic modelling approach would need to be undertaken.

retrospektive Analyse aus Tirol: 42 zusätzliche krankenhausfreie Tage

An Austrian cost-effectiveness analysis of the HerzMobil Tyrol program based on the retrospective cohort study outlined above [25] concluded its cost-effectiveness with incremental cost-effectiveness ratio being 4,773 EUR per one quality adjusted life year gained [41]. It was argued that HerzMobil Tyrol program brought about an average of 42 additional hospital-free days, 40 additional days alive, and 0.12 avoided hospitalizations per patient-year compared with the control arm. Important to emphasise is that the control arm over against which the HerzMobil Tyrol program is analysed included no DMPs, but merely a standard discharge planning and an unstructured follow-up left to the respective family doctor or internist [25].

Berücksichtigung von informellen Pflegekräften

Apart from direct costs to the healthcare system, what could also be considered are costs for informal caregivers who tend to play an important role in taking care of HF patients [79]. For a more holistic perspective, their costs from decreased production could also be taken into account.

[31] ASSESS-DHT Life-cycle framework, question number 31

Further aspects to consider

Further aspects to consider concern the questions of interoperability, reimbursement, acceptance, and ethics.

Vorschlag aus Deutschland: Vereinheitlichung von Projekten

In terms of interoperability, an analysis of telemonitoring in Germany suggests a need to harmonise the variety of HF telemonitoring projects with the goal of being able to scale up beyond regional networks [52]. While some states have invested in harmonisation of the standards and IT systems, others have not. A recent decision by the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA), however, is a step towards convergence as telemedical care was approved as part of standard care for a narrow HF patient group (approx. 150,000 patients) [80] and can be embedded in the established DiGA pathway [81]. Similarities can be found here with the Austrian context where the regions are in charge of this aspect of care of HF patients and, even though there has been a substantial variety in approaches over the past decade, also a convergence towards one type of program (a nurse-led face-to-face DMP) is becoming the standard of care for most of Austrian regions (see B0001). In the Austrian context, this shift is, furthermore, supported by a digital solution that can bring together different data sources for further research on the topic as well as the inclusion of telemonitoring inclusion in the electronic health records, elektronische Gesundheitsakte (ELGA) [11, 82]. The focus on interoperability of data comes also from the European Commission which outlines the need for interoperability at legal, organisational, semantic, and technical levels [83].

Refundierung noch nicht überall möglich

With respect to reimbursement, the results on the added clinical benefit of the addition of telemonitoring have been heterogeneous and hence, in the absence of conclusive evidence, many systems struggle with setting up the reimbursement pathways [52, 84-86].

Pat. äußern Bedenken bzgl. Datenschutz

Concerning further ethical issues reported on in the literature on HF telemonitoring, patients raised concerns regarding privacy intrusion [52, 60, 87] and fear of further social isolation [52], which is particularly pertinent for the vulnerable elderly population in scope of this SR. It was argued in the German context that the high rate of refusal to participate in telemonitoring studies indicates that a substantial proportion of patients are not willing to give up face-to-face contact with medical professionals [52]. That is in line with the World Health Organisation (WHO) guideline on digital interventions which suggests that telemonitoring systems should complement and enhance health system functions through mechanisms such as accelerated exchange of information [88].

weitere Diskussionspunkte

Further issues that require more studying include the discrepancy with regards quality of life of female HF patients, where it was observed that women suffer from worse quality of life than men as assessed by EQ-5D-5L despite their better left-ventricular ejection fraction (LVEF) results [89]. Concerns related to the use of artificial intelligence, its potential biases, and regulatory challenges were highlighted as further points of study [87, 90].

ASSESS-DHT use case analysis

ASSESS-DHT Taxonomie: Zweckbestimmung der Technologie

The taxonomy brought added value with respect to making explicit the medical purpose of the technology, significance of the information provided, vulnerability of the patient's current health state, and information about the use of artificial intelligence (AI). A point of contention arose with respect to defining significance of the information provided by the DHTs in the present SR.

While the category "inform" refers to the provision of information with the purpose of informing clinical or patient management of a disease or conditions, the category "drive" refers to the provision of information with the purpose of driving the management of a disease or conditions. The contention lied in the perceived lack of substantial difference between these two categories as the present digital health technology (DHT) under assessment does, on the one hand, merely inform the healthcare professionals about the health state of the patient, but on the other hand, the purpose of that information is to actually drive changes in the management of the patient. It was unclear which category to use, whether "inform" or "drive". It was concluded by the authors that it is hard to conceive of a DHT where the information is of such little value and purpose that it has no potential to actually drive change in patient management.

in dieser systematischen Übersichtsarbeit: nicht alle ASSESS-DHT Fragen beantwortbar

Because this present SR was not a standard single-technology assessment with just one specific intervention (but it included a class of interventions that were analysed together), it was not possible to answer a number of detailed ASSESS-DHT manual background questions [29]. For instance, questions such as whether users can recover their data also when disconnected, if there is a clear and accessible data retention policy for the DHT, or whether notifications are sent to the user if failure in connections occur. Many of the specific questions regarding the technical performance of the device or its interoperability required detail that was not possible to find on the internet without access to manufacturer's submission file (which we did not have at hand as more interventions were analysed as part of a class). Specific ASSESS-DHT questions on safety, technical safety, and evidence base questions were outside the scope of this SR.

Ongoing studies

laufendes Pilotprojekt

No potentially relevant ongoing RCTs were found. A pre-operation pilot project for the application HerzMobil was found to be currently ongoing [91].

