Digital transformation in hospital care: implementation and evaluation of eHealth in clinical practice

The effects on patients, healthcare professionals and hospital organizations

Laura Kooij

DIGITAL TRANSFORMATION IN HOSPITAL CARE: IMPLEMENTATION AND EVALUATION OF EHEALTH IN CLINICAL PRACTICE

THE EFFECTS ON PATIENTS, HEALTHARE PROFESSIONALS AND HOSPITAL ORGANIZATIONS

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Voor mijn ouders,

Ed Kooij & Marja Kooij-Zwemmer

CONTENTS

CHAPTER 1

General introduction

GENERAL INTRODUCTION

Demographic and societal developments

Worldwide, the population is ageing because of increased life expectancies [1-3], low birth-rates [1], and improved healthcare [2]. This has increased the demand for healthcare, raising concerns about the increasing burden on healthcare systems and increasing care expenses. In the Netherlands, 82.4 million euros were spent on healthcare in 2019, an increase from 77.6 million euros in 2018 [4]. At least half of hospital expenditure was related to inpatient care and day care [5], so switching from inpatient to outpatient care where possible might save money.

Chronic disease

Chronic diseases have increased in prevalence due to demographic trends and behavioral factors such as lack of physical activity, smoking tobacco, or unhealthy nutrition. Overweight and obesity are also risk factors for chronic disease [6]. In 2019, 57% of people and 95% of elderly people (>75 years old) in the Netherlands had a chronic disease. In total, 31% of the general population and 86% of the elderly population had a multimorbidity (two or more chronic conditions) [7]. Chronic diseases are accountable for 71% of all deaths worldwide [6].

Patient centered care

Patient-centeredness is an important aspect of high-quality care and is defined as care that is respectful of and responsive to individual preferences, needs, and values [8]. Patient-centered care means patients are actively involved in their own care and have timely access to information [9]. This care is accessible, collaborative [9] and coordinated [9, 10], and is focused on the individual patient [10]. This is particularly relevant to patients with chronic diseases because they are responsible for the daily management of their condition [11], such as taking medication, adapting their lifestyle, and managing their symptoms [12]. Using skills and knowledge to manage your own disease is also part of self-management [11], and may be improved by support from healthcare professionals [12]. Successful self-management interventions may lead to improved quality of life [13] and reduced readmission rates [14].

Care coordination and transformation

Multiple healthcare professionals care for a patient with a chronic disease, so care needs to be coordinated and integrated [8, 15]. Shared care can improve integration; here, general practitioners and hospital consultants both participate in caring for patients with a chronic condition and exchange information over and above routine discharge and referral letters [16]. Healthcare needs to change to face the present challenges and to ensure that high-

quality, accessible, and affordable care is provided. Using information technology in healthcare, or eHealth, is a promising solution.

Policy and guidelines

In the Netherlands, healthcare change has been advocated by national policies and guidelines. The national agreement on specialist medical care 2019–2022 reported demographic and societal changes such as an aging population, an increase in multimorbidities, and technological developments. To respond to these changes, healthcare needs to transform and adapt [17]. The 'Right Care in the Right Place' policy aims to maintain or improve patient care and prevent the need for more expensive care. It also aims to provide care closer to people's home and replace existing care with the same or better quality of care, for example using eHealth [18]. This is especially relevant for patients with chronic conditions. Healthcare transformation can be supported using effective eHealth solutions to integrate healthcare delivery and to help patients control their own health [17].

In 2014, the Dutch Ministry of Health, Welfare and Sport pledged to support patients in controlling their own health using eHealth solutions. They declared that, within 5 years, 80% of patients with a chronic condition would have access to medical information; that 75% of patients would be able to perform their own health checks together with remote monitoring by healthcare professionals; and that people who receive care and support at home would be able to communicate digitally with a healthcare professional [19].

Digital health and eHealth

The World Health Organization (WHO) defines digital health as *the field of knowledge and practice associated with the development and use of digital technologies to improve health.* This definition includes eHealth [20], which can be defined as *an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve healthcare locally, regionally, and worldwide by using information and communication technology* [21]. Several definitions are available for eHealth, but include the common themes *health* (referring to the healthcare process and delivery of services) and *technology* [22]. In this dissertation, the term eHealth will be used.

Technologies

eHealth is a broad term encompassing a variety of technologies including the Electronic Medical Record (EMR), patient portal, mobile health (mHealth), telehealth, and telemedicine.

Electronic Medical Record

The EMR is a digital version of paper charts [23]; it is "an electronic record of an individual's health information and is created, gathered, managed, and consulted by authorized clinicians and staff within one healthcare organization" [24]. The EMR may include information on a patient's diagnosis, medication, and treatment plan [25].

Patient portal

A patient portal is a secure online environment where patients can access their data from the EMR. It enables communication and information sharing [26], often within one healthcare organization. Patient portals can have multiple features, including access to medical test results, management of upcoming appointments, e-consultation, and possibility to complete questionnaires.

Telehealth

Telehealth is the delivery of healthcare services provided over a distance using information and communication technology (ICT) [27]. This includes remote monitoring of vital signs, and video-consultations between patients and healthcare professionals

Implementation and evaluation of eHealth

The implementation of eHealth solutions in clinical practice is affected by multiple factors, such as technological, social, human, and organizational factors [28]. The development of eHealth should involve continuous evaluation of users' needs [29]. Various frameworks are available to assess user acceptance [30] and to guide the implementation of eHealth solutions [28, 29, 31, 32]. The following frameworks will be used in this dissertation:

- Grol and Wensing [31] suggested assessing barriers and facilitators at different levels, including the innovation (e.g., feasibility) as well as individual professional (e.g., attitude), patient (e.g., skills), social (e.g., collaboration), organizational (e.g., resources), economic and political (e.g., policy and regulations) levels.
- McGinn et al [33] summarized the barriers and facilitators to implementing information technology, highlighting the relevance of individual, organizational, and technical factors.
- The Consolidated Framework for Implementation Research (CFIR) is a guideline for implementation with five domains: intervention characteristics, outer setting, inner setting, individual characteristics, and implementation process [32].
- The Unified Theory of Acceptance and Use of Technology (UTAUT) assesses acceptance of technology. In this model, four key constructs explain behavioral intention and use: (1) performance expectancy – the degree to which an individual believes that using the system will improve job performance, (2) effort expectancy – how easy the system is to use, (3) social influence – how important an individual perceives that

others find it that they should use the system, and (4) facilitating conditions – how much an individual believes that use of the system is supported by an organizational and technical infrastructure. These constructs can also be affected by gender, age, experience, and voluntariness of use [30].

The potential of eHealth

eHealth may improve accessible, coordinated and high-quality care by allowing information to be shared among healthcare professionals and by facilitating patient-centered care. It offers remote consultations and remote care monitoring [34], which may reduce the number of hospital visits and hospital admissions. The COVID-19 pandemic has accelerated the use of eHealth in clinical practice [35]. However, sustainable solutions remain challenging as implementation in healthcare is complex and requires organizational change [36]. Although eHealth has potential, more knowledge is needed on how it will affect clinical practice.

Aim of this dissertation

The aim of this dissertation is to contribute to the knowledge of digital transformation in hospital care by developing and implementing eHealth solutions in clinical practice and to evaluate the effect of these changes on patients, healthcare professionals, and hospital organizations.

Outline of the dissertation:

Healthcare is complex because it involves multiple caregivers taking care of the same patient. Therefore, collaboration between primary care professionals (e.g., general practitioners) and secondary care professionals (hospital staff) is essential. Shared care may contribute to successful transition between primary care and secondary care. This can be supported by technology. In **Chapter 2**, the results of a systematic review on the effectiveness of information technology supported shared care are described.

Different stakeholders are involved in and affected by the implementation of eHealth solutions in a hospital setting. The main stakeholders are medical doctors (who use the solution), hospital managers (who organize implementation), and information technology professionals (who conduct and support implementation). In **Chapter 3**, a qualitative study was conducted to assess barriers and facilitators to patient portal implementation by these multiple stakeholders in different hospitals. This was assessed on different levels; the innovation itself (patient portal) as well as individual, patient, social, organizational, economic and political [31], and technological factors [33].

In **Chapter 4**, a systematic review and meta-analysis was conducted to assess the effects of telehealth on the hospital services use, i.e. hospitalizations and to compare the effects

between telehealth types and health conditions. Peer-reviewed randomized-controlled trials reporting the effect of telehealth interventions compared with usual hospital care were included.

In **Chapter 5,** a mobile health and self-management mobile application was evaluated in high-risk patients with COPD, after hospital admission. At first, pilot testing was conducted to evaluate a prototype of the app. This was followed by a feasibility study that evaluated the effects of the app in clinical practice, app use, self-management, expectations and experiences with the app, patient and nurse satisfaction as well as readmission rates.

In **Chapter 6**, a randomized-controlled trial was conducted to evaluate the superiority of video consultation over face-to-face consultation for patients with obstructive sleep apnea (OSA) using Continuous Positive Airway Pressure (CPAP). We evaluated CPAP use (minutes per night), CPAP adherence, self-efficacy, risk perception, outcome expectancy, video consultation expectations, experiences with technology, and patient and nurse satisfaction.

Nurses' perspectives on eHealth implementation were evaluated more extensively in a qualitative study in **Chapter 7**. This study identified factors affecting implementation of continuous monitoring using a wireless wearable sensor by evaluating nurses' experiences on the nursing ward and their expectations for use in the home setting. Semi-structured interviews were conducted with nurses from three hospitals in the Netherlands, covering constructs of the CFIR framework [32]. The CFIR constructs were also used for data analysis together with one additional factor from the UTAUT [30].

There is a gap between eHealth research and widespread uptake in clinical practice, partly because technology is sometimes implicit and research is conducted with both standalone and interoperable systems. In **Chapter 8**, we discussed how standalone and interoperable systems are used in eHealth evidence development in order to keep up with the pace of IT developments that are relevant to clinical practice. Deciding which technology to use in hospital settings is relevant, so we described the advantages and disadvantages of both systems and explained their use and applications using clinical practice and theoretical models.

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CHAPTER 2

The effectiveness of information technology-supported shared care for patients with chronic disease: a systematic review

Laura Kooij, Wim G Groen, Wim H van Harten

This chapter is based on the published article J Med Internet Res 2017;19(6):e221, with minor adjustments.

ABSTRACT

Background

In patients with chronic disease, many health care professionals are involved during treatment and follow-up. This leads to fragmentation that in turn may lead to suboptimal care. Shared care is a means to improve the integration of care delivered by various providers, specifically primary care physicians (PCPs) and specialty care professionals, for patients with chronic disease. The use of information technology (IT) in this field seems promising.

Objective

Our aim was to systematically review the literature regarding the effectiveness of IT-supported shared care interventions in chronic disease in terms of provider or professional, process, health or clinical and financial outcomes. Additionally, our aim was to provide an inventory of the IT applications' characteristics that support such interventions.

Methods

PubMed, Scopus, and EMBASE were searched from 2006 to 2015 to identify relevant studies using search terms related to shared care, chronic disease, and IT. Eligible studies were in the English language, and the randomized controlled trials (RCTs), controlled trials, or single group pre-post studies used reported on the effects of IT-supported shared care in patients with chronic disease and cancer. The interventions had to involve providers from both primary and specialty health care. Intervention and IT characteristics and effectiveness—in terms of provider or professional (proximal), process (intermediate), health or clinical and financial (distal) outcomes—were extracted. Risk of bias of (cluster) RCTs was assessed using the Cochrane tool.

Results

The initial search yielded 4167 results. Thirteen publications were used, including 11 (cluster) RCTs, a controlled trial, and a pre-post feasibility study. Four main categories of IT applications were identified: (1) electronic decision support tools, (2) electronic health records, (3) IT platform with a call-center, and (4) electronic communication applications. Positive effects were found for decision support-based interventions on financial and health outcomes, such as physical activity. Electronic health record use improved some clinical outcomes. IT platform use resulted in fewer readmissions and better clinical outcomes—for example, in terms of body mass index (BMI). The use of electronic communication applications using text-based information transfer between professionals had a positive effect on the number of PCPs contacting hospitals, PCPs' satisfaction, and confidence.

Conclusions

IT-supported shared care can improve proximal outcomes, such as confidence and satisfaction of PCPs, especially in using electronic communication applications. Positive effects on intermediate and distal outcomes were also reported but were mixed. Surprisingly, few studies were found that substantiated these anticipated benefits. Studies showed a large heterogeneity in the included populations, outcome measures, and IT applications used. Therefore, a firm conclusion cannot be drawn. As IT applications are developed and implemented rapidly, evidence is needed to test the specific added value of IT in shared care interventions. This is expected to require innovative research methods.

INTRODUCTION

In Europe, 77 % of the disease burden is attributable to chronic diseases. For example, 60 million people live with diabetes [1] and 4-10% suffer from chronic obstructive pulmonary disease (COPD) [2]. Cancer is the leading cause of death in Europe with at least 3 million new cases each year, and cancer survivors are increasingly considered as having a chronic disease [3]. Many health care professionals and various providers are involved during treatment and follow-up of patients with these chronic diseases [3,4]. This inevitably increases fragmentation and can lead to suboptimal care [3]. Coordination of care between multiple professionals caring for patients with chronic disease is essential to guarantee quality of care [4,5]. However, coordination and integration of different professionals is often lacking [3,4]. Shared care is a means to improve integration and is defined as "the joint participation of general practitioners (GP) and hospital consultants in the planned delivery of care for patients with a chronic condition, informed by an enhanced information exchange over and above routine discharge and referral letters" [6]. Shared care can improve care delivery, since it involves a collaboration between primary and specialty care professionals, and this delivery of care is expected to be better than the separation of specialty and primary care [7]. Optimal information exchange between health care professionals is very important for the coordination and continuity of care [8,9]. However, oftentimes information exchange between professionals caring for the same patient is suboptimal [9,10], since professionals lack information [9] or the information is not exchanged on time [10].

The use of information technology (IT) seems promising [10] and is increasingly used to support information exchange [6]. IT can improve information accessibility [4,11-13] and can have a positive effect on safety [14,15]. Additionally, IT can support health care processes and has the potential to improve quality [16] and efficiency of care processes [15,16]. For example, electronic referral can improve the quality of care, access to a professional, and decrease costs [17], and electronic reminders can improve efficiency [4].

An overview of the characteristics and effectiveness of IT-supported shared care interventions is lacking. Previous systematic reviews, such as by Smith et al. [7,18] provided a total overview of shared care interventions for chronic disease including IT support. They found shared care to be a promising approach but only three IT-supported shared care interventions were reported on. Therefore, there is a need for more evidence, especially as the selected studies were of low methodological quality [7,18]. We presume that since previous reviews [7,18], considerably more IT-supported shared care interventions have been developed and reported on in the literature. Also, IT applications in health care are being developed and implemented at a rapid pace and involve considerable costs. Therefore, we aim to systematically review the state-of-the-art regarding the effectiveness of IT-supported shared care interventions on the care of patients with chronic diseases: diabetes, chronic obstructive pulmonary disease (COPD), (congestive) heart failure, cardiovascular disease (CVD), hypertension, asthma, or cancer. More specifically, we aim to provide an inventory of the effects of shared care, supported by IT, on the care of patients with chronic diseases and to describe the characteristics of the IT applications that support such interventions.

METHODS

Information sources and search strategy

Studies were identified by searching the literature in EMBASE, Scopus, and PubMed from January 2006 to September 2015. The search consisted of three concepts: (1) shared care, (2) chronic disease, and (3) IT. Several mesh terms were used for these concepts. The full search string is provided in Multimedia Appendix 1. We also checked the reference lists of included articles to detect other relevant studies focusing on (other) chronic diseases ("snowballing method"). As we wanted to provide a total overview of IT-supported shared care interventions, we selected relevant studies from before 2006 from 2 excellent previous reviews (that searched up until 2006) [7,18].

Eligibility criteria

For the selection, we used the following eligibility criteria: (1) English-language studies describing a randomized controlled trial (RCT), nonrandomized controlled study or a single-group before and after study; (2) included a shared care intervention; (3) supported by IT; (4) developed specifically for people with a chronic disease: diabetes, COPD, congestive heart failure, CVD, hypertension, or asthma, or cancer; (5) involved health care providers were both primary care physicians (PCPs) operating outside hospitals or physician practices and specialty health care professionals; and (6) study included outcome measures focusing on at least health or clinical, process, provider or professional and financial outcomes.

Study selection

The first and second authors independently assessed titles and abstracts focusing on the concepts of shared care, type of disease, and study type. IT was not a criterion for the abstract rejection because it was assumed that IT might only be described in the full texts. In the case of ambiguity or when there was no consensus about the abstracts, the full publication was reviewed by the 2 authors. Disagreement was resolved by discussion; when an issue remained unresolved, the decision of a third reviewer (WvH) was decisive. This selection process was similar for the further selection of full texts.

Data extraction

From the selected studies, we report on study characteristics (year, design, measurement time points, and country), patient population (number and type of disease), intervention characteristics (content), IT characteristics (type of application), outcome measures, and effects. The latter were structured according to provider or professional (proximal), process (intermediate), health or clinical and financial (distal) outcomes. These data items were extracted independently by 2 researchers (LK and WG) and disagreement was resolved by discussion.

Risk of bias assessment

We assessed the risk of bias of the included (cluster) RCTs by using the Cochrane risk of bias tool.

The risk of bias was independently assessed by 2 researchers (LK and WG). Disagreement was solved by discussion until consensus was reached. Each aspect and the overall risk of bias of the Cochrane risk of bias tool was graded as high, low, or unclear according to the criteria in the Cochrane handbook [19].

Synthesis of results

For the reporting of this systematic review, we used the PRISMA guidelines [20]. Results were synthesized in a qualitative way as there were large differences in the types of intervention, target populations, and outcome measures. Due to the diversity of intervention characteristics and outcomes measures, we could not conduct a meta-analysis.

RESULTS

Study selection

The primary search yielded 4167 results. After title and abstract selection and the removal of duplicates, 29 papers were read in full text. Nine articles met our inclusion criteria. One

additional study was found by reviewing the reference lists, and we identified 3 additional studies from the previous systematic reviews of Smith et al. [7,18]. Reasons for excluding studies were inappropriate study design, no available full text, lack of a shared care intervention, and/or lack of IT support. Figure 1 gives a detailed overview of the study selection procedure.

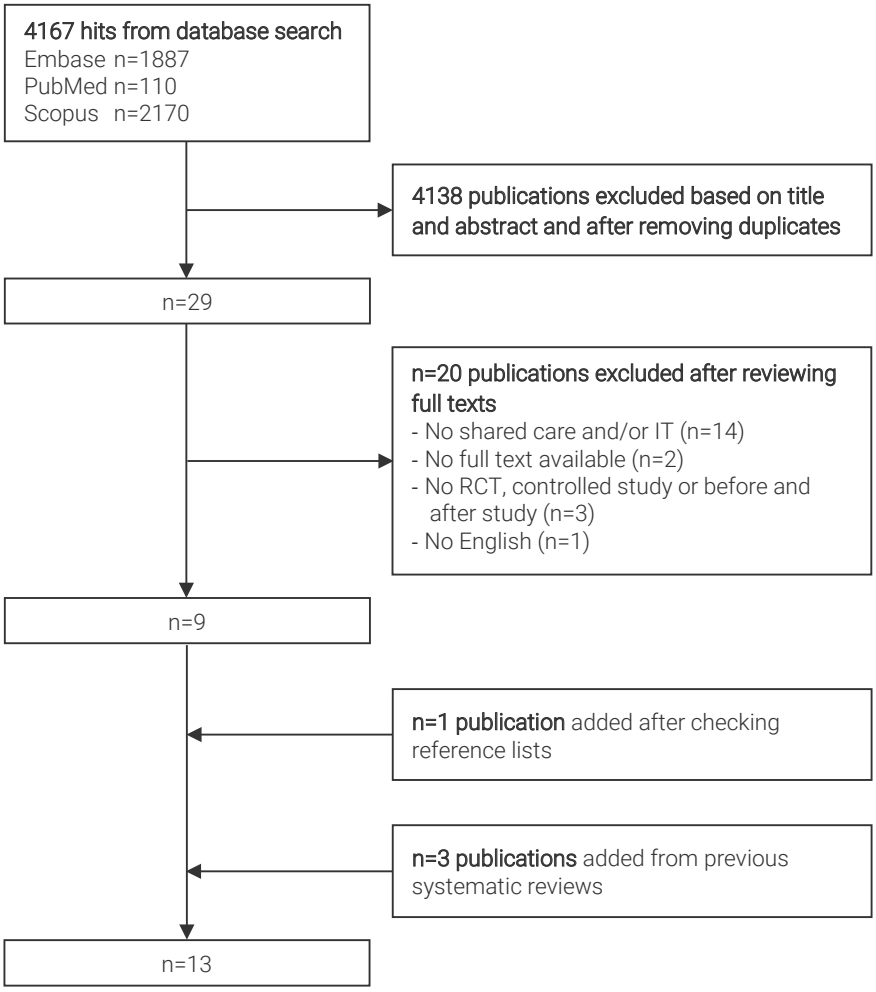

Figure 1. Flowchart of the search and selection procedure

Study characteristics

In total, we included 8 RCTs, 3 cluster RCTs, 1 controlled trial, and 1 pre-post feasibility study. The 13 manuscripts described 11 unique studies. Two papers by Casas et al. [21]

and Garcia-Aymerich et al. [22] described the same intervention but with different patient populations and outcome measures. Lalonde et al. [23] and Santschi et al. [24] both described the same intervention but assessing different outcome measures.

The included studies were conducted in Canada (n=2) [23,24], Italy (n=2) [25,26], Scotland (n=3) [27-29], United States (n=2) [30,31], Australia (n=1) [32], Denmark (n=1) [33], Spain (n=1) [22], and Spain and Belgium (n=1) [21]. The intervention groups were mostly compared with a group receiving usual care [21-25,27,29,30,32,33], with a specialist outpatient and a nurse practitioner clinic [28] or in one case through general correspondence by email [31].

Patient population characteristics

Patient populations included patients with COPD (n=2) [21,22]; chronic kidney disease (CKD; n=2) [23,24]; diabetes (n=3) [25,27,31]; hypertension (n=1) [28]; asthma (n=1) [29]; and multiple conditions, such as heart failure, diabetes, (risk for) CVD (n=1) [26], and cancer (n=2) [32,33]. One study did not specify the target population but considered hospital discharges in general, which included all conditions [30].

Intervention characteristics

The intervention characteristics are presented in Multimedia Appendix 2. There was a large variation in the nature of the interventions, IT applications, and the professionals involved. The primary health care providers who participated in the interventions were PCPs or general practitioners (GPs) (n=11) [21,22,25-33] and pharmacists [23,24]. Specialty care professionals included case managers [21,22,26] and specialists [23,24,28,29,31,33]. However, in 4 interventions the type of specialty care professional was not specified [25,27,30,32].

The objectives varied among the included studies. The majority of the interventions aimed to assess the effectiveness of shared care interventions on the level of distal and/or intermediate outcomes. This included (clinical) patient outcomes [22,24,25,31], sometimes in combination with social and economic settings [27,29]. Other objectives were to study the effects on the number of readmissions, GP contacts with the hospital [21,30], or (diabetes) care outcomes [31]. The impact of a pharmaceutical training and communication network on both distal (pharmaceutical opinions and refusals, clinical outcomes) and proximal outcomes (knowledge and satisfaction of pharmacists) were assessed [24]. Proximal outcomes were also assessed, including tailored information provision to GPs [32] and hospital-based case management [33]. One study aimed to evaluate the feasibility, acceptability, and cost-effectiveness of shared care in comparison with other follow-up approaches [28].

Information technology (IT) characteristics

Four types of IT applications can be distinguished: electronic decision support [26,31], electronic health records (EHRs) [25,27-30], an IT platform combined with a call center [21,22], and electronic communication applications [23,24,32,33]. These will be described in more detail in the next section.

Electronic decision support

The electronic decision support tools were mainly used for care management, specifically for patients with diabetes [31] and (at risk of) CVD, diabetes, or heart failure [26]. A diabetes electronic management system was used to provide PCPs with decision support aimed at reducing cardiovascular risk in diabetes. PCPs received patient-specific and evidence-based information from endocrinologists via secure-email. Based on this information, PCP and patient discussed how to further continue treatment [31]. Decision support was also used to improve care coordination for patients with diabetes, heart failure, and (at risk of) CVD. Therefore, their care managers were provided with notifications and monitoring instruments [26].

Electronic health records

In one nonrandomized controlled study, PCPs and hospital professionals exchanged information via a connected EHR in care for diabetes patients [25]. In a RCT, a connected EHR provided GPs with information regarding their elderly patients' hospital discharge [30]. In 3 cases, the EHRs were "synchronized" and therefore used to store information, which was shared between professionals without technology involved (ie, hardcopies were sent via surface mail). GPs send information to secondary care providers, who add this to their EHR. Consequently GPs periodically receive back the latest updated version [27-29].

IT platform including a web-based call center

An IT platform was used by case managers to manage COPD patients' health records. This platform was connected to a call center that was accessible to PCPs and patients to allow them to contact the case manager. This was part of an intervention aimed at improving health or clinical related outcomes [22] and preventing or reducing of hospitalization [21].

Electronic communication applications

IT applications were used to provide (one-way) electronic communication using text, for example, fax and electronic messaging. This information was provided by specialty care professionals to inform primary care physicians about their patients.

Fax was used to inform GPs about chemotherapy and patient specifics [32]. To improve community pharmacists' control over medication-related problems related to CKD, the

predialysis clinic provided them with medication and clinical information by fax [23,24]. Case managers, specially trained nurses, aimed to improve the coordination and continuity of care for patients with colorectal cancer. They used electronic messaging to inform GPs about their patients, including contact information [33].

Outcome measures and effects

The most striking proximal (professional or provider) [23,32,33], intermediate (process) [21,23,30,31,33], and distal (health or clinical and financial) [22-26,31] results are described for each IT category, and a comprehensive overview is presented in Multimedia Appendix 3.

Electronic decision support

A decision support tool described in an RCT was used with the aim to improve metabolic and cardiovascular risk factor control, process of care, and costs for diabetes patients [31]. In a pre-post feasibility study, electronic decision support was used to support care managers in their care of patients with CVD or heart failure [26].

Health or clinical and financial outcomes

Electronic decision support for case management in a pre-post feasibility study [26] showed multiple statistically significant outcomes, for example, days of physical activity per week increased from 2.5 to 4.2 days (P<.0001) and time from 19.9 to 32.9 min each time, patient self-monitoring behavior increased by 20-27%. Body mass index (BMI), low-density lipoprotein (LDL), and total cholesterol decreased by 10-20%. Both diastolic and systolic blood pressure decreased significantly (P<.0001). Additionally, survey results indicate high levels of satisfaction among physicians, care managers, and patients [26]. However, Smith et al. [31] found a significant difference between intervention and usual care for smoking cessation (96.0%, 343/358 in the intervention; 93.0%, 257/277 in the control group; P=.04) and aspirin use (66.0%, 238/358 in the intervention; 52.0%, 145/277 in the control group; P=.001). A significant effect on other metabolic and coronary artery disease outcomes was not detected. Lower costs were reported benefiting the intervention group. The total mean costs of the intervention were US $6252 compared with US $8564 for the control group (P=.02); the outpatient costs for the intervention were US $1842 and US $2129 for the control group (P=.04). However, these costs were not specifically related to diabetes care [31].

Electronic health records

EHRs were used to (1) share (real-time) data by connecting primary and secondary EHRs [25,30], and (2) synchronize records by collecting professionals' input and storing patients data [27-29].

Provider or professional outcomes

Use of an EHR for hypertension patients was compared with specialists' outpatient- and nurse practitioner (NP) follow-up. Sixty-one percent (90/147) of the GPs had a preference to continue shared care and 32% (47/147) preferred shared care over the usual, outpatient- or NP care [28].

Process outcomes

EHRs were used to inform GPs about hospital discharges. This had no significant effect on the number of PCP visits after discharge nor on rehospitalization rates (18.77%, 351/1870) compared with the control group (19.88%, 356/1791) [30]. The use of "synchronized" EHRs did not seem to affect the number of (unscheduled) consultations [27], admissions [27,29], or GP consultations [29] compared with usual care. However, significant effects were noted for the number of patients receiving a complete (medical) review after 2 years (82.4%, 220/267) in comparison with outpatients (54.1%, 146/270) and with nurse practitioner (74.8%, 202/270) follow-ups [28].

Health or clinical and financial outcomes

Clinical information about diabetes patients was shared between GPs and hospital professionals. This had a significant positive effect on various clinical outcomes—for example, glycated hemoglobin (HbA1c), BMI, and LDL cholesterol [25]. However, the use of "synchronized" health records showed no difference with usual care for most patient-related outcomes, such as psychosocial status [27], or sleep disturbance [29].

IT platform and web-based call center

COPD patients' care managers were accessible for PCPs and patients via a call center that was an integral part of an IT platform in which care managers could also manage health records [21,22].

Process

A significant effect on the number of patients without readmissions was detected: 55% (36/65) of patients in the intervention group compared with 33% (30/90) of patients in the control (P=.03) [21].

Health or clinical and financial outcomes

The intervention was also evaluated on a range of clinical, health-related, quality of life and lifestyle aspects; and on self-management medical treatment and patients' satisfaction. Only statistically significant improvements in BMI and self-management were detected. Patients in the intervention had better knowledge of the name of their disease (81%, 17/21 vs 44%, 18/41 in usual care group; P=.005), awareness of identification of COPD

exacerbations (81%, 17/21 vs 22%, 9/41 in usual care group; *P*<.001), and of exacerbations in early COPD treatment (90%, 19/21 vs 66%, 27/41 in usual care group *P*=.04) than patients receiving usual care—without support from a case manager [22].

Electronic communication applications

Information was transferred from secondary to primary care using electronic communication applications, for example, fax [23,24,32,33].

Provider or professional outcomes

Overall, PCPs were satisfied about the interventions and information [23,32,33]. For example, GPs receiving extra information about their chemotherapy patients were more confident (7% difference with usual care, *P*=.003) and more satisfied than GPs receiving only the usual correspondence (10% difference with usual care, *P*=.002) [32]. Jefford et al. [32] found no effect for GP knowledge, whereas Lalonde et al. [23] found that the knowledge of pharmacist in the intervention group increased by more than 30%.

Process outcomes

The majority of process-related outcomes improved significantly in the included interventions. For example, training combined with a communication network for pharmacists had positive effects on the number of pharmaceutical recommendations [23,24]. GPs were informed by electronic messaging in a care management intervention for patients with colorectal cancer. In the 9 months follow-up period, the case manager intervention showed a decrease in GPs contacting the hospital (*P*=.008). However, no effect was found on patients contacting GPs during daytime (*P*=.25) compared with the control group [33].

Health or clinical and financial outcomes

An effect on systolic BP, but not on diastolic or BP control, was reported in one study [24].

Risk of bias

An overview of the risk of bias is provided in Multimedia Appendix 4. No study was free from the risk of bias. Inherent to the type of intervention blinding either the participants or professionals was not possible. Of the 11 included (cluster) RCTs, 6 studies had adequate random sequence generation; in most cases, computer-generated systems were used. More than half of the studies had a low risk of bias for allocation assessment, mainly because of the use of numbered sealed envelopes. Other aspects that were rated for risk of bias were (1) selective reporting, (2) blinding of outcome assessment, and (3) incomplete outcome data. These items were often not reported, and therefore, score as an unclear risk of bias according to the Cochrane handbook [19].

DISCUSSION

Summary of evidence

We have systematically reviewed 13 studies focusing on IT-supported shared care for patients with a chronic disease. Overall, there seems to be much merit in IT supported shared care interventions.

The reviewed interventions were supported by four main categories of IT applications: (1) electronic decision support systems, (2) EHRs, (3) IT platform and call center, and (4) electronic communication applications. The main positive findings of these studies are (1) electronic decision support-based interventions showed a significant positive effect on reducing costs; (2) connected EHRs improved some clinical outcomes; and (3) the use of an IT platform resulted in fewer readmissions and positive effects on some health or clinical outcomes. However, it failed to show positive effects on quality of life or doctor visits. Additionally, (4) the use of electronic communication applications showed positive results in terms of PCPs' satisfaction, confidence [32], and the lower number of GPs contacting the hospital [33]. However, effects on GPs' knowledge were inconsistent [23,32].

As IT often was only a small part of the intervention, it is hard to determine its real added value in shared care. The reviewed studies varied considerably with regard to the type of intervention, the studied patient population, the IT applications used, and the various outcome measures. As a result of this great variation, and because no study was free from the risk of bias, it is difficult to reliably compare the effects found between the various studies or to make valid generalizations about outcomes that hold true for most chronic patients.

The level of advancedness of included IT applications varied and they have evolved over time. The intervention studies conducted in 1994 [27-29] all used an EHR to manage clinical information and shared this (nonelectronically) between professionals. EHRs have evolved into connected systems that ensure real-time information exchange. Examples are the EHRs used in the studies of Gurwitz et al. [30] and Carallo et al. [25]. Surprisingly, in 2008 and 2011, fax was still used to transfer information from secondary to primary care, and on the other hand innovative electronic decision support systems were used as well [26,31]). Such "intelligent" systems support professionals in their care of patients, for example, by sending automatic alerts or providing tailored advice. Based on this review we regard this as the most advanced IT application to support shared care.

Comparison with previous work

The findings of our review are comparable with previous reviews on shared or integrated care, in the way that these also reported mixed overall results. For example, Smith et al. reviewed the effectiveness of shared care studies for patients with chronic disease [7,18]. The results of the included studies were mixed, and therefore, they pose that it was not possible to draw conclusions about the effectiveness of the interventions. Also the reviewed interventions were complex and consisted of multiple elements that precluded attribution of the effects to the different elements. Additionally, in line with our review, the studies were of low methodological quality [7,18].

Ouwens et al. [34] reviewed integrated care interventions and also found heterogeneity in patient populations, outcomes, and interventions. Although integrated care appears to be an effective approach, this heterogeneity may lead to incorrect conclusions [34]. A similar conclusion was drawn in the review of Aubin et al. on the effects of interventions to improve continuity of follow-up care for cancer patients. In this review, a shared care model was used in 14 of 63 studies, and even though some effects in separate studies were found, no clear conclusions could be drawn because the results were too mixed [35]. Again, just as in the review of Smith et al. [7,18], the interventions were complex, which makes it hard to determine which elements of the intervention were effective and which were not. Overall, it seems difficult to determine the real added value of shared care as a result of mixed results and heterogeneity in the included populations and intervention elements.

The use of IT based interventions in these previous reviews was minimal and also a description of the applications and their effects was lacking [7,18]. We found several IT-supported share care interventions but unfortunately, we were unable to draw firm conclusions about the added value of IT because it is not evaluated as a single component.

Future research

Nowadays, many IT applications have been or are being developed to support health care processes [16], but despite this, we only found a surprising small number of publications analyzing their effectiveness in a controlled study. The rapid development of IT applications for shared care purposes is currently not underpinned by rigorous studies showing its added value. Although in evidence-based medicine the RCT is regarded as the gold standard design, there may be drawbacks in using this design for evaluating health care IT applications. RCTs are, by nature, time and cost intensive and may not be able to keep up with fast developing technologies. In other words, when the results of a RCT are finally available, the IT may be outdated. Other research designs could provide more information and save time [36] and may better keep up with the rapid development of IT. Another

approach to reflect the rapid development of IT is to measure the feasibility of an IT intervention in a smaller population within a larger RCT [37].

The assessment of the risk of bias of the studies indicates that there is room for improvement in several areas. For example, concealment of intervention allocation and the lack of blinding of participants were not clearly described. This can mean that the effects are overestimated, and it may also be due to the type of intervention. In future research, researchers should provide estimates (as blinding is seldom possible) about how likely it is that this will influence the outcomes. The measurements should also be described more accurately and preferably distinguish proximal or intermediate or distal outcomes because the exact mechanism of intervention and effects is often unclear. Also better standardization on outcome assessments by using a framework, such as the chronic care model (CCM) [5] may be useful. This is a framework to improve clinical and functional outcomes for patients suffering from a chronic disease, and IT can support that model. Key elements are clinical information systems, including databases and care protocol systems. But other applications are also increasingly used to share data with patients, such as patient portals and PHRs. These are applications to provide patients with their clinical information and the ability to share this information [38,39]. Patients' needs are important, and care should be focused on patients' preferences to improve quality of care [40]. Professionals should work together, by means of a shared care model, to meet the needs of patients [41]. In line with this, the definition of shared care may be open to discussion or other care models may be increasingly relevant.

Future research must adapt to these aspects and developments. It is also relevant to examine the processes and time points for which IT will be most valuable in supporting shared care.

Limitations

A limitation of this study is the inclusion of "IT" as a search term in the initial search (title or abstract selection). We therefore might have missed studies that were supported by IT but did not mention this in the title or abstract. Furthermore, although we included a broad range of terms in our search, we may not have retrieved all studies that in fact are a shared care intervention. Our search was conducted from 2006 to January 2015, and we added IT-supported shared care studies from before 2006 from the review of Smith et al. [7,18] Although unlikely, we might miss relevant studies from before 2006 that were not reviewed by Smith et al. [7,18] because they used slightly different search terms.

Conclusions

Despite the potential benefits of using IT to support shared care in chronic diseases, we found surprisingly few—whether controlled or uncontrolled—studies that substantiated these anticipated benefits. Studies showed a large heterogeneity in the study populations, outcome measures, and IT applications. The reviewed interventions reported many positive effects on (proximal) provider or professionals outcomes (such as GPs' satisfaction and confidence). To a lesser extent, positive effects on intermediate (GPs contacting the hospital) and distal outcomes (costs and readmissions) were also reported. Nonetheless, a firm conclusion cannot be drawn on the effect of IT-supported shared care — especially its clinical effect. As IT applications for shared care are developed and implemented rapidly, we are in need of more and better evidence on the specific added value of IT in shared care interventions, and this is expected to require innovative research methods.

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Abbreviations

BMI: body mass index
BP: blood pressure
CKD: chronic kidney disease
COPD: chronic obstructive pulmonary disease
CVD: cardiovascular disease
EHR: electronic health record
GP: general practitioner
IT: information technology
LDL: low-density lipoprotein
NP: nurse practitioner
PCP: primary care physician
PHR: personal health record
RCT: randomized controlled trial

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MULTIMEDIA APPENDICES

Multimedia Appendix 1 – Search strategy in PubMed

#4 "Study type"

((random*[tiab] AND (controlled[tiab] OR control[tiab] OR placebo[tiab] OR versus[tiab] OR vs[tiab] OR group[tiab] OR groups[tiab] OR comparison[tiab] OR compared[tiab] OR arm[tiab] OR arms[tiab] OR crossover[tiab] OR cross-over[tiab]) AND (trial[tiab] OR study[tiab])) OR ((single[tiab] OR double[tiab] OR triple[tiab]) AND (masked[tiab] OR blind*[tiab]))) OR ((random*[ot] AND (controlled[ot] OR control[ot] OR placebo[ot] OR versus[ot] OR vs[ot] OR group[ot] OR groups[ot] OR comparison[ot] OR compared[ot] OR arm[ot] OR arms[ot] OR crossover[ot] OR cross-over[ot]) AND (trial[ot] OR study[ot])) OR ((single[ot] OR double[ot] OR triple[ot]) AND (masked[ot] OR blind*[ot]))) OR before and after stud* [tiab] OR "Randomized Controlled Trials as Topic"[Mesh] OR "Interrupted Time Series Analysis"[Mesh] OR ITS stud* [tiab] OR interrupted time ser* [tiab] OR "Controlled Clinical Trials as Topic"[Mesh] OR "Controlled Clinical Trial" [Publication Type] OR "Non-Randomized Controlled Trials as Topic"[Mesh]

#3 "Cancer and other chronic diseases"

((neoplasms [mesh] OR cancer* [tiab] OR tumor* [tiab] OR tumour* [tiab] OR neoplasm* [tiab]
OR malignan* [tiab]) OR (cancer patient* [tiab] OR cancer survivor* [tiab] OR "Pulmonary Disease, Chronic Obstructive"[Mesh] OR COPD [tiab] OR COAD [tiab] OR (chronic obstructive [tiab] AND (airway [tiab] OR lung [tiab] OR pulmonary [tiab])) OR "Diabetes Mellitus"[Mesh] OR "Diabetes Mellitus, Type 1"[Mesh] OR "Diabetes Mellitus, Type 2"[Mesh] OR diabet* [tiab] OR MODY [tiab] OR NIDDM [tiab] OR IDDM [tiab] OR "heart failure" OR "cardiovascular disease") OR
"Asthma"[Mesh] OR asthma* [tiab]) OR ("Hypertension"[Mesh] OR ((High [tiab] OR higher [tiab]
OR highest [tiab]) AND blood pressur* [tiab]) OR hypertens* [tiab])

#2 "Shared Care"

(delivery of health care, integrated [mesh] OR ((shar* [tiab] OR integrat* [tiab] OR cooperat* [tiab] OR integrat* [tiab] OR collaborat* [tiab] OR link* [tiab] OR exchange* [tiab]) AND (care [tiab]))) AND ((general practitioners [mesh] OR general practice physician* [tiab] OR gp [tiab] OR gps [tiab] OR family doctor* [tiab] OR family physician* [tiab] OR primary health care [mesh] OR primary health care [tiab] OR primary care [tiab]) OR (secondary care [mesh] OR secondary care [tiab] OR secondary health care [tiab] OR hospitals [mesh] OR

hospital* [tiab]) OR (Tertiary Healthcare [mesh] OR (tertiar* [tiab] AND (healthcar* [tiab] OR care [tiab] OR caring [tiab])))

#1 "Information Technology"

medical informatics [mesh] OR medical informatic* [tiab] OR information systems [mesh] OR medical records [mesh] OR computer technolog* [tiab] OR information management [mesh] OR information and communication technology [mesh] OR information system* [tiab] OR medical records systems, computerized [mesh] OR information storage and retrieval [mesh] OR electronic health records [mesh] OR electronic health record* [tiab] OR EHR [tiab] OR EMR [tiab] OR ict [tiab] OR it [tiab] OR systems integration [mesh] OR information exchange [tiab] OR medical records [mesh] OR information dissemination [mesh] OR data integration [tiab] OR information management [mesh]

Comparable search strategies were performed in Embase and Scopus. Specific features and requirements of each database were taken into account.