Limitations

Limitationen

Limitations of the present study are related to methods, context, and the technology.

zeitl. Begrenzung (ab 2010)

Ausschluss von Abstracts, wenn Hausbesuche nicht erwähnt wurden

Methods-related limitations include limitations to the systematic search with respect to time (since 2010) and language (English and German), which might have meant that relevant studies published before the cut-off time point or in another language were missed. Furthermore, in the process of screening of abstracts, the authors excluded those studies that did not mention some variation of face-to-face home visits, which might have led to the exclusion of relevant literature.

in einer Studie auch Patient:innen mit Diabetes inkludiert

Context-related limitations include a proportion of diabetes patients without the HF diagnosis being part of one of the studies assessed [35]. Also, there was a lack of consistency between telemonitoring interventions in the studies assessed with respect to their length (one to two vs six months) and very low reporting standard in one of the studies under assessment [35]. Furthermore, the detail in inclusion and exclusion criteria differed between the studies, with respect to significant aspects such as age, NYHA class, or severity of comorbidities upon entering the study.

unterschiedliche Technologien verfügbar

Technology-related limitations stem from the fact that the present SR was approached as a single technology assessment, even though the technological solutions used for telemonitoring patients in the studies as well as in the Austrian context vary. The devices used in the studies are dated between 2007 and 2015, which is a significant limitation given the speed of technological innovations over the past decade. However, because the common denominator between the studies and the Austrian context was deemed sufficient by the authors, all these devices were approached as one category of devices. Due to this decision, many individual detailed assessment questions suggested by ASSESS-DHT Manual or the Life-cycle framework [29] that pertained to a single technology were not possible, or too complex to be answered within the scope of this present SR.

8 Conclusion

moderate Evidenz für potenziellen Nutzen von Telemonitoring

We found evidence of moderate strength suggesting a hint towards the conclusion that telemonitoring combined with face-to-face DMPs is more effective than DMPs alone when it comes of rehospitalisation due to HF and HRQoL. The evidence found provides low certainty for the benefit of telemonitoring in DMPs and the authors conclude that there is a need for more evidence that could establish the clinical effectiveness of telemonitoring in the specific Austrian context and that could serve as a basis for a robust cost-effectiveness evaluation.

Studie mit kleiner Population und überlappenden Konfidenzintervallen

Even though the key study driving the conclusion was conducted in a high standard, it does not follow that the conclusion is also of high certainty because it was a pilot study that was significantly underpowered and the confidence intervals with respect to rehospitalisations due to HF were wide and overlapping. Furthermore, interventions in the clinical trials analysed were very heterogeneous in nature and their success seems to depend on a number of clinical, technical, and human factors. And, because the results on the effects of telemonitoring interventions are equally very heterogeneous and the applicability of the data that drive this recommendation is limited, it is expected that new study results could potentially influence the effect estimate considerably. Especially, as the DHT at stake is a Class IIb medical device, a quality controlled study done in the specific Austrian context entrenched in the established DMPs could answer the research question with sufficient certainty. Focusing on the critical clinical and organisation outcomes, such study should analyse the added value of telemonitoring itself, examine attitudes of health professionals delivering the intervention, as well as examine one of the pivotal aspects of telemonitoring that is presumably very much context dependent, which is compliance with the up-to-date telemonitoring application used. The evaluation concept is supposed to serve as a yardstick when considering the preparation of such study.

potenzielle Rolle des Evaluationskonzepts

unzureichende Daten für die Kosteneffektivität

There was no data of sufficient quality found that would answer whether the addition of telemonitoring to HF DMPs is a cost-effective intervention. This lack of robust economic evidence represents a major evidence gap. It is recommended that a comprehensive cost-effectiveness analysis is performed from the perspective of Austrian payers and a budget impact analysis is conducted for long-term sustainability of the intervention.

Empfehlungen für Evaluationskonzept zu ...

The key tentative recommendations based on the evaluation concept include the following:

... Studiendesign ...

1. A controlled study, or a high-quality observation study, should be considered to establish the added benefit of a Class IIb telemonitoring medical device under assessment.
2. Critical outcomes that could be considered include: HF-related mortality, HRQoL, and compliance.

... und Endpunkten

3. Results from the study could be applied into health economic modelling (that was already conducted based on retrospective data from Tyrol) to establish cost-effectiveness of telemonitoring as part of DMPs.
4. Organisational questions that have an impact on health professionals and that present a key evidence gap could be surveyed.

5. Equal opportunities for patients could be considered both in the study context as well as when establishing the telemonitoring HF DMPs.
6. Implementation and monitoring structures could be put in place to oversee the DHT's development later in the life-cycle.

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Appendix

Evidence tables of individual studies included for clinical effectiveness and safety

Table A-1: Telemonitoring with DMPs for patients with HF: Results from randomised controlled trials

Author, year	Bowles et al. (2009) [35]	Mizukawa et al. 2019 [34]	Pekmezaris et al. (2012) [38]
Country	USA	Japan	USA
Sponsor	Centers for Disease Control and Prevention	Hiroshima Prefecture Cardiac Ikiiki Centers	New York State Dep. of Health
Intervention/Product	Telemonitoring on top of in-person nurse visits	Telemonitoring on top of in-person nurse visits	Telemonitoring on top of in-person nurse visits
Comparator	In-person nurse visits (usual care) and in-person nurse visits with telephone contact	In-person visits and usual care without visits	In-person nurse visits (usual care)
Study design	Randomised controlled trial	Randomised controlled trial	Randomised controlled trial
Study period	NA	01/2013 – 09/2015	07/2007 – 03/2009
Number of pts	Total (TMG vs TG vs UCG) 303 (98[32] vs 93 vs 112)[33]	Total (TMG vs SMG vs UCG) 57 (20 vs 18 vs 19)[34]	Total (TMG vs UCG) 168 (83 vs 85)
Inclusion criteria	Post-hospitalisation home care with diagnosis of HF or diabetes, 55 years of age and older, cognitively intact, able to hear and see well enough to use the equipment, English speaking, having a fixed telephone	Post-hospitalisation (within 2 years) home care with HF diagnosis, NYHA class II-IV at registration (but III to IV if exacerbated)	Post-hospitalisation home care with HF diagnosis, 65 years of age and older
Exclusion criteria	Pts followed by other programs	Severe comorbidity, inability to stand or communicate by telephone, cognitive impairment scores of ≤20 out of 30 on HDS-R, physical difficulty undergoing the trial	NA
Primary outcome measure	Efficacy: Rehospitalisation for all causes at 60 days Safety: NA Economics: NA	Efficacy: HRQoL measured via MLWHFQ Safety: NA Economics: NA	Efficacy: rehospitalisation for all causes, total LOS Safety: NA Economics: cost to the healthcare system
Secondary outcome measure	Efficacy: ED visit at 60 days, subjective health status rating	Efficacy: all cause mortality rate, rehospitalisation for all causes, rehospitalisation due to HF, adherence	NA

[32] 86 pts had the diagnosis of HF and 12 of diabetes.

[33] mITT analysis reports on 303 pts, as 35 pts did not meet the threshold. Despite randomization, there were significantly more HF patients in the Telemonitoring group (84%) compared to the Telephone group (54%) and Usual care group (59%).

[34] Of 61 recruited, 59 agreed to participate. Of 59, 1 withdrew consent right after randomization and 1 died – hence 57 pts are considered as total.

Author, year	Bowles et al. (2009) [35]	Mizukawa et al. 2019 [34]	Pekmezaris et al. (2012) [38]
Age of patients, IG vs CGs, mean yrs (±SD)	75 (NA)[35]	70.5 (±13.3) vs 69.4 (±12.9) vs 74.5 (±12.1)	81 (±7) vs 83 (±7)
Sex, female:male, IG vs CGss n	191:112[35]	10:10 vs 3:15 vs 9:10	47:36 vs 57:28
Ethnicity, white:other, IG vs CGs, n (%)	unclear[36]	NA[37]	75:8 (90.4:9.6) vs 78:7 (91.8:8.2)
Life expectancy <6 mos, IG vs CGs, n (%)	NA	NA	41 (50.0) vs 36 (42.9)
Primary HF diagnosis, IG vs CGs, n (%)	197 (65)	NA	64 (77.1) vs 54 (63.5)[38]
NYHA III – IV, IG vs CGs, n (%)	NA	11 (55.0) vs 7 (38.9) vs 6 (31.6)	NA
MLWHFQ, IG vs CGs, mean n (±SD)	NA	47.6 (±26.8) vs 37.3 (±22.7) vs 32.2 (±27.8)	NA
Risk for rehospitalisation	Pra scores: mean 0.37[39]	NA	NA
Follow-up (months)	3[40]	24[41]	3[42]
Loss to follow-up, n (%)	35 (10.4)	13 (22)	unclear[43]
Outcomes			
Efficacy			
All cause mortality rate, IG vs CGs, n (%), CI%]	NA	3 (15.0) [0.0-30.6] vs 4 (22.2) 3.0-41.4] vs 3 (15.8) [0.0-32.2]	NA
Rehospitalisation for all causes, IG vs CGs, n (%), [CI%]	16 (16) [9.7-25.3] vs 17 (17) [11.1-27.8] vs 9 (10) [3.8-14.8][44]	12 (60.0) [36.1-80,9] vs 11 (61.1) [35.7-82.7] vs 13 (68.4) [43.4-87.4] [45]	42 (51) vs 41 (48)[46]

[35] Reported for the full population, not divided between intervention and control.

[36] Not stated exactly, but population of study mainly Caucasian.

[37] Presumably East Asian ethnicity.

[38] All the remaining pts had secondary HF diagnosis.

[39] Indicating low to moderate risk for readmission

[40] 1-2 months intervention, 1 month follow-up.

[41] 12 months intervention, 12 months follow-up.

[42] 2 months intervention, 1 month follow-up.

[43] No loss to follow-up reported, yet several reported numbers do not follow the expected percentages that would be assumed if there was no loss to follow-up.

[44] At 2 months. Presumably rehospitalization from any cause, but not explicit in the manuscript.

[45] At 24 months.

[46] At 3 months. Also, no p value was reported and hence CI could not be calculated.

Author, year	Bowles et al. (2009) [35]	Mizukawa et al. 2019 [34]	Pekmezaris et al. (2012) [38]
Rehospitalisation due to HF, IG vs CGs, n (%), [CI%]	NA	4 (20.0) [5.7-43.7] vs 5 (27.8) [9.7-53.5] vs 11 (57.9) [33.5-79.7][45]	NA
HRQoL, IG vs CGs, point imporvement at 24 months	No significant difference in health ratings, depression rates, or health status adjusting for site, number of visits, or HF diagnosis[47]	MLWHFQ 12 vs 0 vs 0, p=0.039	NA
Hospital LOS, IG vs CGs, n of days, average (±SD)	NA	NA	4.9 (±8.2) vs 4.8 (±10.2)
ED visit at 60 days, IG vs CGs, n (%), [CI%]	17 (17) [10.6-26.4] vs 17 (17) [11.1-27.8] vs 9 (10) [3.8-14.8]	NA	NA
Compliance, IG, n (%) of pts at 12 months follow-up	NA	14 (70)[48]	NA
Depression, PHQ-9, point improvement at 3 months	No significant difference in depression scores after adjustments for HF and number of nursing visits	NA	NA
Safety			
	NA	NA	NA
Economics			
Cost to healthcare system, IG vs CGs, n average cost (±SD)	NA	NA	6756 (±12 398) vs 7483 (±14 055)[49]

Abbreviations: CG … controlled group, ED … emergency department, HDS-R … Hasegawa's Dementia Scale Revised, HRQoL … health-related quality of life, HF … heart failure, IG … intervention group, LOS … length of stay, MLWHFQ … Minnesota Living with Heart Failure Questionnaire, mITT … modified intention to treat analysis, NA … not available,
NYHA … New York Heart Association, pts … patients, SMG … self-management group, TMG … telemonitoring group, TG … telephone group, UCG … usual care group

[47] No other numerical detail reported, except the narrative description above.