Multimedia Appendix 2 – Study and information technology (IT) characteristics

Study	Design				Intervention characteristics and supporting information technology (in italics)
	Patient target population	Measurement time points	Control group	Outcome measures	
Ciccone et al., 2010 [26] Pre–post feasibility study	CVD[a], diabetes, heart failure and/or risk of CVD patients (n=1160)	Baseline, 6, 12, and 18 months	Not applicable	Feasibility and effectiveness in terms of quality of life, therapy adherence, clinical outcomes (BP[b], cholesterol, and glycosylated hemoglobin blood level)	"To evaluate effectiveness of a disease and care management model and care managers nurses". – Patient is part of health care team including specialists, GPs[c] and care managers – Care Managers are appointed to GPs – Personal patient care plan – Care managers used an *evidence–based decision support tool* including, for example, health record, notifications related to patients' health situation, monitoring, and patient information materials.
Smith et al., 2008 [31] Cluster RCT[d]	Physicians (n=97)[e] and diabetes patients (n=639)	Baseline and follow–up: 21 months (mean; 3–36)	Control group: standard information about cardio–vascular risk reduction via email	Process of diabetes care, metabolic and cardiovascular risk factor control, and costs	"To assess the effects of specialist telemedicine intervention on diabetes care outcomes" – Endocrinolo–gist received medical data from *DEMs*[f] and *EHR*[g]. Based on this information they could write a tailored advice regarding cardiovascular risk using a *Web–form.* Additionally evidence based information was selected from the *digital library.* Advice and evidence based messages were sent via *secure–email* to primary care (automatic) 48 hours before patients' visit. They could also pick the message up via the *DEMS*. – Primary care and patient decided how to continue after receiving the information.

Study	Design				Intervention characteristics and supporting information technology (in italics)
	Patient target population	Measurement time points	Control group	Outcome measures	
Carallo et al., 2015 [25], Controlled study (1:2)	Diabetes mellitus type 2 patients (n=312)	Baseline and 1 year	Usual care: follow–up by hospital professionals (quarterly). GPs are informed by letter	Efficacy of the integrated care model in respect of clinical care	"To verify theefficacy of an integrated care model including GPs empowerment and use of a *Web–based EHR* in relation to usual care in a clinical setting". – Clinical care management shared between GPs and hospital professionals – *Connected EHR* to exchange clinical information – Diabetes type 2 training for GPs – Follow up by both GP (quarterly) and hospital professionals (annually).
Gurwitz et al., 2014 [30] RCT	Elderly patients (>65) (all conditions included); hospital discharges (n=3661)	At least six months after end of study	Usual care: follow up at discharge	Primary care visits in 7–, 14, and 30–day periods after hospital discharge and rehospitalization within 30 days	"To assess the effect of *EHR–based* transitional care intervention on having an outpatient visit with a primary care provider after discharge on being rehospitalized within 30 days of discharge" – Use of *EHR* to inform GPs about their patients' hospital discharge – GPs received extra medication related information and notification for planning a post hospitalization visit – Primary care provider's support staff received a message to plan a visit with the primary care provider (except when EHR shows that visit is already planned).

Study	Design				Intervention characteristics and supporting information technology (in italics)
	Patient target population	Measurement time points	Control group	Outcome measures	
DICE, 1994 [27], RCT	Diabetes patients—insulin and non–insulin treated (n=274)	Baseline and 2 years	Usual care: patients were seen approximately every 4 months and received (computer generated) reminder letters about regular appointments	Metabolic control, psychosocial status, knowledge, wellbeing and treatment satisfaction, beliefs and control, disruption of normal activities, numbers of consultations and admissions, frequency of metabolic monitoring, and costs	"To evaluate effectiveness and efficiency of computer coordinated integrated care for insulin and non–insulin treated patients" – 3 or 4 monthly GP and annually hospital visits. – Integrated care guidelines for GPs – *Computer–based patient record*: to notify GP (patient consults and clinical information) and patients (to make GP appointment) and for coordination of patient records. GP added relevant information after a consult to the record, sent it back to hospital where the hospital updated computerized record and returned it to GP.

Study	Design				Intervention characteristics and supporting information technology (in italics)
	Patient target population	Measurement time points	Control group	Outcome measures	
Drummond et al., 1994 [29], RCT (2x2x2; integrated or conventional outpatient care; peak flow self–monitoring or usual monitoring; enhanced or usual education)	Patients with asthma (n=712) visiting chest outpatient clinics	Baseline and 1 year	Usual care: 3 monthly visits at outpatient clinic. Receive clinical questionnaire before visit to give to specialist	Number of prescriptions for bronchodilators and inhaled steroids, use of oral steroids, general practice consultations, hospital admissions, sleep disturbance and other restrictions on normal activity; psychological aspects; patient satisfaction and costs	"To evaluate in clinical, social, and economic terms, the effectiveness of integrated care" – Annually review of patients records by chest physicians using *computer–based patient record* – 3 monthly visits to GP – Computer generated questionnaire sent to patients and GP. GP sends all clinical documents to hospital professional who adds information to patient computerized record. GP receives a copy including advice for changes in care.
McGhee et al., 1994 [28], RCT (3) groups[h]	Patients with (controlled) hypertension (n=831)	Baseline and 2 years	Outpatient care and nurse practitioner clinic careh	Effectiveness (number of patients with complete review after 2 years), acceptability (eg, preferences and (dis) advantages), and costs	"To investigate the feasibility, acceptability and cost effectiveness of shared general practitioner – hospital care for well–controlled hypertensive patients in an urban area by comparing this group with a specialist outpatient clinic and nurse practitioner clinic." – Shared care between GP, specialist, patient and laboratory with determined roles. Annually patient review by GP. *Computerized database* used to create medical record (two pages) for GP and patient record summary ("personal health booklet") – After consult: GP sent medical record, results of clinical exams and patient–held record to shared care registry – Results reviews by staff using a protocol and marked abnormalities are reviewed by a specialist Updated medical record including letter is sent back to GP.

Study	Design				Intervention characteristics and supporting information technology (in italics)
	Patient target population	Measurement time points	Control group	Outcome measures	
Casas et al., 2006 [21], RCT (1:1.5)	COPD[i] patients (n=155)	1, 3, 6, 9, and 12 months	Usual care without additional support	Primary: hospital readmission. Secondary: mortality and utilization of health care resources	Assess the effectiveness of an integrated care intervention, supported by ICT[j], on prevention of hospitalizations – Patient assessment at discharge – Self– management program for patients – Patient tailored care plan shared between case manager and primary care professionals – *ICT[j] platform* for case management to manage health records including *Web–based call center* to contact case manager. Follow up: specialized nurse and primary care team (Barcelona) and GP (Leuven).
Garcia–Aymerich et al., 2007 [22] RCT (1:2 ratio)	COPD patients (n=113)	Baseline, 6, and 12 months	Control group: patients received usual care without additional support after discharge	Effectiveness: clinical, health–related quality of life, lifestyle, self–management, medical treatment, and patients' satisfaction	"To assess the effectiveness of an integrate care intervention to enhance clinical status, health– related quality of life, lifestyle, self– management, medical treatment, and patients' satisfaction to explain reduction in readmissions" – Patient assessment at discharge, – Self– management program for patients – Patient tailored care plan (by case manager and primary care) – *ICT platform* for case management to manage health records including *Web–based call center* to contact case manager. – Follow up: specialized nurse and primary care team (Barcelona).

Study	Design				Intervention characteristics and supporting information technology (in italics)
	Patient target population	Measurement time points	Control group	Outcome measures	
Jefford et al., 2008 [32] RCT (1:1)	GPs taking care of cancer patients (n=97)	Baseline and 7 days (range 6–15)	Usual information without extra fax	GPs' confidence, knowledge, satisfaction, and perception	"To examine the effectiveness of information regarding chemotherapy, potential adverse effects and recommended managements in improving GPs knowledge, confidence, satisfaction regarding communication, and shared care and perception of information received". *Fax* was used to provide GPs with extra information about patient–, chemotherapy specific and contact information.
Lalonde et al., 2008 [23] Cluster RCT	Pharmacies (n=42), pharmacists (n=101)	Baseline and 6 months	Usual care without ProFiL program	Feasibility and impact: primary outcomes: number of pharmaceutical opinions or refusals, secondary: pharmacists' knowledge and satisfaction	"Assess the feasibility and impact of implementing ProFiL (to improve community pharmacists' management of medication related problems), on the incidence of pharmaceutical opinions and refusals." – Community pharmacists received training, access to hospital consultation service and communication network. – *Fax* was used to inform community pharmacists about patients' medication and clinical information. – Pharmacists could sent recommendations to the specialist (standard from)
Santschi et al., 2011 [24] Cluster RCT	Pharmacies (n=42), pharmacists (n=101), and chronic kidney disease patients (n=90)	Baseline and 6 months	Usual care without ProFiL program	Change in BP, number of patients with BP controlled, number of hypertension drug related problems, and community–pharmacist intervention	"To assess the impact of ProFiL (to improve community pharmacists' management of medication related problems) on BP control and management of hypertension management." – Community pharmacists received training, access to hospital consultation service and communication network. – *Fax* was used to send community pharmacists, at baseline, a summary with clinical information (health problems, BP levels, laboratory results, medications).

Study	Design				Intervention characteristics and supporting information technology (in italics)
	Patient target population	Measurement time points	Control group	Outcome measures	
Wulff et al., 2013 [33] RCT (1:1)	Patients with colorectal cancer or highly probably diagnoses (n=280) from a hospital surgical department	Baseline and follow–up 270 days (divided in 90 day periods).	Usual care. GPs received electronic note about diagnosis and electronic discharge summary after treatment	GP evaluations and patients' contacts with GPs	"To analyze effects of hospital–based case management on GPs' evaluation of intersectoral collaboration and information from the hospital, patients contact with GPs during daytime and out of hour" – Case manager informs GP about patients' condition – GPs received extra *electronic summary message* (on top of usual information received from surgeons) regarding patients' consult with case manager and regarding change in care when surgical department was involved.

[a] CVD: cardiovascular disease.
[b] BP: blood pressure.
[c] GP: general practitioner.
[d] RCT: randomized controlled trial.
[e] randomized group.
[f] DEM: diabetes electronic management system.
[g] EHR: electronic health record.
[h] Patients were randomized between shared and outpatient care. The nurse practitioner clinic care group was added as an additional comparative group.
[i] COPD: chronic obstructive pulmonary disease.
[j] ICT: information and communication technology.

Multimedia Appendix 3 – Outcome measures and effects

Study	Outcome measures and effects
Ciccone et al., 2010 [26]	*Provider or professional[a]:*
	+[b] High satisfaction from physicians, care managers and patients[c]
	Health or clinical and financial[a]:
	+ Self efficacy, coping, to be able to access social support[c]
	+ Self–monitoring behavior increased, additional 20–27%[c] of patients per condition
	+ Adoption of healthy diet increase from 39.4% to 80.7%[c]
	+ Physical activity (days per week): from 2.53 to 4.18 (*P*<.0001)
	+ Time spent on physical activity: from 19.87 to 32.90 minutes per time (*P*<.0001)
	+ Reduction 10–20%: BMI[d], low–density lipoprotein, total cholesterol , high–density lipoprotein level, total cholesterol[b]
	+ Decrease in diastolic and systolic blood pressure: *P*<.0001
	+ SF–12 score (physical and mental health status); average score increased 5.28 points in follow–up[c]
Smith et al., 2008 [31]	*Process[e]:*
	X[b] Process of diabetes care: (*P*=.41)
	Health or clinical and financial[e]:
	Metabolic and coronary artery disease risk:
	X such as: HbA_{1c} (*P*=.60), LDL–C <100 mg/dL (*P*=.70), blood pressure (*P*=.11), insulin (*P*=.99)
	+ Smoking cessation: (*P*=.04)
	+ Aspirin use: (*P*=.001)
	Costs 1 year after intervention, mean (bootstrap 95%CI)
	+ Total cost ($): *P*=.02
	+ Outpatient cost ($), *P*=.04
Carallo et al., 2015 [25]	*Health or clinical and financial:*
	+ HbA1c: decreased (*P*=.01)[a]
	+ LDL cholesterol decreased in intervention group (*P*=.003)[a]; and control group (*P*=.001)
	+ BMI: decreased (*P*=.03)[a]
	X Blood pressure, triglycerides, and waist[a,f]

Study	Outcome measures and effects
Gurwitz et al., 2014 [30]	*Process:*
	Number of primary care provider visits after discharge within:
	X 7 days: 27.5% vs. 28.3%. Hazard ratio: 0.95 (95% CI 0.83–1.1)[c,e]
	X 14 days: 52.9% vs. 52.5%. Hazard ratio: 0.98 (95% CI 0.89–1.1[c,e]
	X 30 days: 68.6% vs. 68.8%. Hazard ratio: 0.99 (95% CI 0.91–1.1)[c,e]
	Rehospitalization in 30–day period after discharge:
	X 18.8% vs. 19.9%. Hazard ratio for 0.94 (95% CI 0.81–1.1)[c,e]
DICE [27]	*Process:*
	X Unscheduled admissions, or disruption of normal activities[c,e]
	–[b] No. of routine diabetic care visits (during trial): difference 95% CI –0.9 to –0.1
	Health or clinical and financial:
	X Metabolic control: glycated hemoglobin, BMI, creatinine, systolic and diastolic blood pressure[e]
	X Knowledge: diabetes, urine and blood testing, foot care, diet, general management (both non–insulin and insulin dependent patients)[c,e]
	X Psychosocial status (diabetes health questionnaire): eating problems, anxiety, depression[c,e] Support (only insulin dependent patients)[c,e]
	– Support (only non–insulin dependent patients): 95%CI difference 0.06 – 4.5 (significant at 5% level)[e]
	X Beliefs: personal control, situation control, satisfaction with treatment, wellbeing[c,e] Medical control (only for insulin dependent)[c,e]
	+ Beliefs: medical control (only for non–insulin dependent patients): 95%CI difference 0.5–6.3 (significant at 5% level)[e]
	Costs
	+ Costs mean costs per visit £1.70 (95% CI £1.16–£2.47) in intervention and £8 (95% CI £5.23–£ 12.12) for usual care[c,e]
Drummond et al., 1994 [29]	*Process*
	X No of general practice asthma consultations, 95% CI: 1.11 (0.95–1.31)[c,e]
	X No of hospital admissions for asthma, 95% CI: 1.31 (0.87–1.96)[c,e]
	– Hospital admissions (not owning peak flow meter at start), 95% CI: 1.76 (1.09 to 2.85), P<.05[e]
	Health or clinical and financial:
	X Pulmonary function[c,e]

Study	Outcome measures and effects
	Sleep disturbance:
	X No. of nights disturbed/week: 1.01 (95% CI 0.85–1.21)[c,e]
	X No. of days of restricted activity/month: 1.20 (95% CI 0.78–1.84)[c,e]
	+ No. of disturbed nights (owning peak flow meter at start), 95% CI: 1.92 (1.02 to 3.64), P<.05[e]
	Use of bronchodilators and inhaled and oral steroids:
	X No. of bronchodilators prescribed: 0.95 (95% CI 0.83–1.09)[c,e]
	X No. of inhaled steroids prescribed: 0.98 (95% CI 0.88–1.09)[c,e]
	X No of courses of oral steroids used: 0.97 (95% CI 0.79–1.20)[c,e]
	Psychosocial outcomes[c,e]:
	X Anxiety: 0 (95% CI −0.56 to 0.63); self–efficacy: 0 (95% CI −0.05 to 0.09); living with asthma scale: 0 (95% CI −0.10 to 0.11); depression: 1 (95% CI 0.89–1.11)
	+ Being in control of asthma "all the time" 8 (CI 95% 1–16). P<0.05[e]
	Patients' perceptions;
	+ choosing integrated care; 75% (intervention) vs. 62 (usual care)%, P<.05[e]
	+ perceiving disadvantages of integrated care; 37% (intervention) vs. 50% (usual care), P<.05[e]
	– perceiving advantages of integrated care; 40% (intervention) vs. 47% (usual care), P<.05[e]
	+ perceiving attributes of general practitioner and advantage of integrated care; 11% (intervention) vs 5% (usual care), P<.05[e]
	– no. (%) "very satisfied" with medical care over past year; 77% (intervention) vs. 86% (integrated care), P<.05[e]
	Costs
	+ Integrated care saved patients £39.52 per year, the hospital £3.06 (average) per patient per year and general practitioners £2.41 per patient per year[c]
McGhee et al., 1994 [28]	*Provider or professional:*
	+ 61.2% of general practitioners preferred shared care to continue; 13.6% did not; 25.2% was not sure[c]
	32% of general practitioners preferred shared care (over usual, outpatient –or NP care)
	Process
	+ Complete review shared vs. outpatient care, P<.001
	+ Complete review received shared vs. nurse practitioner clinical care, P<.05

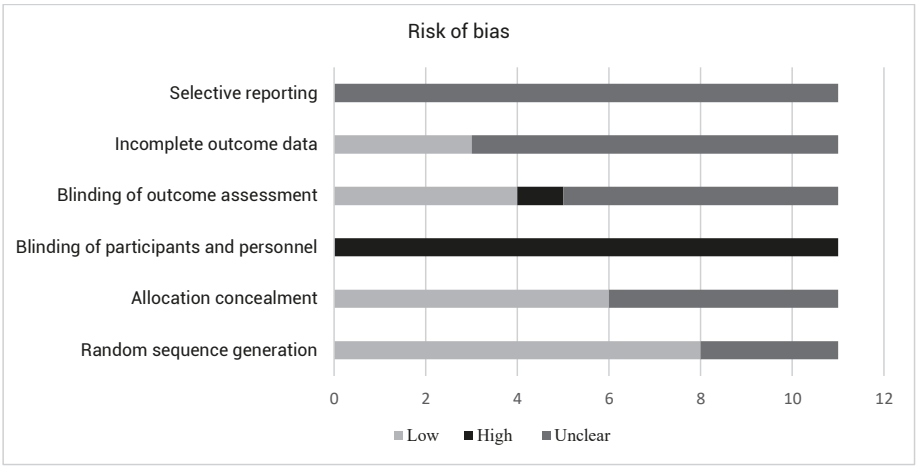
Study	Outcome measures and effects
	Health or clinical and financial:
	X Clinical outcomes: blood pressure [c,e]
	Shared care patients: 48.2% preference for shared care to outpatient care, 22% no preference, and 29.8% for outpatient care[c]
	Total costs
	+ Per complete review (total including patient and NHS): shared care: £40.86; Outpatient care £71.32; NP clinic care £43.67[c]
Casas et al., 2006 [21]	*Process*
	+ Number of readmissions: *P*=.028[e]
	+ Rate of readmissions (follow–up year): *P*=.03[e]
	+ Difference readmissions (per year): *P*=.003[e]
	+ Survival without readmissions: *P*=.03[e]
	X Doctor visits: (Barcelona): *P*=.44[e]; (Leuven): *P*=.45[e]
	Health or clinical and financial:
	X Total deaths: (*P*=.67)[e]
Garcia–Aymerich et al., 2007 [22]	*Health or clinical and financial[d]:*
	Clinical outcomes (change baseline – 12 months)[e]
	X Dyspnea: *P*=.30; FEV1: *P*=.57; FEV1/FCV: *P*=.86; PaO2 (mmHg): *P*=.36; PaCO2 (mmHg): *P*=.59
	– BMI: *P*=.01
	Quality of life (change between baseline – 12 months)[e]
	X Health related quality of life: *P*=.56
	X Generic health–related quality of life: *P*=.27
	Lifestyle (at 12 months)[e]:
	X Smoking: *P*=.35
	X Physical activity: *P*=.78
	Self–management (at 12 months)[e]:
	+ Knowledge: name of disease: *P*=.005 ; identification of COPD exacerbation: *P* < .001; early treatment of COPD exacerbation: *P*=.04;
	X Adherence to oral treatment: *P*=.57
	+ Adherence to inhaled treatment: *P*<.009; correct inhaler manoeuvre: *P*<.001
	X Satisfaction: *P*=.18

Study	Outcome measures and effects
Jefford et al., 2008 [32]	*Provider or professional*[e]*:*
	+ Confidence: *P*=.003
	X Knowledge of adverse effects: *P*=.37
	X Knowledge of reasons for referral: *P*=.32
	+ Satisfaction: *P*=.002
	Perception of information[e]:
	+ Usefulness of correspondence: P<.001
	+ Information was instructive: P<.001, easy to understand: P<.005 and right length: P<.001
Lalonde et al., 2008 [23]	*Provider or professional:*
	+ Knowledge score pre–post difference 34% (95%CI: 29–40%)[a,c]
	Overall satisfaction rated as "excellent": workshop (77%)[a,c]; communication–network program (23%)[a,c]; consultation service (27%)[a,c]
	Process
	Pharmaceutical opinions:
	+ During study: difference (95% CI): 0.48 (0.20–0.76)[b,d]
Santschi et al., 2011 [24]	*Process*[e]
	+ Number of written recommendations: *P*=.007
	+ Hypertension related recommendations: *P*=.009
	Health or clinical and financial[e]*:*
	X Systolic blood pressure (unadjusted change): *P*=.45
	+ Systolic blood pressure (adjusted change): *P*=.021
	X Diastolic blood pressure (unadjusted change): *P*=.11 (adjusted change): *P*=.35
	X Blood pressure control (unadjusted relative risk): *P*=.07 and (adjusted relative risk): *P*=.13
Wulff et al., 2013 [33]	*Provider or professional:*
	+ Patient–specific information from hospital on: psychological effects: *P*=.002; social effects: *P*=.0039 and missed to be informed about information already given to patient by specialist *P*=.042
	Process:
	+ Number of GPs contacting hospital: *P*=.008
	X Patient contact with general practitioners during daytime in follow–up (1–270 days), *P*=.91 (incidence ratio) *P*=.25 (proportion ratio)

Study	Outcome measures and effects	
	−/X	Patient contact with general practitioners during out–of–hours in follow–up (1–270 days), *P*=.09 (incidence ratio) and *P*=.02 (proportion ratio)

[a] intervention group only
[b] "+"; indicates a positive effect (for the intervention), "-"; indicates a negative effect and "X"; indicates no effect
[c] Researchers did not provide (specific) *P*-value
[d] BMI: Body Mass Index
[e] intervention versus control grop
[f] control group only

Multimedia Appendix 4 – Risk of bias



Number of studies (total n=11)

CHAPTER 3

Barriers and facilitators affecting patient portal implementation from an organizational perspective: qualitative study

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ABSTRACT

Background

The number of patient portals is rising, and although portals can have positive effects, their implementation has major impacts on the providing health care institutions. However, little is known about the organizational factors affecting successful implementation. Knowledge of the specific barriers to and facilitators of various stakeholders is likely to be useful for future implementations.

Objective

The objective of this study was to identify the barriers to and facilitators of patient portal implementation facing various stakeholders within hospital organizations in the Netherlands.

Methods

Purposive sampling was used to select hospitals of various types. A total of 2 university medical centers, 3 teaching hospitals, and 2 general hospitals were included. For each, 3 stakeholders were interviewed: (1) medical professionals, (2) managers, and (3) information technology employees. In total, 21 semistructured interviews were conducted using the Grol and Wensing model, which describes barriers to and facilitators of change in health care practice at 6 levels: (1) innovation; (2) individual professional; (3) patient; (4) social context; (5) organizational context; and (6) economic and political context. Two researchers independently selected and coded quotes by applying this model using a (deductive) directed content approach. Additional factors related to technical and portal characteristics were added using the model of McGinn et al., developed for implementation of electronic health records.

Results

In total, we identified 376 quotes, 26 barriers, and 28 facilitators. Thirteen barriers and 12 facilitators were common for all stakeholder groups. The facilitators' *perceived usefulness* (especially less paperwork) was mentioned by all the stakeholders, followed by subjects' *positive attitude*. The main barriers were *lack of resources* (namely, lack of staff and materials), *financial difficulties* (especially complying with high costs, lack of reimbursements), and *guaranteeing privacy and security* (eg, strict regulations). Both similarities and differences were found between stakeholder groups and hospital types. For example, managers and information technology employees mainly considered *guaranteeing privacy and security* as a predominant barrier. *Financial difficulties* were particularly mentioned by medical professionals and managers.

Conclusions

Patient portal implementation is a complex process and is not only a technical process but also affects the organization and its staff. Barriers and facilitators occurred at various levels and differed among hospital types (eg, *lack of accessibility*) and stakeholder groups (eg, *sufficient resources*) in terms of several factors. Our findings underscore the importance of involving multiple stakeholders in portal implementations. We identified a set of barriers and facilitators that are likely to be useful in making strategic and efficient implementation plans.

INTRODUCTION

Patient-centeredness is an important element of high-quality care: effective communication between patients and their health care professionals, and information access can both contribute considerably to this [1]. According to the Institute of Medicine, "patients should have unfettered access to their own medical information" [2] to support them in taking control of their health (eg, using medical information to make informed health-related decisions) [2]. Information technology (IT) can play an important role in improving access to this information [3], and it also improves the participation of patients in their own care [4]. In health care, an increasingly popular way to facilitate this is by using patient portals [5]. Patient portals can be defined as "applications which are designed to give the patient secure access to health information and allow secure methods for communication and information sharing" [6], as well as for administrative purposes [7], and are mostly provided by a single health care institution [6,8]. These portals are often connected to the electronic health record (EHR) of an institution—defined as tethered patient portals [9]—to provide access to patients' medical information [3,10-12]. Some institutions allow patient portals to facilitate communication between patients and health care professionals [3,6,12], view their appointments and provide patient education [11,13], share information [12], request for repeat medication prescriptions [3], and provide tailored feedback [11,13]. Patient portals may have a range of functionalities that enable information exchange (such as having access to the EHR), which in turn may facilitate and improve the communication between the patient and the health care professional [11,14]. Previous research showed that patients are especially satisfied with access to information from the EHR and the list of their appointments [11]. Portal use can also have a positive effect on self-management of conditions [15-18], communication between patients and providers, quality of care [16,17] and participation in treatment [17]. Patient empowerment can also be improved; the accessibility of information can especially contribute to "patients' knowledge" and their "perception of autonomy and being respected" [19]. On the other hand, effects on health outcomes are reported to be mixed [6]. In summary,

patient portals can be important as they provide patients with access to their own medical information, enable interaction with their health care professionals [8], and aim to involve patients in their own care processes [1].

Although patient portals can have positive effects and may develop into a standard element of care [20], their implementation has major impacts on health care institutions as it often involves a complex change in an organization [1]. This can be affected by multiple factors at the micro (eg, "individuals"), meso (eg, "resources"), and macro (eg, "sociopolitical context") levels [21]. Several implementation models are available, such as "The Consolidated Framework for Implementation Research (CFIR)," which is used in many studies as a guiding framework [22-24]. CFIR consists of 5 levels at which barriers and facilitators can occur during implementation: (1) technology-related factors (eg, "adaptability," "complexity," and "cost"); (2) outer setting (eg, "policy and incentives"); (3) inner setting (eg, "resources"); (4) process (eg, "engagement of stakeholders"); and (5) individual health professionals (eg, "individual's knowledge"). In this model, patients are part of the "outer setting," suggesting that the CFIR framework is aimed primarily at institutions [24]. Another example is the "Fit between Individuals, Tasks, and Technology" (FITT) framework, which is aimed at the adoption of IT [25]. The comprehensive model of Grol and Wensing [26] summarizes the barriers to and facilitators of change in health care practice at 6 levels: (1) innovation; (2) individual professional; (3) patient; (4) social context; (5) organizational context; and (6) economic and political context. McGinn et al. [21] argue that the consideration of various stakeholder opinions can contribute to successful implementations. However, previous research mainly focused on perceptions of single stakeholder groups regarding patient portal implementation, such as physicians [27] or nurses [28]. This highlights the importance of identifying the opinions of many stakeholders during patient portal implementation. Furthermore, it remains unclear which factors are important in accomplishing change in the various groups [26].

Previous research focused on patient involvement in developing patient portals [5,14], but little is yet known about organizational factors that facilitate or hinder patient portal implementation [6]. Such knowledge is essential because the number of portals is rising. In the Netherlands, in 2017, more than 25% of hospitals provided patients with access to a patient portal, whereas this was under 10% in 2015 [29]. Comprehensive information can provide a framework for upcoming patient portal implementations, or other eHealth applications, in hospitals. The objective of this study was, therefore, to identify the barriers and facilitators among the various stakeholders within hospital organizations in the Netherlands regarding the implementation of tethered patient portals.

METHODS

Sampling procedure

Purposive sampling was used to select hospitals of the 3 different types existing in the Netherlands. In total, 2 university medical centers (UMCs), 3 teaching and 2 general hospitals (including one collaborative oncology hospital comprising 3 general hospitals) were included. Hospitals were selected by means of convenience sampling using the authors' network or by Web searching, and hospitals in various phases of implementation (contemplation, preparation, or implementation) were included. Contact persons in the hospitals were approached by phone or email. Snowball sampling was used for the selection of respondents, meaning that we informed the contact persons about the objective of the study and also asked them for contact information for 3 stakeholders, including (1) medical professionals (doctor or nurse practitioners [Advanced Practice Registered Nurses]) [30], (2) managers, and (3) IT employees.

Table 1. Barriers and facilitators at various levels of Grol and Wensing.

Levels of Grol and Wensing [26]	Examples of barriers and facilitators
Innovation: patient portal	Accessibility, attractiveness, and credibility
Individual professional	Knowledge, attitude, and motivation to change
Patient	Knowledge, skills and attitude
Social context	Opinions of colleagues, culture of the networks, and collaboration
Organizational context	Organization of care processes, staff, and resources
Economic and political context	Financial arrangements, regulations, and policies

If the contact person belonged to one of these groups, they were also asked to participate. Once the stakeholders had agreed to participate, an interview was scheduled with each person individually. In total, 8 hospitals were approached, of which 7 agreed to participate, and 21 subjects participated in the study. No ethical review is needed for this type of study. All participants were informed about the purpose of the study, and participation was voluntary. Verbal consent for audio recording the interviews was obtained for every participant. All data were analyzed and presented anonymously.

Data collection procedure

The interviews were conducted by the first author (LK). A few days before the interview, each participant received a confirmation email suggesting a scheduled date and time. A document was attached describing the objectives of the study and a topic list for the interview. We also added our own definition of a typical patient portal: "a personal digital

environment, facilitated by a health care institution, for example a hospital. Patients need to login to the portal to get access to, for example, their medical file (with results), patient information and appointments. Patients can also fill in questionnaires and receive personalized advice regarding, for example, quality of life and physical activity." We used a semistructured interview that was structured by applying the comprehensive model of Grol and Wensing [26] that summarizes the barriers to and facilitators of change in health care practice. This model describes 6 levels at which barriers and facilitators can occur: (1) innovation: patient portal; (2) individual professional; (3) patient; (4) social context; (5) organizational context; and (6) economic and political context. All these barriers and facilitators are described in Table 1.

All interviews were performed by telephone and lasted for, on average, 20 min. Participants were first asked for their consent to make audio recordings of the interviews. Then, the purpose of the interview was introduced, and subjects were asked if they received the introductory email. This email was then briefly discussed such that the subjects were aware of the topics to be discussed. After that, questions were asked about participants' characteristics, such as their age and work experience. To make sure an unambiguous definition of a patient portal was used, participants were asked what their definition of a patient portal was, and if necessary, it was complemented with our definition. Then, we asked them about their perceived barriers to and facilitators of patient portal implementation at all 6 levels [26]. If necessary, for example, if the question was unclear, the interviewer provided examples (and these were also sent per email). At the end of the interview, the participants were asked to suggest additional topics or issues, if any, that had not yet been covered. The interviews were in Dutch, and the questions in Multimedia Appendix 1 are translations.

Data analysis

The first author transcribed all interviews verbatim. Two researchers (LK and WG) independently selected text fragments that reflected a barrier to or facilitator of portal implementation and coded the transcripts in Excel according to the model of Grol and Wensing [26]. A directed content approach was used, which is mainly a deductive approach as a pre-existing model is used for coding [31]. If quotes did not fit into the Grol and Wensing model [26], we looked for categories from the McGinn model [21], which was developed for implementation of EHRs. These models have considerable overlap, but the Grol and Wensing model [26] mainly covers socio-dynamic factors, whereas the McGinn model [21] also covers technical and portal characteristics. For the remaining quotes we created new categories, which is an inductive approach. To enhance clarity and unambiguity of the categories, we renamed them to better reflect the nature of being a barrier or a facilitator. A complete overview of the categories is presented in Multimedia Appendix 2. Coding

was discussed between LK and WG until consensus was reached. Saturation of the data was checked by the first author by assessing (post hoc) the percentage of new categories appearing with the analysis of every subsequent hospital.

RESULTS

Characteristics of the subjects

In total, we interviewed 21 stakeholders from 7 hospitals. We included 3 from each hospital including medical professionals (n=7), managers (n=7), and IT employees (n=7). The stakeholder group labeled medical professionals consisted of medical specialists (n=4) and nurse practitioners (n=3). The group of managers included a medical director (n=1), hospital division or department managers (n=5), and a project manager (n=1). IT employees were application specialists or managers (n=3), an IT manager (n=1), an IT architect and information manager (n=1), and a patient portal project manager (n=2). Mean age was 44.8 years (SD 6.7; range 25-61) and 57% (12/21) were female. We included 6 respondents (6/21, 29%) from UMCs, 9 respondents (9/21, 43%) from teaching hospitals, and 6 (6/21, 29%) from general hospitals. Participants' work experience varied from 6 years or less (10/21, 48%) to more than 21 years (3/21, 14%). An overview of participants' characteristics is listed in Table 2.

Barriers to and facilitators of patient portal implementation

In total, we selected 376 quotes and identified 26 barriers and 28 facilitators. The results are presented according to the 6 levels of the Grol and Wensing model [26]. The full list of all barriers and facilitators—including the number of subjects for each stakeholder group—is presented in Multimedia Appendix 3. After the inclusion of 7 hospitals (using purposive sampling), we analyzed the data saturation. The data were found to be saturated, meaning that after analyzing the first 6 hospitals, no new categories emerged from the transcripts of the final hospital. We therefore did not include further hospitals.

Due to the high number of identified barriers and facilitators, only those common to all stakeholder groups (medical professionals, managers, and IT employees) are presented here. To demonstrate the similarities and differences between stakeholder groups and between hospitals types, their most mentioned barriers and facilitators are presented as well.

Barriers and facilitators common to all stakeholder groups

In total, 13 barriers and 12 facilitators (Table 3) were identified that were common to all stakeholder groups. The most relevant barriers and facilitators for each level are presented

based on the number of subjects (and percentage of the total subjects) and are highlighted in italics. Quotes are used to illustrate the barriers and facilitators for each level that were mentioned by the majority of the subjects.

Table 2. Participants' characteristics (N=21).

Characteristics	**n (%)**
Gender	
Female	12 (57)
Male	9 (43)
Age (years)	
20–29	3 (14)
30–39	3 (14)
40–49	7 (33)
50–59	6 (29)
>60	2 (10)
Hospital	
University medical centers	6 (29)
Teaching hospital	9 (42)
General hospital	6 (29)
Work experience in current position in organization (years)	
≤5	10 (48)
6–10	3 (14)
11–15	1 (5)
16–20	4 (19)
≥21	3 (14)

Table 3. Barriers to and facilitators of patient portal implementation mentioned by all stakeholder groups and ranked by number of subjects.

Barriers and facilitators	**Stakeholders**			
	Medical professionals (n=7)	Managers (n=7)	IT employees (n=7)	Total (n=21)
Innovation: patient portal				
Barriers				
Guaranteeing privacy and security	1(14)	5 (71)	5 (71)	11 (52)
Lack of accessibility	2 (29)	4 (57)	3 (43)	9 (43)
Lack of perceived usefulness	4 (57)	1 (14)	2 (29)	7 (33)
Facilitators				
Perceived usefulness	7 (100)	7 (100)	7 (100)	21 (100)
Perceived ease of use	2 (29)	2 (29)	1 (14)	5 (24)
Attractiveness	1 (14)	1 (14)	2 (29)	4 (19)
Participation of end users during implementation	1 (14)	1 (14)	1 (14)	3 (14)
Individual professional				
Facilitators				
Positive attitude	3 (43)	7 (100)	3 (43)	13 (62)
Motivation to change	4 (57)	2 (29)	2 (29)	8 (38)
Having knowledge	1 (14)	2 (29)	2 (29)	5 (24)
Patient				
Barrier				
Lack of sufficient eHealth literacy	4 (57)	5 (71)	4 (57)	13 (62)
Social context				
Barrier				
Negative attitude or opinion of medical professionals	4 (57)	3 (43)	1 (14)	8 (38)
Facilitator				
Positive attitude or opinion of medical professionals	1 (14)	2 (29)	2 (29)	5 (24)
Organizational context				
Barriers				
Lack of resources	4 (57)	5 (71)	6 (86)	15 (71)

Table 3. Continued.

Barriers and facilitators	Stakeholders			
	Medical professionals (n=7)	Managers (n=7)	IT employees (n=7)	Total (n=21)
Lack of time and increased workload	4 (57)	3 (43)	1 (14)	8 (38)
Innovation–averse culture	1 (14)	4 (57)	1 (14)	6 (29)
Lack of suitable specialist staff	1 (14)	2 (29)	3 (43)	6 (29)
Adjusting organization of care processes is difficult	2 (29)	1 (14)	2 (29)	5 (24)
Structure of the organization	2 (29)	1 (14)	2 (29)	5 (24)
Change in task and new responsibilities	1 (14)	1 (14)	2 (29)	4 (19)
Facilitators				
Management support	2 (29)	3 (43)	3 (43)	8 (38)
Communication to promote the portal	1 (14)	4 (57)	1 (14)	6 (29)
Innovation–oriented culture	2 (29)	2 (29)	1 (14)	5 (24)
Economic and political context				
Barrier				
Financial difficulties	5 (71)	6 (86)	3 (43)	14 (67)
Facilitator				
Facilitating laws and regulations	1 (14)	2 (29)	1 (14)	4 (19)

Innovation: patient portal

Barriers

Lack of perceived usefulness, *lack of accessibility*, and *guaranteeing privacy and security* were identified as barriers for portal implementation. Important reasons related to the privacy and security were the regulations, the availability of privacy-sensitive information on the portal, and the requirements for a safe login. The login or authorization method used in the Netherlands—the so-called digital identity DigiD with additional text messaging verification—was mentioned very frequently and can therefore be considered a major barrier. This DigiD login consists of a username and password of the user's own choice and provides citizens with access to hundreds of government websites in the Netherlands [32]:

> *The security is a barrier for both the organization, and the implementation of the portal, as well for patients. The moment we secure the data according to the law and regulations, we notice that the use is not what it could be. [Manager, university medical center]*

Due to the privacy and security aspects, accessibility of the portal is increasingly becoming a limitation, and this was mainly because of the requirement for a DigiD login. Subjects mentioned lack of perceived usefulness because the portal implementation can lead to discord and practical difficulties. In addition, the portal only provides information for one health care institution, so patients do not have a complete overview of their health information.

Facilitators

Perceived usefulness, attractiveness, perceived ease of use, and *participation of end users* during implementation were seen as facilitators for implementation. All subjects (n=21) see *perceived usefulness* as a facilitator because the implementation of a patient portal could result in fewer consults, less paperwork, higher quality of care, and financial savings. Also for patients, multiple benefits were listed, including more involvement in their treatment, more transparency, and better accessibility of information:

> *It saves a lot of paperwork and hassles. It sounds ideal to me. Currently patients receive so many paper documents that they don't have an overview anymore. If we centralize this on a portal it will be more clear for them. [Medical professional, general hospital]*

A good project team and the *participation of the end users during implementation* —both patients and hospital staff—can be beneficial because their input can be used to make adjustments during the development phase. *Perceived ease of use* and specifically the design of the portal can facilitate portal use, and the *attractiveness* was widely considered to be a requirement.

Individual professional

Facilitators

No barriers were common for all the stakeholder groups. However, all groups see *motivation to change*, *knowledge*, and their own *positive attitude* as a facilitator:

> *I am very happy that we are starting with this development and that we, I think, are taking positive steps for the healthcare in the Netherlands. [Manager, teaching hospital]*

Patient

Barriers

Only barriers were anticipated for patients (common to all stakeholder groups), especially related to patients' characteristics and patient portal use. These barriers included *lack of eHealth literacy.* This can be due to the diversity of the patient population because it will include immigrants, older patients, and people with limited literacy skills. These specific groups may experience difficulty using a portal. Patients might also fear using the portal or simply need time to get used to it:

> *We have a lot of patients with low levels of literacy […] So a lot of people without digital access to information, and no computer. That is a barrier for the portal in this hospital.*
> *[Manager, teaching hospital]*

Social context

Barrier and facilitator

Negative attitude or opinion of medical professionals was seen as a barrier and a facilitator by all stakeholder groups. They stated that this is because of doctors' resistance regarding transparency of medical information, negative outcome expectancy because they think they will receive more questions and phone calls, and they are sometimes afraid to lose control:

> *…a lot of professionals are very tense about it. They are used to have the control when they get in touch with a patient or have an appointment with a patient. Now it is possible for patients to interfere with this. Doctors and other professionals are tense about that. So that is a barrier for implementation.*
> *[Manager, university medical center]*

However, *positive attitude or opinion of medical professionals* was seen as a facilitator. When medical professionals are enthusiastic, it can facilitate the implementation, and they can influence others in a positive way. It was also mentioned that medical professionals asked for IT services for patients to be improved:

> *There is also an explicit request from the medical staff to support, what they call patient IT, so that is positive.*
> *[IT employee, general hospital]*

Organizational context

Barriers

Lack of resources, *lack of time* and *increased workload*, *innovation-averse hospital culture*, *lack of suitable specialist staff*, *difficult to adjust organization of care processes*, *structures of the organization*, and *change in task and new responsibilities* were identified as barriers. *Lack of resources* was seen as a barrier, and although material resources—such as a lack of advanced IT materials—can be a reason, mainly the lack of human resources was mentioned by stakeholders. These resources are not only essential for implementation but also to maintain the portal and to ensure the continuity of service to patients, once the portal has been implemented. IT employees are especially important because this process requires specific knowledge. This technical knowledge is often lacking in hospitals, and it may therefore be necessary to hire suitable specialist staff. This means that there should be enough money to attract resources, which can be a problem because the budgets of hospitals are limited:

> *An organization has limited resources nowadays, so yes that is a barrier. It is not that we can open a cash box and say we will hire 20 more people to finish this together. That is not how it works.*
> *[Medical professional, teaching hospital]*

The *innovation-averse culture* in hospitals is often identified as a barrier. One reason for this is that each person wants to give his or her opinion (about the portal), and that all opinions need to be taken into account, which inevitably slows down the implementation. Health care is also seen as essentially conservative—especially by managers—meaning that health care organizations and professionals need to get used to a new medium such as a patient portal.

These new services may affect hospitals' care processes, which can be difficult to adjust. Patients usually have access to their portal 24 hours a day, 7 days a week. If they experience a problem or they ask a question, it should be addressed quickly, and this may not always be possible. *Adjusting the organization of care processes* might be necessary, for example, concerning the transparency of medical information on the portal. Adjusting these care processes can be a barrier because they are sometimes ambiguous and usually difficult to change. This may also lead to *changes in tasks and new responsibilities* for the staff. New tasks or changes in existing work processes and responsibilities may result in informing patients about the portal and answering questions that arise when reading medical information on the portal. But also *lack of time and increased workload* was noted as a barrier, and the time investment required from medical professionals was especially seen as a problem. Furthermore, *organizational structures* can also hinder implementation

for the reason that each division in a hospital tends to have its own management, policy agreements, and prioritizing approach.

Facilitators

Management support, communication to promote the portal, and *innovation-oriented culture* were seen as facilitators. The support of hospitals' management can facilitate portal implementation, especially when there is a hospital-wide strategy on eHealth—and patient portals—available. On the other hand, if this is missing, then that can be a barrier to implementation. *Management support* and approval can also be a facilitator; it can help the organization to focus on the implementation instead of on the internal discussion whether or not to implement the portal:

> *…the decision of the board means everything, because then you are not going to discuss if we are going to do it and why but we are going to do this and how […] that is an absolute must and facilitator for this kind of project to be implemented.*
> *[IT employee, university medical center]*

Clear *communication (to promote the portal)* was indicated to be facilitating and relevant for staff because it can reduce professionals' misunderstanding, for example, regarding functionalities on the portal. Sessions to inspire staff about eHealth can facilitate implementation, and hospitals can use publicity to raise awareness about the availability of the portal and thereby increase accessibility for patients.

An *innovation-oriented culture* can help for the reason that the implementation is supported by the organization, the staff are stimulated and feel motivated, and there is a positive mood.

Economic and political context

Barrier

Financial difficulties were seen as a barrier mainly because funding is often a problem, and technical adjustments are expensive. In addition, the reimbursement for certain applications, for example, e-consults, has not yet been arranged:

> *The barrier is that it is not directly insured care, it is a bit luxurious (to provide it to patients now). So you have to find funding for it.*
> *[Medical professional, general hospital]*

Facilitator

Facilitating laws and regulations can be beneficial, and especially the support by the government in the Netherlands for portal implementation is seen as a facilitator.

Comparison of stakeholder groups

We found similarities between stakeholders, for example, regarding *perceived usefulness*, but also differences (Table 4). Overall, the findings regarding *lack of resources* were fairly similar among the groups, although the majority (5/7, 71%) of the IT employees also mentioned that there are *sufficient resources* available. *Guaranteeing privacy and security* was mentioned by both managers (5/7, 71%) and IT employees (5/7, 71%) as a barrier. The majority of medical professionals (4/7, 57%) and managers (5/7, 71%) mentioned *lack of sufficient eHealth literacy* of patients as a barrier.

However, we also found differences between stakeholder groups. The *negative attitude or opinion of medical professionals* was often seen as a barrier, especially by medical professionals. They were most often negative about providing patients with medical information via the patient portal because they were afraid it would lead to more work (such as more questions from patients), and they were worried about losing control. A remarkable finding is that all the managers (7/7, 100%) see their own *positive attitude* as a facilitator; however, this is true for only less than the half (3/7, 43%) of the other groups. All the medical professionals mentioned the *perceived usefulness* of the portal, but they (4/7, 57%) also indicated a *lack of perceived usefulness* because they think that the portal can lead to practical problems. However, the majority of this group is *motivated to change* (4/7, 57%) compared with only a minority in the other 2 stakeholder groups (both 2/7, 29%).

Table 4. Top 3 barriers and facilitators for each stakeholder group and ranked by number of subjects.

Barriers and facilitators by stakeholder group	n (%)
Medical professionals (n=7)	
Perceived usefulness (+[a])	7 (100)
Financial difficulties (–[b])	5 (71)
Lack of perceived usefulness (–)	4 (57)
Motivation to change (+)	4 (57)
Lack of sufficient eHealth literacy (–)	4 (57)
Negative attitude or opinion of medical professionals (–)	4 (57)
Lack of resources (–)	4 (57)
Lack of time and increased workload (–)	4 (57)

Table 4. Continued.

Barriers and facilitators by stakeholder group	n (%)
Managers (n=7)	
Perceived usefulness (+)	7 (100)
Positive attitude (+)	7 (100)
Financial difficulties (–)	6 (86)
Guaranteeing privacy and security (–)	5 (71)
Lack of sufficient eHealth literacy (–)	5 (71)
Lack of resources (–)	5 (71)
IT[c] employees (n=7)	
Perceived usefulness (+)	7 (100)
Lack of resources (–)	6 (86)
Guaranteeing privacy and security (–)	5 (71)
Sufficient resources (+)	5 (71)

[a]"+" indicates facilitator.
[b]"–" indicates barrier.
[c]IT: information technology.

Comparison of hospital types

In Table 5, the top 3 barriers and facilitators for each hospital type are listed. A complete overview of all barriers and facilitators—including the number of subjects for each hospital type—is presented in Multimedia Appendix 4. Differences were found in the barriers mentioned by subjects from different hospital types. The majority (5/6, 80%) of subjects from UMCs mentioned *lack of accessibility* as a barrier, and the difficult login method was especially seen as a barrier in these hospitals. In general hospitals, most subjects think that the *positive attitude* or *opinion of medical professionals* will facilitate implementation because medical professionals are enthusiastic. *Lack of time and increased workload* is also an important barrier in general hospitals because everybody is already always busy. Along with the differences, we also found similarities between the 3 hospital types. *Perceived usefulness* was mentioned by all subjects (21/21, 100%), but also *lack of resources* was seen in every hospital type as an important barrier. The UMCs and general hospitals see that the *lack of sufficient eHealth literacy* can hinder patient portal use. The most similarities were found between the teaching and general hospitals. *Positive attitude, guaranteeing privacy and security*, and *financial difficulties* were mentioned by the majority of subjects in both teaching and general hospitals. This is an important difference from the UMCs, which can perhaps be explained by differences in the financing of these hospital types.

Table 5. Barriers and facilitators—top 3 for each hospital type and ranked by number of subjects.

Barriers and facilitators by hospital type	n (%)
UMCs[a] (n=6)	
Perceived usefulness (+[b])	6 (100)
Lack of accessibility (–[c])	5 (83)
Lack of sufficient eHealth literacy (–)	4 (67)
Lack of resources (–)	4 (67)
Teaching hospitals (n=9)	
Perceived usefulness (+)	9 (100)
Lack of resources (–)	7 (78)
Financial difficulties (–)	7 (78)
Guaranteeing privacy and security (–)	6 (67)
Positive attitude (+)	6 (67)
General hospitals (n=6)	
Perceived usefulness (+)	6 (100)
Positive attitude (+)	5 (83)
Guaranteeing privacy and security (–)	4 (67)
Lack of sufficient eHealth literacy (–)	4 (67)
Positive attitude or opinion of medical professionals (+)	4 (67)
Lack of resources (–)	4 (67)
Lack of time and increased workload (–)	4 (67)
Financial difficulties (–)	4 (67)

[a]UMC: university medical center.
[b]"+" indicates facilitator.
[c]"–" indicates barrier.

Comparison of hospitals with and without an implemented patient portal

Although we did not explicitly ask the included hospitals in which phase of implementation they were, we could deduce this from the interviews. In total, we included 7 hospitals. Two of these hospitals had no patient portal but were planning implementation. Three hospitals had minimal experience with portals—small pilots with limited functionalities or a classic portal version—but were also in the implementation phase. Only 2 hospitals had an active patient portal; however, stakeholders of one hospital mentioned they were still implementing to extend their current functionalities. In Table 6, we list the barriers and facilitators that were mentioned by (at least one stakeholder) all the included hospitals

both with a patient portal (n=2) and without a patient portal (n=5). A complete overview is presented in Multimedia Appendix 5. Although there were similarities (eg, *financial difficulties*, *lack of sufficient eHealth literacy*), we also found differences. All hospitals without a patient portal mentioned *negative attitude or opinion of medical professionals* and *lack of specialist staff* as barriers. These factors could negatively influence implementation. Although the hospitals with a patient portal see barriers for the implementation of their patient portals, they also mentioned multiple facilitators, for example, *perceived ease of use*, *motivation to change*, and *sufficient resources*. The barriers *lack of a generic guideline* (n=1) and *participation of end users during implementation* (n=1) were only mentioned by hospitals with a patient portal. *Lack of a generic guideline* was a barrier expressed by a manager (n=1), meaning that it could have been beneficial for implementation if there would have been coordination or a standard format. All stakeholders of one hospital that had implemented a portal noticed *participation of end users during implementation*. In that case, they referred back to the implementation and stated that it was useful to involve end users—both patients and health care professionals—during implementation and for each hospital division to be well represented in the project organization.

Table 6. Barriers and facilitators mentioned by all hospitals (at least one subject per hospital) with and without a patient portal and ranked by total number of subjects.

Barriers and facilitators of hospitals with and without a patient portal	**Hospitals with a patient portal[a], n (%)**	**Hospitals without a patient portal[b], n (%)**
Barriers and facilitators common for hospitals with and without a patient portal (ie, unanimously reported by hospitals of both groups)		
Barriers		
Financial difficulties	4 (67)	10 (67)
Lack of sufficient eHealth literacy	4 (67)	9 (60)
Lack of resources	2 (33)	12 (80)
Negative attitude or opinion of colleagues in general	3 (50)	9 (60)
Facilitators		
Perceived usefulness	6 (100)	15 (100)
Positive attitude	3 (50)	10 (67)
Barriers and facilitators only reported unanimously by hospitals with a patient portal		
Barriers		
Lack of time and increased workload	4 (67)	
Innovation–averse culture	3 (50)	

Table 6. Continued.

Barriers and facilitators of hospitals with and without a patient portal	Hospitals with a patient portal[a], n (%)	Hospitals without a patient portal[b], n (%)
Adjusting organization of care processes	3 (50)	
Structures of the organization	3 (50)	
Change in task and new responsibilities	2 (33)	
Facilitators		
Perceived ease of use	3 (50)	
Motivation to change	2 (33)	
Having knowledge	2 (33)	
Positive attitude or opinion of medical professionals	2 (33)	
Good collaboration with colleagues	2 (33)	
Sufficient resources	2 (33)	
Conducive financial arrangements	2 (33)	
Barriers only reported unanimously by hospitals without a patient portal		
Barriers		
Negative attitude or opinion of medical professionals		7 (47)
Lack of suitable specialist staff		5 (33)

[a]n=2 hospitals; n=6 subjects.
[b]n=5 hospitals; n=15 subjects.

DISCUSSION

Summary of main findings

In this study, we have presented an overview of the barriers and facilitators related to patient portal implementation among various stakeholders within the hospital organization. In total, we identified 26 barriers and 28 facilitators. Positive factors related to *perceived usefulness* (eg, cost savings, accessibility for patients to their information) were mentioned by all subjects. The facilitators individuals' *positive attitude* and *management support* (eg, strategy plan for eHealth and patient portals) were also mentioned by majority of the subjects. The main barriers reported were *lack of resources* (especially lack of staff), *financial difficulties* (high costs, lack of reimbursement), and *guaranteeing privacy and security* (eg, strict regulations). We want to emphasize that no inferences can be drawn about the prevalence of phenomena observed beyond the current sample.

We found several similarities between stakeholders (eg, regarding *perceived usefulness*) but also remarkable differences that highlight the importance of involving multiple stakeholders. One interesting finding is that approximately half the medical professionals see their own *positive attitude* and *motivation to change* as facilitators. Although medical professionals' motivation to change is the highest of all stakeholder groups, *lack of time and increased workload* was perceived by them as a barrier. Apparently, they are willing to change, but at the same time, they assume that they do not have enough time to achieve implementation and portal use. The barriers *guaranteeing privacy and security* and *lack of resources* were mentioned by the majority of IT employees. This shows the challenges this group is dealing with when implementing a secure portal. Managers were the only group of which all (7/7, 100%) stated that they had a *positive attitude.* This is in clear contrast with the proportion of medical professionals and IT employees (both 3/7, 43%). Managers also stand out in their statements about the culture with more than the half of the managers (4/7, 57%) thinking the culture is hindering implementation, whereas only a minority of both the medical professionals (1/7, 14%) and IT employees (1/7, 14%) stated this. Managers mentioned that hospital culture is conservative and slow to change.

Comparison with previous research

Koivunen et al. [28] identified nurses' barriers and facilitators regarding portal implementation. Their findings were comparable with ours; for example, concerning the barriers *lack of resources* and *lack of time*. However, in their study, nurses were included and were mainly negative because they had doubts about the benefits of the portal; moreover, they were unwilling to use a new technical tool because they believed that their primary tasks are to be more important. This differs from our findings as we found *positive attitudes* among all included stakeholders (medical professionals, managers, and IT employees), and all our subjects mentioned *perceived usefulness* as a facilitator for patient portal implementation. One reason for these differences may be the selection of stakeholders, as we focused on those directly involved and did not include nurses, only medical doctors and nurse practitioners ("Advanced Practice Registered Nurses") [30]. Keplinger et al. [27] also considered physicians' attitudes regarding patient portal implementation. Some of their findings are in line with ours, for example, the expected increase in workload and positive attitudes regarding the patient portal. However, they also found differences in attitudes both before and after implementation. For example, before implementation, more than half of the physicians assumed that their workload would increase, whereas only one-third actually experienced such an increase in workload.

McGinn et al. [21] showed the relevance of including the perspectives of various stakeholders regarding EHR implementation. Their results are both similar and different from our results. They found that the main factors common to all stakeholder groups

were found at various levels and included "perceived ease of use," "costs," "motivation to use EHR," and "privacy and security concerns." These findings are similar to ours perhaps because *financial difficulties, guaranteeing privacy and security,* and *positive attitude* were mentioned by the majority of our subjects. The use of the internet and other electronic applications is becoming increasingly common in health care [33], and patients' eHealth literacy needs to be taken into account. *Participation of end users during implementation* was mentioned as a facilitator and can be used to focus on the eHealth literacy of the users.

McGinn et al. [21] argue that the consideration of various stakeholder opinions may contribute to successful EHR implementations. Similarities with and differences from our results were found. The main factors common to all stakeholder groups were found at various levels and included "design and technical concerns," "costs," "lack of time and workload," and "privacy and security." The findings are similar to ours, and this can be the case because both EHRs as well as patient portals are complex technologies that affect multiple levels of an organization. However, we also found differences because in our study, *perceived usefulness* and *lack of sufficient eHealth literacy (patients)* were mentioned by the majority of the subjects. *Lack of accessibility* (because of login methods perceived as difficult) was mentioned by almost half of the subjects. This difference can be due to an EHR being primarily aimed at professionals and a patient portal being primarily intended as a service for patients. The differences found among these implementation studies highlight the importance of identifying barriers and facilitators for each technology separately taking into account the perspectives of the several stakeholder groups that are involved.

Implementation frameworks and models

There are many implementation models, and they have considerable overlap [34]. A combination of 2 models was used for categorization of the selected quotes, that is, the model of Grol and Wensing [26] for socio-dynamic factors and by McGinn [21] mainly for portal characteristic and technical factors. Although this combination of frameworks appeared to be a feasible approach, we also added categories and renamed existing ones, so they better match with our findings. An essential difference between our approach and, the CFIR framework is that in our study, patients are included as a separate factor, whereas in the CFIR framework, they are part of the "outer setting" [24]. In the FITT framework, separate categories such as "social context" and "organizational context" are missing, and the aspects related to social interaction, for example, are categorized under "individual" within the FITT model. We found these categories to be relevant as a separate level because many subjects reported on them [25]. In the McGinn model [21], a subcategory is "participation of end users during the design," which does not cover all the input we received, particularly because it is not aimed at the complete implementation process. One of the added categories is *participation of end users during implementation.*

Another new category is *sufficient eHealth literacy,* which encompasses the skills and knowledge necessary to use electronic applications [33]. The models we used only address patients' skills and knowledge [26] and applicability—of EHR implementation—to patients' characteristics [21]. Patients' lack of eHealth literacy was identified as a barrier by the majority of the subjects.

Practical suggestions and insights for portal implementations

Our findings suggest that implementation is affected by barriers and facilitators at various levels. McGinn et al. [21] describe 3 key levels: the macro, meso, and micro levels. We present some suggestions and insights for organizations that intend to implement a patient portal.

Micro level: individual and social factors

Our findings suggest that stakeholders' *positive attitudes* can contribute to implementation. They greatly value their colleagues' opinions, so apparently this can play a crucial role in the implementation process. Clear communication with all stakeholders during the implementation process and about the patient portal functionalities can increase stakeholders' understanding and can help to avoid misunderstandings.

Meso level: organizational and operational developments

The implementation can be affected by operational factors in the organization [21]; for example, *lack of resources*, *management support*, and *lack of suitable specialist staff*. To successfully implement a patient portal, a project team is essential that includes resources and staff with technical knowledge about patient portals and implementation processes. Management support is important; for example, by including the plan for portal implementation in their organizational strategy. Organizations should also be aware that the implementation of a patient portal is not only a technical implementation but also involves a change in the organizational socio-dynamics, including changes in employees' tasks, new responsibilities, and a shift in control from health care professionals to patients.

Macro level: sociopolitical influences

Governments in Western countries are increasingly promoting and supporting portal implementation and use. In the United States, financial support is generated by the Health Information Technology for Economic and Clinical Health Act and arranged by the Centers for Medicare and Medicaid Services. The goal of these incentive programs is to support the implementation [35], adoption, and "meaningful use" of the EHRs [6,35,36]. This includes, for example, providing patients with access to or acquiring an electronic copy of their health data [36]. In the Netherlands, the Ministry of Health and the Dutch Hospital Association developed a funding program to support information exchange for both patients and

professionals. The ultimate goal of this program is that in 2020, all Dutch people will have access to their own medical information. Therefore, all institutions must have a patient portal by the end of 2019 or a link to a Personal Health Record (PHR) to which the institution can upload medical information [37]. Government commitment thus can be beneficial for hospitals, especially in view of the opportunities for funding. Hospitals can exploit governments' ambitions and policies and patient representatives demands, for example, to make EHR data accessible for every patient, as a motivation to facilitate implementation.

Limitations

This study has several limitations. First, we used semistructured interviews in which we provided participants with prompts/examples for each level. Providing subjects with examples may have restricted participants in their answers about new barriers and facilitators or to "think outside the box" on these topics, so we might have missed factors. However, we used the combined models of Grol and Wensing [26] and McGinn et al. [21], and many stakeholders mentioned barriers and facilitators that fell outside our scope. Although we have confidence in the richness of the current data, we already reached data saturation after 6 hospitals, limiting the total number of hospitals and subjects. There were also differences in the included hospitals with regard to the phase of patient portal implementation. Some had already provided a portal, whereas others were in the middle of the implementation process or had no portal at all. Although we found only limited differences between the hospitals with and without an implemented patient portal, this could still have introduced bias into the responses because of the recall or the imagination of information. This means that the results might have been influenced by the current state of hospitals because participants sometimes had to recall information from the time of implementation or had to imagine an implementation process (if there is no portal or no implementation).

Although we presented many different types of barriers and facilitators, we acknowledge that quantity should not be taken as a proxy for importance. We therefore added quotes to the results so as to highlight the specific nature of specific barriers and facilitators. For data analysis, we used a directed content analysis (deductive) approach. This can be a possible limitation because we started with an already existing model with defined categories. However, as the methods allows, we did not completely hold on to the categories in the models as we added additional categories ourselves and renamed the existing (generic) categories to barriers and facilitators that better fit our findings. Despite these limitations this is, to the best of our knowledge, the first qualitative study to identify barriers and facilitators for patient portal implementation involving multiple stakeholder groups.

Future perspectives and research directions

Instead of organizing health care around professionals and institutions, some contend that it should increasingly be arranged around patients [2]. In a recent review, we found little evidence for the efficacy of IT-supported shared care [38]; however, many initiatives exist that may facilitate patient-centered or shared care. We already see movement in this direction as information systems are evolving from purely organizational to regional and even international systems [39]. For instance, a PHR is an example of an application in which patients can access their health information that has been collected from various health care institutions but is controlled by the patients [40]. In several European countries, these national systems have already been introduced. For example, in France, there is a national initiative called "Dossier Médical Personnel," which is accessible over the internet. The information is uploaded by the involved clinicians; however, patients are in charge about what is included in the portal and who is authorized to access it. In Estonia, health professionals transfer information into a system called the "Estonian Health Information System," providing patients with information via a patient portal [41]. These initiatives show a shift from hospital-financed, -owned, and -managed health records for which access is granted through portals, toward PHRs in which providers upload the data and ownership by patients is facilitated. The present uptake/compliance rates of portals are however still rather low (seldom above 50%), so this is an aspect that should receive attention if widespread use is foreseen.

Future research is necessary to confirm the practical utility of our proposed model when used among various stakeholder groups and to test whether it is useful to tailor implementation strategies to these various stakeholders, and organizations, taking possible development routes into account. In addition, there is a lack of knowledge regarding the association between patient portal implementation and patient portal adoption (ie, actual uptake and use by patients). One important element we identified is eHealth literacy, and this should ideally be included in the implementation and evaluation strategies for health technology tools. Moreover, the expectations before implementations and the experiences afterward can vary among health care professionals [27] and patients [11]. Further research into "satisfiers" determining the attitude of professionals toward using these technologies is recommended because evidence of the effectiveness of technology-related aspects on patient empowerment and on health outcomes is a strong facilitator.

Conclusions

Patient portal implementation is a complex process that is not just a technical process, but it also affects an organization and its staff. We found barriers and facilitators at various levels that differed depending on hospital types (eg, *lack of accessibility*) and stakeholder groups (eg, *sufficient resources*) in terms of several factors. Our findings underscore

the importance of involving multiple stakeholders in portal implementation projects. We identified a set of barriers and facilitators, which are likely to be useful in making strategic and efficient portal implementation plans.

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
EHR: electronic health record
FITT: Fit between Individuals, Tasks, and Technology
IT: information technology
PHR: personal health record
UMC: university medical centers

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MULTIMEDIA APPENDICES

Multimedia Appendix 1 – Interview questions

1. Participants were first asked for their consent to make audio recordings of the interviews. After that, questions were asked about participants' characteristics, such as their age and work experience. We also asked participants what their definition of a patient portal was, and if necessary, it was complemented with our definition. Our definition: "a patient portal is a personal digital environment, facilitated by a health care institution, for example a hospital. Patients need to login to the portal to get access to, for example, their medical file (with results), patient information and appointments. Patients can also fill in questionnaires and receive personalized advice regarding, for example, quality of life and physical activity."

2. Barriers and facilitators

A. Individual professional

Do you, as an individual professional, anticipate barriers to and facilitators for implementing a patient portal? If yes, which barriers and facilitators?

Examples:

- Your knowledge regarding the implementation of a patient portal
- Your attitude regarding the implementation of a patient portal
- Your motivation regarding the implementation of a patient portal

B. Patient

Do you anticipate barriers and/or facilitators for patients using a patient portal? If yes, which barriers/facilitators?

Examples:

- Patients' knowledge about a patient portal
- Patients' skills in using a patient portal
- Patients' attitude regarding a patient portal

C. Social context

Do you anticipate barriers and/or facilitators (regarding the implementation of a patient portal) concerning the social context in your organization?

Examples:

- Opinion of colleagues
- Culture within the organization
- Collaboration

D. Organizational context

Do you anticipate barriers and/or facilitators (regarding the implementation of a patient portal) concerning the social context in your organization?

Examples:

- Organization of care processes
- Staff
- Resources

E. Economic and political context

Do you anticipate barriers and/or facilitators (regarding the implementation of a patient portal) concerning the social context in your organization?

Examples:

- Financial arrangements
- Laws and regulations
- Policy

F. Patient portal characteristics

Do you anticipate barriers and/or facilitators (regarding the implementation of a patient portal) concerning the patient portal characteristics?

Examples:

- Accessibility of the patient portal
- Attractiveness of the patient portal
- Ease of use of the patient portal
- Credibility of the content of the patient portal

Multimedia Appendix 2 – Barriers and facilitators categorized according to the model of Grol & Wensing and the model of McGinn.

Barriers and facilitators	Grol & Wensing [26]	McGinn [21]
Innovation		
Barriers/facilitators		
Guaranteeing privacy and security/ Privacy and security		Privacy and security concerns
Lack of accessibility/ Good accessibility	Accessibility	
Lack of attractiveness/Attractiveness	Attractiveness	
Lack of interoperability/ Interoperability with EHR		Interoperability
Lack of perceived usefulness/ Perceived usefulness		Perceived usefulness
Lack of tailored content/ Content tailored to patients		Content appropriate for the users (relevance)
Facilitators		
Credibility	Credibility	
Participation of end–users during implementation		Participation of end–users in the design
Perceived ease of use		Perceived ease of use
Perceived usefulness		Perceived usefulness
Individual professional		
Barriers/facilitators		
Lack of knowledge/Having knowledge	Knowledge	Knowledge (main category)
Lack of motivation to change/ Motivation to change	Motivation to change	Motivation/inertia to use EHR (readiness)/ resistance to use the EHR
Facilitators		
Positive attitude	Attitude	Attitude (main category)
Patient		
Barriers/facilitators		
Lack of sufficient eHealth literacy/ Sufficient eHealth literacy		

Barriers and facilitators	Grol & Wensing [26]	McGinn [21]
Negative attitude/lack of need/ Positive attitude demand		Patients' attitudes and preferences towards EHR
Social Context		
Barriers/facilitators		
Negative attitude or opinion of colleagues in general/Positive attitude and opinion of colleagues in general	Opinion of colleagues	Attitude of colleagues about EHR
Negative attitude or opinion of medical professionals/Positive attitude or opinion of medical professionals	Opinion of colleagues	Attitude of colleagues about EHR
Barrier		
Varying opinions about IT security	Opinion of colleagues	
Facilitators		
Varying opinions about implementation	Opinion of colleagues	
Early adapters		
Good collaboration with colleagues	Collaboration	
Organizational context		
Barriers/facilitators		
Lack of suitable specialist staff/suitable staff	Staff	
Lack of resources/sufficient resources	Resources	Resources available/ Material resources (access to EHR)/Human resources (IT support, other)
Innovation–averse hospital culture/ Innovation oriented–hospital culture	Culture of the networks (social context)	Innovation culture
Barriers		
Adjusting organization of care processes is difficult	Organization of care process	
Change in task and new responsibilities		Change in task
Lack of time and increased workload		Lack of time and workload
No strategic plan and lack of organizational priority/management support		Management (strategic plan to implement EHR)

Barriers and facilitators	Grol & Wensing [26]	McGinn [21]
Organization is not ready for implementation	Readiness	
Structure of the organization	Structures	
Facilitator		
Communication to promote the portal		Communication (included promotional activities)
Economic and political context		
Barriers/facilitators		
Financial difficulties/conducive financial arrangements	Financial arrangements	Financing of EHR/ Financial support/Cost issues
Third–party dependency/Good collaboration with third parties		
Lack of generic guidelines	Policies	
Restrictions imposed by laws and regulations/Facilitating law– and regulations	Regulations	
Supporting healthcare policies	Policies	Health care policies and socio political context

Multimedia Appendix 3 – Barriers to and facilitators of patient portal implementation for each stakeholder group and ranked by number of subjects

Barriers and facilitators	Stakeholders			
	Medical professionals[a] n (%)	Managers[a], n (%)	IT[b] employees[a], n (%)	Total (n=21), n(%)
Innovation: patient portal				
Barriers				
Guaranteeing privacy and security	1(14)	5 (71)	5 (71)	11 (52)
Lack of accessibility	2 (29)	4 (57)	3 (43)	9 (43)
Lack of perceived usefulness	4 (57)	1 (14)	2 (29)	7 (33)
Lack of interoperability	0 (0)	1 (14)	1 (14)	2 (10)
Lack of attractiveness	0 (0)	1 (14)	0 (0)	1 (5)
Lack of tailored content	1 (14)	0 (0)	0 (0)	1 (5)
Facilitators				
Perceived usefulness	7 (100)	7 (100)	7 (100)	21 (100)
Perceived ease of use	2 (29)	2 (29)	1 (14)	5 (24)
Attractiveness	1 (14)	1 (14)	2 (29)	4 (19)
Participation of end users during implementation	1 (14)	1 (14)	1 (14)	3 (14)
Privacy and security	2 (29)	0 (0)	1 (14)	3 (43)
Good accessibility	0 (0)	2 (29)	0 (0)	2 (10)
Credibility	0 (0)	2 (29)	0 (0)	2 (10)
Content tailored to patients	0 (0)	1 (14)	0 (0)	1 (5)
Interoperability with EHR	0 (0)	0 (0)	1 (14)	1 (5)
Individual professional				
Barriers				
Lack of knowledge	0 (0)	2 (29)	2 (29)	4 (19)
Lack of motivation to change	1 (14)	0 (0)	0 (0)	1 (5)
Facilitators				
Positive attitude	3 (43)	7 (100)	3 (43)	13 (62)
Motivation to change	4 (57)	2 (29)	2 (29)	8 (38)

Barriers and facilitators	Stakeholders			
	Medical professionals[a] n (%)	Managers[a], n (%)	IT[b] employees[a], n (%)	Total (n=21), n(%)
Having knowledge	1 (14)	2 (29)	2 (29)	5 (24)
Patient				
Barriers				
Lack of sufficient eHealth literacy	4 (57)	5 (71)	4 (57)	13 (62)
Negative attitude/lack of need	0 (0)	2 (29)	0 (0)	2 (10)
Facilitators				
Sufficient eHealth literacy	2 (29)	2 (29)	0 (0)	4 (19)
Positive attitude/demand	1 (14)	0 (0)	1 (14)	2 (10)
Social context				
Barriers				
Negative attitude or opinion of medical professionals	4 (57)	3 (43)	1 (14)	8 (38)
Negative attitude or opinion of colleagues in general	3 (43)	0 (0)	3 (43)	6 (29)
Varying opinions about IT security	0 (0)	0 (0)	1 (14)	1 (5)
Facilitators				
Positive attitude or opinion of colleagues in general	0 (0)	2 (29)	4 (57)	6 (29)
Positive attitude or opinion of medical professionals	1 (14)	2 (29)	2 (29)	5 (24)
Good collaboration with colleagues	0 (0)	2 (29)	2 (29)	4 (19)
Early adopters	0 (0)	3 (43)	0 (0)	3 (14)
Varying opinions about implementation	1 (14)	0 (0)	0 (0)	1 (5)
Organizational context				
Barriers				
Lack of resources	4 (57)	5 (71)	6 (86)	15 (71)
Lack of time and increased workload	4 (57)	3 (43)	1 (14)	8 (38)
Innovation–averse culture	1 (14)	4 (57)	1 (14)	6 (29)
Lack of suitable specialist staff	1 (14)	2 (29)	3 (43)	6 (29)

Barriers and facilitators	Stakeholders			
	Medical professionals[a] n (%)	Managers[a], n (%)	IT[b] employees[a], n (%)	Total (n=21), n(%)
Adjusting organization of care processes is difficult	2 (29)	1 (14)	2 (29)	5 (24)
Structure of the organization	2 (29)	1 (14)	2 (29)	5 (24)
Change in task and new responsibilities	1 (14)	1 (14)	2 (29)	4 (19)
Organization is not ready for implementation	2 (29)	2 (29)	0 (0)	4 (19)
No strategic plan and lack of organizational priority	0 (0)	2 (29)	0 (0)	2 (10)
Facilitators				
Management support	2 (29)	3 (43)	3 (43)	8 (38)
Communication to promote the portal	1 (14)	4 (57)	1 (14)	6 (29)
Sufficient resources	1 (14)	0 (0)	5 (71)	6 (29)
Innovation–oriented culture	2 (29)	2 (29)	1 (14)	5 (24)
Suitable specialist staff	0 (0)	1 (14)	0 (0)	1 (5)
Economic and political context				
Barriers				
Financial difficulties	5 (71)	6 (86)	3 (43)	14 (67)
Restrictions imposed by laws and regulations	0 (0)	3 (43)	1 (14)	4 (19)
Third–party dependency	0 (0)	1 (14)	1 (14)	2 (10)
Lack of generic guidelines	0 (0)	1 (14)	0 (0)	1 (5)
Facilitators				
Facilitating laws and regulations	1 (14)	2 (29)	1 (14)	4 (19)
Conducive financial arrangements	0 (0)	2 (29)	1 (14)	3 (14)
Good collaboration with third parties	0 (0)	1 (14)	1 (14)	3 (14)
Supporting healthcare policies	0 (0)	3 (43)	0 (0)	3 (14)

[a]n=7
[b]IT: information technology

Multimedia Appendix 4 – Barriers to and facilitators of patient portal implementation for each hospital type and ranked by number of subjects

Barriers and facilitators	Hospital types			
	UMC[a], n (%)	Teaching hospitals[b], n (%)	General hospitals[a], n (%)	Total (n=21), n(%)
Innovation: patient portal				
Barriers				
Guaranteeing privacy and security	1 (17)	6 (67)	4 (67)	11 (52)
Lack of accessibility	5 (83)	4 (44)	0 (0)	9 (43)
Lack of perceived usefulness	1 (17)	4(44)	2 (33)	7 (33)
Lack of interoperability	0 (0)	2 (22)	0 (0)	2 (10)
Lack of attractiveness	0 (0)	1 (11)	0 (0)	1 (5)
Lack of tailored content	0 (0)	1 (11)	0 (0)	1 (5)
Facilitators				
Perceived usefulness	6 (100)	9 (100)	6 (100)	21 (100)
Perceived ease of use	2 (33)	2 (22)	1 (17)	5 (24)
Attractiveness	0 (0)	2 (22)	2 (33)	4 (19)
Participation of end users during implementation	3 (50)	0 (0)	0 (0)	3 (14)
Privacy and security	1 (17)	2 (22)	0 (0)	3 (14)
Good accessibility	0 (0)	1 (11)	1 (17)	2 (10)
Credibility	1 (17)	1 (11)	0 (0)	2 (10)
Content tailored to patients	0 (0)	1 (11)	0 (0)	1 (5)
Interoperability with EHR	0 (0)	0 (0)	1 (17)	1 (5)
Individual professional				
Barriers				
Lack of knowledge	2 (33)	1 (11)	1 (17)	4 (19)
Lack of motivation to change	0 (0)	0 (0)	1 (17)	1 (5)
Facilitators				
Positive attitude	2 (33)	6 (67)	5 (83)	13 (62)
Motivation to change	3 (50)	3 (33)	2 (33)	8 (38)

Barriers and facilitators	Hospital types			
	UMC[a], n (%)	Teaching hospitals[b], n (%)	General hospitals[a], n (%)	Total (n=21), n(%)
Having knowledge	1 (17)	3 (33)	1 (17)	5 (24)
Patient				
Barriers				
Lack of sufficient eHealth literacy	4 (67)	5 (55)	4 (67)	13 (62)
Negative attitude/lack of need	1 (17)	1 (11)	2 (33)	4 (19)
Facilitators				
Sufficient eHealth literacy	0 (0)	2 (22)	2 (33)	4 (19)
Positive attitude/demand	1 (17)	1 (11)	0 (0)	2 (10)
Social context				
Barriers				
Negative attitude or opinion of medical professionals	3 (50)	4 (44)	1 (17)	8 (38)
Negative attitude or opinion of colleagues in general	3 (50)	2 (22)	1 (17)	6 (29)
Varying opinions about IT security	0 (0)	0 (0)	1 (17)	1 (5)
Facilitators				
Positive attitude or opinion of colleagues in general	3 (50)	3 (33)	0 (0)	6 (29)
Positive attitude or opinion of medical professionals	1 (17)	0 (0)	4 (67)	5 (24)
Good collaboration with colleagues	2 (33)	0 (0)	2 (33)	4 (19)
Early adopters	1 (17)	1 (11)	1 (17)	3 (14)
Varying opinions about implementation	0 (0)	1 (11)	0 (0)	1 (5)
Organizational context				
Barriers				
Lack of resources	4 (67)	7 (78)	4 (67)	15 (71)
Lack of time and increased workload	2 (33)	2 (22)	4 (67)	8 (38)
Innovation–averse culture	2 (33)	3 (33)	1 (17)	6 (29)
Lack of suitable specialist staff	2 (33)	3 (33)	1 (17)	6 (29)

Barriers and facilitators	Hospital types			
	UMC[a], n (%)	Teaching hospitals[b], n (%)	General hospitals[a], n (%)	Total (n=21), n(%)
Adjusting organization of care processes is difficult	3 (50)	1 (11)	1 (17)	5 (24)
Structure of the organization	1 (17)	2 (22)	2 (33)	5 (24)
Change in task and new responsibilities	3 (50)	0 (0)	1 (17)	4 (19)
Organization is not ready for implementation	1 (17)	0 (0)	2 (33)	3 (14)
No strategic plan and lack of organizational priority	1 (17)	0 (0)	1 (17)	2 (10)
Facilitators				
Management support	3 (50)	5 (55)	0 (0)	8 (38)
Communication to promote the portal	2 (33)	3 (33)	1 (17)	6 (29)
Sufficient resources	2 (33)	2 (22)	1 (17)	5 (24)
Innovation–oriented culture	0 (0)	4 (44)	1 (17)	5 (24)
Suitable specialist staff	0 (0)	0 (0)	1 (17)	1 (5)
Economic and political context				
Barriers				
Financial difficulties	3 (50)	7 (78)	4 (67)	14 (67)
Restrictions imposed by laws and regulations	2 (33)	1 (11)	1 (17)	4 (19)
Third–party dependency	1 (17)	0 (0)	1 (17)	2 (10)
Lack of generic guidelines	0 (0)	0 (0)	1 (17)	1 (5)
Facilitators				
Facilitating laws and regulations	2 (33)	2 (22)	0 (0)	4 (19)
Conducive financial arrangements	1 (17)	1 (11)	1 (17)	3 (14)
Supporting healthcare policies	1 (17)	1 (11)	1 (17)	3 (14)
Good collaboration with third parties	1 (17)	0 (0)	1 (17)	2 (10)

[a] total n=2 hospitals; total n=6 subjects
[b] total n=3 hospitals; total n=9 subjects

Multimedia Appendix 5 – Barriers to and facilitators of patient portal implementation for hospitals with and without a patient portal and ranked by number of subjects

Barriers and facilitators	Hospitals with a patient portal[a], n (%)	Hospitals without a patient portal[b], n (%)
Innovation: patient portal		
Barriers		
Guaranteeing privacy and security	2 (33)	9 (60)
Lack of accessibility	2 (33)	7 (47)
Lack of perceived usefulness	1 (17)	6 (40)
Lack of interoperability	0 (0)	2 (13)
Lack of attractiveness	0 (0)	1 (7)
Lack of tailored content	0 (0)	1 (7)
Facilitators		
Perceived usefulness	6 (100)	15 (100)
Perceived ease of use	3 (50)	2 (13)
Attractiveness	0 (0)	4 (27)
Participation of end-users during implementation	3 (50)	0 (0)
Privacy and security	1 (17)	2 (13)
Accessibility	0 (0)	2 (13)
Credibility	0 (0)	2 (13)
Content tailored to patients	0 (0)	1 (7)
Interoperability with EHR	0 (0)	1 (7)
Individual professional		
Barriers		
Lack of knowledge	1 (17)	3 (20)
Lack of motivation to change	0 (0)	1 (7)
Facilitators		
Positive attitude	3 (50)	10 (67)
Motivation to change	2 (33)	6 (40)
Having knowledge	2 (33)	3 (20)

Barriers and facilitators	Hospitals with a patient portal[a], n (%)	Hospitals without a patient portal[b], n (%)
Patient		
Barriers		
Lack of sufficient eHealth literacy	4 (67)	9 (60)
Negative attitude/lack of need	1 (17)	4 (27)
Facilitators		
Sufficient eHealth literacy	0 (0)	4 (27)
Positive attitude/demand	1 (17)	1 (7)
Social context		
Barriers		
Negative attitude or opinion of medical professionals	1 (17)	7 (47)
Negative attitude or opinion of colleagues in general	3 (50)	3 (20)
Different opinions about IT security	1 (17)	0 (0)
Facilitators		
Positive attitude or opinion of medical professionals	2 (33)	3 (20)
Positive attitude or opinion of colleagues in general	1 (17)	5 (33)
Different opinions about implementation	0 (0)	1 (7)
Organizational context		
Barriers		
Innovation–averse culture	3 (50)	3 (20)
Lack of resources	2 (33)	12 (80)
Lack of time and increased workload	4 (67)	4 (27)
Lack of suitable specialist staff	1 (17)	5 (33)
Adjusting organization of care processes is difficult	3 (50)	2 (13)
Structure of the organization	3 (50)	2 (13)
Change in task and new responsibilities	2 (33)	2 (13)
Organization is not ready for implementation	1 (17)	3 (20)
No strategic plan and lack of organizational priority	0 (0)	2 (13)
Facilitators		
Innovation–oriented culture	1 (17)	4 (27)
Good collaboration with colleagues	2 (33)	2 (13)

Barriers and facilitators	Hospitals with a patient portal[a], n (%)	Hospitals without a patient portal[b], n (%)
Early adopters	0 (0)	3 (20)
Management support	2 (33)	6 (40)
Sufficient resources	2 (33)	4 (27)
Communication to promote the portal	2 (33)	4 (27)
Suitable specialist staff	0 (0)	2 (13)
Economic and political context		
Barriers		
Financial difficulties	4 (67)	10 (67)
Restrictions imposed by laws and regulations	0 (0)	4 (27)
Third–party dependency	1 (17)	1 (7)
Lack of generic guidelines	1 (17)	0 (0)
Facilitators		
Supporting laws and regulations	2 (33)	3 (20)
Conducive financial arrangements	2 (33)	1 (7)
Supporting healthcare policies	0 (0)	3 (20)
Good collaboration with third parties	1 (17)	1 (7)

[a] total n=2 hospitals; total n=6 subjects
[b] total n=5 hospitals; total n=15 subjects

CHAPTER 4

The effect of telehealth on hospital services use: systematic review and meta-analysis

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ABSTRACT

Background

Telehealth interventions, that is, health care provided over a distance using information and communication technology, are suggested as a solution to rising health care costs by reducing hospital service use. However, the extent to which this is possible is unclear.

Objective

The aim of this study is to evaluate the effect of telehealth on the use of hospital services, that is, (duration of) hospitalizations, and to compare the effects between telehealth types and health conditions.