[48] Number of pts that were at least 70.0% compliant with daily data transmission using telemonitoring, with no break in information transfer for > 30 days (except during hospitalization).

[49] Costs from 2012 in dollars we converted using average exchange rate of dollar to euro from 2012 and adjusted for inflation between 2012 and 2025 to compare the cost of the intervention in today's value of euro. The sums are reported on 77/83 pts (IG) and 78/83 pts (CG).

Risk of bias tables and GRADE evidence profile

Internal validity of the included studies was judged by two independent researchers. In case of disagreement a third researcher was involved to solve the differences. A more detailed description of the criteria used to assess the internal validity of the individual study designs can be found in the Internal Manual of the AIHTA [2] and in the Guidelines of EUnetHTA [3].

Table A-2: Risk of bias – study level (randomised studies), see [32]

Trial	Endpoints	Bias arising from the randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall risk of bias
Bowles et al. (2009) [35]	Rehospitalisation for all causes	Low	Some concerns	High[50]	High (same footnote)	High (same footnote)	High
	HRQoL	Low	Some concerns	High (same footnote)	High (same footnote)	High (same footnote)	High
	ED visit at 60 days	Low	Some concerns	High (same footnote)	High (same footnote)	High (same footnote)	High
Mizukawa et al. (2012) [34]	All cause mortality rate	Low	Low	Low	Low	Low	Low
	Rehospitalisation for all causes/for HF	Low	Low	Low	Low	Low	Low
	HRQoL	Low	Low	Low	Some concerns	Low	Some concerns
	Compliance	Low	Low	Low	Low	Low	Low
Pekmezaris et al. (2012) [38]	Rehospitalisation for all causes	Low	Low	Low	Low	Some concerns	Some concerns
	Hospital LOS	Low	Low	Low	Low	Some concerns	Some concerns
	Cost to healthcare system	Low	Low	Low	Low	Some concerns	Some concerns

[50] In the absence of appropriate reporting of baseline data as well as outcome data, the risk is judged as high.

Table A-3: Evidence profile: efficacy and safety of telemonitoring as part of DMPs for HF patients [34, 35, 38]

Quality assessment							Summary of findings				
Number of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Number of patients		Effect		Quality
							[intervention]	[comparison]	Relative (95% CI)	Absolute (95% CI)	
All cause mortality rate											
1	Randomised trial	Not serious	NA	Not serious	Serious	NA	3/20	3/19	0.95	150/1000	moderate ⊕⊕⊕◯
Rehospitalisation for all causes in HF pts											
2	Randomised trial	Not serious	Not serious	Not serious	Serious	NA	54/103	54/104	1.01	524/1000	moderate ⊕⊕⊕◯
Rehospitalisation for all causes in HF and diabetes pts											
1	Randomised trial	Serious	NA	Not serious	Not serious	NA	16/98	9/112	2.03	162/1000	moderate ⊕⊕⊕◯
Rehospitalisation due to HF											
1	Randomised trial	Not serious	NA	Not serious	Serious	NA	4/20	10/19	0.38	200/1000	moderate ⊕⊕⊕◯
HRQoL											
1	Randomised trial	Not serious	NA	Not serious	Serious	NA	12/20	0/19	NA	NA	moderate ⊕⊕⊕◯
Hospital LOS											
1	Randomised trial	Not serious	NA	Not serious	Not serious	NA	83	85	NA	NA	high ⊕⊕⊕⊕
ED visit at 60											
1	Randomised trial	Serious	NA	Not serious	Not serious	NA	17/98	9/112	2.16	173/1000	moderate ⊕⊕⊕◯
Compliance											
1	Randomised trial	Not serious	NA	Not serious	Serious	NA	14/20	NA	NA	NA	moderate ⊕⊕⊕◯

Abbreviations: CI … confidence interval, ED … emergency department, HF … heart failure, HRQoL … health-related quality of life, LOS … length of stay, NA … not available

Comments: If serious or very serious, please give reasons for the classification (mandatory)

Nomenclature for GRADE table:

Limitations: 0: no limitations or no serious limitations; -1: serious limitations

Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency

Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty

Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

Applicability table

Table A-4: Summary table characterising the applicability of a body of studies

Domain	Description of applicability of evidence
Population	Population of the present SR was to some extent similar to the target population of the decision. Majority of the patient included were Caucasian, just like the target population. However, the key outcomes driving the recommendations come from the Japanese study, where presumably East Asian population was most prevalent [34]. Inclusion and exclusion criteria from the studies were also judged to be relevant to the decision population as the patients were elderly and, for the most part, had the diagnosis of HF. One study lacked information about exclusion criteria [38], while there was variation in the more detailed inclusion and exclusion criteria in [34, 35] that were judged not to have a major impact on the conclusion of the present SR.
Intervention	The transmission technology used by patients in the studies was partially obsolete (used between 2007 and 2015), however, its key aspects are well established and remain the same (weight scale, glucometer, or pulse oximeter) even in the newer versions that are based on mobile phone applications. The face-to-face aspects of the DMPs were equally substantially similar and thus applicatble to the decision context.
Comparators	Same as the information about face-to-face DMPs, the DMP control arm of the interventions was sufficiently similar.
Outcomes	The outcomes found in the literature were, to a large extent, in line with the outcomes predefined in the project protocol and relevant for making a conclusion with respect to clinical added benefit.
Setting	The settings included were USA and Japan. It remains a question therefore whether they translate sufficiently well to the Austrian decision setting.