Methods

We searched PubMed, Scopus, and the Cochrane Library from inception until April 2019. Peer-reviewed randomized controlled trials (RCTs) reporting the effect of telehealth interventions on hospital service use compared with usual care were included. Risk of bias was assessed using the Cochrane Risk of Bias 2 tool and quality of evidence according to the Grading of Recommendations Assessment, Development and Evaluation guidelines.

Results

We included 127 RCTs in the meta-analysis. Of these RCTs, 82.7% (105/127) had a low risk of bias or some concerns overall. High-quality evidence shows that telehealth reduces the risk of all-cause or condition-related hospitalization by 18 (95% CI 0-30) and 37 (95% CI 20-60) per 1000 patients, respectively. We found high-quality evidence that telehealth leads to reductions in the mean all-cause and condition-related hospitalizations, with 50 and 110 fewer hospitalizations per 1000 patients, respectively. Overall, the all-cause hospital days decreased by 1.07 (95% CI −1.76 to −0.39) days per patient. For hospitalized patients, the mean hospital stay for condition-related hospitalizations decreased by 0.89 (95% CI −1.42 to −0.36) days. The effects were similar between telehealth types and health conditions. A trend was observed for studies with longer follow-up periods yielding larger effects.

Conclusions

Small to moderate reductions in hospital service use can be achieved using telehealth. It should be noted that, despite the large number of included studies, uncertainties around the magnitude of effects remain, and not all effects are statistically significant.

INTRODUCTION

Many see the COVID-19 crisis as an opportunity to stimulate digital transformation. We can expect digital care and eHealth to receive a boost during this era. Creativity and flexibility are stimulated to formulate an answer to challenges in patients fearing infection in a hospital and to social distancing being necessary within hospital premises. Telehealth, defined as health care provided over a distance using information and communication technology (ICT) to enable interaction between patients and health professionals [1], may offer a solution. However, the efficacy of telehealth is unclear. When the dust has settled, there is a need to properly evaluate experiences and the evidence base underlying various forms of telehealth.

In addition, digital transformation is considered in response to the need to improve patient centeredness and concerns about growing health care expenditures [2,3]. Limiting the need for inpatient care, which is the main driver of hospital costs, may reduce health care expenditures [4,5]. Manufacturers' claims and commercial pilot reports seem to dominate the debate, and policy makers frequently embrace those claims. In the Netherlands, the government presumes that hospital care can return to a very low percentage of annual volume growth in view of the anticipated effects of digital transformation. However, the extent to which telehealth can reduce hospital service use remains unclear. Some reviews have reported on the effect of telehealth on this outcome, finding both reductions and increases in hospital service use [6-8]. A recent systematic overview of telehealth interventions found that the effect on all-cause hospitalizations ranged from a reduction of 13.8% to an increase of 4.7% [6]. No prior review has compared the effects between health conditions, and most have focused on a single telehealth type, limiting generalizability [6-8]. Firm evidence for economic benefits is also limited, as cost-effectiveness studies are sparse and show contradictory results [9,10]. Moreover, telehealth can be implemented in various ways. Telehealth interventions include (1) video consultation, (2) automated device-based monitoring, (3) web-based monitoring, (4) interactive voice response (IVR) systems, (5) mobile telemonitoring, and (6) structured telephone support (STS) [6].

We conducted a systematic literature review of randomized controlled trials (RCTs) aiming to provide an overview of the evidence for the effect of telehealth on hospital services use, that is, all-cause and condition-related hospitalizations, and their duration (per patient and per hospitalization). Furthermore, we evaluated the risk of bias in all studies, as well as the quality of evidence for all outcomes. Finally, we explored which types of telehealth are most effective and which patient groups are the optimal target for reducing hospital service use.

METHODS

Overview

This review followed the guidelines of the Cochrane Handbook, with some modifications [11]. Notably, we used reporting of the outcomes of interest as an inclusion criterion, selected studies and extracted data partially in duplicate (20%), and deviated somewhat from the suggested algorithm to judge the risk of bias arising from the randomization process (Multimedia Appendix 1).

Data sources and searches

We searched MEDLINE, Scopus (Elsevier), and the Cochrane Central Register of Controlled Trials (Wiley) from inception up to April 2019. The search strategy (

Multimedia Appendix 2) was developed by GMP using MeSH (Medical Subject Headings) terms and reference lists of relevant reviews until it encompassed all important keywords, and the search found all pertinent articles included in earlier reviews. WHVH and CJMD critically evaluated the search strategy before implementation.

Eligibility criteria

RCTs and cluster RCTs reporting the use of telehealth interventions compared with usual care were included. Telehealth was defined as health care interventions provided over a distance using ICT to enable interactions between patients and health professionals or among health professionals. Patients of any age and with any health conditions were considered. Reported outcomes included at least one of the following: all-cause hospitalization, condition-related hospitalization, or length of hospital stay. We considered only published, English, full-text, and peer reviewed articles. We did not apply any restrictions to the setting or date of publication.

This review follows the taxonomy of telehealth interventions developed in another systematic review [8], which differentiates between video consultations, (automated) device-based monitoring, web-based telemonitoring, IVR, mobile telemonitoring, and STS.

Video consultations are defined as any intervention using synchronous, two-way, audio-visual communication between patients and health care providers to perform triage or provide health advice. If measurement devices were provided, measurements were communicated solely during the video consultations.

In device-based monitoring, patients are provided with devices to measure vital signs or to report symptoms essential for detecting changes in health status. Automated alerts triggering actions from health care providers, such as phone calls, are frequently included.

Web-based telemonitoring includes interventions using a web portal to enable patients to report vital signs and symptoms, and to enable health professionals to provide educational material and feedback.

In IVR systems, patients are required to enter vital signs and symptoms through their home or mobile telephone in response to automated questions. These systems are typically combined with automated alerts that trigger actions from health care providers.

With mobile telemonitoring, patients actively submit vital signs and symptoms through their personal mobile devices. Vital signs are measured using external measurement devices.

STS provides patients with a specified number of telephone contacts for a given period of time, during which patients report their health status and receive health advice, medication adjustments, or referrals to health professionals.

We defined condition-related hospitalizations as hospitalizations due to the targeted health conditions. Studies that explicitly reported only condition-related outcomes are not aggregated with all-cause outcomes, as outcomes resulting from causes other than the condition of interest are unknown in that case, which could bias the results.

For the mean length of hospital stay, the total number of hospital days was divided by the total number of hospital stays. This is in contrast to the number of hospital days, where the total number of hospital days was divided by the total number of patients.

Data collection and extraction

GMP screened all titles and abstracts. This screening was independently verified on a sample basis (10%) by LK and AL. Screening of full text articles was performed identically. Disagreements were resolved through discussion, or adjudication by CJMD. Screening was performed using the Covidence systematic review software [12].

Using a standardized data extraction form, GMP extracted the following data from all included studies: study characteristics (eg, country and setting), population characteristics (eg, health condition, age, and gender), intervention details (eg, ICT components used and frequency of use), and outcomes (hospitalizations, length of hospital stay, and hospital days; Multimedia Appendix 3). Data extraction was verified by LK on a sample basis.

Assessment of risk of bias

We used the Cochrane Risk of Bias 2 (RoB 2) tool to assess the risk of bias for each study [13]. A number of rules were derived from the manual to ensure consistent judgments between reviewers (Multimedia Appendix 1). GMP assessed the risk of bias of all studies. Risk of bias assessment was performed independently and in duplicate for all studies by LK, AL, or CJMD. Disagreements were resolved through discussion or arbitration by a third reviewer, if necessary. The authors of the studies were not contacted for additional information in case of missing data or methodological unclarities.

Data synthesis and analysis

Risk differences between telehealth and usual care were calculated for data reported as cumulative incidences. Cumulative incidences reported as percentages were converted to the number of participants with events. For data reported as means, such as the mean number of hospitalizations per patient, the mean differences (MDs) between telehealth and usual care were calculated. Missing SDs were calculated, where possible. All calculations were performed according to Chapter 6 of the Cochrane Handbook [14]. Meta-analyses were conducted with the meta package in R, Version 3.6.3, (R Foundation for Statistical Computing) [15], using Mantel-Haenszel random-effects models. Hartung-Knapp adjustment is used to better reflect the uncertainty in the estimation of between-study heterogeneity in CIs [16,17].

The overall quality of evidence was rated according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Multimedia Appendix 4) [18]. GMP rated the quality of evidence for each outcome (Multimedia Appendix 5). This rating was verified by all other authors, and disagreements were resolved by discussion.

We conducted subgroup analyses for health conditions that were studied in at least two articles, as well as for each type of telehealth, length of follow-up, and risk of bias. These analyses were planned a priori. The risk of bias was analyzed using the robvis package in R [19]. To assess publication bias, we visually inspected funnel plots (using the meta package in R).

RESULTS

Study selection

The search identified 2544 records. After removing duplicates, 1410 records remained for the screening of titles and abstracts, through which 1114 (79.0%) records were excluded. We assessed 296 full-text articles for eligibility and excluded 120 articles. Of the remaining

176 articles, 127 (72.2%) provided sufficient data for inclusion in the meta-analysis (Multimedia Appendix 6). Figure 1 provides an overview of the study selection process.

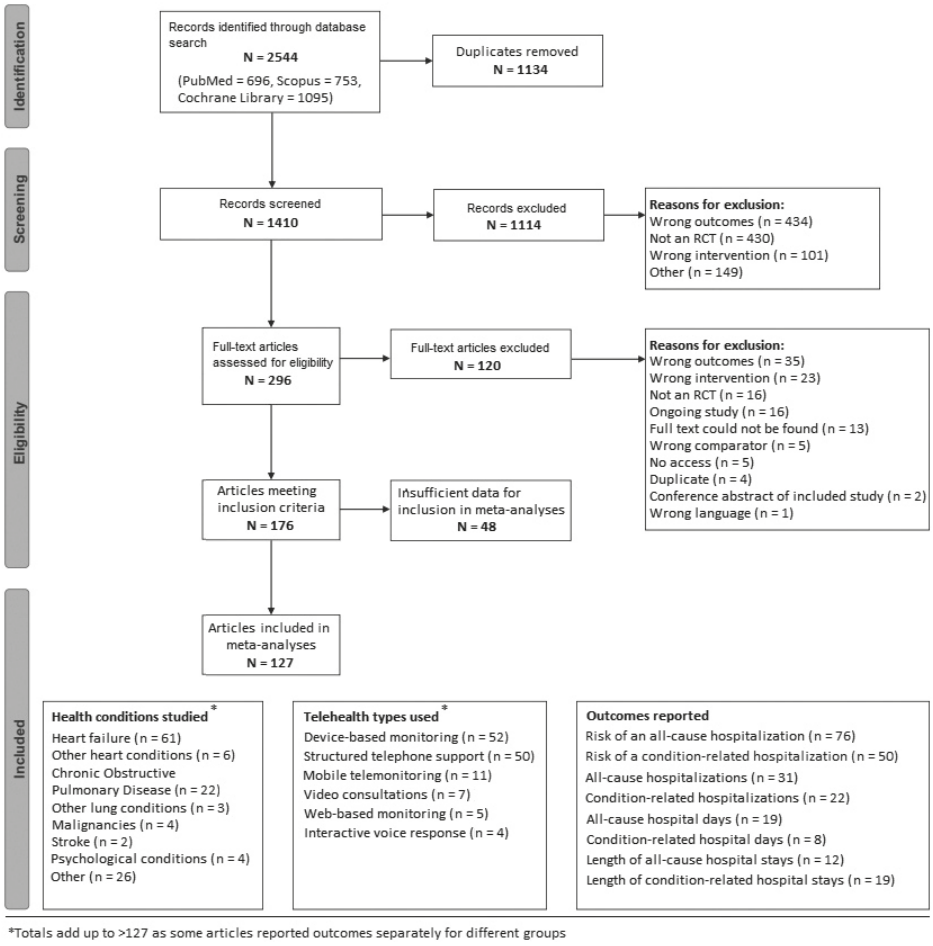

Figure 1. Study selection flowchart and study characteristics. RCT: randomized controlled trial.

Study characteristics

An overview of telehealth types, health conditions, and outcomes is provided in Figure 1 (details are provided in Multimedia Appendix 3). Most studies were conducted in Europe (n=55) and North America (n=41).

Risk of bias

We judged 50 articles to be at low overall risk of bias, 55 to have some concerns, and 22 to be at high risk of bias. Most articles were assessed at low risk of bias for all five domains (64/127, 50.4% to 98/127, 77.2%), except for selection of the reported result (63/127, 49.6%; Figure 2). High risk was found for bias arising from the randomization process in only 3 articles, bias due to deviations from intended interventions in one, due to missing outcome data in 11, bias in measurement of the outcome in one, and in selection of the reported result in 1 out of 127 articles. Weighted risk of bias summaries are provided for each analysis in Multimedia Appendix 5. In the analyses of condition-related hospitalizations and the length of hospital stay due to any cause, studies at high risk of bias in at least one domain cumulatively accounted for approximately 20% of the weight. In all other analyses, this figure was below 10%.

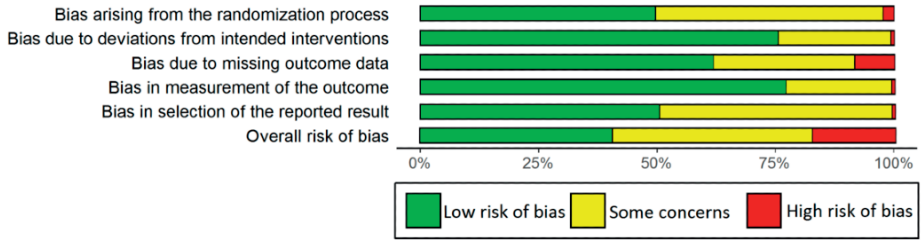

Figure 2. Unweighted risk of bias summary.

Outcomes

The summary of findings table (Table 1) provides a comprehensive overview of the main results for all outcomes.

For each analysis, most RCTs used device-based monitoring or STS and included mainly patients with heart failure or chronic obstructive pulmonary disease (COPD; details Multimedia Appendix 3). Complete analyses are available in Multimedia Appendix 5.

The outcomes are reported as rates in 14 articles. Although these could not be incorporated in the meta-analyses, an overview of these results is provided in Multimedia Appendix 7.

Table 1. Summary of findings table for the effect of telehealth interventions on various outcome measures compared with usual care.

Outcome	Studies (RCTs[a]), n	Participants, n	Follow–up (months)	Usual care estimate	Intervention effect estimate	Effect estimate (95% CI)	GRADE[b] Strength of evidence[c]	Plain language summary
Patients with an all–cause hospitalization (patients hospitalized per 1000 patients)	76	34,423	1–60	373	355	Risk difference: −18 (−30 to −0)	High	The number of patients hospitalized for any cause is reduced by 4.8%[d]
Patients with a condition–related hospitalization (hospitalizations per 1000 patients)	50	20,867	1–60	237	200	Risk difference: −37 (−60 to −20)	High	The number of patients hospitalized for the condition targeted is reduced by 15.6%[d]
Mean all–cause hospitalizations per patient (hospitalizations per 1000 patients)	31	11,191	3–12	880	830	Mean difference: −50 (−140 to +30)	High	All–cause hospitalizations are reduced by 5.7%[d]
Mean condition–related hospitalizations per patient (hospitalizations per 1000 patients)	22	3461	1–60	470	360	Mean difference: −110 (−200 to −10)	High	Condition–related hospitalizations are reduced by 23.4%[d]
All–cause hospital days[e](hospital days per patient)	19	9735	0–60	6.06	4.99	Mean difference: −1.07 (−1.76 to −0.39)	High	The mean number of days spent in the hospital for any cause per patient is reduced by 17.7%[d]

Table 1. Continued.

Outcome	Studies (RCTs[a]), n	Participants, n	Follow–up (months)	Usual care estimate	Intervention effect estimate	Effect estimate (95% CI)	GRADE[b] Strength of evidence[c]	Plain language summary
Condition–related hospital days[e] (hospital days per patient)	8	1216	3–60	2.84	1.71	Mean difference: −1.13 (−1.64 to −0.61)	Moderate[f]	The mean number of days spent in the hospital for the condition targeted is reduced by 39.8%[d]
Length of all–cause hospital stay[g] (days per hospitalization)	12	1964	0–60	8.37	7.89	Mean difference: −0.48 (−1.50 to 0.53)	Low[h]	Hospitalizations for any cause are 5.7%[d] shorter with telehealth
Condition–related hospital length of stay[g] (days per hospital stay)	15	2047	0–24	2.92	2.03	Mean difference: −0.89 (−1.42 to −0.36)	High	Hospitalizations for the condition targeted are 30.5%[d] shorter with telehealth

[a] RCT: randomized controlled trial.
[b] GRADE: Grading of Recommendations Assessment, Development and Evaluation.
[c] 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.
[d] Percentages were calculated by dividing the effect estimate by the usual care estimate.
[e] Participants are the unit of analysis.
[f] Downgraded by one level for risk of publication bias.
[g] Hospitalizations are the unit of analysis.
[h] Downgraded by one level for risk of bias and another for imprecision.

Risk of all-cause hospitalization

The risk of all-cause hospitalization was reported by 76 RCTs, including 34,423 participants. The analysis provides high-quality evidence for a risk difference of −18 (95% CI −30 to 0) hospitalized patients per 1000 patients (−4.8% of usual care).

Risk of condition-related hospitalization

We found 50 RCTs reporting the risk of condition-related hospitalization, including 20,867 participants. The absolute risk was reduced by 37 per 1000 patients (95% CI 20-60), with high-quality evidence (−5.7% of usual care). When stratified by health condition, only the heart failure group showed a statistically significant effect (risk difference = −0.03), although the subgroup difference was not significant (*P*=.40).

Mean all-cause hospitalizations

We found 31 RCTs reporting the mean number of all-cause hospitalizations per patient, including 11,191 participants. Follow-up varied between 3 and 12 months. The analysis showed high-quality evidence for an MD of −50 (95% CI −140 to +30) hospitalizations per 1000 patients, a 5.7% reduction with regards to the number of hospitalizations in the usual care group. Only the COPD subgroup showed a statistically significant MD between telehealth and usual care of −200 (95% CI −390 to −10) hospitalizations per 1000 patients. No effects were found for heart failure and other diseases. In addition, an RCT studying malignancies reported an MD of +0.09 hospitalizations per patient compared with usual care but did not report a SD and was therefore excluded from the meta-analysis.

Mean condition-related hospitalizations

The mean number of condition-related hospitalizations per patient was reported in 22 RCTs, including 3461 participants. Follow-up varied between 1 and 60 months. The analysis showed high-quality evidence for an MD of −110 (−200 to −10; −23.4% of usual care) hospitalizations per 1000 patients with telehealth compared with usual care. Differences between outcomes appeared to depend on the length of follow-up (P<.01). The difference increased gradually with a longer follow-up from an MD of −90 between 3 and 6 months up to a reduction of 1190 hospitalizations per 1000 patients for outcomes reported after more than 12 months. When stratified by health condition, only heart failure showed a statistically significant effect (MD −120; −200 to −40 hospitalizations per 1000 patients).

All-cause hospital days

The mean number of days patients were hospitalized for any cause was reported in 19 RCTs including 9735 participants. Overall, the analysis showed high quality evidence for an MD of −1.07 (95% CI −1.76 to −0.39) hospital days per patient. In addition, 9 RCTs reported the total number of days for which patients were hospitalized, and 2 reported the rate of

hospital days. Furthermore, 1 RCT reported an MD of +0.60 hospital days with telehealth compared with usual care but did not report an SD nor the necessary information to calculate one. These 12 RCTs, which included 3144 participants, could not be incorporated in the meta-analysis.

Condition-related hospital days

The mean number of days patients were hospitalized for the condition of interest was reported by 8 RCTs, including a total of 1216 participants. The analysis showed moderate quality evidence of an MD of −1.13 (95% CI −1.64 to −0.61) hospital days per patient. The quality of evidence was downgraded because of risk of publication bias. A statistically significant difference was found for the length of follow-up (P<.01), with longer follow-up resulting in larger reductions in hospital days. It is notable that when stratified by health condition, a statistically significant result was only achieved in heart failure (MD −1.06 hospital days, 95% CI −1.71 to −0.40). For COPD, an MD of −1.75 (95% CI −4.62 to 1.11) was found. In addition, 7 studies reported the total number of days patients were hospitalized, and one reported the rate of hospital days. These studies, including 2492 participants, could not be included in the meta-analysis.

Length of all-cause hospital stay for hospitalized patients

A total of 12 RCTs reported length of all-cause hospital stay, including 1964 hospitalized patients. Low-quality evidence was found for an MD of −0.48 (95% CI −1.44 to +0.47 days) hospital days per stay. The quality of evidence was downgraded by one level for risk of bias and by another for imprecision. Subgroup differences were found between different lengths of follow-up (P<.01) and different levels of risk of bias (P≤.01), but no clear trends were found. Three studies reported the length of hospital stay as medians and IQRs, and they could therefore not be included in the meta-analysis.

Length of condition-related hospital stay for hospitalized patients

Fifteen RCTs reported length of condition-related hospital stay, including 2047 hospitalized patients. The analysis showed high-quality evidence for an MD of −0.89 hospital days per stay (95% CI −1.42 to −0.36 days).

Subgroup differences were found in reporting outcomes at different lengths of follow-up (P<.01). An MD of −3.95 hospital days per stay (95% CI −6.06 to −1.84 days) was found for reporting between 7 and 12 months, whereas other MDs ranged from −1.00 to −0.42 days. An additional 3 RCTs reported the length of hospital stay as medians and IQRs and 4 did not report SDs nor any information that could be used to calculate them. These 7 RCTs, including 922 participants, were therefore excluded from the meta-analysis.

DISCUSSION

Principal findings

Our review indicates that the risk of all-cause hospitalization decreased significantly by 18 hospitalizations per 1000 patients (−4.8%) and 37 (−15.6%) for condition-related hospitalizations. We found high-quality evidence that, compared with usual care, telehealth leads to reductions in mean all-cause (MD −0.05, 95% CI −0.14 to 0.03 hospitalizations per patient; −5.7% of usual care) and condition-related hospitalizations (MD −0.11, 95% −0.20 to −0.01; −23.4%), that is, 50 to 110 fewer mean hospitalizations, respectively, per 1000 patients. Overall, it is evident that all-cause hospital days decreased significantly with a mean of −1.07 (−17.7%) hospital days per patient and condition-related hospital days with −1.13 (−39.8%) days, although evidence for the latter was only moderate. For hospitalized patients, the mean stay for any cause could potentially be reduced (MD −0.48 days, 95% CI −1.50 to 0.53; 5.7%, low-quality evidence), and mean stay for condition-related hospitalizations even more (MD −0.89 days, 95% CI −1.42 to −0.36; 30.5%, high-quality evidence). The effects were similar for various health conditions and types of telehealth. A trend was observed for studies with longer follow-up periods, yielding larger effects. It should, however, be noted that, although this is a systematic review including a large number of studies, uncertainties around the magnitude of effects remain, and not all differences were statistically significant.

The quality of evidence was high for most of the analyses. Downgrading was only necessary for two analyses because of the risk of bias, risk of publication bias, and imprecision because of a small cumulative sample size. Overall, there were approximately as many articles with some concerns as there were articles at low risk of bias. The main culprits were insufficient reporting of the randomization method, lack of available trial registrations or study protocols, and incomplete outcome data (mostly due to deaths). None of these aspects necessarily indicate issues with the study itself, but rather with the reporting of a study. It is desirable that more information is made available, such as by providing web-based supplementary material.

Comparison with prior work

In our review, the most commonly used telehealth types were device-based monitoring and STS. In general, only small differences in effects were found between telehealth types, which did not appear to be relevant. This finding is in line with a Cochrane review including RCTs investigating the effect of either STS or device-based monitoring in the management of heart failure, which also found no difference [20]. It should be explored whether design aspects, such as monitoring frequency or duration, or patient engagement, could explain the differences in effect. Furthermore, patient compliance is often important

for the success of telehealth interventions. For example, the patients must consistently take and send measurements, be available for telephone contacts or video consultations, or report symptoms. If these actions are not taken by the patient, telehealth interventions cannot function. Therefore, it is important to consider patient preferences during the design process [21,22].

Studies including patients with heart failure or COPD accounted for the majority of the weight in the meta-analyses of this review, although the effects found for other health conditions seemed similar. No other review has combined the results for multiple health conditions. However, reviews of heart failure and COPD specifically are available for comparison. A systematic review including reviews on telehealth for chronic heart failure patients published between 1996 and 2014 found low-quality evidence for absolute risk reductions in patients with an all-cause hospitalization of 4.7% to 13.8% and of 3.7% to 8.2% for patients with a condition-related hospitalization [6]. Our estimate for patients with all-cause hospitalization was considerably lower (2%) and more precise. This is caused by the larger number of studies (75 in our study vs 8 in the other meta-analysis) and thus participants in our analysis (N=30,937 vs N=2343). Our estimate for patients with condition-related hospitalization was similar (3.8%). A recent review on telehealth for heart failure patients also found a trend toward reduced hospitalizations [23]. Another recent review, on coronary heart disease patients, found a relative risk of 0.56 (95% CI 0.39-0.81), although absolute differences were also small [24].

A systematic overview of reviews including COPD patients found 3 reviews investigating the effect of telehealth on hospitalizations, all of which found a reduction in hospitalizations [7]. Another systematic review reported reduced hospitalizations in 8 out of 11 studies, ranging from −10% to −63%. The findings were similar for all-cause hospitalization and condition-related hospitalizations [25]. Our review confirms the reduction in hospitalizations also found in previous reviews and provides a more realistic estimate of the effect through meta-analyses, which was rarely performed in previous reviews.

In a systematic overview of the use of telehealth for various chronic health conditions, reviews on health conditions other than heart failure or COPD also found only a few articles, except for diabetes [8]. This result is consistent with the findings of our review. As COPD and heart failure only make up a small part of the care provided by hospitals [26], more research is necessary on the effect of telehealth on hospital services use in health conditions other than COPD and heart failure, which are also highly prevalent.

The length of follow-up seems to be an important factor influencing the effect of telehealth in our review. We found subgroup differences in length of hospital stay (both all-cause and

condition-related), condition-related hospitalizations, and condition-related hospital days, with larger effect sizes for studies with longer follow-up. A similar trend was observed for all-cause hospital days. One review reported a reduction in mortality at 6 months, with no differences at 1 year [21]. No other reviews assessed differences in effects between the lengths of follow-up.

When telehealth replaces face-to-face contact, it is clear that this can aid in reducing outpatient contacts and supporting social distancing in outpatient departments. In view of the small effects on hospitalizations and moderate effects on hospital inpatient days, it is important to determine whether telehealth actually contributes to cost reduction. Telehealth comes at a cost, for example, because health professionals make phone calls, conduct video consultations, or interpret data. To reduce the costs of interventions, automation of some of these aspects, for example, by developing algorithms to recognize deterioration of patients' health status, should be studied. Although we investigated whether the mechanism by which telehealth is often claimed to reduce costs is indeed present, we did not directly investigate whether costs were reduced. Thorough budget impact and cost-effectiveness studies are needed to reach firm conclusions in this domain.

Limitations

This review has several strengths and limitations. First, the wide scope enabled us to find a large number of articles meeting our inclusion criteria. Furthermore, we quantitatively compared the effects achieved in different health conditions using different types of telehealth and length of follow-up. Another important strength is that we assessed all included articles for risk of bias and graded the strength of evidence for each analysis, providing a comprehensive overview of the evidence on the effect of telehealth on hospital service use.

The wide scope also acts as a double-edged sword in that it makes the participants in the various studies less comparable than in a typical review. This concern is alleviated by the fact that we did not find significant differences between health conditions or types of telehealth, although for some comparisons only a few studies were available. Telehealth interventions often entail many more changes to the health care process, besides the application of technology [27]. The effect of the telehealth type thus becomes entangled with the effects of changes to processes and infrastructure, which requires a more detailed analysis to unravel. Study selection was performed partially in duplicate, which may have caused some articles to have been missed. As we only included peer reviewed articles published in English, it is unknown what evidence exists in other languages. This review is further limited by our scope, which focuses on types of telehealth requiring interaction between patients and health professionals. Passive forms of digital health care, such as

self-management applications or health information provision, were not included. These types of services could reduce hospital service use [28], while potentially being more efficient in terms of resource use because of their passive nature. Furthermore, we did not contact the study authors for details in the case of missing data or methodological unclarities.

Conclusions

Thus, the effects of telehealth are small to moderate and appear to be stronger for condition-related outcomes than for all-cause outcomes. Further research is needed to obtain more insight into the effects of telehealth on other diseases, apart from COPD and heart failure, and into which aspects of telehealth interventions result in positive effects.

Finally, in the context of the COVID-19 crisis, it is important to acknowledge that a great deal of health care can be provided from a distance, eliminating the need for vulnerable individuals to come to a potentially hazardous environment to receive health care and enabling hospitals to continue providing care to all who need it.

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GMP was involved in the study concept and design, data acquisition (abstract and full-text screening, risk of bias assessment, data extraction), analyses and interpretation of the results, and drafting and revising of the manuscript. CJMD was involved in the study concept and design, interpretation of the results, and critically revised the manuscript for important intellectual content. LK and AL were involved in data acquisition and critically revised the manuscript. WHVH was involved in the study concept, obtained funding, and critically revised the manuscript. CJMD and WHVH both supervised the study equally. All authors approved the final version of the manuscript.

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Abbreviations

COPD: chronic obstructive pulmonary disease
GRADE: Grading of Recommendations Assessment, Development and Evaluation
ICT: information and communication technology
IVR: interactive voice response
MD: mean difference
MeSH: Medical Subject Headings
RCT: randomized controlled trial
STS: structured telephone support

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MULTIMEDIA APPENDICES

Multimedia Appendix 1 – Deviation from and clarification of the Cochrane Risk of Bias 2 Tool guidance document

Deviation

Randomization: The algorithm suggested by the Cochrane Risk of Bias 2 guidance document immediately judges randomization to be at high risk of bias if the next allocation could have been known (e.g. due to a systematic allocation method or small block sizes). We, instead, assessed randomization as "Some concerns" if this was the case, but there were no relevant differences in baseline characteristics between groups. We only assessed randomization as high risk of bias if it was clear that none of the components met the criteria proposed in the manual, or important differences in baseline characteristics were observed.

Clarification

Selective outcomes reporting: If no trial registration or study protocol was available to check whether the outcomes of interest for our review were planned for analysis, the default judgement for this outcome was "Some concerns". If a trial registration or study protocol *was* available, it had to be checked whether the outcomes of interest for our review were indeed planned a priori. If that was the case, our judgement was "Low risk". If hospital services use was not mentioned in the trial registration or study protocol, but was reported as a secondary outcome in the article, our judgement was "Some concerns". If these outcomes were not planned according to the trial registration or study protocol, but were reported in the article as primary outcome measure, our judgement was "High risk". If they were planned as a secondary outcome measure, but reported as primary outcome in the article, our judgement was also "High risk".

Multimedia Appendix 2 – Search syntaxes for PubMed, Scopus, and the Cochrane Library (CENTRAL)

PubMed

((((((((((((((((((((((((telehomecare[All Fields] OR "remote consultation"[All Fields]) OR (remote[All Fields] AND ("referral and consultation"[MeSH Terms] OR ("referral"[All Fields] AND "consultation"[All Fields]) OR "referral and consultation"[All Fields] OR "consultation"[All Fields]))) OR ("remote consultation"[MeSH Terms] OR ("remote"[All Fields] AND "consultation"[All Fields]) OR "remote consultation"[All Fields] OR "teleconsultation"[All Fields])) OR "telephone follow-up"[All Fields]) OR "telephone followup"[All Fields]) OR "telephone case management"[All Fields]) OR "telephone case-management"[All Fields]) OR "telerehabilitation"[MeSH Terms]) OR ("telerehabilitation"[MeSH Terms] OR "telerehabilitation"[All Fields])) OR "telemedicine"[MeSH Terms]) OR ("telemedicine"[MeSH Terms] OR "telemedicine"[All Fields])) OR ("telemedicine"[MeSH Terms] OR "telemedicine"[All Fields] OR "ehealth"[All Fields])) OR e-health[All Fields]) OR "videoconferencing"[MeSH Terms]) OR ("videoconferencing"[MeSH Terms] OR "videoconferencing"[All Fields])) OR ("telemedicine"[MeSH Terms] OR "telemedicine"[All Fields] OR "telehealth"[All Fields])) OR telehealthcare[All Fields]) OR "home telemonitoring"[All Fields]) OR telemonitoring[All Fields]) OR ("remote sensing technology"[MeSH Terms] NOT "satellite imagery"[MeSH Terms])) OR "wireless technology"[MeSH Terms]) OR "wearable electronic devices"[MeSH Terms]) OR (((((("health"[MeSH Terms] OR "health"[All Fields]) AND care[All Fields]) OR "health care"[All Fields]) OR care[All Fields]) AND (("internet based"[All Fields] OR "computer based"[All Fields]) OR "phone based"[All Fields]))) AND ((((("patients"[MeSH Terms] OR "patients"[All Fields]) OR "patient"[All Fields]) AND (((rehospitalization[All Fields] OR rehospitalisation[All Fields]) OR re-hospitalization[All Fields]) OR re-hospitalisation[All Fields])) OR ((((("hospitalization"[MeSH Terms] OR "hospitalization"[All Fields]) OR "hospitalisation"[All Fields]) OR ("patient readmission"[MeSH Terms] OR readmission[All Fields])) OR (((("length of stay"[MeSH Terms] OR "length of stay"[All Fields]) OR "stay length"[All Fields]) OR "hospital stay"[All Fields]))))) AND (Randomized Controlled Trial[ptyp] OR ((RCT[All Fields] OR "randomized controlled trial"[All Fields]) OR "randomised controlled trial"[All Fields])) NOT protocol[All Fields]

Scopus

((((TITLE-ABS-KEY (telehomecare)) OR (TITLE-ABS-KEY ("remote consultation")) OR ((TITLE-ABS-KEY (remote) AND TITLE-ABS-KEY (consultation))) OR (TITLE-ABS-KEY (teleconsultation)) OR (TITLE-ABS-KEY ("telephone follow-up")) OR (TITLE-ABS-KEY ("telephone follow up")) OR (TITLE-ABS-KEY (telerehabilitation)) OR (TITLE-ABS-KEY (telemedicine)) OR (TITLE-ABS-KEY (ehealth)) OR (TITLE-ABS-KEY ("e health")) OR (TITLE-ABS-KEY (mhealth)) OR (TITLE-ABS-KEY ("m-health")) OR (TITLE-ABS-

KEY (videoconferencing)) OR (TITLE-ABS-KEY (telehealth)) OR (TITLE-ABS-KEY (telehealthcare)) OR (TITLE-ABS-KEY (“home telemonitoring”)) OR (TITLE-ABS-KEY (telemonitoring))) OR ((((TITLE-ABS-KEY (health) AND TITLE-ABS-KEY (care))) OR (TITLE-ABS-KEY (“health care”)) OR (TITLE-ABS-KEY (care))) AND ((TITLE-ABS-KEY (“internet based”)) OR (TITLE-ABS-KEY (“computer based”)) OR (TITLE-ABS-KEY (“phone based”))))) AND ((TITLE-ABS-KEY (rehospitalization)) OR (TITLE-ABS-KEY (rehospitalisation)) OR (TITLE-ABS-KEY (re-hospitalisation)) OR (TITLE-ABS-KEY (readmission)) OR (TITLE-ABS-KEY (re-admission)) OR (TITLE-ABS-KEY (hospitalization)) OR (TITLE-ABS-KEY (“length of stay”)) OR (TITLE-ABS-KEY (“stay length”)) OR (TITLE-ABS-KEY (“hospital stay”)))) AND ((TITLE-ABS-KEY (rct)) OR (TITLE-ABS-KEY (“randomized controlled trial”)) OR (TITLE-ABS-KEY (“randomised controlled trial”)))

Cochrane Library Trials (CENTRAL)

ID	Search	Hits
#1	(telehomecare):ti,ab,kw (Word variations have been searched)	26
#2	“remote consultation”	385
#3	(remote) AND consultation	646
#4	teleconsultation	591
#5	“telephone follow-up”	1119
#6	“telephone followup”	15
#7	“telephone case management”	13
#8	telerehabilitation	417
#9	MeSH descriptor: [Telerehabilitation] explode all trees	74
#10	telemedicine	3190
#11	MeSH descriptor: [Telemedicine] explode all trees	2044
#12	ehealth	999
#13	e-health	5549
#14	videoconferencing	559
#15	MeSH descriptor: [Videoconferencing] explode all trees	178
#16	telehealth	1143
#17	telehealthcare	29
#18	“home telemonitoring”	148
#19	telemonitoring	854
#20	MeSH descriptor: [Remote Sensing Technology] 1 tree(s) exploded	29
#21	MeSH descriptor: [Wireless Technology] explode all trees	33
#22	MeSH descriptor: [Wearable Electronic Devices] explode all trees	314
#23	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #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	12119

#24	(health) AND care	105320
#25	"health care"	56537
#26	care	226606
#27	#24 OR #25 OR #26	226606
#28	"internet based"	2907
#29	"computer based"	2419
#30	"phone based"	536
#31	#28 OR #29 OR #30	5751
#32	#27 AND #31	2428
#33	#23 OR #32	14026
#34	rehospitalization	1460
#35	rehospitalisation	359
#36	re-hospitalization	523
#37	re-hospitalisation	525
#38	MeSH descriptor: [Patient Readmission] explode all trees	922
#39	MeSH descriptor: [Length of Stay] explode all trees	6694
#40	"length of stay"	18062
#41	"stay length"	315
#42	"hospital stay"	17639
#43	MeSH descriptor: [Hospitalization] explode all trees	12870
#44	hospitalization	35929
#45	re-admission	579
#46	#34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR # 45	164544
#47	#33 AND #46	5633
#48	"RCT"	27981
#49	"randomized controlled trial"	778363
#50	MeSH descriptor: [Randomized Controlled Trial] explode all trees	126
#51	#48 OR #49 OR #50	785408
#52	#47 AND #51	4690

Multimedia Appendix 3 – Characteristics of studies included in the meta-analyses

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Abraham 2011 [1]	CardioMEMS	USA	Hospital, not further specified	Heart failure	Device–based monitoring	Also received usual care
Al–Sutari 2017 [2]	None declared	Jordan	Teaching hospital	Heart failure	Structured telephone support	n.a.
Amara 2017 [3]	Biotronik SE & Co.	France	Hospital, multicentre	Supraventricular arrhythmia	Device–based monitoring	Ambulatory visits at 1–3 months and 12 months.
Angermann 2012 [4]	University of Wuerzburg.	Germany	Hospital, multicentre	Heart failure	Structured telephone support	Treatment plans, comprehensive discharge letters, appointment with GP or cardiologist within 7–14 days.
Antoniades 2012 [5]	Austin Hospital	Australia	Metropolitan Hospital	COPD	Device–based monitoring	Adherence to established guidelines, assessment by trained respiratory nurse, COPD education, social work, occupational therapy, close post–discharge follow–up with access to outreach nursing, assistance in developing self–management plan.
Arendts 2018 [6]	[5]State Health Research Advisory Council of Western Australia	Australia	Hospital	n.a.	Structured telephone support	n.a.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Basch 2016 [7]	National Cancer Institute, Memorial Sloan Kettering Cancer Center	USA	Hospital	Cancer	Web–based monitoring	n.a.
Bekelman 2015 [8]	Veterans Affairs	USA	Hospital	Heart failure	Interactive voice response	Information sheets outlining self–care, and care at discretion of regular VA provider, potentially including cardiology specialty care, CHF education, etc.
Bell 2015 [9]	Vanderbilt University Medical Center; National Heart, Lung, and Blood Institute (NHLBI)	USA	Academic hospital	Heart failure	Structured telephone support	n.a.
Biese 2018 [10]	Duke Endowment; the Kenan Family Foundation; Mr. John A. McNeill, Jr.	USA	Hospital	n.a.	Structured telephone support	n.a.
Bohingamu Mudiyanselage 2018 [11]	Victorian Government; Barwon Health	Australia	Community	Mixed	Device–based monitoring	n.a.
Böhm 2016 [12]	Medtronic PLC	Germany	Hospital	Heart failure	Device–based monitoring	n.a.
Bonetti 2018 [13]	Universidade Federal do ParanÃ¡	Brazil	Hospital	Cardiovascular disease	Structured telephone support	No post–discharge care.
Boriani 2013 [14]	Medtronic Bakken Research Center	Italy	Hospital	Heart failure	Device–based monitoring	In–office visits at baseline and 8 months.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Boriani 2017 [15]	Medtronic	Multinational	Hospital	Heart failure	Device–based monitoring	n.a.
Bourbeau 2003 [16]	Boehringer Ingelheim Canada; Fonds de la Recherche en SantÃ© du QuÃ©bec.	Canada	Hospital	COPD	Structured telephone support	n.a.
Bowles 2009 [17]	Centers for Disease Control and Prevention	USA	Community	Heart failure or diabetes	Structured telephone support	Home nursing according to evidence–based disease–management protocol.
Bowles 2009b [17]	Centers for Disease Control and Prevention	USA	Community	Heart failure or diabetes	Device–based monitoring	Home nursing according to evidence–based disease–management protocol.
Bowles 2011 [18]	National Institute of Nursing Research	USA	Community	Heart failure	Device–based monitoring	Home visits.
Boyne 2012 [19]	The Province of Limburg in The Netherlands; the Annadal Foundation Maastricht; Astra Zeneca [an unrestricted grant]; the Rescar Foundation Maastricht	The Netherlands	Hospital	Heart failure	Interactive voice response	Two fewer follow–up visits than the usual care group.
Braun 2009 [20]	Not reported	Israel	Hospital	Miscellaneous	Structured telephone support	Patients receive a \Discharge Report\" including patient history

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Chau 2012 [21]	Not reported.	Hong Kong	Hospital	COPD	Device–based monitoring	Home visits from the community nurse educating patients on use of medication, purse–lip breathing, lifestyle modification, and exercise
Chaudhry 2010 [22]	National Heart Blood and Lung Institute	USA	Hospital	Heart failure	Interactive voice response	n.a.
Chen 2011 [23]	Chang Gung Memorial Hospital	Taiwan	Hospital	Chronic Kidney Disease	Structured telephone support	n.a.
Chen 2019 [24]	Not reported	China	Hospital	Heart failure	Structured telephone support	Single educational session before discharge.
Chiantera 2005 [25]	Not reported	Italy	Hospital	Acute coronary syndrome	Device–based monitoring	n.a.
Cleland 2005 [26]	Not reported.	United Kingdom	Hospital	Heart failure	Device–based monitoring	n.a.
Comin–Colet 2016 [27]	Telefonica Soluciones S.A; IMIM.	Spain	Hospital	Heart failure	Device–based monitoring	n.a.
Dansky 2008 [28]	Robert Wood Johnson Foundation	USA	NA	Heart failure	Device–based monitoring	Routine home visits.
Dar 2009 [29]	Honeywell HomMed	UK	Hospital	Heart failure	Device–based monitoring	Initial home visit by study nurse. Regular clinic review, including life–style advice and medication optimalization.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Datta 2010 [30]	US Department of Veterans Affairs	USA	Primary care	Mixed	Structured telephone support	Phone contacts at 6 and 24 months to collect secondary outcome data.
De Jong 2017 [31]	Maastricht University Medical Centre	The Netherlands	Hospital	IBD	Web–based monitoring	At least one scheduled outpatient visit per year.
Dendale 2012 [32]	The Belgian Government Health Insurance Institute	Belgium	Primary care	Heart failure	Device–based monitoring	Standard one hour education course. Outpatient follow up after 2 weeks. Planned in–patient clinic follow–up at 3 and 6 months.
De San Miguel 2013 [33]	Australian Department of Health and Aging	Australia	Community	COPD	Device–based monitoring	COPD book.
De Vito Dabbs 2016 [34]	National Institute of Nursing Research	USA	Academic Hospital	Lung transplant	Mobile telemonitoring	Scripted discharge instructions of 60 minutes, and an instruction binder.
DeWalt 2006 [35]	Pfizer Health Literacy Initiative; the Robert Wood Johnson Clinical Scholars Program; the University of North Carolina Program on Health Outcomes; the National Institute of Nursing Research, NIH	USA	Hospital	Heart failure	Structured telephone support	Heart failure education pamphlet written at 7th grade level and usual care from primary physician.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Dhalla 2014 [36]	Canadian Institutes of Health Research; the Ontario Ministry of Health and Long–Term Care; the Green Shield Canada Foundation; the University of Toronto Department of Medicine; the Academic Funding Plan Innovation Fund.	Canada	Hospital	Miscellaneous	Structured telephone support	n.a.
Dinesen 2012 [37]	Bureau of Business and Construction	Denmark	Hospital	COPD	Device–based monitoring	Home exercises and contacting GP or emergency doctor when needed.
Domingues 2011 [38]	FundaÃ§Ã£o Instituto de Pesquisas EconÃ´micas; Conselho Nacional de Desenvolvimento CientÃ-fico e TecnolÃ³gico.	Brazil	Hospital	Heart failure	Structured telephone support	n.a.
Dougherty 2005 [39]	National Institutes of Health, National Institute for Nursing Research	USA	Hospital	Sudden cardiac arrest	Structured telephone support	Standardized hospital–based education (booklets and videos developed by the ICD manufacturer) and outpatient clinic visits.
Dudas 2002 [40]	University of California, San Francisco, Department of Medicine RESPECT grant program.	USA	Hospital	Mixed	Structured telephone support	n.a.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Ferrante 2010 [41]	Not explicitly reported; GESICA Foundation implied	Argentina	Hospital	Heart failure	Structured telephone support	n.a.
Finlayson 2018 [42]	Australian Research Council Discovery Project Grants Scheme	Australia	Hospital	Miscellaneous	Structured telephone support	Routine discharge planning, rehabilitation advice, and potentially community nursing.
Fors 2018 [43]	Centre for Person–Centred Care, University of Gothenburg	Sweden	Academic hospital	Mixed	Structured telephone support	According to guidelines
Gallagher 2017 [44]	Columbia University	USA	Academic hospital	Heart failure	Device–based monitoring	Medication
Garbutt 2010 [45]	Agency for Healthcare Research and Quality	USA	Community	Asthma	Structured telephone support	Care according to guideline recommendations.
Gattis 1999 [46]	Not reported	USA	Academic hospital	Heart failure	Structured telephone support	The pharmacist explained the purpose of each drug and the importance of adherence.
Gellis 2014 [47]	New York State Department of Health	USA	Community	Heart failure or COPD	Device–based monitoring	n.a.
GESICA 2005 [48]	GESICA Foundation; Roche; Boehringer Ingelheim; BagÃ³; Pharmacia; Novartis; Merck Sharp; Dohme	Argentina	Mixed	Heart failure	Structured telephone support	Three–monthly in–clinic follow–up.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Giordano 2009 [49]	Italian Ministry of Health	Italy	Hospital	Heart failure	Structured telephone support	Pre–discharge education.
Goodwin 2014 [50]	Novartis Pharmaceuticals	Canada; USA	Hospital	Breast cancer	Structured telephone support	n.a.
Gray 2000 [51]	National Library of Medicine's Telemedicine Initiative	USA	Hospital, NICU	Low birth weight	Web–based monitoring	n.a.
Hale 2016 [52]	Presentcare Inc	USA	Hospital	Heart failure	Device–based monitoring	n.a.
Halimi 2008 [53]	Biotronik Inc	France	Hospital	Heart failure	Device–based monitoring	n.a.
Hannan 2013 [54]	Not reported	USA	Unclear	n.a.	Structured telephone support	n.a.
Hansen 2018 [55]	Abbott (formerly St Jude Medical)	Germany	Hospital	Heart failure	Structured telephone support	n.a.
Hanssen 2009 [56]	Haukeland University Hospital; the Norwegian Nurse Association; the Meltzer Foundation for grants; the Norwegian Lung and Heart Foundation.	Norway	Academic hospital	Myocardial infarction	Structured telephone support	n.a.
Harrison 2011 [57]	Surgical Outcomes Research Centre	Australia	Hospital	Colorectal cancer	Structured telephone support	n.a.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Härter 2016a [58]	Kaufmännische Krankenkasse Hannover	Germany	Unclear	Various chronic conditions; heart failure; depression or schizophrenia	Structured telephone support	Not reported
Härter 2016b [58]	Kaufmännische Krankenkasse Hannover	Germany	Unclear	Heart failure	Structured telephone support	Not reported
Härter 2016c [58]	Kaufmännische Krankenkasse Hannover	Germany	Unclear	Depression or schizophrenia	Structured telephone support	Not reported
Hebert 2008 [59, 60]	AHRQ	USA	Hospital	Heart failure	Structured telephone support	n.a.
Hindricks 2014 [61]	Biotronik SE & Co	Germany	Hospital	Heart failure	Device–based monitoring	n.a.
Ho 2016 [62]	National Taiwan University (NT–CESRP–101R7608–3)	Taiwan	University hospital	COPD	Web–based monitoring	n.a.
Imhof 2012 [63]	Age Foundation Zurich, Ebnet Foundation Teufen, Heinrich und Erna Walder Foundation Zurich, City of Winterthur	Switzerland	Community	n.a.	Structured telephone support	n.a.
Ishani 2016 [64]	VA Center for Innovation	USA	Hospital	Chronic kidney disease	Device–based monitoring	n.a.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Jakobsen 2015 [65]	The Philanthropic Foundation TrygFonden (grant 7561–08), The Health Insurance Foundation (grant 2011B003), The Danish Lung Association, The Toyota Foundation (grant OH/BG 7003), The Frederiksberg Foundation (grant 2010–88), and a Lykfeldtâ€™s grant.	Denmark	University hospital	COPD	Videoconferencing	n.a.
Javadpour 2013 [66]	Shiraz University of Medical Science	Iran	Hospital	Bipolar disorder	Structured telephone support	Pharmacotherapy (and eight psychoeducation sessions)
Jerant 2001 [67]	UCD School of Medicine Hibbard E. Williams research grant	USA	Unclear	Heart failure	Structured telephone support	Two in–person visits, and provision of emergency contact numbers.
Jódar–Sánchez 2014 [68]	The Spanish Ministry of Science and Innovation.	Spain	Community	COPD	Device–based monitoring	n.a.
Kalter–Leibovici 2017 [69]	Maccabi Institute for Health Services Research; The Medical Research Infrastructure Development and Health Services Fund by the Sheba Medical Center	Israel	Hospital	Heart failure	Device–based monitoring	Bi–annual in–clinic follow–up visits

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Kessler 2018 [70]	Air Liquide Healthcare	Multinational	Community	COPD	Mobile telemonitoring	n.a.
Ko 2017 [71]	Chinese University of Hong Kong	Hong Kong	Hospital	COPD	Structured telephone support	Two in–person 1–hour educational sessions
Koehler 2011 [72]	Greman Federal Ministry of Economics and Technology; Robert Bosch Healthcare; InterComponentWare; Aipermon	Germany	Hospital	Heart failure	Device–based monitoring	Care according to guidelines
Kraai 2016 [73]	Dutch Ministry of Health, Department of Pharmaceutical Affairs and Medical Technology.	The Netherlands.	Hospital	Heart failure	Device–based monitoring	Computer Decision Support System providing guideline–based treatment recommendations.
Krum 2013 [74]	National Health and Medical Research Council; National Heart Foundation of Australia; Medical Benefits Fund	Australia	Community	Heart failure	Interactive voice response	Care according to guidelines, and an individualized patient diary.
Kulshreshtha 2010 [75]	Partners Healthcare	USA	Hospital	Heart failure	Device–based monitoring	n.a.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Laramee 2003 [76]	University of Vermont General Clinical Research Center; Novartis Pharmaceuticals	Canada	Hospital	Heart failure	Structured telephone support	Standard in–patient care plus case manager, 15–page CHF booklet, weight logs, self–care activities summary sheets, computerized medication lists, a guide for measuring sodium intake, as well as scales and pillboxes as needed.
Lavesen 2016 [77]	Capital Region of Denmark	Denmark	Hospital	COPD	Structured telephone support	Appointment in the outpatient clinic 3 months post discharge. A discharge summary was sent to the GP.
Lindegaard Pedersen 2017 [78]	Aarhus University Hospital	Denmark	Hospital	Malnourishment	Structured telephone support	Standard in–hospital care. Discharge arrangements with home care provider, including meal service, food delivery, and home care.
Luthje 2015 [79]	Medtronic Inc.	Germany	Hospital	Heart failure	Device–based monitoring	n.a.
Lyng 2012 [80]	The Swedish Governmental Agency for Innovation Systems; the Swedish Heart and Lung foundation	Sweden	Hospital	Heart failure	Device–based monitoring	n.a.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Mabo 2012 [81]	Biotronik SE and Co. KG	France	Hospital	Heart failure	Device–based monitoring	No in–clinic follow–ups unless indicated by a level 1 or 2 alarm.
Martin–Lesende 2013 [82]	Spanish Ministry of Health, Social Services and Equality	Spain	Hospital	Heart failure and / or chronic lung disease	Mobile telemonitoring	Regular medical examinations and on–demand telephone contacts or home visits.
Mayo 2008 [83]	Canadian Institute of Health Research	Canada	Hospital	Stroke	Structured telephone support	n.a.
Milsis 2012 [84]	EU / e–TEN project \ Healthwear\""	Greece	Hospital	COPD	Device–based monitoring	n.a.
Morgan 2017 [85]	British Heart Foundation; Boston Scientific Ltd; Medtronic Ltd; St Jude Medical	UK	Hospital	Heart failure	Device–based monitoring	Alerts for device malfunction.
Olivari 2018 [86]	European Commission	Italy	Hospital	Heart failure	Device–based monitoring	n.a.
Ong 2016 [87]	AHRQ	USA	Academic hospital	Heart failure	Device–based monitoring	n.a.
Osmera 2014 [88]	Faculty of Health and Social Studies, University of South Bohemia	Czech Republic	Hospital	Heart failure	Device–based monitoring	Yearly outpatient visits.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Paquette 2013 [89]	Quebec Interuniversity Nursing Intervention Research Group; Quebec MinistÃ¨re de l'Ã‰ducation, du Loisir et du Sport; University of Montreal; The Gustav Levinschi Foundation of the CHU Sainte–Justine; The Canadian Nurses Foundation; The Faculty of Nursing, University of Montreal	Canada	Academic Hospital	Tonsillitis	Structured telephone support	n.a.
Pekmezaris 2012 [90]	New York State Department of Health	USA	Community	Heart failure	Videoconferencing	Face–to–face nurse visits at the nurse's discretion.
Pekmezaris 2018 [91]	Patient–Centered Outcomes Research Institute	USA	Hospital	Heart failure	Device–based monitoring	Routine visits every three months
Phillips 2001 [92]	Not reported	USA	Hospital	Spinal cord injury	Videoconferencing	Scheduled post–discharge visit at 2 months.
Pinnock 2013 [93]	Chief Scientist Office, NHS Applied Research Programme Grant	Scotland	Hospital	COPD	Device–based monitoring	Self–management booklet, written management plan, emergency medication supply.
Riegel 2002 [94]	Pfizer Inc.	USA	Unclear	Heart failure	Structured telephone support	n.a.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Riegel 2006 [95]	American Heart Association	USA	Hospital	Heart failure	Structured telephone support	Written discharge instructions. Verbal if Spanish speaking personnel was available.
Ringbaek 2015 [96]	Not reported	Denmark	Hospital	COPD	Device–based monitoring	All patients were managed according to national and international guidelines.
Rollman 2009 [97]	NIH	USA	Hospital	Depression	Structured telephone support	At the discretion of patients' PCP.
Sardu 2016 [98]	NIH	Italy	Hospital	Heart failure	Device–based monitoring	Follow–up with the treating physician at 10 days after hospital discharge, and at 1, 3, 6, and 12 months.
Scherr 2009 [99]	Novartis Pharma Austria; Roche Pharma Austria; Mobilkom Austria	Austria	Hospital	Heart failure	Device–based monitoring	Pharmacological intervention.
Schwarz 2008 [100]	National Institute of Nursing Research; NIH; Ohio Board of Regents	USA	Hospital	Heart failure	Device–based monitoring	n.a.
Seto 2012 [101]	Toronto General Hospital Foundation; Natural Sciences and Engineering Research Council of Canada Strategic Research Network	Canada	Hospital	Heart failure	Device–based monitoring	Clinic visits every 2 weeks to every 3 to 6 months depending on disease severity.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Shany 2017 [102]	The Department of State and Regional Development of New South Wales Government; the Australian Research Council; the Sydney West Area Health Service; University of New South Wales.	Australia	Community	COPD	Device–based monitoring	Weekly scheduled home visits by a respiratory nurse.
Smolis–Bąk 2015 [103]	Not reported	Poland	Hospital	Heart failure	Device–based monitoring	Patients trained in the rehabilitation unit for an average of 3 weeks.
Soran 2008 [104]	Centers for Medicare & Medicaid Services Baltimore	USA	Hospital	Heart failure	Device–based monitoring	One–on–one educational session and heart failure booklet.
Soriano 2018 [105]	FundaciÃ³n TeÃ³filo Hernando, Universidad AutÃ³noma de Madrid; Linde Healthcare.	Spain	Hospital	COPD	Device–based monitoring	n.a.
Sorknaes 2013 [106]	European Commission; Danish Health Foundation; Danish Nurses' Organization; University of Southern Denmark; OUH–Odense University Hospital; Svendborg Hospital.	Denmark	Hospital, multicentre	COPD	Videoconferencing	NA

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Spaniel 2015 [107]	Ministry of Health	Czech Republic	NA	Schizophrenia or schizoaffective disorder	Device–based monitoring	n.a.
Steventon 2012 [108]	Department of Health	England	Community	COPD, heart failure, or diabetes	Device–based monitoring	n.a.
Takahashi 2012 [109]	Mayo Foundation Institutional Funds; National Center for Research Resources, NIH; NIH Roadmap for Medical Research	USA	Hospital	Miscellaneous	Device–based monitoring	Access to primary and specialty office visits, phone nursing, urgent clinic visits, and ER visits.
Tomita 2009 [110]	National Institute on Aging	USA	Unclear	Heart failure	Web–based monitoring	Three–month regular check up.
Tsuchihashi–Makaya 2013 [111]	Japanese Ministry of Health, Labour and Welfare; the Japan Heart Foundation; Pfizer Health Research Foundation	Japan	Hospital	Heart failure	Structured telephone support	Medical treatment, routine cardiologist follow–up, and biweekly home visits until 2 months post–discharge.
Van Den Berg 2016 [112]	Hospital Trust Funds; NHMRC Partnership Grant Cognitive Impairment and Physical Conditions	Australia	Hospital	Stroke	Videoconferencing	n.a.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Vasilopoulou 2017 [113]	General Secretariat for Research and Technology; National Strategic Reference Framework, European Union.	Greece	Hospital	COPD	Device–based monitoring	n.a.
Venter 2012 [114]	Lakes District Health Board, Lake Taupo Primary Health Organisation; Healthcare of New Zealand	New Zealand	Primary care	Mixed	Device–based monitoring	Regular home visits, and systematic assessment and care planning.
Vesterby 2017 [115]	CareTech Innovation, European Regional Development Fund; Fund for Clinical Research, Central Denmark Region; Animation Hub, Danish Ministry of Science, Innovation and Higher Education	Denmark	Hospital	Hip replacement	Videoconferencing	n.a.
Vianello 2016 [116]	European Commission	Italy	Unclear	COPD	Device–based monitoring	Medical treatment according to guidelines. No other structural care.
Vuorinen 2014 [117]	The Finnish Funding Agency for Technology and Innovation; VTT Technical Research Centre of Finland	Finland	Hospital	Heart failure	Device–based monitoring	Support for self–management by a team of 2 physicians, a specialized heart failure nurse, and a physiotherapist.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Wade 2011 [118]	Aetna Inc; Intel Inc	USA	Community	Heart failure	Device–based monitoring	Case management facilitating healthcare processes.
Wagenaar 2019 [119]	Foundation 'Care Within Reach'	The Netherlands	Hospital	Heart failure	Device–based monitoring	n.a.
Wakefield 2008 [120]	Department of Veterans Affairs, Veterans Health Administration, Health Services Researech and Development	USA	Hospital	Heart failure	Videoconferencing	In–clinic follow–ups.
Waldmann 2008 [121]	AOK Schleswig–Holstein; Card Guard Europe; Segeberger Kliniken	Germany	Hospital	Coronary artery disease	Device–based monitoring	n.a.
Walker 2018 [122]	European Commission	UK, Estonia, Sweden, Spain, Slovenia	Hospital	COPD	Device–based monitoring	n.a.
Weintraub 2010 [123]	GlaxoSmithKline Inc; Philips Medical Systems Inc; Health Hero Network Inc	USA	Hospital	Heart failure	Device–based monitoring	n.a.
Wong 2005 [124]	Not reported	China	Hospital	COPD	Structured telephone support	n.a.

Author, year	Sponsorship source	Country	Setting	Health condition	Telehealth type	Usual care
Xu 2010 [125]	Asthma Foundations of Australia; Royal Children's Hospital Foundation Brisbane Australia.	Australia	Hospital	Asthma	Structured telephone support	GP or hospital outpatient care.
Young 2013 [126]	Cancer Institute New South Wales Health Services Research Program	Australia	Hospital	Colorectal cancer	Structured telephone support	n.a.
Zhao 2009 [127]	Hong Kong Polytechnic University	China	Community	Coronary heart disease	Structured telephone support	Two home visits (one in week 1, one in week 3).

MULTIMEDIA APPENDIX 4 – GRADE PROTOCOL

Risk of bias

Rate down one level if:

There are studies with a high risk of bias for any one domain that cumulatively account for a weight of 60% in an analysis. For example, if 4 studies in one analysis are all rated at high risk of bias for incomplete outcome data, and each of those studies received a weight of 15% in the meta-analysis, the quality of evidence would be rated down by one level.

OR

There are studies with an unclear risk of bias for any three domains, which cumulatively account for a weight of 60% in an analysis.

Rate down two levels if:

There are studies with a high risk of bias for any two domains that cumulatively account for a weight of 60% in an analysis. For example, if 4 studies in one analysis are all rated at high risk of bias for incomplete outcome data, and each of those studies received a weight of 15% in the meta-analysis, the quality of evidence would be rated down by one level.

OR

There are studies that have a high risk of bias for any one domain, AND an unclear risk of bias for any three domains, cumulatively accounting for a weight of 60% in an analysis.

Inconsistency

Rate down by one level if:

Unexplained heterogeneity is at least equal to 60% for 3 of the 4 methods of stratification (by health condition, telehealth type, follow-up, and risk of bias). Unexplained heterogeneity is computed as

$$\textit{Unexplained heterogeneity} = I^2 * \textit{Residual heterogeneity}$$

Imprecision

Rate down by one level if:

Fewer than 2000 participants are included in the analysis AND the confidence interval of the point estimate overlaps no effect.

Rate down by two levels if:

There are very few events, and confidence intervals of both relative and absolute effects fail to exclude a null effect.

Publication bias

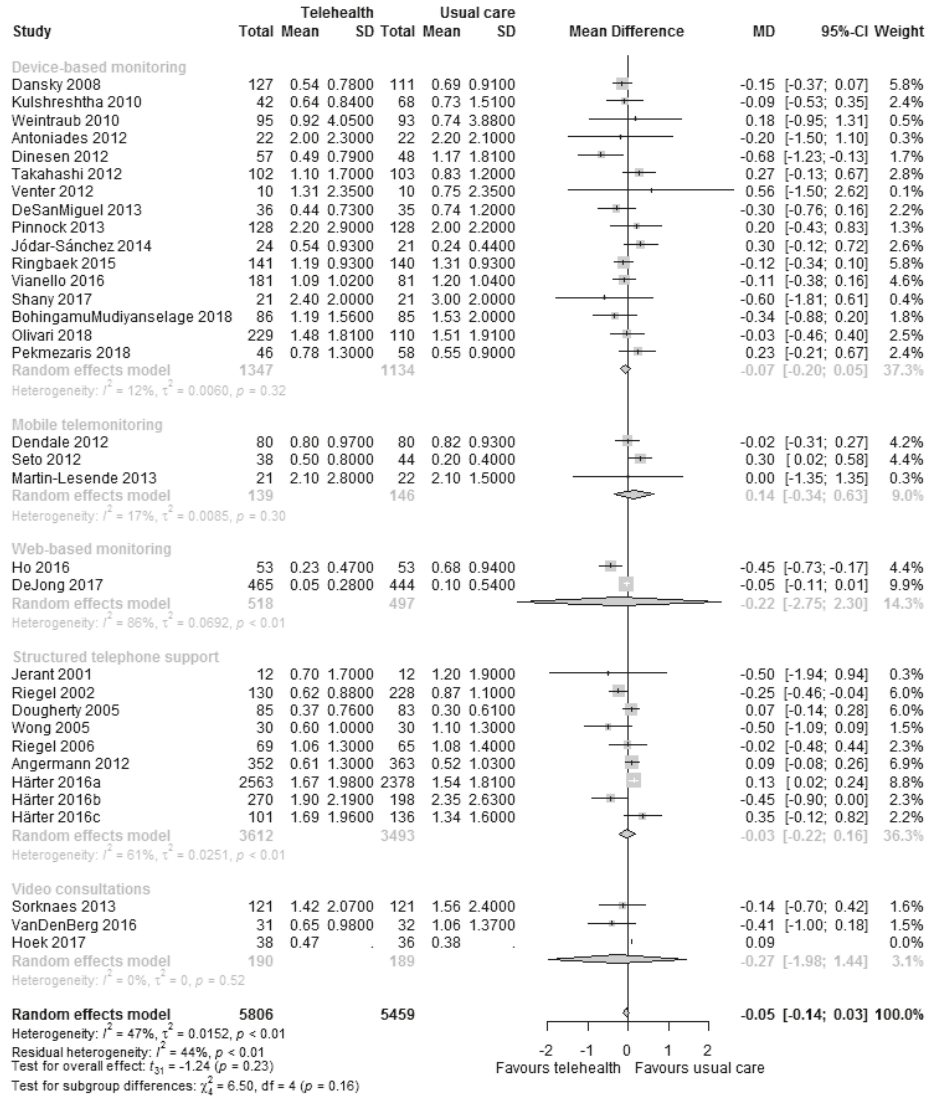
Rate down by at most one level if:

Funnel plot asymmetry found by visual inspection suggests publication bias or there are much fewer small studies than large studies.

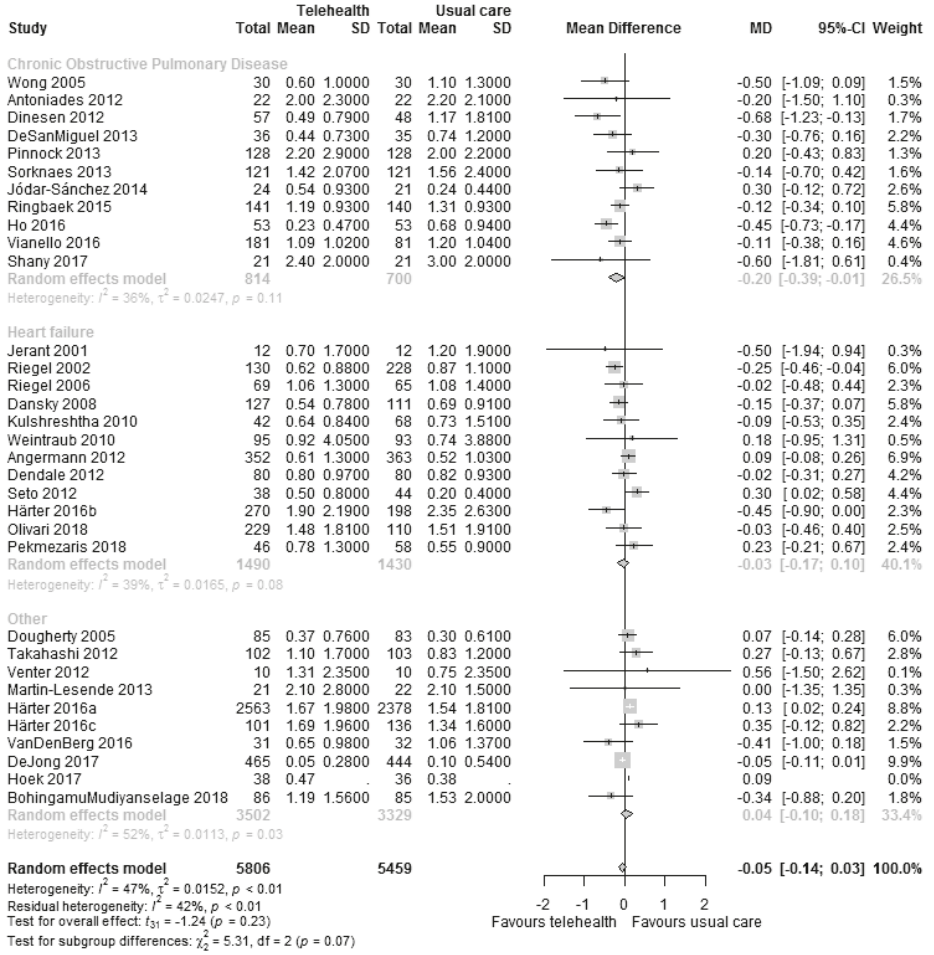
Multimedia Appendix 5 – GRADE assessments including inconsistency, risk of bias, imprecision, and publication bias

All-cause hospitalizations

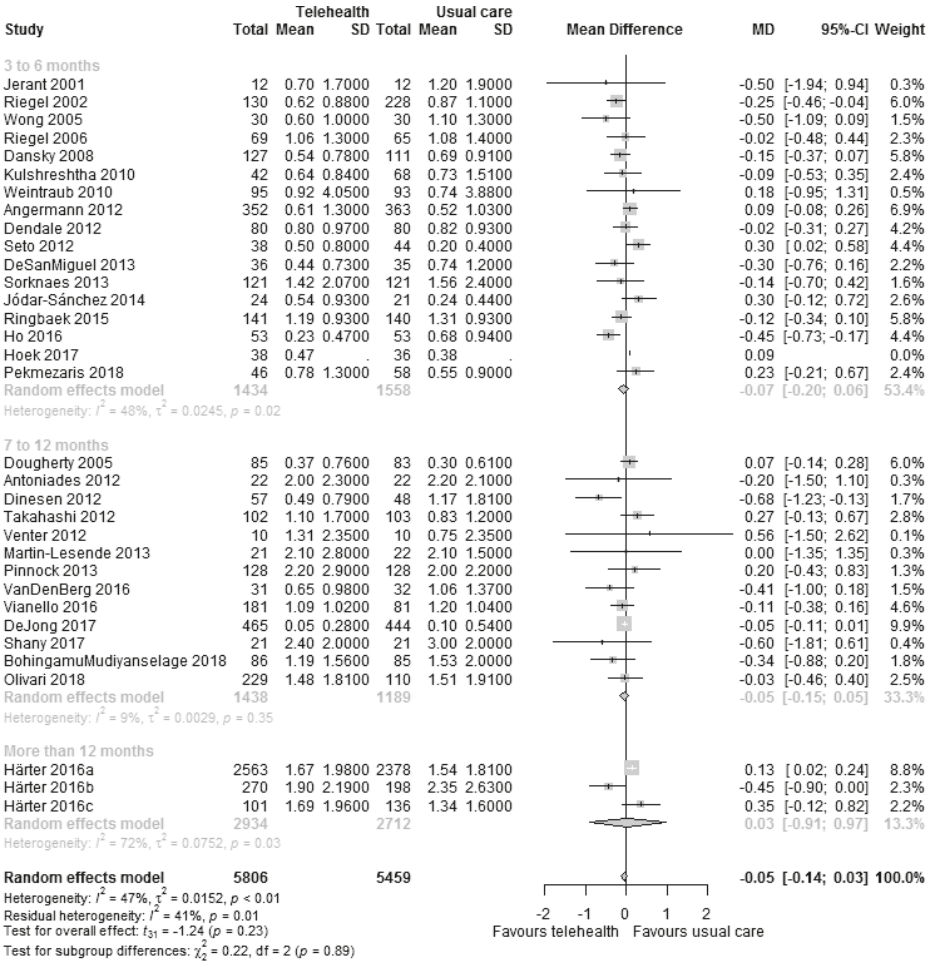
Inconsistency



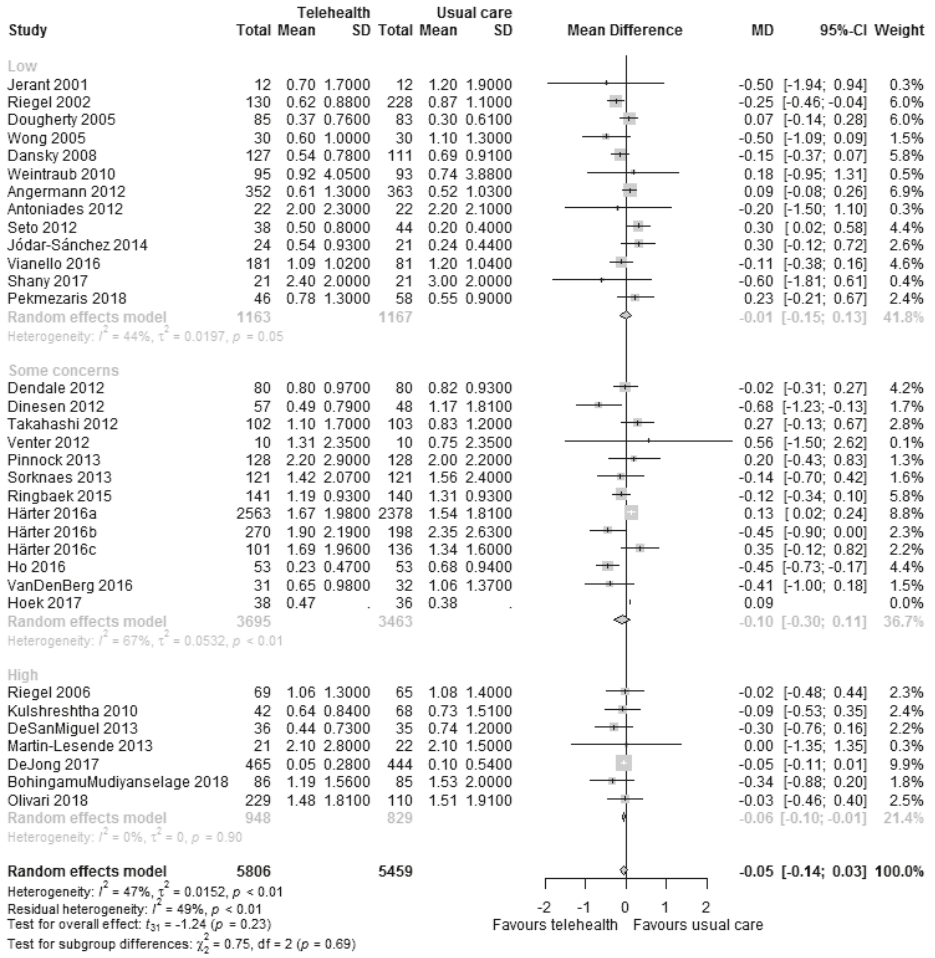
Multimedia Appendix 5. Figure 1. Forest plot of all-cause hospitalizations for telehealth compared to usual care, stratified by telehealth type



Multimedia Appendix 5. Figure 2. Forest plot of all-cause hospitalizations for telehealth compared to usual care, stratified by health condition



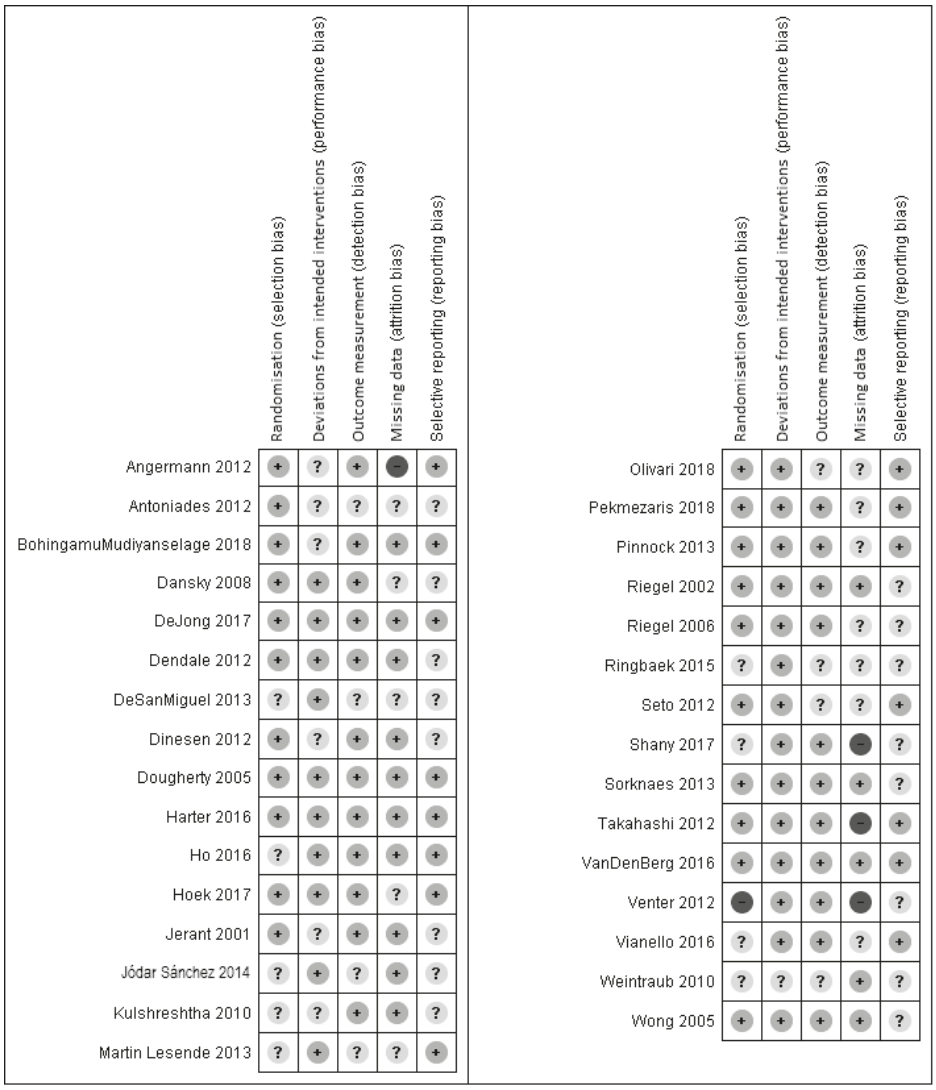
Multimedia Appendix 5. Figure 3. Forest plot of all-cause hospitalizations for telehealth compared to usual care, stratified by length of follow-up



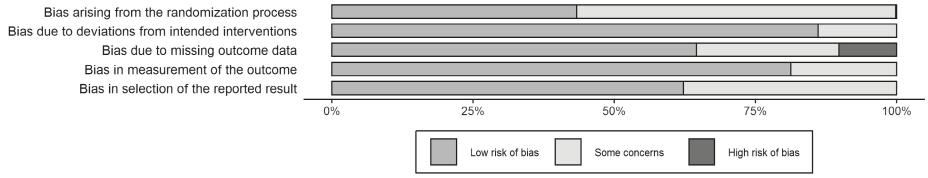
Multimedia Appendix 5. Figure 4. Forest plot of all-cause hospitalizations for telehealth compared to usual care, stratified by risk of bias

Unexplained heterogeneity is below 15% for each analysis. Additionally, the majority of confidence intervals overlaps, and although point estimates do vary, do not consider it enough to downgrade quality of evidence.

Risk of bias



Multimedia Appendix 5. Figure 5. Risk of bias for each domain per study reporting all-cause hospitalizations



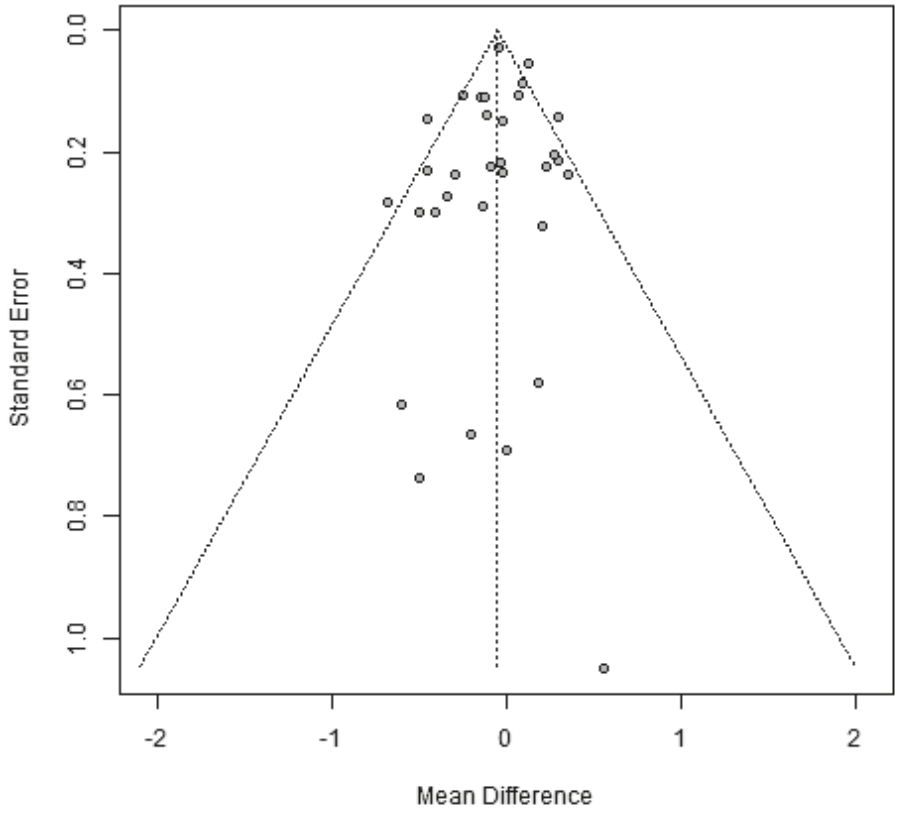
Multimedia Appendix 5. Figure 6. Cumulative weighted risk of bias for each domain for all-cause hospitalizations

The majority of studies has a low risk of bias, so the quality of evidence is not downgraded.

Imprecision

Although the confidence interval of the summary estimate does overlap a null effect, the analysis included well over 2000 participants. Therefore we did not downgrade quality of evidence for imprecision.

Publication bias



Multimedia Appendix 5. Figure 7. Funnel plot for all-cause hospitalizations

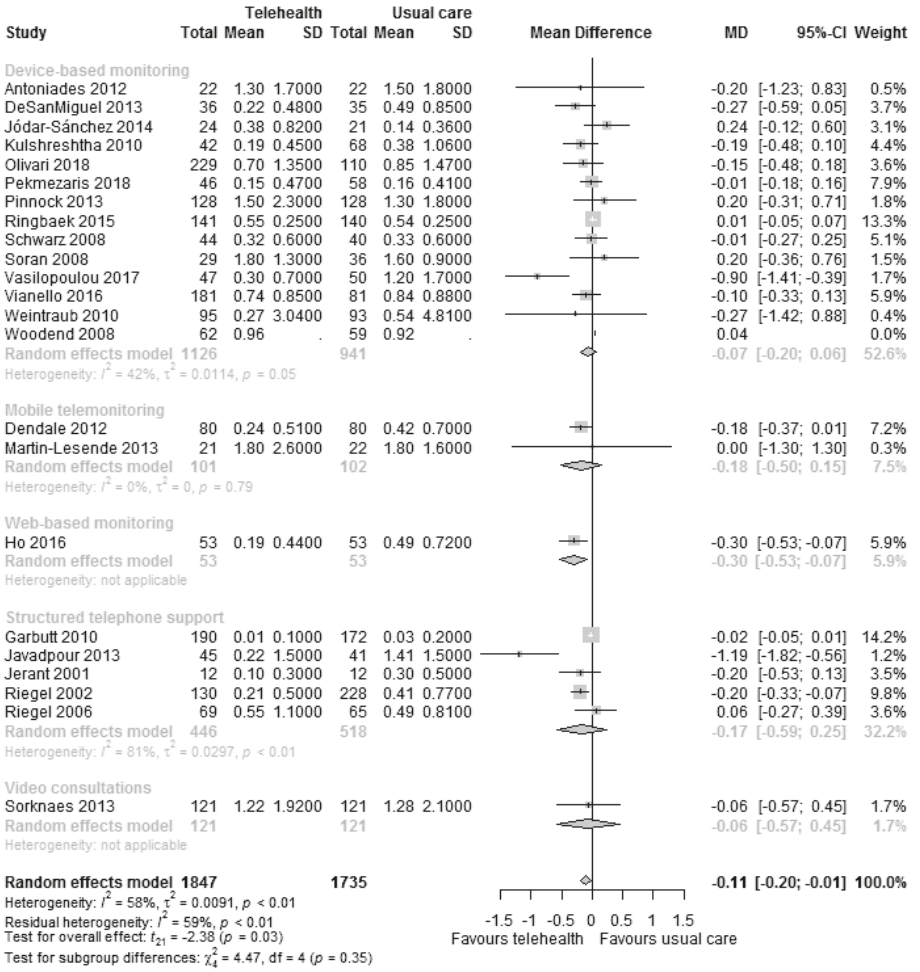
The funnel plot appears to be quite symmetrical, so downgrading for publication bias is not necessary.