Research questions

Table A-5: EUnetHTA assessment elements used

Description of the technology	
Element ID	Research question
B0001	What is telemonitoring as part a disease management program (DMP) and the comparator of a DMP alone?
B0002	What is the claimed benefit of telenmonitoring with DMPs compared to DMPs alone?
B0003	What is the phase of development and implementation of telemonitoring in DMPs for patients with HF?
B0004	What supplies are needed to use telemonitoring in DMPs for patients with HF?
B0008	Who administers telemonitoring in DMPs for patients with HF and in what context and level of care are they provided?
B0009	What kind of special premises are needed to use telemonitoring in DMPs for patients with HF?
A0021	What is the reimbursement status of telemonitoring in DMPs for patients with HF?

Health problem and Current Use	
Element ID	Research question
A0002	What is the disease or health condition in the scope of this assessment?
A0003	What are the known risk factors for heart failure?
A0004	What is the natural course of heart failure?
A0005	What is the burden of disease for patients with heart failure?
A0006	What are the consequences of heart failure for the society?
A0024	How is heart failure currently diagnosed according to published guidelines and in practice?
A0025	How is heart failure currently managed according to published guidelines and in practice?
A0007	What is the target population in this assessment?
A0023	How many people belong to the target population?
A0011	How much can telemonitoring for HF patients be utilised?

Clinical Effectiveness	
Element ID	Research question
D0001	What is the expected beneficial effect of telemonitoring on mortality?
D0006	How does telemonitoring affect progression (or recurrence) of heart failure?
D0016	How does the use of telemonitoring affect activities of daily living?
D0013	What is the effect of telemonitoring on disease-specific quality of life?
D0017	Was the use of telemonitoring worthwhile?

Literature search strategies

Search strategy for Cochrane

Search Name: Telecardiology	
Search date: 18.07.2025	
ID	Search
#1	MeSH descriptor: [Heart Failure] explode all trees
#2	((heart OR cardiac OR myo?cardial) NEAR (failure* OR de?compens* OR de-compens*)):ti,ab,kw
#3	(HF):ti,ab,kw
#4	#1 OR #2 OR #3
#5	MeSH descriptor: [Hospitalization] this term only
#6	(hospitali?*):ti,ab,kw
#7	MeSH descriptor: [Patient Discharge] explode all trees
#8	((after* OR post*) NEAR (release* OR discharge* OR hospitali?*)):ti,ab,kw
#9	#5 OR #6 OR #7 OR #8
#10	#4 AND #9
#11	(disease NEXT management NEXT program*):ti,ab,kw
#12	(DMP):ti,ab,kw
#13	MeSH descriptor: [Telemedicine] this term only
#14	(tele?med*):ti,ab,kw
#15	(tele-med*):ti,ab,kw
#16	(tele*health):ti,ab,kw
#17	tele-health
#18	("virtual medicine")
#19	MeSH descriptor: [Mobile Applications] this term only
#20	MeSH descriptor: [Internet] explode all trees
#21	MeSH descriptor: [Cell Phone] explode all trees
#22	MeSH descriptor: [Computers, Handheld] explode all trees
#23	MeSH descriptor: [Medical Informatics Applications] this term only
#24	MeSH descriptor: [Therapy, Computer-Assisted] this term only
#25	(app OR apps):ti
#26	(app OR apps):ab
#27	(online OR web OR internet OR digital*):ti
#28	((online OR web OR internet OR digital*) NEAR/3 (based OR application* OR intervention* OR program* OR therap*)):ab
#29	(phone* OR telephone* OR smart*phone* OR smart-phone* OR cell*phone* OR cell-phone* OR smart*watch* OR smart-watch*):ti
#30	((phone* OR telephone* OR smart*phone* OR smart-phone* OR cell*phone* OR cell-phone* OR smart*watch* OR smart-watch*) NEAR/3 (based OR application* OR intervention* OR program* OR therap*)):ab
#31	(mobile health OR m*health OR m-health OR e*health OR e-health OR e*mental OR e-mental):ti
#32	((mobile health OR m*health OR m-health OR e*health OR e-health OR e*mental OR e-mental) NEAR/3 (based OR application* OR intervention* OR program* OR therap*)):ab
#33	(mobile* NEAR/3 (based OR application* OR intervention* OR device* OR technolog*)):ti,ab,kw
#34	(tele*monitor*):ti,ab,kw (Word variations have been searched)
#35	(tele-monitor*):ti,ab,kw (Word variations have been searched)
#36	(tele*manag*):ti,ab,kw (Word variations have been searched)
#37	(tele-manag*):ti,ab,kw (Word variations have been searched)
#38	(tele*surveil*):ti,ab,kw (Word variations have been searched)
#39	(tele-surveil*):ti,ab,kw (Word variations have been searched)

#40	(tele?cardiolog*) (Word variations have been searched)
#41	(tele-cardiolog*) (Word variations have been searched)
#42	#11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41
#43	#10 AND #42
#44	((tele-medic* OR tele?medic* OR tele?health OR tele-health OR tele?monitor* OR tele-monitor* OR tele?manag* OR tele-manag* OR tele?surveil* OR tele-surveil*) NEAR ((heart OR cardiac OR myo?cardial) NEXT (failure* OR de?compens* OR de-compens*) OR HF)):ti,ab,kw
#45	(Herz?Mobil*) (Word variations have been searched)
#46	#43 OR #44 OR #45
#47	#43 OR #44 OR #45 with Publication Year from 2010 to 2025, in Trials
#48	#43 OR #44 OR #45 with Cochrane Library publication date Between Jan 2010 and Jul 2025
#49	#47 OR #48
#50	English:la
#51	German:la
#52	#50 OR #51
#53	#49 AND #52
#54	(conference proceeding):pt
#55	(abstract):so
#56	(clinicaltrials OR trialsearch OR ANZCTR OR ensaiosclinicos OR Actrn OR chictr OR cris OR ctri OR registroclinico OR clinicaltrialsregister OR DRKS OR IRCT OR Isrctn OR rctportal OR JapicCTI OR JMACCT OR jRCT OR JPRN OR Nct OR UMIN OR trialregister OR PACTR OR R.B.R.OR REPEC OR SLCTR OR Tcr):so
#57	#54 OR #55 OR #56
#58	#53 NOT #57
Total hits: 486	

Search strategy for Embase

Search Name: Telecardiology	
Search date: 18.07.2025	
ID	Search
#1	'heart failure'/exp (failure* OR de$compens* OR 'de compens*')
#2	(heart OR cardiac OR myo$cardial) NEAR/2
#3	hf:ti,ab
#4	#1 OR #2 OR #3
#5	'hospitalization'/mj
#6	'hospital discharge'/exp
#7	((after* OR post*) NEAR/2 (release* OR discharge* OR hospitali?*)):ti,ab
#8	#5 OR #6 OR #7
#9	#4 AND #8
#10	'disease management program'/exp
#11	'disease management program*'
#12	dmp:ti,ab
#13	'tele-med*':ti,ab 'telemedicine'/mj
#14	'telemed*':ti,ab OR 'tele?med*':ti,ab OR
#15	'telemonitoring'/exp
#16	'virtual medicine'
#17	'telehealth'/mj
#18	telehealth OR tele?health

#19	'tele-health'
#20	'mobile application'/exp/mj
#21	'internet'/mj
#22	'mobile phone'/exp
#23	'personal digital assistant'/exp
#24	'computer assisted therapy'/exp/mj
#25	app:ti,ab OR apps:ti,ab
#26	online:ti OR web:ti OR internet:ti OR digital*:ti
#27	((online OR web OR internet OR digital*) NEAR/2 (based OR application* OR intervention* OR program* OR therap*)):ab
#28	phone*:ti OR telephone*:ti OR smart$phone*:ti OR 'smart phone*':ti OR cell$phone*:ti OR 'cell phone*':ti OR smart$watch*:ti OR 'smart watch*':ti
#29	((phone* OR telephone* OR smart$phone* OR 'smart phone*' OR cell$phone* OR 'cell phone*' OR smart$watch* OR 'smart watch*') NEAR/3 (based OR application* OR intervention* OR program* OR therap*)):ab
#30	'mobile health':ti OR m$health:ti OR 'm-health':ti OR e$health:ti OR 'e-health':ti OR e$mental:ti OR 'e-mental':ti
#31	(('mobile health' OR mhealth OR 'm-health' OR ehealth OR 'e-health' OR emental OR 'e-mental') NEAR/3 (based OR application* OR intervention* OR program* OR therap*)):ab
#32	(('mobile health' OR mhealth OR 'm-health' OR ehealth OR 'e-health' OR emental OR 'e-mental') NEAR/3 (based OR application* OR intervention* OR program* OR therap*)):ab
#33	(('mobile health' OR m$health OR 'm-health' OR e$health OR 'e-health' OR e$mental OR 'e-mental') NEAR/3 (based OR application* OR intervention* OR program* OR therap*)):ab
#34	(mobile* NEAR/2 (based OR application* OR intervention* OR device* OR technolog*)):ti,ab
#35	telemonitor*:ti,ab OR tele?monitor*:ti,ab
#36	'tele-monitor*':ti,ab
#37	'telemanag*':ti,ab OR 'tele?manag*':ti,ab
#38	'tele-manag*':ti,ab
#39	'telesurveil*':ti,ab OR 'tele?surveil*':ti,ab
#40	'tele-surveil*':ti,ab
#41	'telecardiology'/exp
#42	telecardiolog* OR tele?cardiolog*
#43	'tele-cardiolog*'
#44	#10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43
#45	#9 AND #44
#46	('tele medic*' OR tele$medic* OR tele$health OR tele health' OR tele$monitor* OR 'tele monitor* OR tele$manag* OR 'tele manag*' OR tele$surveil* OR 'tele surveil*') NEAR/2 (heart OR cardiac OR myo$cardial) NEAR/2 (failure* OR de$compens* OR 'de compens*')
#47	herzmobil* OR herz?mobil*
#48	'herz mobil*'
#49	#45 OR #46 OR #47 OR #48
#50	(#45 OR #46 OR #47 OR #48) AND [2010-2025]/py
#51	#50 AND [2010-2025]/py AND ([english]/lim OR [german]/lim)
#52	#51 AND 'Conference Abstract'/it
#53	'clinical trial':dtype
#54	#52 OR #53
#55	#51 NOT #54
Total hits: 723	

Search strategy for Medline via Ovid

Search Name: Telecardiology	
Search date: 18.07.2025	
ID	Search
#1	exp Heart Failure/ (160756)
#2	((heart or cardiac or myo?cardial) adj3 (failure* or de?compens* or de-compens*)).mp. (302698)
#3	HF.ti,ab. (72291)
#4	1 or 2 or 3 (336854)
#5	*Hospitalization/ (50591)
#6	hospitali#*.mp. (472421)
#7	*Patient Discharge/ (18499)
#8	((after* or post*) adj3 (release* or discharge* or hospitali#*)).mp. (124074)
#9	5 or 7 or 8 (182650)
#10	4 and 9 (9801)
#11	disease management program*.mp. (2241)
#12	DMP.ti,ab. (3669)
#13	exp Telemedicine/ (53515)
#14	tele-medicine.ti,ab. (183)
#15	tele?medicine.ti,ab. (22649)
#16	virtual medicine.mp. (103)
#17	tele?health.mp. (19133)
#18	tele-health.mp. (372)
#19	exp Mobile Applications/ (15294)
#20	exp Internet/ (107404)
#21	exp Cell Phone/ (26188)
#22	exp Computers, Handheld/ (15892)
#23	Medical Informatics Applications/ (2555)
#24	Therapy, Computer-Assisted/ (7051)
#25	(app or apps).ti. (14610)
#26	(online or web or internet or digital*).ti. (167537)
#27	((online or web or internet or digital*) adj3 (based or application* or intervention* or program* or therap*)).ab. (97982)
#28	(phone* or telephone* or smart?phone* or smart-phone* or cell?phone* or cell-phone* or smart?watch* or smart-watch*).ti. (31624)
#29	((phone* or telephone* or smart?phone* or smart-phone* or cell?phone* or cell-phone* or smart?watch* or smart-watch*) adj3 (based or application* or intervention* or program* or therap*)).ab. (20866)
#30	(mobile health or mhealth or m-health or ehealth or e-health or e?mental or e-mental).ti. (10686)
#31	(mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab. (27597)
#32	tele?monitor*.ti,ab. (2684)
#33	tele-monitor*.ti,ab. (225)
#34	tele?manag*.ti,ab. (82)
#35	tele-manag*.ti,ab. (19)
#36	tele?surveil*.ti,ab. (35)
#37	tele-surveil*.ti,ab. (5)
#38	tele?cardiolog*.mp. (309)
#39	tele-cardiolog*.mp. (29)
#40	11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 (432684)
#41	10 and 40 (369)