Summary: Unexplained heterogeneity is well below the threshold value of 60%, the majority of studies has a low risk of bias, and risk for publication bias appears low. The confidence interval of the summary estimate overlaps a null effect (-0.14 to 0.03), however we did not downgrade the quality of evidence because of the high number of participants included in the analysis.

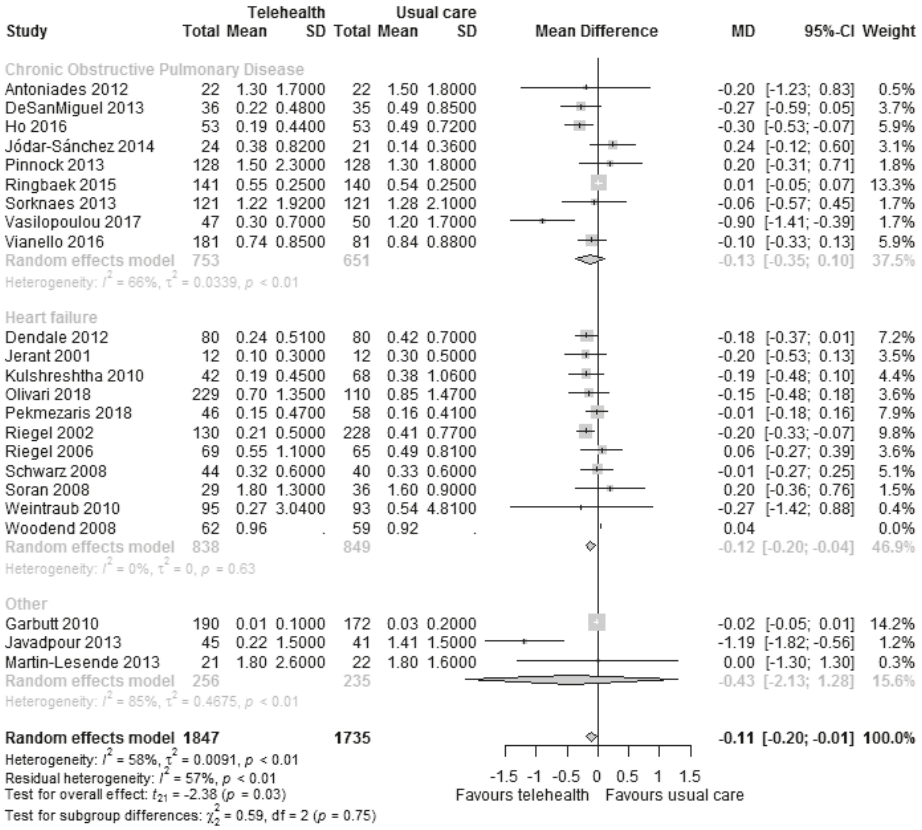
Overall judgement: High quality of evidence

Condition-related hospitalizations

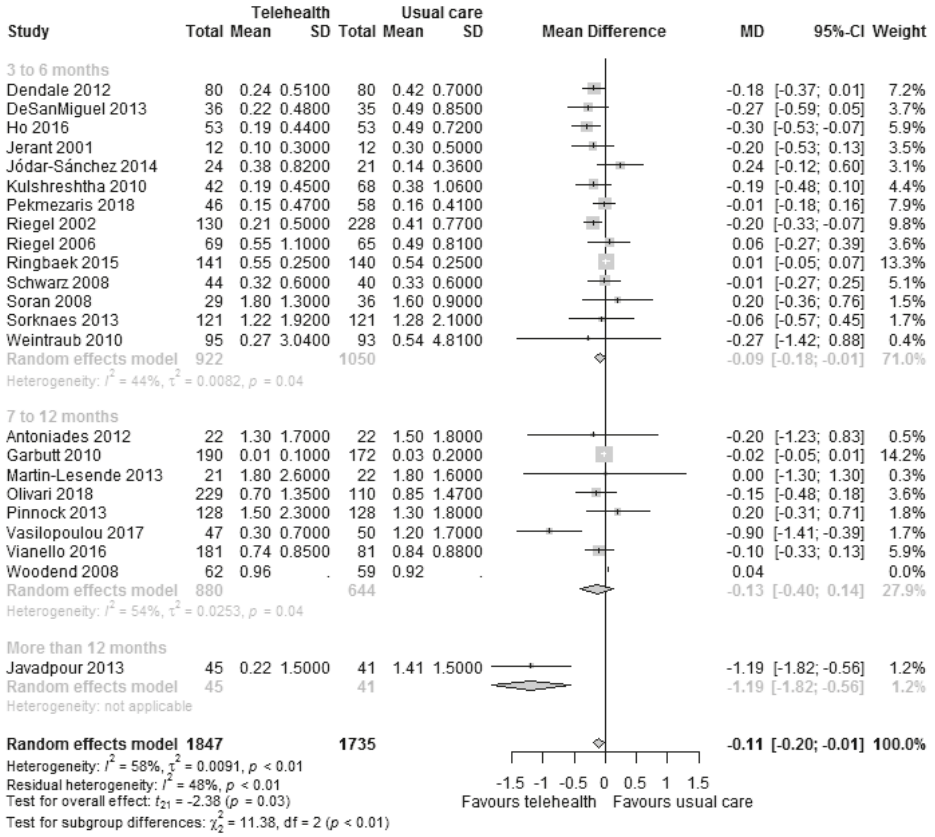
Inconsistency



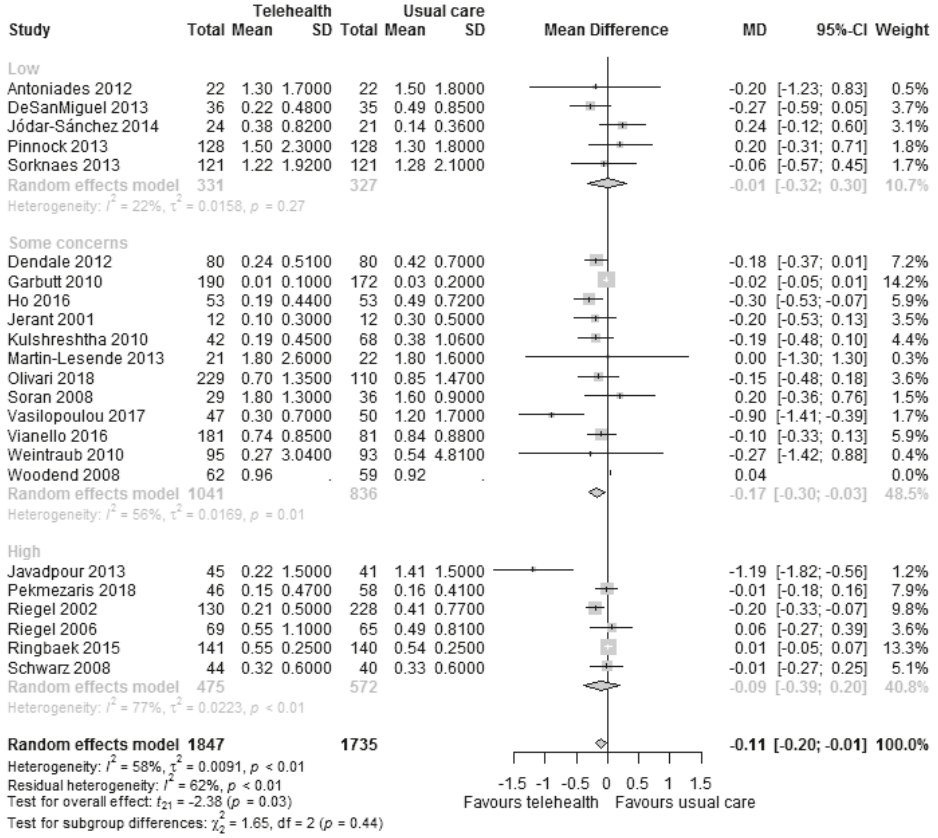
Multimedia Appendix 5. Figure 8. Forest plot of condition-related hospitalizations for telehealth compared to usual care, stratified by telehealth type



Multimedia Appendix 5. Figure 9. Forest plot of condition-related hospitalizations for telehealth compared to usual care, stratified by health condition



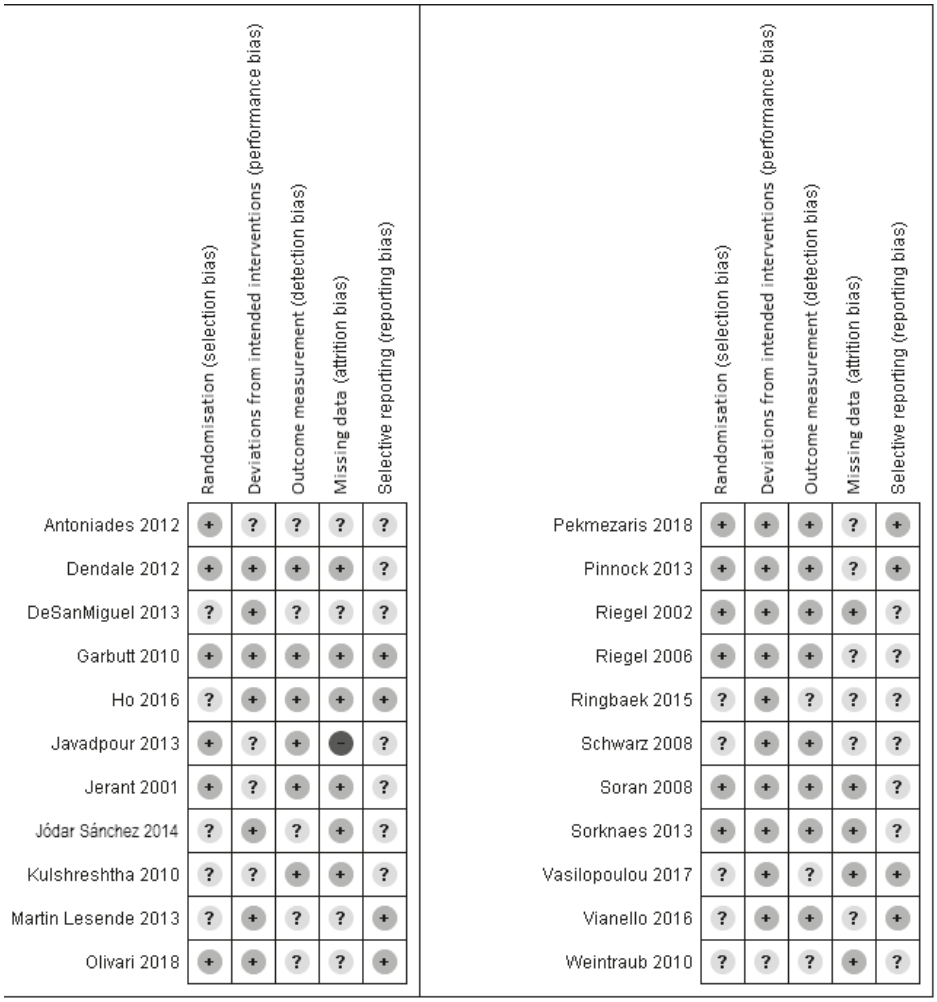
Multimedia Appendix 5. Figure 10. Forest plot of condition-related hospitalizations for telehealth compared to usual care, stratified by length of follow-up



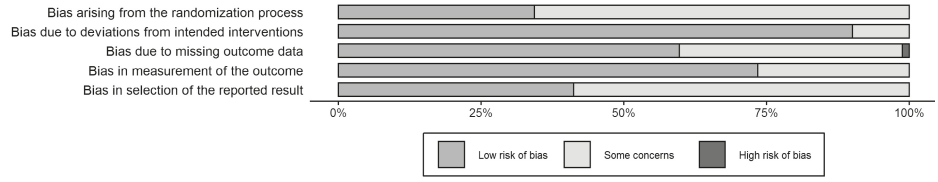
Multimedia Appendix 5. Figure 11. Forest plot of condition-related hospitalizations for telehealth compared to usual care, stratified by risk of bias

Unexplained heterogeneity is below 40% for all analyses. Additionally, the majority of confidence intervals overlap, and variation in point estimates seems reasonable. Therefore, we do not downgrade for inconsistency.

Risk of bias



Multimedia Appendix 5. Figure 12. Risk of bias per domain per study reporting condition-related hospitalizations



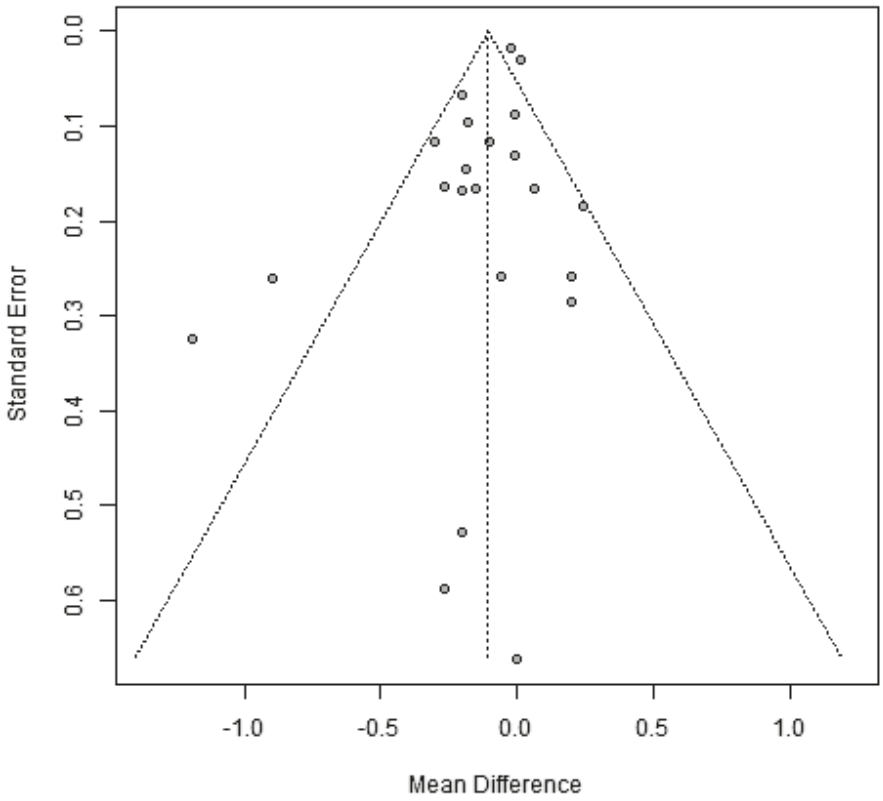
Multimedia Appendix 5. Figure 13. Weighted risk of bias summary per domain for condition-related hospitalizations

More than 50% of the weight is accounted for by studies at low risk of bias in three out of the five domains. Thus, downgrading is not necessary.

Imprecision

The confidence interval of the summary estimate does not overlap a null effect, and the analysis included well over 2000 participants, so there is no need to downgrade the quality of evidence.

Publication bias



Multimedia Appendix 5. Figure 14. Funnel plot for condition-related hospitalizations

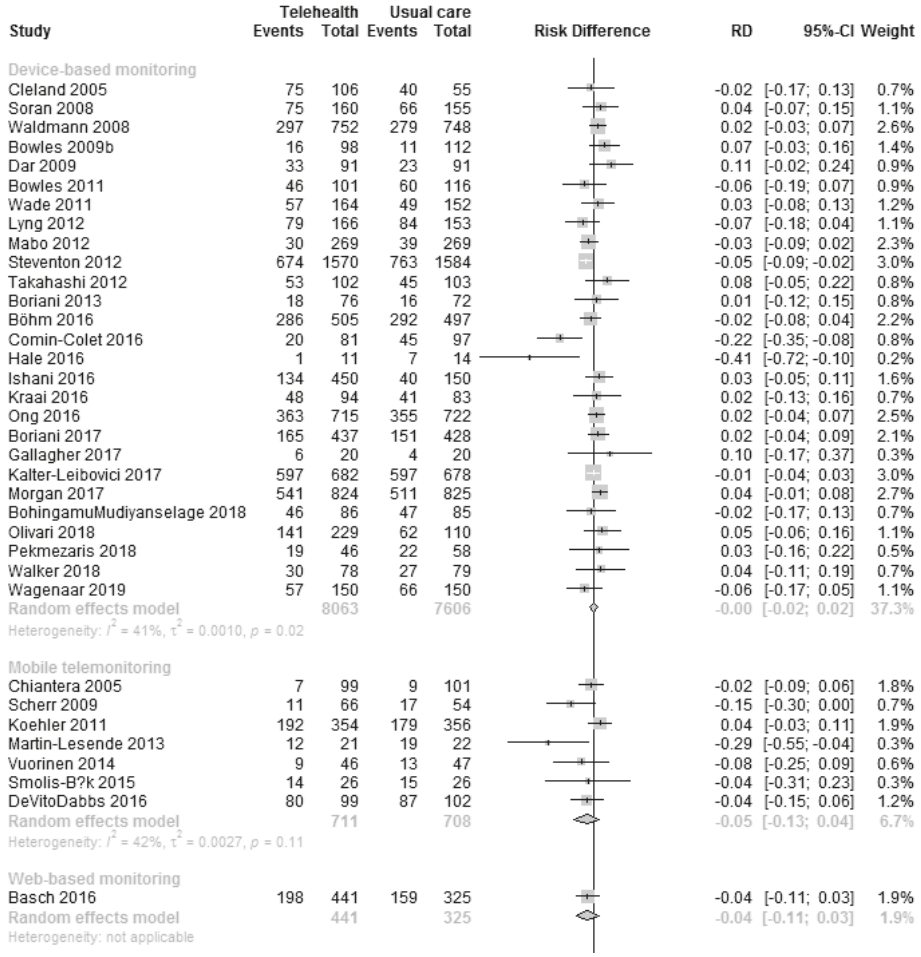
The funnel plot appears to be fairly symmetrical, so there is no reason to downgrade the quality of evidence for publication bias.

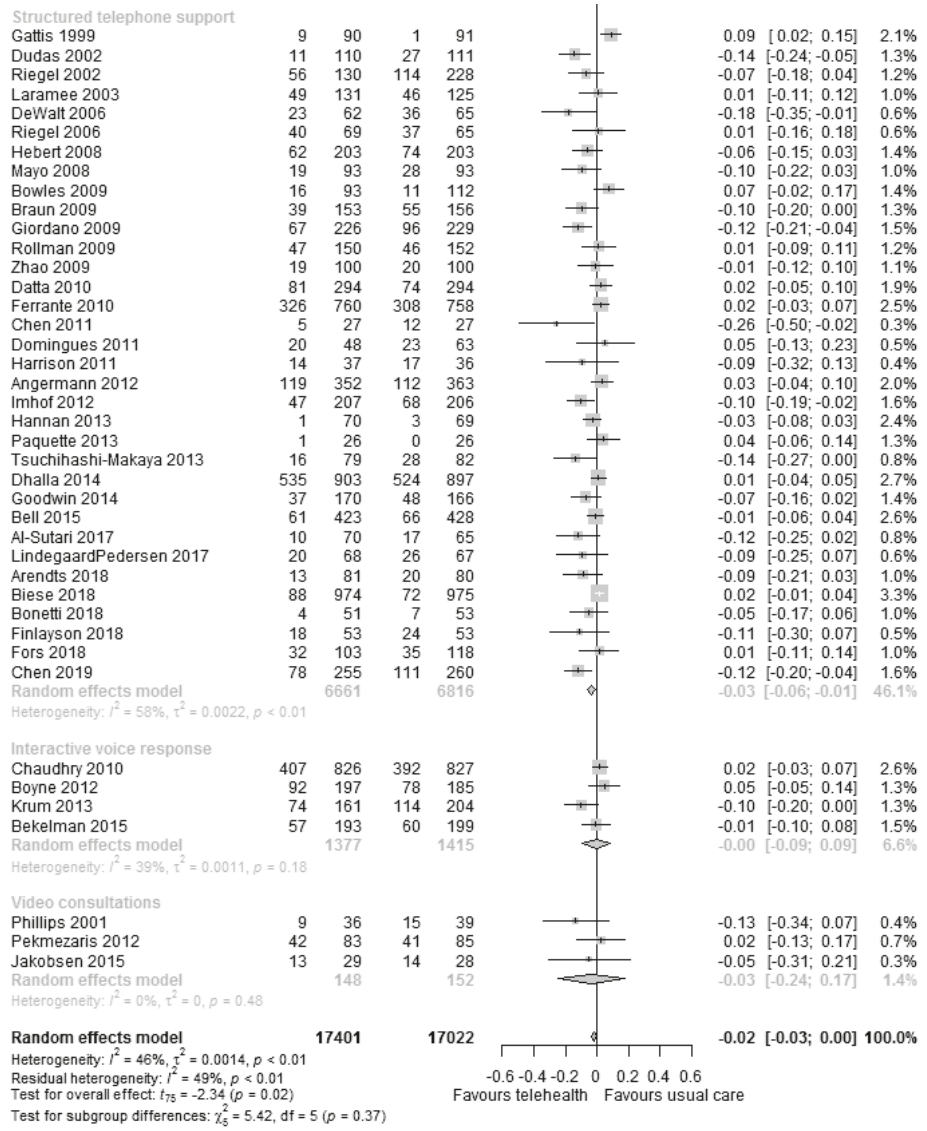
Summary: Unexplained heterogeneity is well below the threshold value of 60%, imprecision is limited owing to the large number of participants, the majority of studies has a low risk of bias, and risk for publication bias appears low.

Overall judgement: High quality of evidence.

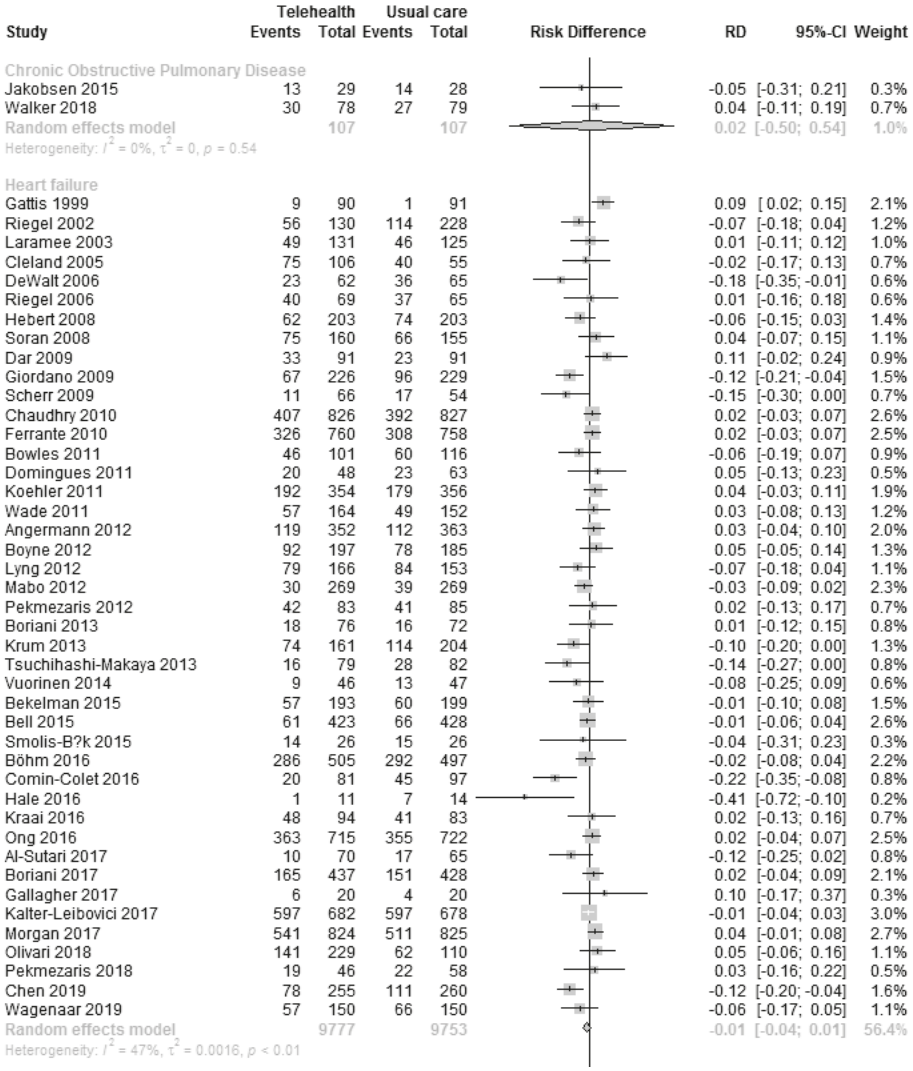
Participants with an all-cause hospitalization

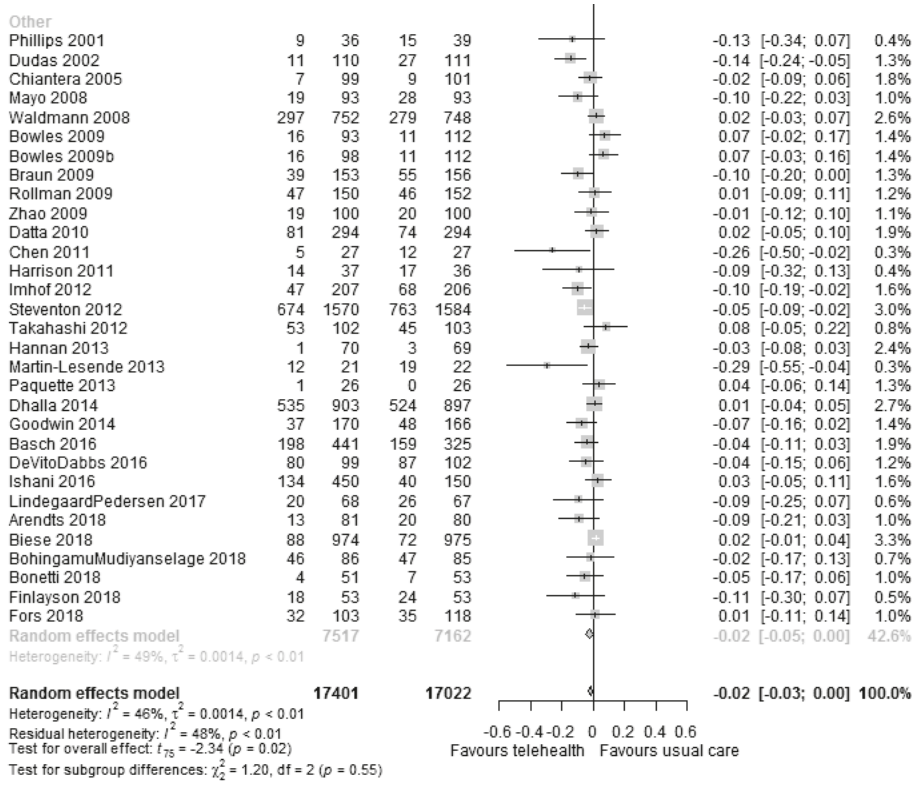
Inconsistency



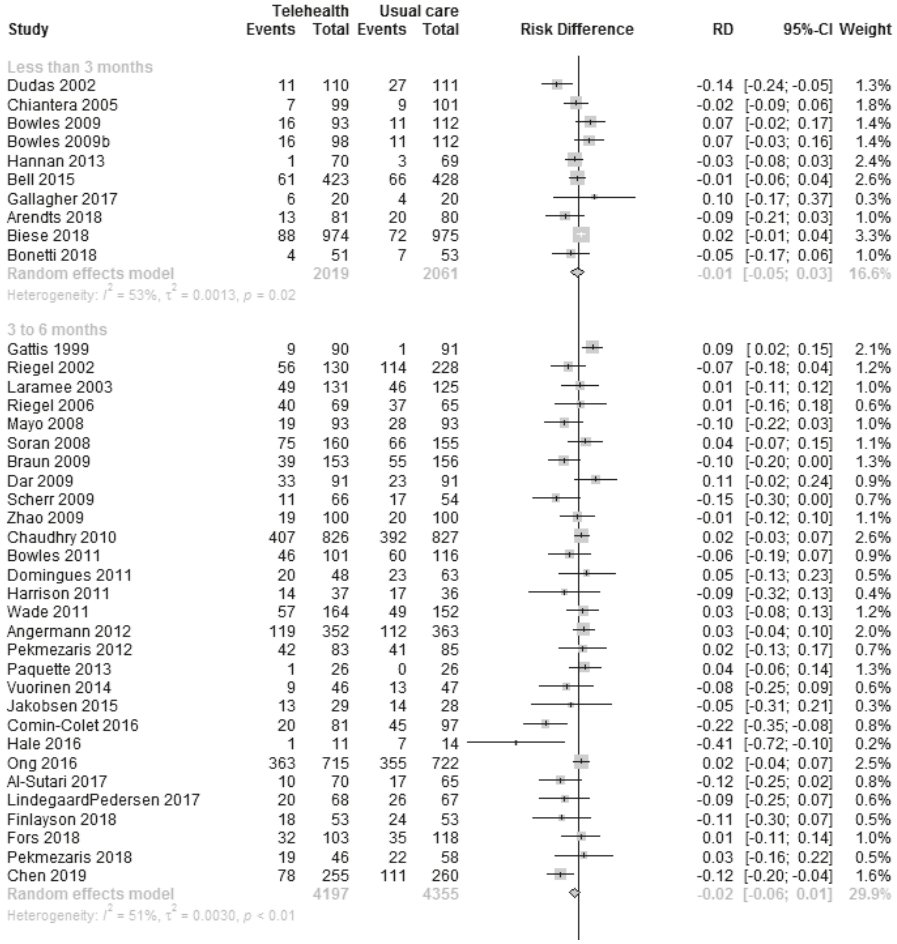


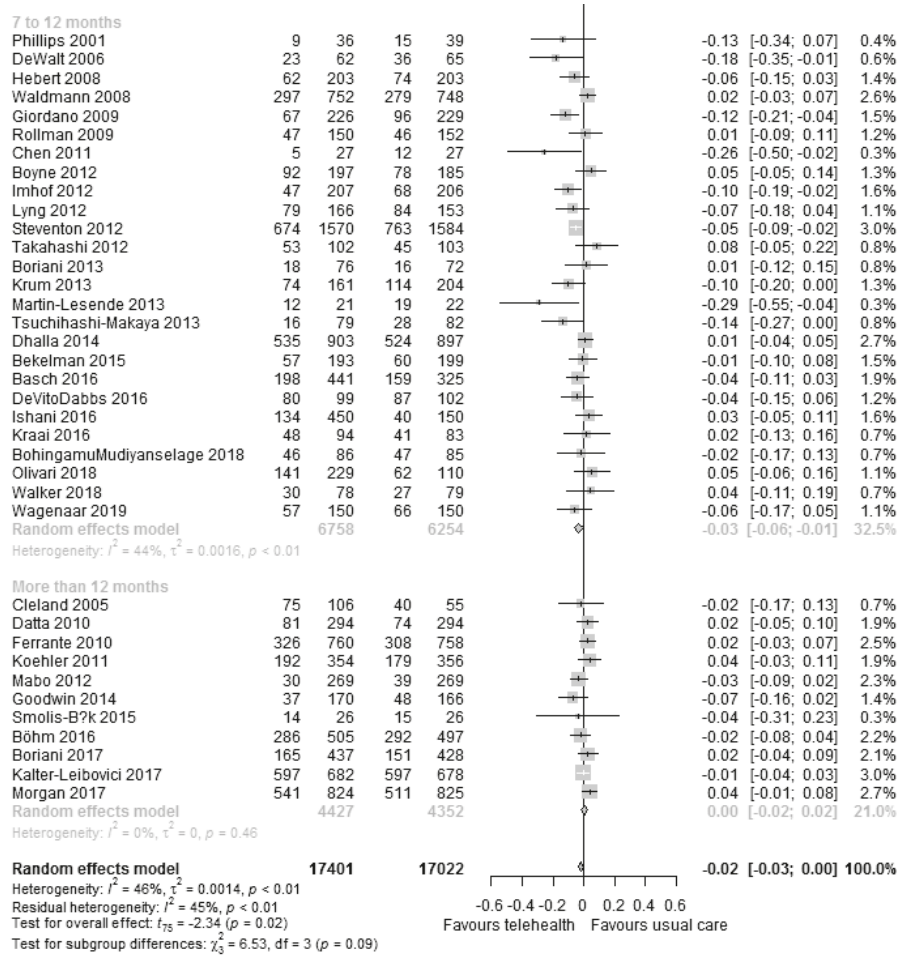
Multimedia Appendix 5. Figure 15. Forest plot of participants with an all-cause hospitalization for telehealth compared to usual care, stratified by telehealth type


Study
Telehealth Events Total
Usual care Events Total
Risk Difference
RD 95%-CI Weight
Chronic Obstructive Pulmonary Disease
Jakobsen 2015 13 29 14 28 -0.05 [-0.31; 0.21] 0.3%
Walker 2018 30 78 27 79 0.04 [-0.11; 0.19] 0.7%
Random effects model 107 107 0.02 [-0.50; 0.54] 1.0%
Heterogeneity: I^2 = 0%, τ^2 = 0, p = 0.54
Heart failure
Gattis 1999 9 90 1 91 0.09 [0.02; 0.15] 2.1%
Riegel 2002 56 130 114 228 -0.07 [-0.18; 0.04] 1.2%
Laramee 2003 49 131 46 125 0.01 [-0.11; 0.12] 1.0%
Cleland 2005 75 106 40 55 -0.02 [-0.17; 0.13] 0.7%
DeWalt 2006 23 62 36 65 -0.18 [-0.35; -0.01] 0.6%
Riegel 2006 40 69 37 65 0.01 [-0.16; 0.18] 0.6%
Hebert 2008 62 203 74 203 -0.06 [-0.15; 0.03] 1.4%
Soran 2008 75 160 66 155 0.04 [-0.07; 0.15] 1.1%
Dar 2009 33 91 23 91 0.11 [-0.02; 0.24] 0.9%
Giordano 2009 67 226 96 229 -0.12 [-0.21; -0.04] 1.5%
Scherr 2009 11 66 17 54 -0.15 [-0.30; 0.00] 0.7%
Chaudhry 2010 407 826 392 827 0.02 [-0.03; 0.07] 2.6%
Ferrante 2010 326 760 308 758 0.02 [-0.03; 0.07] 2.5%
Bowles 2011 46 101 60 116 -0.06 [-0.19; 0.07] 0.9%
Domingues 2011 20 48 23 63 0.05 [-0.13; 0.23] 0.5%
Koehler 2011 192 354 179 356 0.04 [-0.03; 0.11] 1.9%
Wade 2011 57 164 49 152 0.03 [-0.08; 0.13] 1.2%
Angermann 2012 119 352 112 363 0.03 [-0.04; 0.10] 2.0%
Boyne 2012 92 197 78 185 0.05 [-0.05; 0.14] 1.3%
Lyng 2012 79 166 84 153 -0.07 [-0.18; 0.04] 1.1%
Mabo 2012 30 269 39 269 -0.03 [-0.09; 0.02] 2.3%
Pekmezaris 2012 42 83 41 85 0.02 [-0.13; 0.17] 0.7%
Boriani 2013 18 76 16 72 0.01 [-0.12; 0.15] 0.8%
Krum 2013 74 161 114 204 -0.10 [-0.20; 0.00] 1.3%
Tsuchihashi-Makaya 2013 16 79 28 82 -0.14 [-0.27; 0.00] 0.8%
Vuorinen 2014 9 46 13 47 -0.08 [-0.25; 0.09] 0.6%
Bekelman 2015 57 193 60 199 -0.01 [-0.10; 0.08] 1.5%
Bell 2015 61 423 66 428 -0.01 [-0.06; 0.04] 2.6%
Smolis-B?k 2015 14 26 15 26 -0.04 [-0.31; 0.23] 0.3%
Böhm 2016 286 505 292 497 -0.02 [-0.08; 0.04] 2.2%
Comin-Colet 2016 20 81 45 97 -0.22 [-0.35; -0.08] 0.8%
Hale 2016 1 11 7 14 -0.41 [-0.72; -0.10] 0.2%
Kraai 2016 48 94 41 83 0.02 [-0.13; 0.16] 0.7%
Ong 2016 363 715 355 722 0.02 [-0.04; 0.07] 2.5%
Al-Sutari 2017 10 70 17 65 -0.12 [-0.25; 0.02] 0.8%
Boriani 2017 165 437 151 428 0.02 [-0.04; 0.09] 2.1%
Gallagher 2017 6 20 4 20 0.10 [-0.17; 0.37] 0.3%
Kalter-Leibovici 2017 597 682 597 678 -0.01 [-0.04; 0.03] 3.0%
Morgan 2017 541 824 511 825 0.04 [-0.01; 0.08] 2.7%
Olivari 2018 141 229 62 110 0.05 [-0.06; 0.16] 1.1%
Pekmezaris 2018 19 46 22 58 0.03 [-0.16; 0.22] 0.5%
Chen 2019 78 255 111 260 -0.12 [-0.20; -0.04] 1.6%
Wagenaar 2019 57 150 66 150 -0.06 [-0.17; 0.05] 1.1%
Random effects model 9777 9753 -0.01 [-0.04; 0.01] 56.4%
Heterogeneity: I^2 = 47%, τ^2 = 0.0016, p < 0.01

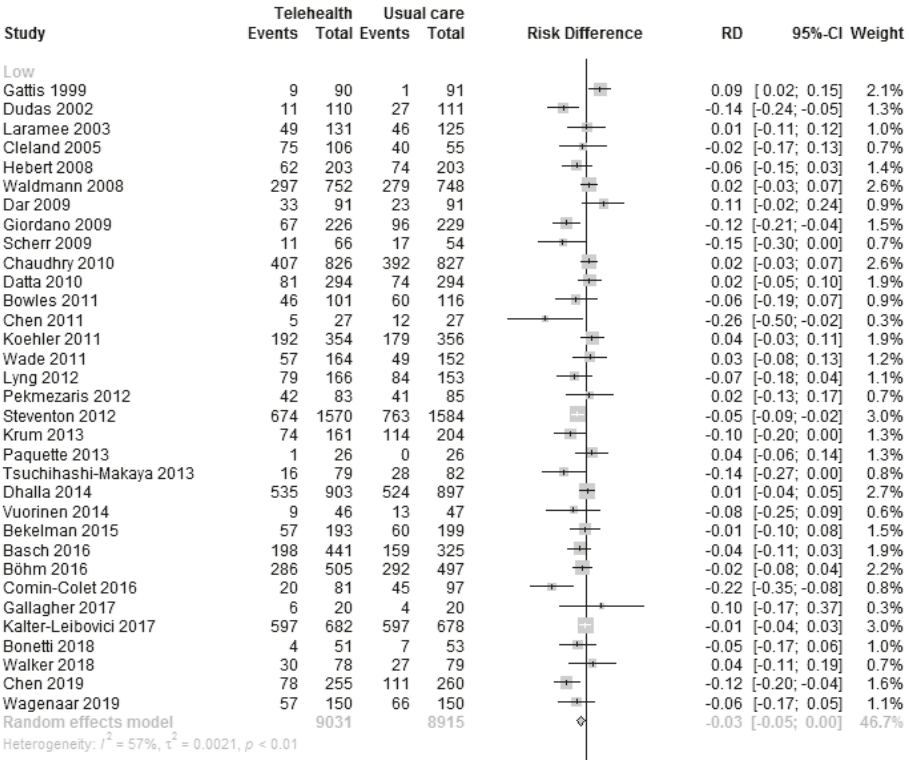


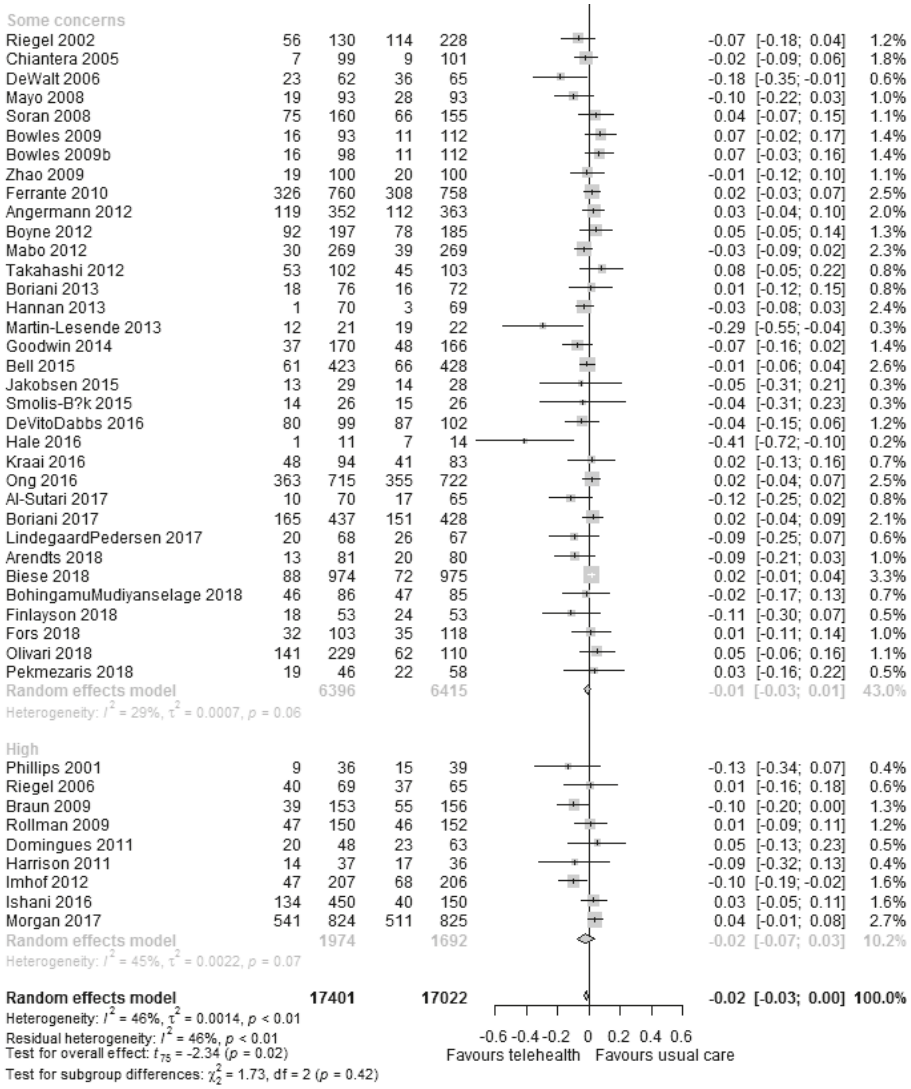
Multimedia Appendix 5. Figure 16. Forest plot of participants with an all-cause hospitalization for telehealth compared to usual care, stratified by health condition