#42	((tele-medic* or tele?medic* or tele?health or tele-health or tele?monitor* or tele-monitor* or tele?manag* or tele-manag* or tele?surveil* or tele-surveil*) adj3 (((heart or cardiac or myo?cardial) adj3 (failure* or de?compens* or de-compens*)) or HF)).ti,ab. (373)
#43	Herz?Mobil*.mp. (17)
#44	41 or 42 or 43 (719)
#45	limit 44 to yr="2010 - 2025" (631)
#46	limit 45 to (english or german) (611)
#47	remove duplicates from 46 (611)
Total hits: 611	

Search strategy for HTA-INATHTA

Search Name: Telecardiology	
Search date: 18.07.2025	
ID	Search
1	(tele-cardiolog*) OR (telecardiolog*) OR (("tele-surveil*") OR (telesurveil*) OR ("tele-manag*") OR (telemanag*) OR ("tele-monitor*") OR (telemonitor*) OR ((mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[Title] OR (mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[abs]) OR (((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental)[title]) OR (((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)[title]) OR (((online OR web OR internet OR digital*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((online OR web OR internet OR digital*)[title]) OR ((app OR apps)[Title] OR (app OR apps)[abs]) OR ("Therapy Computer-Assisted"[mh]) OR ("Medical Informatics Applications"[mh]) OR ("Computers Handheld"[mhe]) OR ("Cell Phone"[mhe]) OR ("Internet"[mhe]) OR ("Mobile Applications"[mh]) OR ("Telemetry"[mh]) OR ("Telemedicine"[mh])) OR ("Telemetry"[mh]) OR (tele-med*) OR (telemed*) OR ("Telemedicine"[mh]),"4502","2025-07-18T18:15:58.000000Z"
2	((heart OR cardiac OR myocardial) AND (failure* OR decompens* OR de-compens*)) OR ("Heart Failure"[mhe]),"481","2025-07-18T18:17:14.000000Z"
3	(((heart OR cardiac OR myocardial) AND (failure* OR decompens* OR de-compens*)) OR ("Heart Failure"[mhe])) AND ((tele-cardiolog*) OR (telecardiolog*) OR (("tele-surveil*") OR (telesurveil*) OR ("tele-manag*") OR (telemanag*) OR ("tele-monitor*") OR (telemonitor*) OR ((mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[Title] OR (mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[abs]) OR (((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental)[title]) OR (((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)[title]) OR (((online OR web OR internet OR digital*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((online OR web OR internet OR digital*)[title]) OR ((app OR apps)[Title] OR (app OR apps)[abs]) OR ("Therapy Computer-Assisted"[mh]) OR ("Medical Informatics Applications"[mh]) OR ("Computers Handheld"[mhe]) OR ("Cell Phone"[mhe]) OR ("Internet"[mhe]) OR ("Mobile Applications"[mh]) OR ("Telemetry"[mh]) OR ("Telemedicine"[mh])) OR ("Telemetry"[mh]) OR (tele-med*) OR (telemed*) OR ("Telemedicine"[mh])),"136","2025-07-18T18:17:34.000000Z"
4	((((heart OR cardiac OR myocardial) AND (failure* OR decompens* OR de-compens*)) OR ("Heart Failure"[mhe])) AND ((tele-cardiolog*) OR (telecardiolog*) OR (("tele-surveil*") OR (telesurveil*) OR ("tele-manag*") OR (telemanag*) OR ("tele-monitor*") OR (telemonitor*) OR ((mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[Title] OR (mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[abs]) OR (((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental)[title]) OR (((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)[title]) OR (((online OR web OR internet OR digital*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((online OR web OR internet OR digital*)[title]) OR ((app OR apps)[Title] OR (app OR apps)[abs]) OR ("Therapy Computer-Assisted"[mh]) OR ("Medical Informatics Applications"[mh]) OR ("Computers Handheld"[mhe]) OR ("Cell Phone"[mhe]) OR ("Internet"[mhe]) OR ("Mobile Applications"[mh]) OR ("Telemetry"[mh]) OR ("Telemedicine"[mh])) OR ("Telemetry"[mh]) OR (tele-med*) OR (telemed*) OR ("Telemedicine"[mh]))) AND (((after* OR post*) AND (release* OR discharge* OR hospitali*)) OR ("Patient Discharge"[mhe]) OR (hospitali*) OR ("Hospitalization"[mhe])),"46","2025-07-18T18:18:37.000000Z"
5	(DMP) OR ("disease management programmes") OR ("disease management programs") OR ("disease management programme") OR ("disease management program"),"42","2025-07-18T18:19:28.000000Z"
6	((DMP) OR ("disease management programmes") OR ("disease management programs") OR ("disease management programme") OR ("disease management program")) AND (((heart OR cardiac OR myocardial) AND (failure* OR decompens* OR de-compens*)) OR ("Heart Failure"[mhe])),"5","2025-07-18T18:19:54.000000Z"
7	HerzMobil*,"0","2025-07-18T18:21:10.000000Z"

8	Herz-Mobil*,"0","2025-07-18T18:21:21.000000Z"
9	(Herz-Mobil*) OR (HerzMobil*) OR (((DMP) OR ("disease management programmes") OR ("disease management programs") OR ("disease management programme") OR ("disease management program")) AND (((heart OR cardiac OR myocardial) AND (failure* OR decompens* OR de-compens*)) OR ("Heart Failure"[mhe]))) OR (((((heart OR cardiac OR myocardial) AND (failure* OR decompens* OR de-compens*)) OR ("Heart Failure"[mhe])) AND ((tele-cardiolog*) OR (telecardiolog*) OR (("tele-surveil*") OR (telesurveil*) OR ("tele-manag*") OR (telemanag*) OR ("tele-monitor*") OR (telemonitor*) OR ((mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[Title] OR (mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[abs]) OR (((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental)[title]) OR (((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)[title]) OR (((online OR web OR internet OR digital*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((online OR web OR internet OR digital*)[title]) OR ((app OR apps)[Title] OR (app OR apps)[abs]) OR ("Therapy Computer-Assisted"[mh]) OR ("Medical Informatics Applications"[mh]) OR ("Computers Handheld"[mhe]) OR ("Cell Phone"[mhe]) OR ("Internet"[mhe]) OR ("Mobile Applications"[mh]) OR ("Telemetry"[mh]) OR ("Telemedicine"[mh])) OR ("Telemetry"[mh]) OR (tele-med*) OR (telemed*) OR ("Telemedicine"[mh]))) AND (((after* OR post*) AND (release* OR discharge* OR hospitali*)) OR ("Patient Discharge"[mhe]) OR (hospitali*) OR ("Hospitalization"[mhe]))),"49","2025-07-18T18:22:28.000000Z"
10	((Herz-Mobil*) OR (HerzMobil*) OR (((DMP) OR ("disease management programmes") OR ("disease management programs") OR ("disease management programme") OR ("disease management program")) AND (((heart OR cardiac OR myocardial) AND (failure* OR decompens* OR de-compens*)) OR ("Heart Failure"[mhe]))) OR (((((heart OR cardiac OR myocardial) AND (failure* OR decompens* OR de-compens*)) OR ("Heart Failure"[mhe])) AND ((tele-cardiolog*) OR (telecardiolog*) OR (("tele-surveil*") OR (telesurveil*) OR ("tele-manag*") OR (telemanag*) OR ("tele-monitor*") OR (telemonitor*) OR ((mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[Title] OR (mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[abs]) OR (((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental)[title]) OR (((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)[title]) OR (((online OR web OR internet OR digital*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((online OR web OR internet OR digital*)[title]) OR ((app OR apps)[Title] OR (app OR apps)[abs]) OR ("Therapy Computer-Assisted"[mh]) OR ("Medical Informatics Applications"[mh]) OR ("Computers Handheld"[mhe]) OR ("Cell Phone"[mhe]) OR ("Internet"[mhe]) OR ("Mobile Applications"[mh]) OR ("Telemetry"[mh]) OR ("Telemedicine"[mh])) OR ("Telemetry"[mh]) OR (tele-med*) OR (telemed*) OR ("Telemedicine"[mh]))) AND (((after* OR post*) AND (release* OR discharge* OR hospitali*)) OR ("Patient Discharge"[mhe]) OR (hospitali*) OR ("Hospitalization"[mhe])))) FROM 2010 TO 2025,"40","2025-07-18T18:22:50.000000Z"
11	(((Herz-Mobil*) OR (HerzMobil*) OR (((DMP) OR ("disease management programmes") OR ("disease management programs") OR ("disease management programme") OR ("disease management program")) AND (((heart OR cardiac OR myocardial) AND (failure* OR decompens* OR de-compens*)) OR ("Heart Failure"[mhe]))) OR (((((heart OR cardiac OR myocardial) AND (failure* OR decompens* OR de-compens*)) OR ("Heart Failure"[mhe])) AND ((tele-cardiolog*) OR (telecardiolog*) OR (("tele-surveil*") OR (telesurveil*) OR ("tele-manag*") OR (telemanag*) OR ("tele-monitor*") OR (telemonitor*) OR ((mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[Title] OR (mobile* AND (based OR application* OR intervention* OR device* OR technolog*))[abs]) OR (((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental)[title]) OR (((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)[title]) OR (((online OR web OR internet OR digital*) AND (based OR application* OR intervention* OR program* OR therap*))[abs]) OR ((online OR web OR internet OR digital*)[title]) OR ((app OR apps)[Title] OR (app OR apps)[abs]) OR ("Therapy Computer-Assisted"[mh]) OR ("Medical Informatics Applications"[mh]) OR ("Computers Handheld"[mhe]) OR ("Cell Phone"[mhe]) OR ("Internet"[mhe]) OR ("Mobile Applications"[mh]) OR ("Telemetry"[mh]) OR ("Telemedicine"[mh])) OR ("Telemetry"[mh]) OR (tele-med*) OR (telemed*) OR ("Telemedicine"[mh]))) AND (((after* OR post*) AND (release* OR discharge* OR hospitali*)) OR ("Patient Discharge"[mhe]) OR (hospitali*) OR ("Hospitalization"[mhe])))) FROM 2010 TO 2025) AND (English OR German)[Language],"19","2025-07-18T18:23:17.000000Z"
Total hits: 19	

HTA Austria
Austrian Institute for
Health Technology Assessment
GmbH