Study
Telehealth Events Total
Usual care Events Total
Risk Difference
RD 95%-CI Weight
Less than 3 months
Dudas 2002 11 110 27 111 -0.14 [-0.24; -0.05] 1.3%
Chiantera 2005 7 99 9 101 -0.02 [-0.09; 0.06] 1.8%
Bowles 2009 16 93 11 112 0.07 [-0.02; 0.17] 1.4%
Bowles 2009b 16 98 11 112 0.07 [-0.03; 0.16] 1.4%
Hannan 2013 1 70 3 69 -0.03 [-0.08; 0.03] 2.4%
Bell 2015 61 423 66 428 -0.01 [-0.06; 0.04] 2.6%
Gallagher 2017 6 20 4 20 0.10 [-0.17; 0.37] 0.3%
Arendts 2018 13 81 20 80 -0.09 [-0.21; 0.03] 1.0%
Biese 2018 88 974 72 975 0.02 [-0.01; 0.04] 3.3%
Bonetti 2018 4 51 7 53 -0.05 [-0.17; 0.06] 1.0%
Random effects model 2019 2061 -0.01 [-0.05; 0.03] 16.6%
Heterogeneity: I^2 = 53%, τ^2 = 0.0013, p = 0.02
3 to 6 months
Gattis 1999 9 90 1 91 0.09 [0.02; 0.15] 2.1%
Riegel 2002 56 130 114 228 -0.07 [-0.18; 0.04] 1.2%
Laramee 2003 49 131 46 125 0.01 [-0.11; 0.12] 1.0%
Riegel 2006 40 69 37 65 0.01 [-0.16; 0.18] 0.6%
Mayo 2008 19 93 28 93 -0.10 [-0.22; 0.03] 1.0%
Soran 2008 75 160 66 155 0.04 [-0.07; 0.15] 1.1%
Braun 2009 39 153 55 156 -0.10 [-0.20; 0.00] 1.3%
Dar 2009 33 91 23 91 0.11 [-0.02; 0.24] 0.9%
Scherr 2009 11 66 17 54 -0.15 [-0.30; 0.00] 0.7%
Zhao 2009 19 100 20 100 -0.01 [-0.12; 0.10] 1.1%
Chaudhry 2010 407 826 392 827 0.02 [-0.03; 0.07] 2.6%
Bowles 2011 46 101 60 116 -0.06 [-0.19; 0.07] 0.9%
Domingues 2011 20 48 23 63 0.05 [-0.13; 0.23] 0.5%
Harrison 2011 14 37 17 36 -0.09 [-0.32; 0.13] 0.4%
Wade 2011 57 164 49 152 0.03 [-0.08; 0.13] 1.2%
Angermann 2012 119 352 112 363 0.03 [-0.04; 0.10] 2.0%
Pekmezaris 2012 42 83 41 85 0.02 [-0.13; 0.17] 0.7%
Paquette 2013 1 26 0 26 0.04 [-0.06; 0.14] 1.3%
Vuorinen 2014 9 46 13 47 -0.08 [-0.25; 0.09] 0.6%
Jakobsen 2015 13 29 14 28 -0.05 [-0.31; 0.21] 0.3%
Comin-Colet 2016 20 81 45 97 -0.22 [-0.35; -0.08] 0.8%
Hale 2016 1 11 7 14 -0.41 [-0.72; -0.10] 0.2%
Ong 2016 363 715 355 722 0.02 [-0.04; 0.07] 2.5%
Al-Sutari 2017 10 70 17 65 -0.12 [-0.25; 0.02] 0.8%
LindegaardPedersen 2017 20 68 26 67 -0.09 [-0.25; 0.07] 0.6%
Finlayson 2018 18 53 24 53 -0.11 [-0.30; 0.07] 0.5%
Fors 2018 32 103 35 118 0.01 [-0.11; 0.14] 1.0%
Pekmezaris 2018 19 46 22 58 0.03 [-0.16; 0.22] 0.5%
Chen 2019 78 255 111 260 -0.12 [-0.20; -0.04] 1.6%
Random effects model 4197 4355 -0.02 [-0.06; 0.01] 29.9%
Heterogeneity: I^2 = 51%, τ^2 = 0.0030, p < 0.01



Multimedia Appendix 5. Figure 17. Forest plot of participants with an all-cause hospitalization for telehealth compared to usual care, stratified by length of follow-up

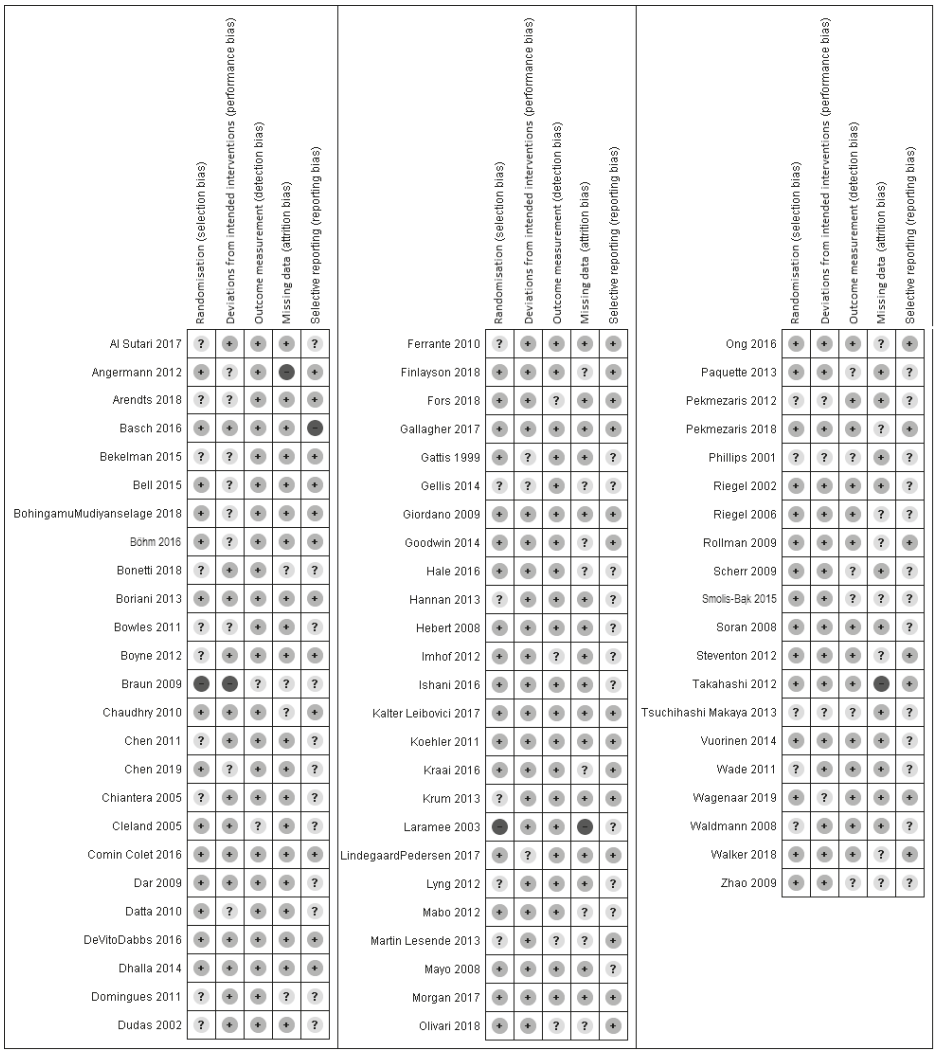

Telehealth
Usual care
Study
Events Total Events Total
Risk Difference
RD 95%-CI Weight
Low
Gattis 1999 9 90 1 91 0.09 [0.02; 0.15] 2.1%
Dudas 2002 11 110 27 111 -0.14 [-0.24; -0.05] 1.3%
Laramee 2003 49 131 46 125 0.01 [-0.11; 0.12] 1.0%
Cleland 2005 75 106 40 55 -0.02 [-0.17; 0.13] 0.7%
Hebert 2008 62 203 74 203 -0.06 [-0.15; 0.03] 1.4%
Waldmann 2008 297 752 279 748 0.02 [-0.03; 0.07] 2.6%
Dar 2009 33 91 23 91 0.11 [-0.02; 0.24] 0.9%
Giordano 2009 67 226 96 229 -0.12 [-0.21; -0.04] 1.5%
Scherr 2009 11 66 17 54 -0.15 [-0.30; 0.00] 0.7%
Chaudhry 2010 407 826 392 827 0.02 [-0.03; 0.07] 2.6%
Datta 2010 81 294 74 294 0.02 [-0.05; 0.10] 1.9%
Bowles 2011 46 101 60 116 -0.06 [-0.19; 0.07] 0.9%
Chen 2011 5 27 12 27 -0.26 [-0.50; -0.02] 0.3%
Koehler 2011 192 354 179 356 0.04 [-0.03; 0.11] 1.9%
Wade 2011 57 164 49 152 0.03 [-0.08; 0.13] 1.2%
Lyng 2012 79 166 84 153 -0.07 [-0.18; 0.04] 1.1%
Pekmezaris 2012 42 83 41 85 0.02 [-0.13; 0.17] 0.7%
Steventon 2012 674 1570 763 1584 -0.05 [-0.09; -0.02] 3.0%
Krum 2013 74 161 114 204 -0.10 [-0.20; 0.00] 1.3%
Paquette 2013 1 26 0 26 0.04 [-0.06; 0.14] 1.3%
Tsuchihashi-Makaya 2013 16 79 28 82 -0.14 [-0.27; 0.00] 0.8%
Dhalla 2014 535 903 524 897 0.01 [-0.04; 0.05] 2.7%
Vuorinen 2014 9 46 13 47 -0.08 [-0.25; 0.09] 0.6%
Bekelman 2015 57 193 60 199 -0.01 [-0.10; 0.08] 1.5%
Basch 2016 198 441 159 325 -0.04 [-0.11; 0.03] 1.9%
Böhm 2016 286 505 292 497 -0.02 [-0.08; 0.04] 2.2%
Comin-Colet 2016 20 81 45 97 -0.22 [-0.35; -0.08] 0.8%
Gallagher 2017 6 20 4 20 0.10 [-0.17; 0.37] 0.3%
Kalter-Leibovici 2017 597 682 597 678 -0.01 [-0.04; 0.03] 3.0%
Bonetti 2018 4 51 7 53 -0.05 [-0.17; 0.06] 1.0%
Walker 2018 30 78 27 79 0.04 [-0.11; 0.19] 0.7%
Chen 2019 78 255 111 260 -0.12 [-0.20; -0.04] 1.6%
Wagenaar 2019 57 150 66 150 -0.06 [-0.17; 0.05] 1.1%
Random effects model 9031 8915 -0.03 [-0.05; 0.00] 46.7%
Heterogeneity: I^2 = 57%, τ^2 = 0.0021, p < 0.01



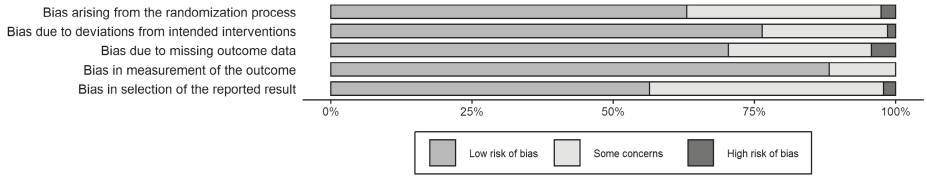
Multimedia Appendix 5. Figure 18. Forest plot of participants with an all-cause hospitalization for telehealth compared to usual care, stratified by risk of bias

The amount of unexplained heterogeneity is below 25% for each analysis. Furthermore, the majority of confidence intervals appears to overlap, and variation between point estimates seems limited. Therefore, there is no reason to downgrade quality of evidence for inconsistency.

Risk of bias



Multimedia Appendix 5. Figure 19. Risk of bias per domain per study reporting participants with an all-cause hospitalization



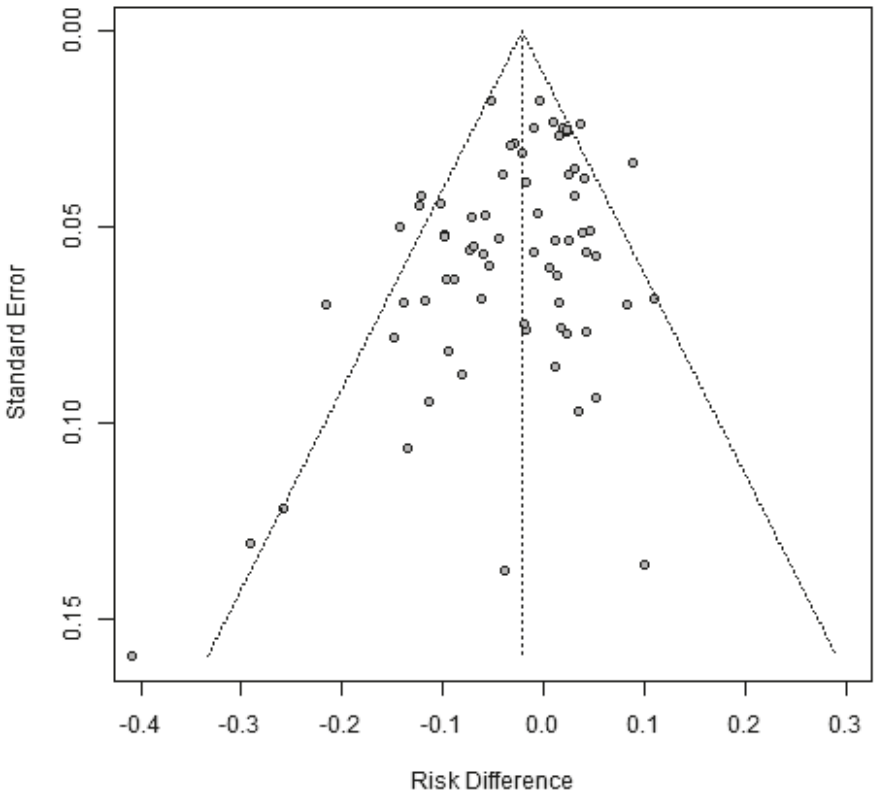
Multimedia Appendix 5. Figure 20. Cumulative weighted risk of bias for each domain for participants with an all-cause hospitalization

In each domain of risk of bias, articles with a low risk of bias represent a weight of more than 50%. Therefore, there is no reason to downgrade the quality of evidence for risk of bias.

Imprecision

The confidence interval of the summary estimate does not overlap a null effect, and the analysis included well over 2000 participants. Therefore, quality of evidence is not downgraded.

Publication bias



Multimedia Appendix 5. Figure 21. Funnel plot for participants with an all-cause hospitalization

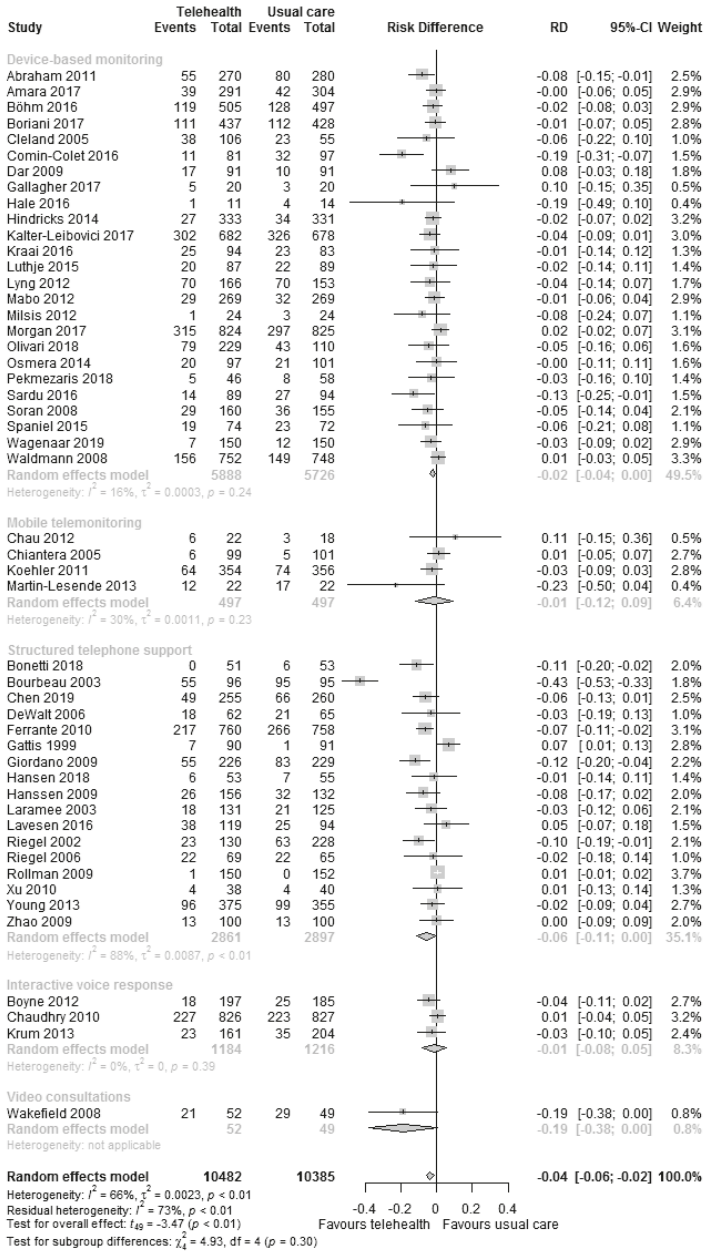
The funnel plot appears to be quite symmetrical, so downgrading for publication bias does not seem necessary.

Summary: Unexplained heterogeneity is well below the threshold value of 60%, imprecision is limited owing to the large number of participants, the majority of studies has a low risk of bias, and risk for publication bias appears low.

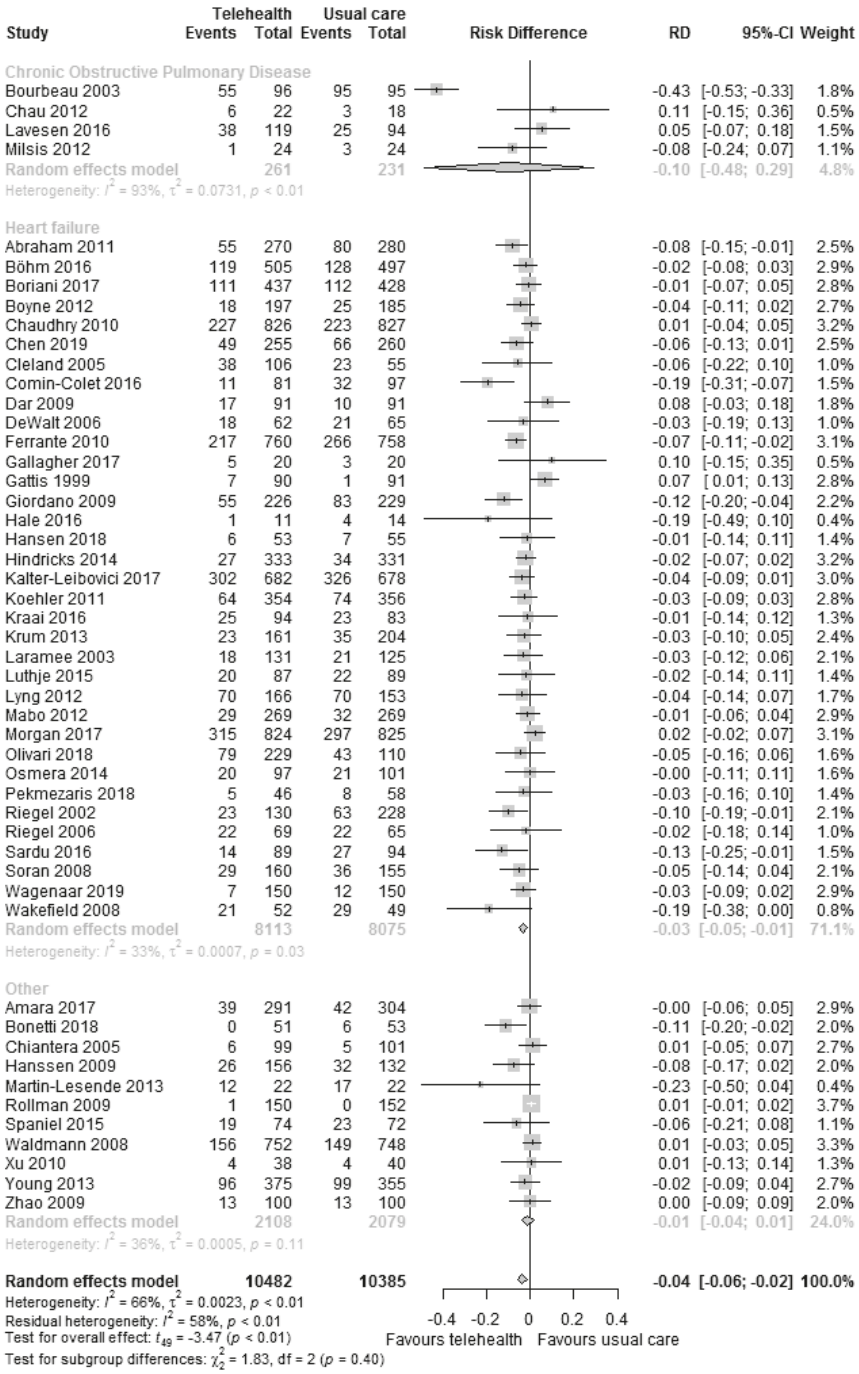
Overall judgement: High quality of evidence

Participants with a condition-related hospitalization

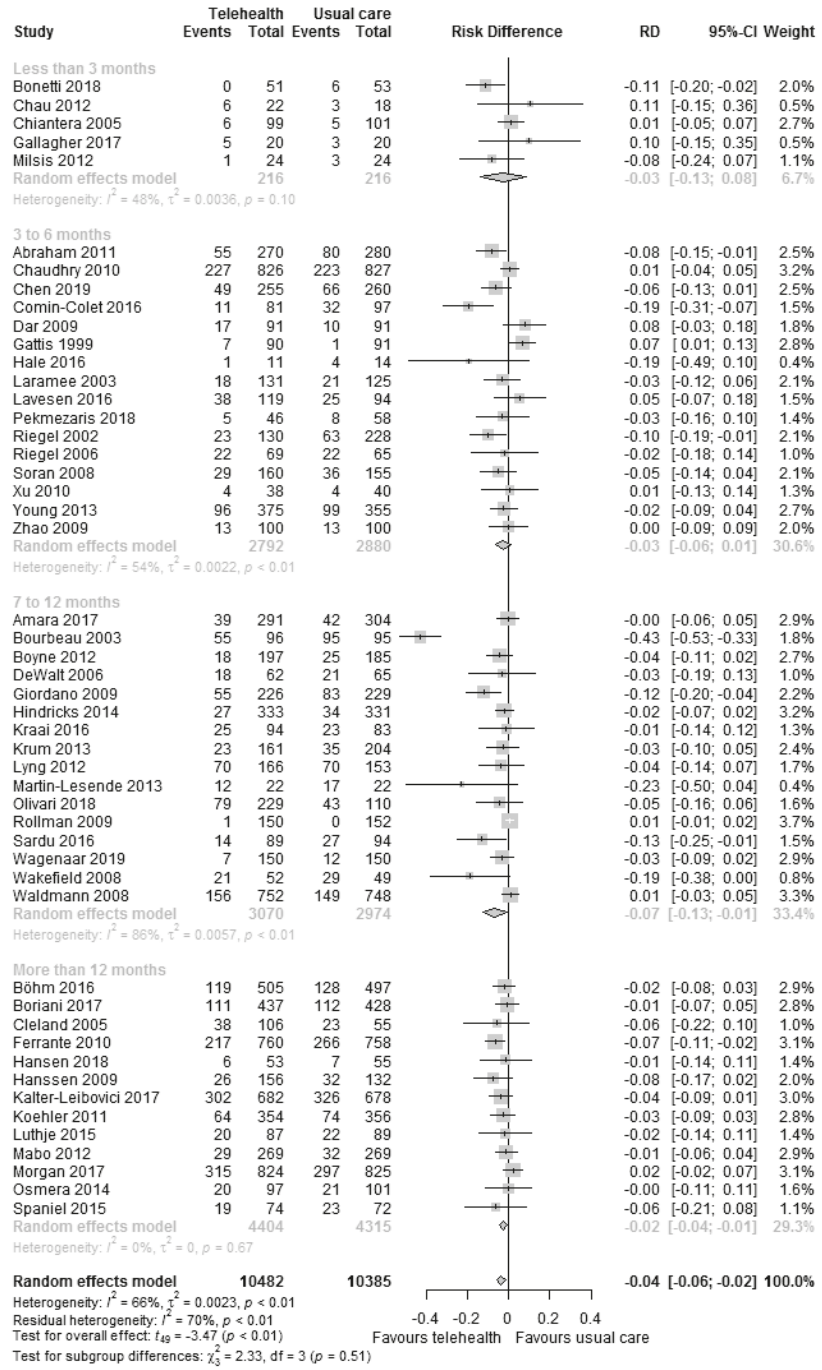
Inconsistency



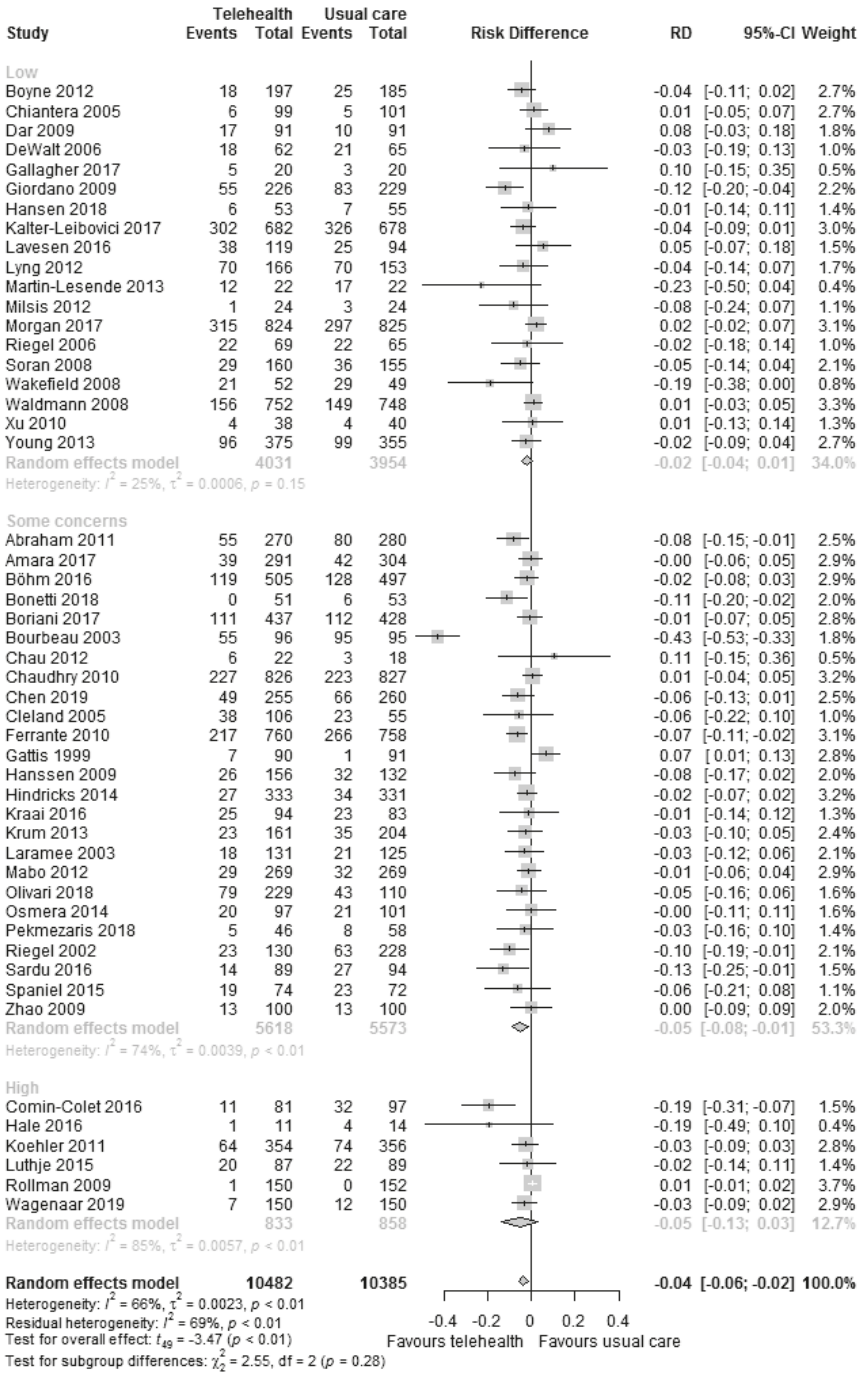
Multimedia Appendix 5. Figure 22. Forest plot of participants with a condition-related hospitalization for telehealth compared to usual care, stratified by telehealth type



Multimedia Appendix 5. Figure 23. Forest plot of participants with a condition-related hospitalization for telehealth compared to usual care, stratified by health condition



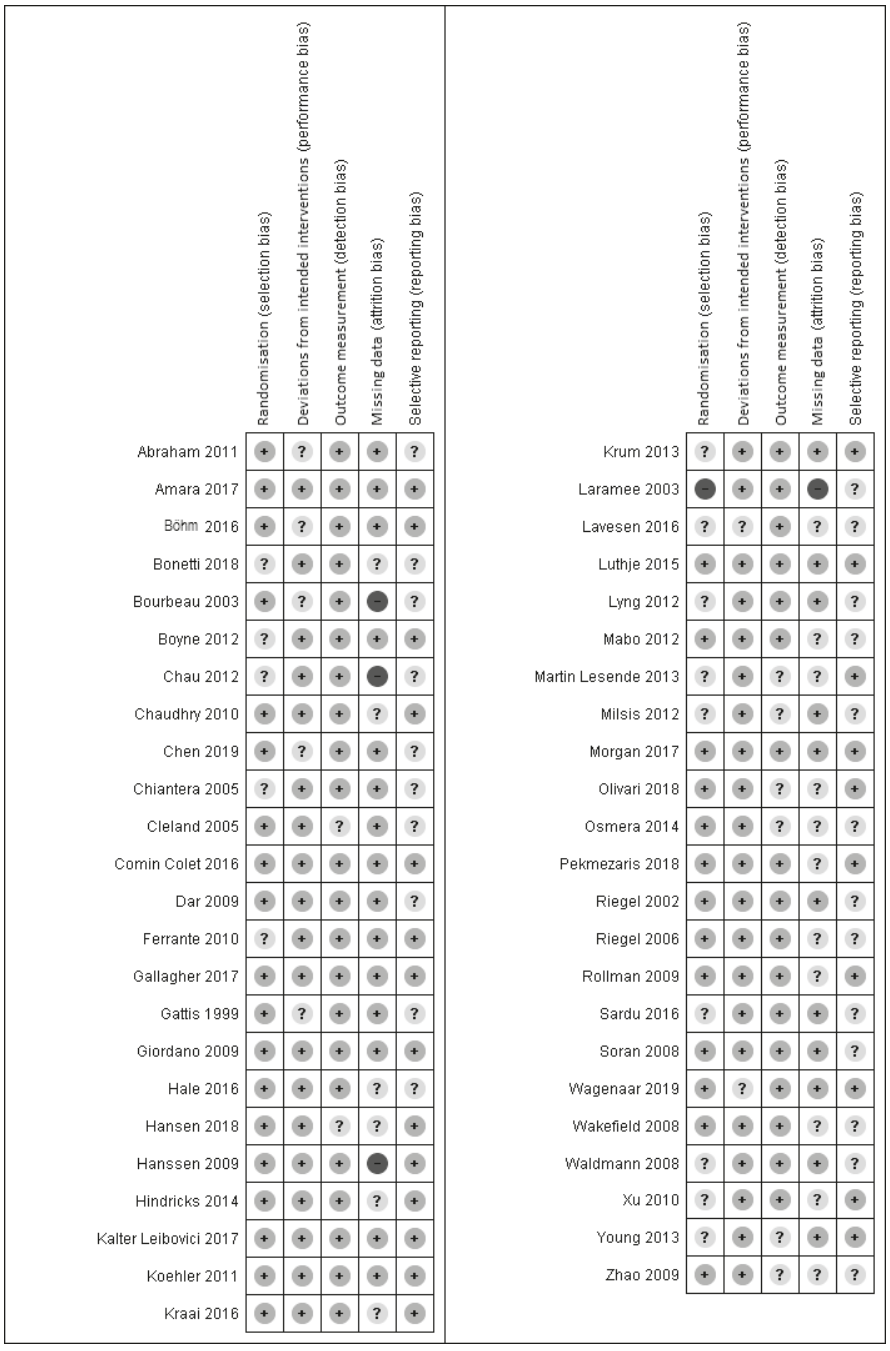
Multimedia Appendix 5. Figure 24. Forest plot of participants with a condition-related hospitalization for telehealth compared to usual care, stratified by length of follow-up



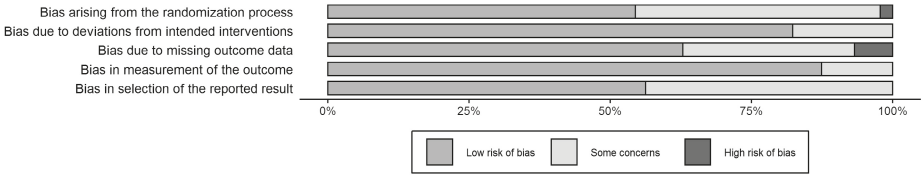
Multimedia Appendix 5. Figure 25. Forest plot of participants with a condition-related hospitalization for telehealth compared to usual care, stratified by risk of bias

Unexplained heterogeneity is below 60% for all analyses. Additionally, confidence intervals overlap largely, and variation in point estimates seems reasonable. Therefore, I do not downgrade for inconsistency.

Risk of bias



Multimedia Appendix 5. Figure 26. Risk of bias per domain per study reporting participants with a condition-related hospitalization



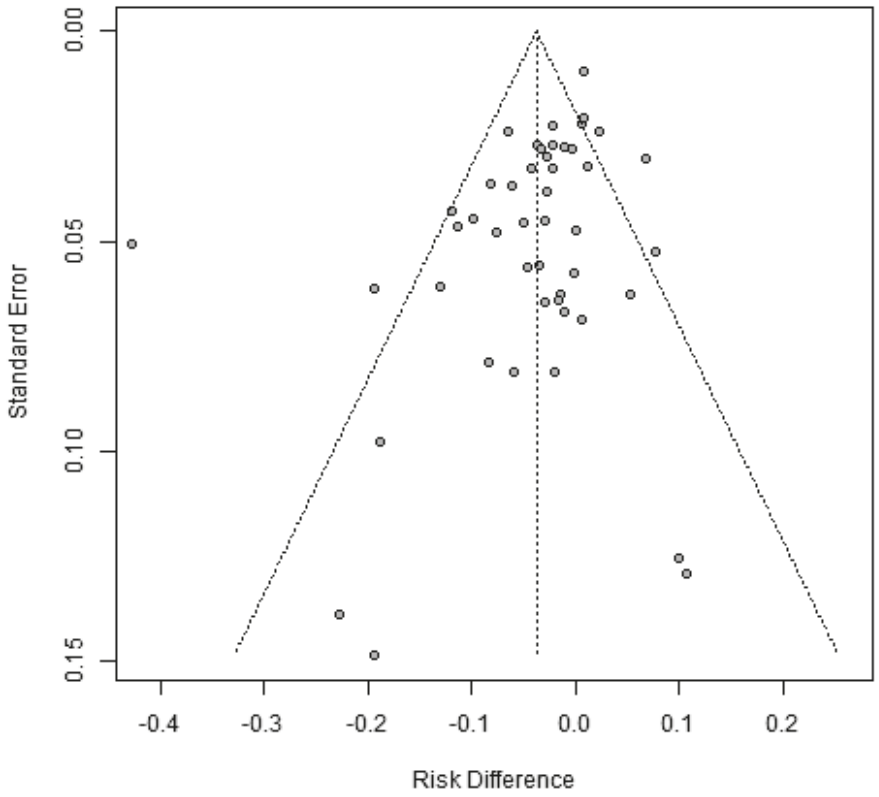
Multimedia Appendix 5. Figure 27. Weighted risk of bias summary per domain for participants with a condition-related hospitalization

Studies at a low risk of bias accounted for more than 50% of the weight in the meta-analysis in each domain. Thus, the quality of evidence is not downgraded for risk of bias.

Imprecision

The confidence interval of the point estimate does not overlap a null effect, and a large number of participants were included. Therefore, the quality of evidence is not downgraded for imprecision.

Publication bias



Multimedia Appendix 5. Figure 28. Funnel plot for participants with a condition-related hospitalization

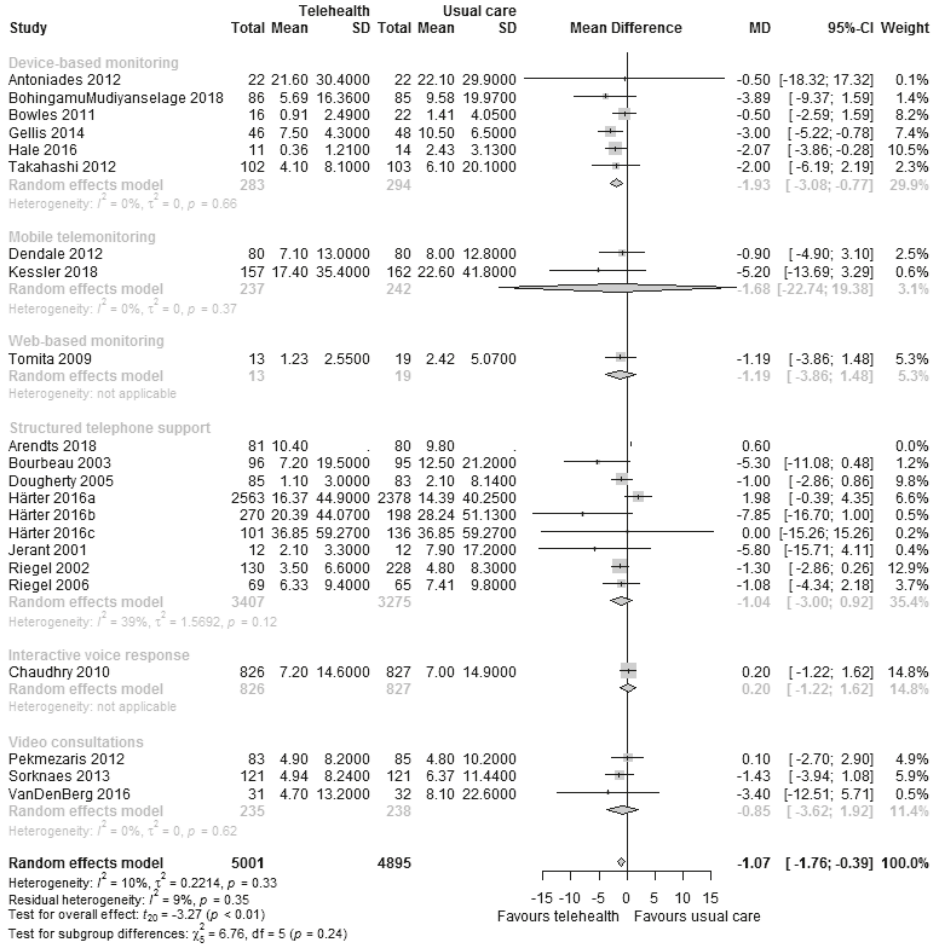
The funnel plot appears to be quite symmetrical, so risk of publication bias seems small. Therefore, quality of evidence is not downgraded for risk of publication bias.

Summary: Unexplained heterogeneity is below the threshold value of 60%, imprecision is limited owing to the large number of participants, the majority of studies has a low risk of bias, and risk for publication bias appears low.

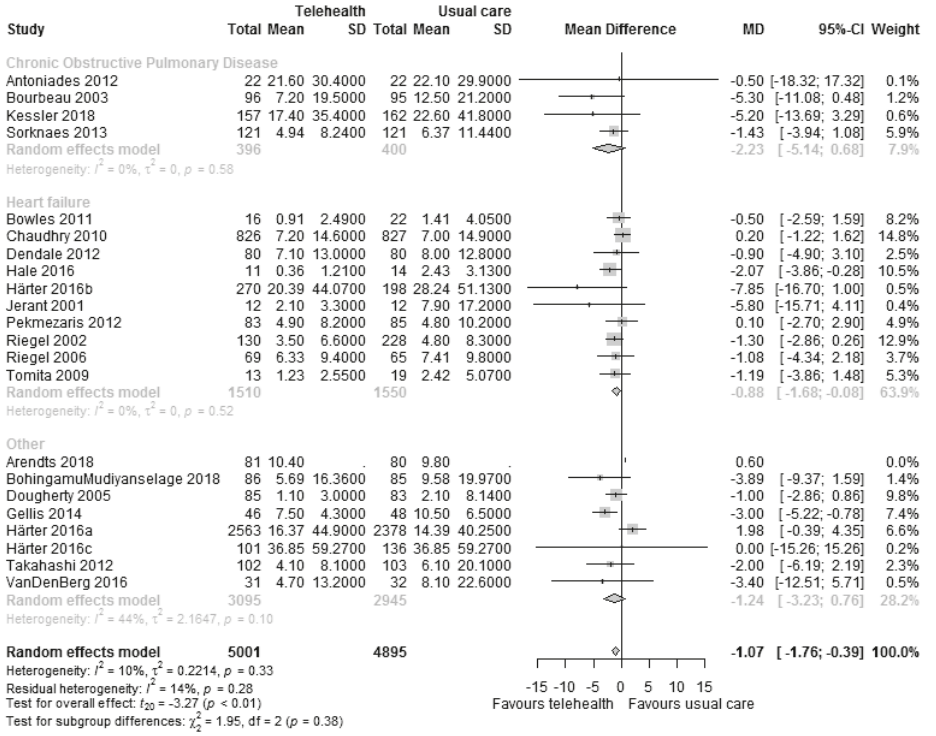
Overall judgement: High quality of evidence

All-cause hospital days

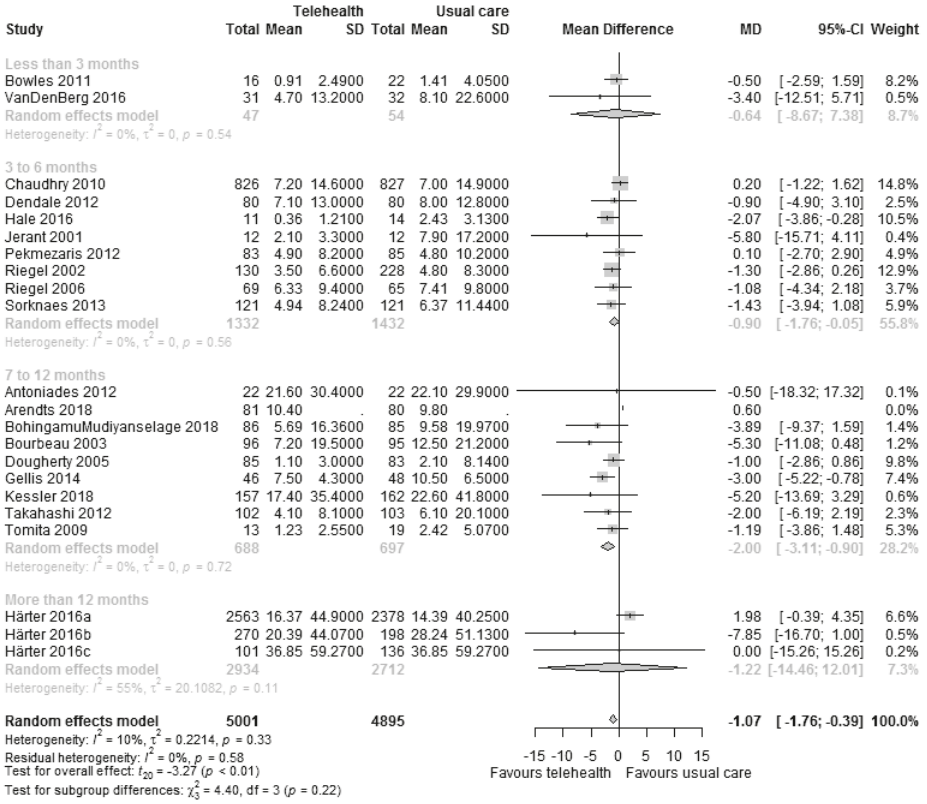
Inconsistency



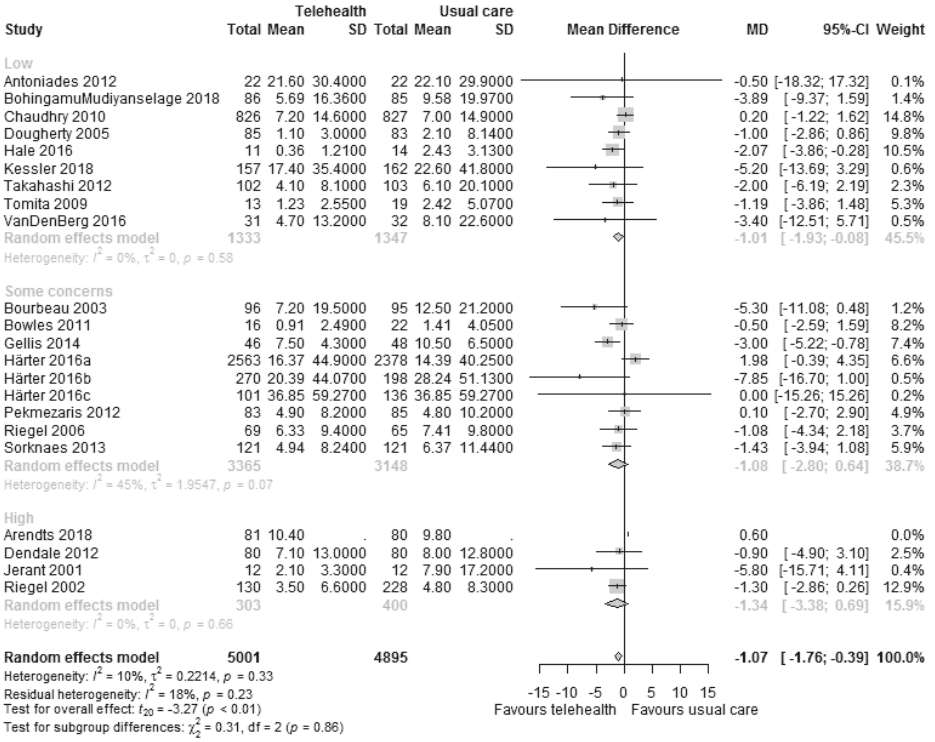
Multimedia Appendix 5. Figure 29. Forest plot for all-cause hospital days for telehealth compared to usual care, stratified by telehealth type



Multimedia Appendix 5. Figure 30. Forest plot for all-cause hospital days for telehealth compared to usual care, stratified by health condition



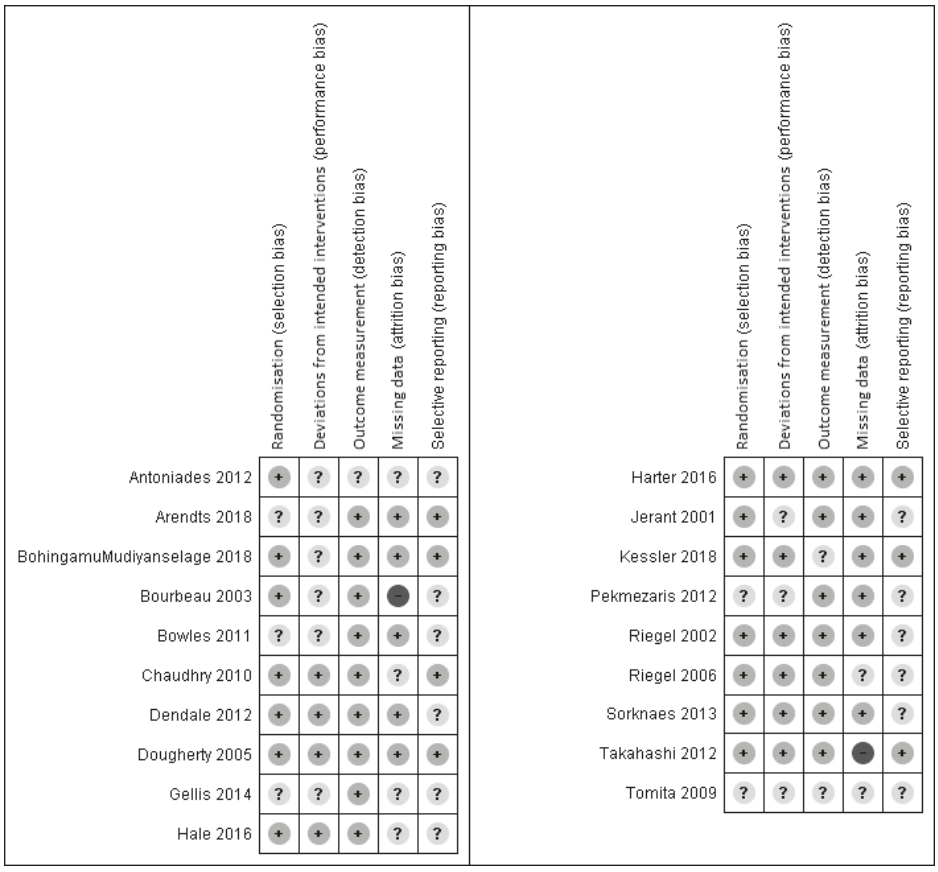
Multimedia Appendix 5. Figure 31. Forest plot for all-cause hospital days for telehealth compared to usual care, stratified by length of follow-up



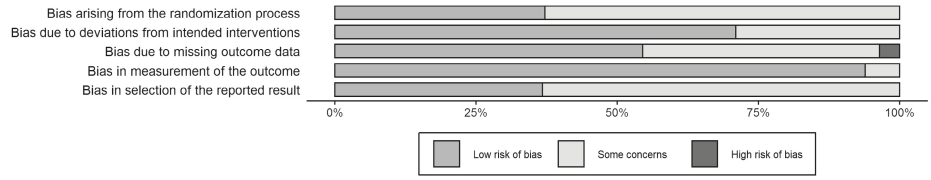
Multimedia Appendix 5. Figure 32. Forest plot for all-cause hospital days for telehealth compared to usual care, stratified by risk of bias

Residual heterogeneity is below 10%, the majority of confidence intervals overlap, and variation between point estimates seems reasonable. Therefore, quality of evidence is not downgraded for inconsistency.

Risk of bias



Multimedia Appendix 5. Figure 33. Risk of bias per domain per study reporting all-cause hospital days



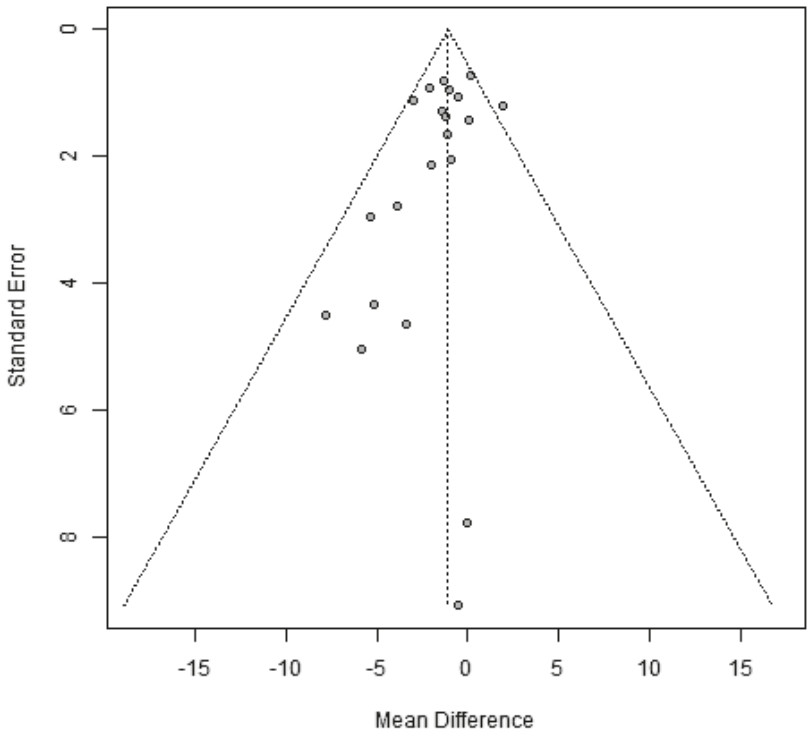
Multimedia Appendix 5. Figure 34. Weighted risk of bias summary per domain for all-cause hospital days

There was only one domain wherein studies with some concerns in terms of risk of bias accounted for more than 60% of the weight in the meta-analysis. Thus, there is no reason to downgrade the quality of evidence for risk of bias.

Imprecision

The confidence interval of the summary estimate does not overlap a null effect, and the analysis included well over 2000 participants, so there is no need to downgrade the quality of evidence.

Publication bias



Multimedia Appendix 5. Figure 35. Funnel plot for all-cause hospital days

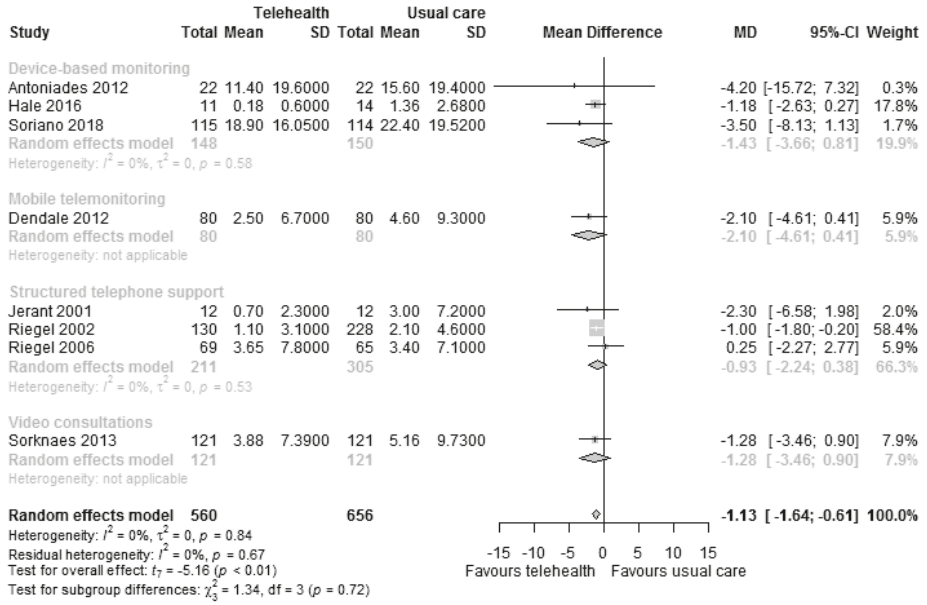
A limited amount of asymmetry can be observed in the funnel plot. However, as the GRADE guidelines recommend being very conservative when it comes to downgrading quality of evidence for publication bias, we consider this to be a close call, but do not downgrade the quality of evidence.

Summary: Unexplained heterogeneity is well below the threshold value of 60%, imprecision is limited owing to the large number of participants, and the majority of studies has a low risk of bias. There may be some risk of publication bias, however we do not consider this sufficiently convincing to downgrade quality of evidence.

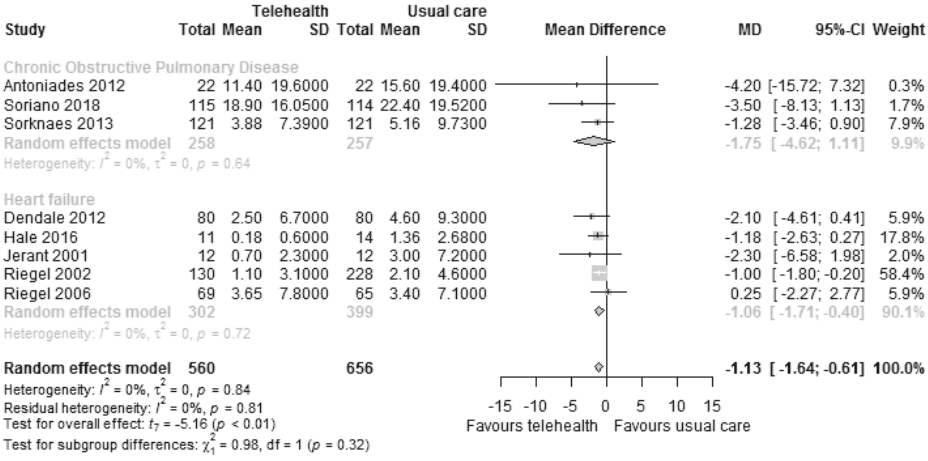
Overall judgement: High quality of evidence

Condition-related hospital days

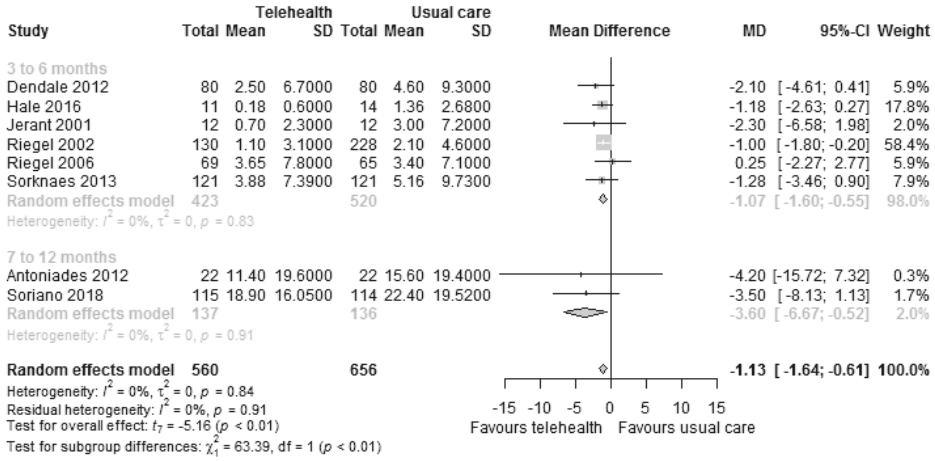
Inconsistency



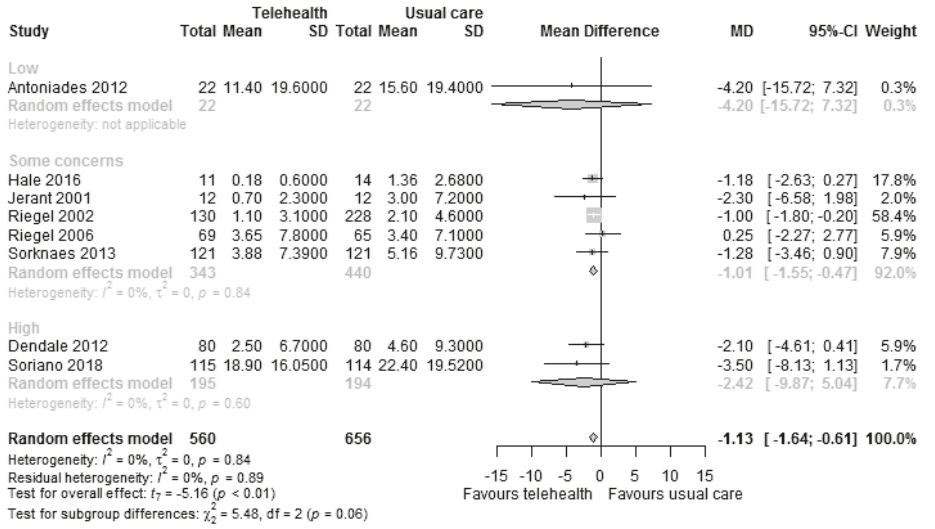
Multimedia Appendix 5. Figure 36. Forest plot for condition-related hospital days for telehealth compared to usual care, stratified by telehealth type



Multimedia Appendix 5. Figure 37. Forest plot for condition-related hospital days for telehealth compared to usual care, stratified by health condition



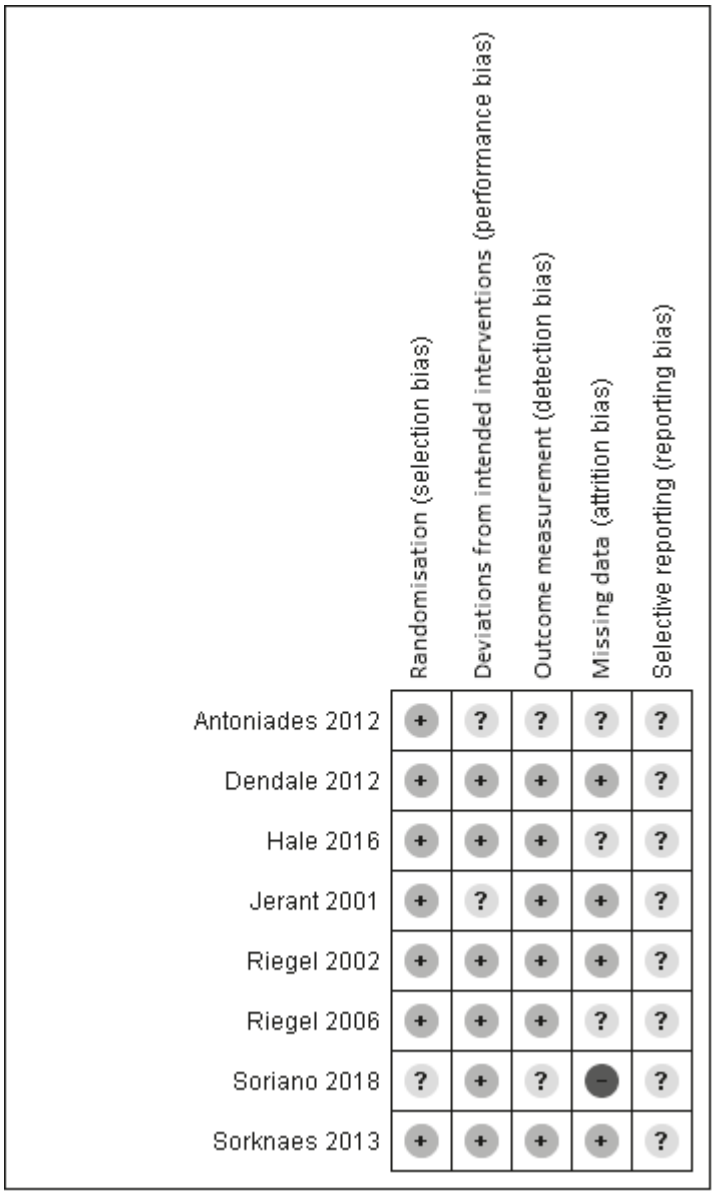
Multimedia Appendix 5. Figure 38. Forest plot for condition-related hospital days for telehealth compared to usual care, stratified by length of follow-up



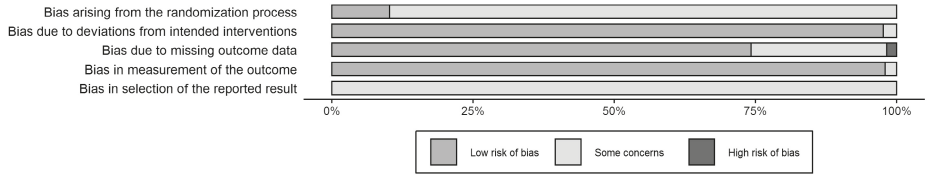
Multimedia Appendix 5. Figure 39. Forest plot for condition-related hospital days for telehealth compared to usual care, stratified by risk of bias

Each analysis shows 0% heterogeneity. Although 0% heterogeneity seems unlikely, the majority of confidence intervals appears to overlap, and variation between point estimates seems reasonable. Therefore, we do not downgrade quality of evidence for inconsistency.

Risk of bias



Multimedia Appendix 5. Figure 40. Risk of bias per domain per study reporting condition-related hospital days



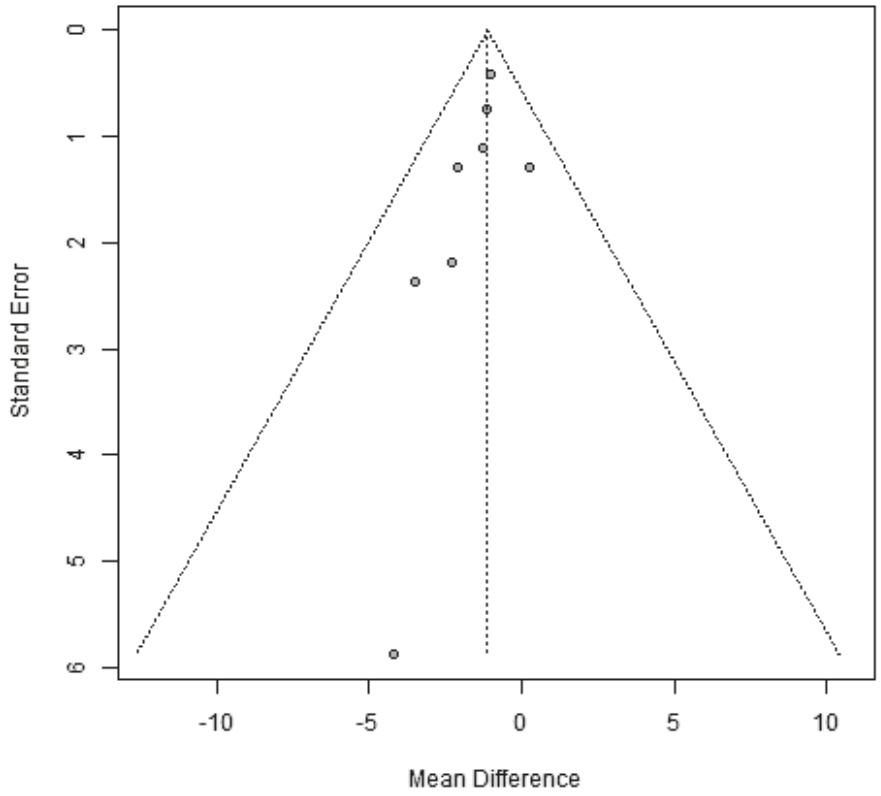
Multimedia Appendix 5. Figure 41. Weighted risk of bias summary for condition-related hospital days

More than 50% of the weight is accounted for by studies at low risk of bias in three out of the five domains. Thus, downgrading is not necessary.

Imprecision

Although the analysis included fewer than 2000 participants, the confidence interval does not overlap a null effect, so there does not seem to be a need to downgrade the quality of evidence.

Publication bias



Multimedia Appendix 5 Figure 42. Funnel plot for condition-related hospital days

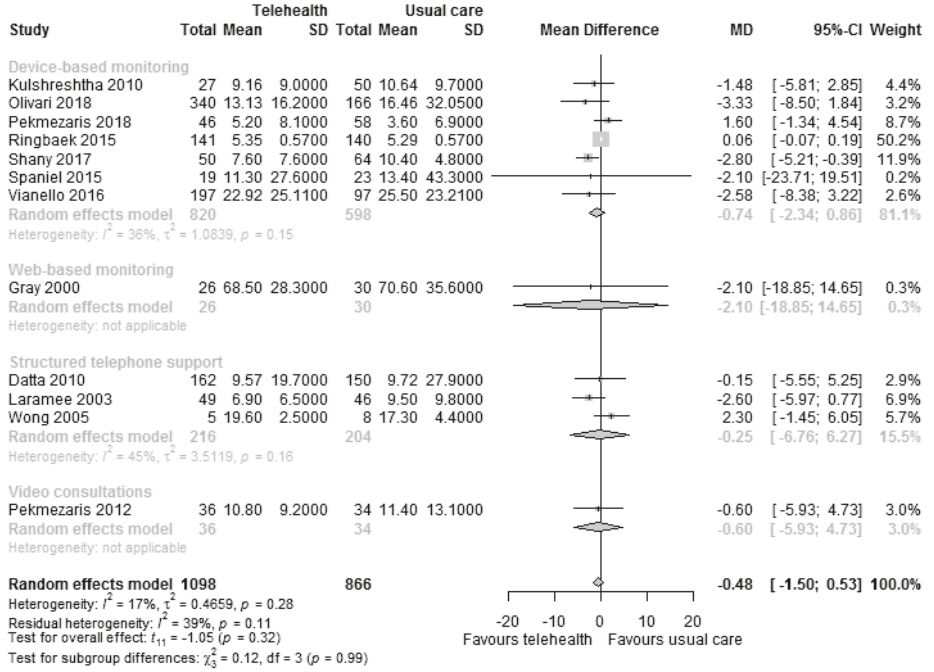
The funnel plot appears to be convincingly asymmetrical, which is why we downgrade the quality of evidence by 1 level for risk of publication bias.

Summary: Unexplained heterogeneity is well below the threshold value of 60%, imprecision is limited, and the majority of studies has a low risk of bias. However, we downgrade the quality of evidence by one level for risk of publication bias.

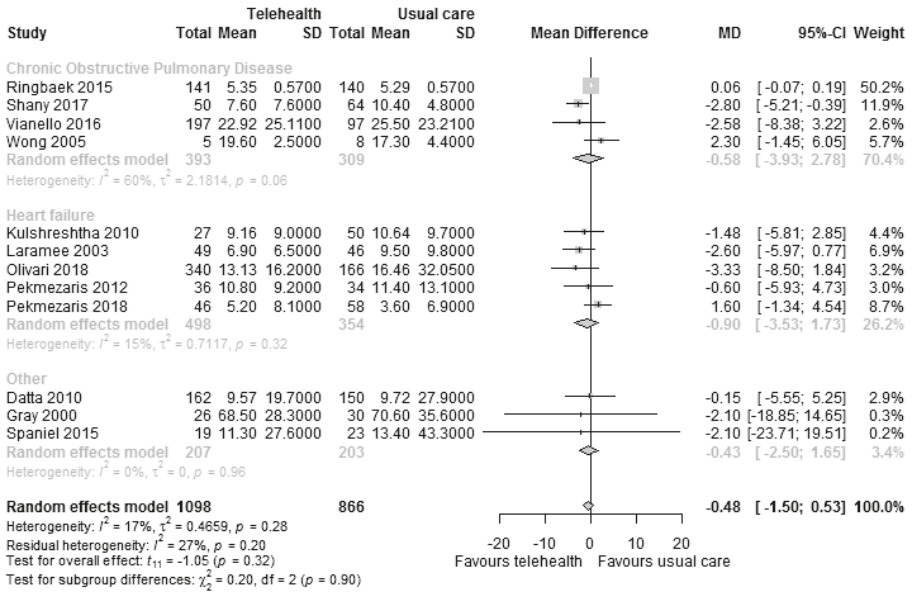
Overall judgement: Moderate quality of evidence

Length of all-cause hospital stay

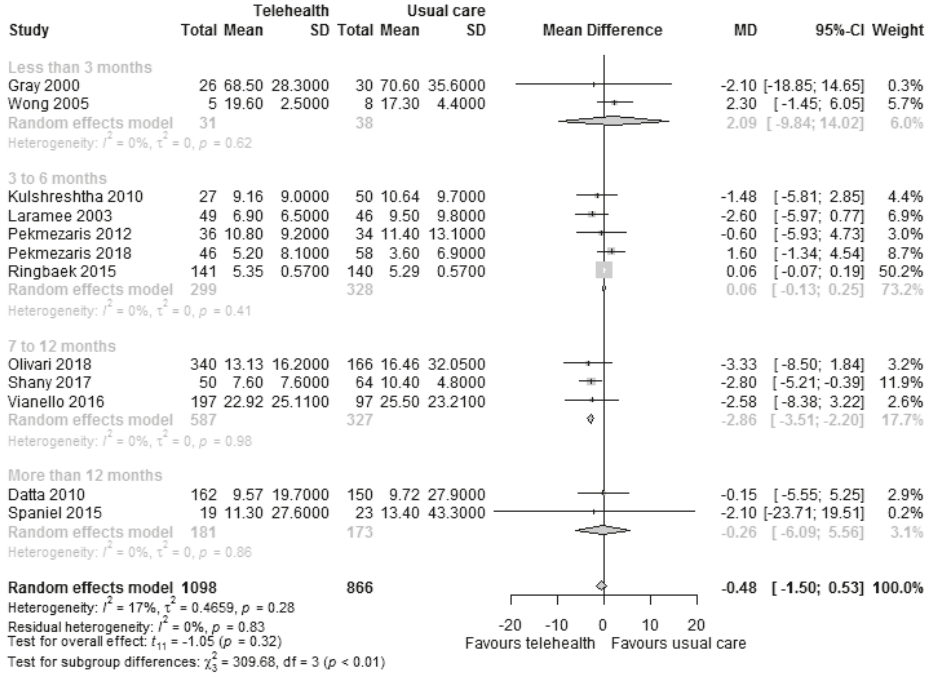
Inconsistency



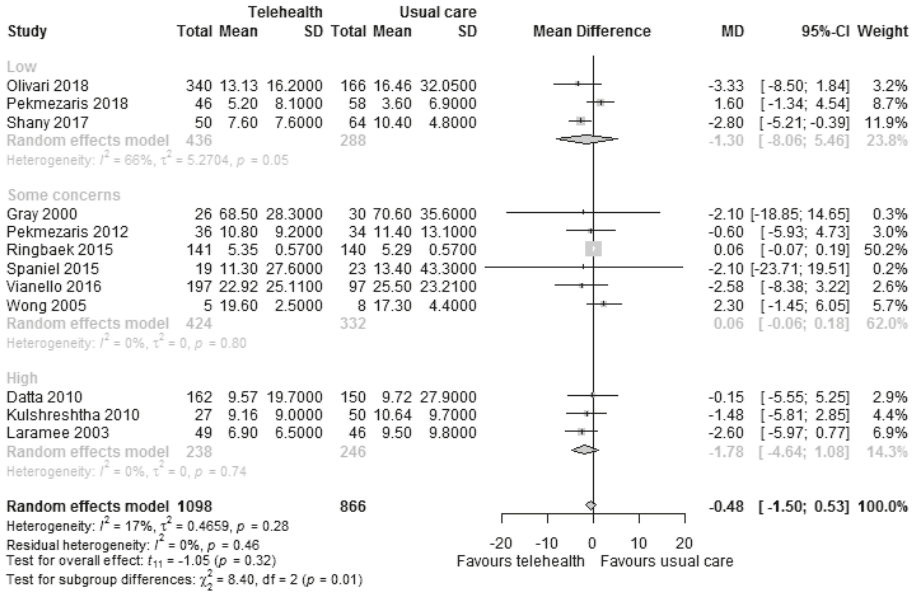
Multimedia Appendix 5. Figure 43. Forest plot for length of all-cause hospital stay for telehealth compared to usual care, stratified by telehealth type



Multimedia Appendix 5. Figure 44. Forest plot for length of all-cause hospital stay for telehealth compared to usual care, stratified by health condition



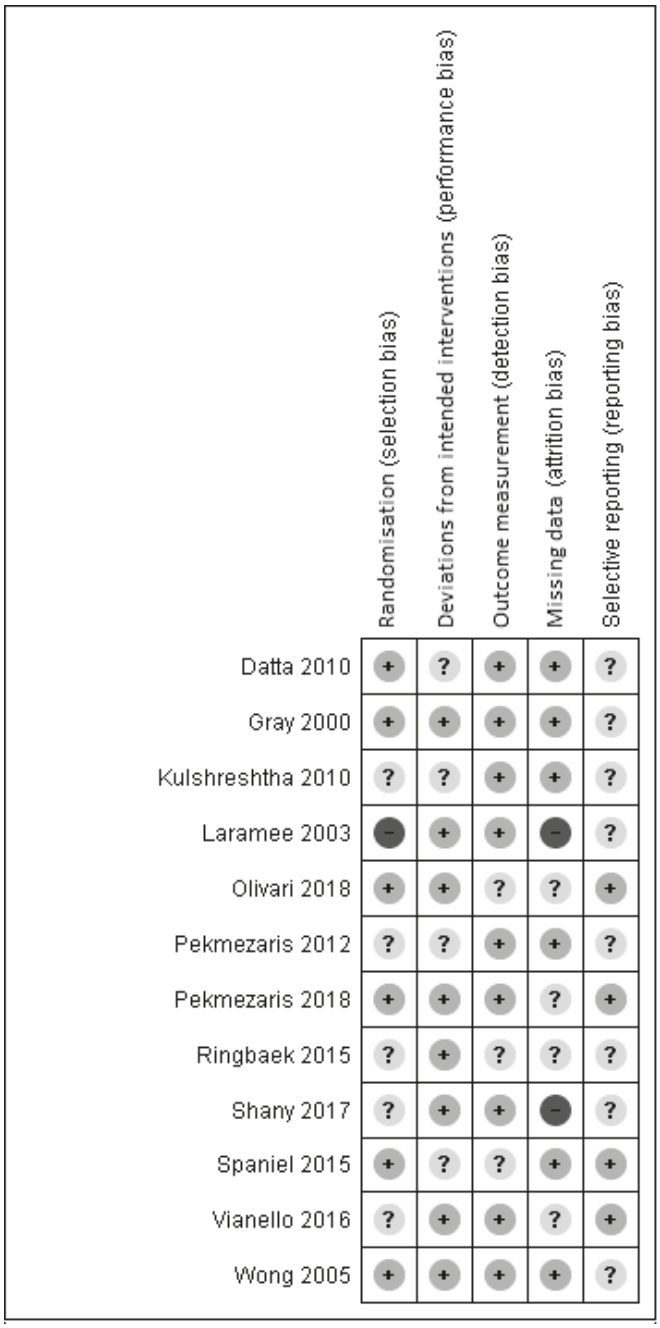
Multimedia Appendix 5. Figure 45. Forest plot for length of all-cause hospital stay for telehealth compared to usual care, stratified by health condition



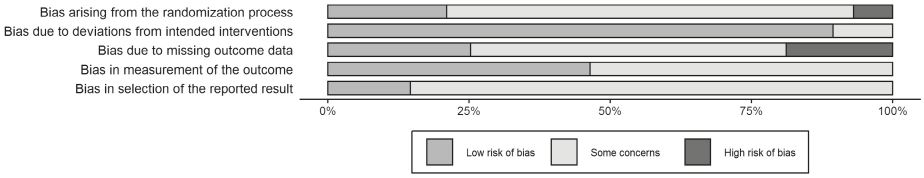
Multimedia Appendix 5. Figure 46. Forest plot for length of all-cause hospital stay for telehealth compared to usual care, stratified by risk of bias

The amount of unexplained heterogeneity is below 10% for each analysis. Furthermore, the majority of confidence intervals appears to overlap, and variation between point estimates seems limited. Therefore, there is no reason to downgrade quality of evidence for inconsistency.

Risk of bias



Multimedia Appendix 5. Figure 47. Risk of bias per domain per study reporting length of all-cause hospital stay



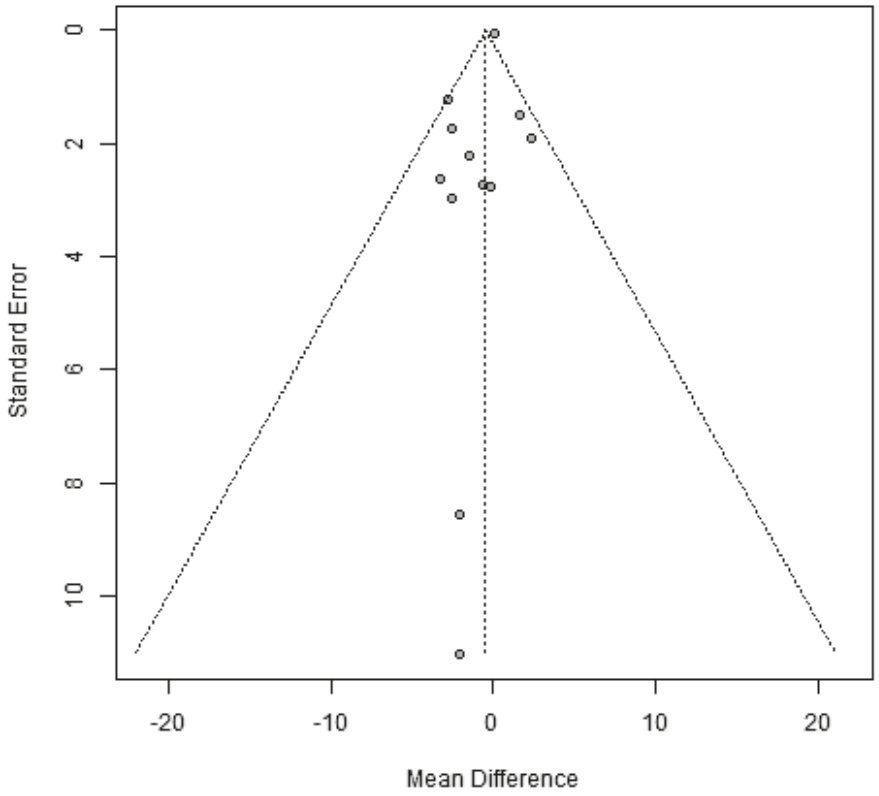
Multimedia Appendix 5 Figure 48. Weighted risk of bias summary per domain for length of all-cause hospital stay

Articles with some concerns regarding risk of bias accounted for a weight of more than 60% in 4 domains. Therefore, quality of evidence is rated down by one level for this aspect.

Imprecision

Because the confidence interval of the summary estimate overlaps no effect, and the analysis included less than 2000 participants, we downgrade the quality of evidence by 1 level.

Publication bias



Multimedia Appendix 5. Figure 49. Funnel plot for length of all-cause hospital stay

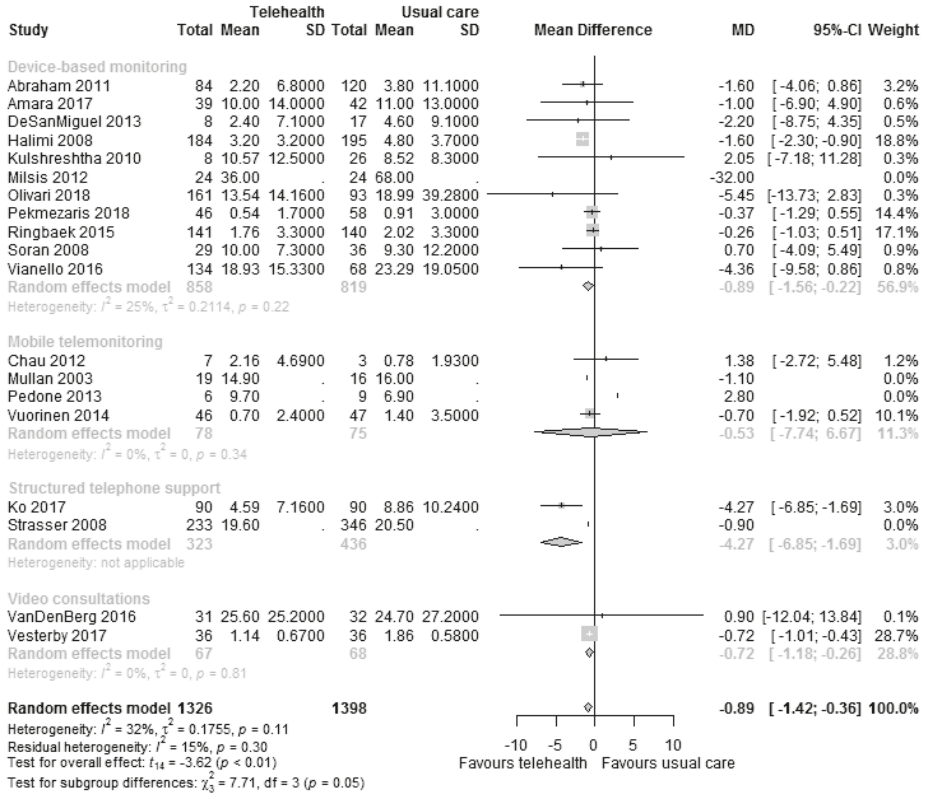
A limited amount of asymmetry can be observed in the funnel plot. However, as the GRADE guidelines recommend being very conservative when it comes to downgrading quality of evidence for publication bias, we consider this to be a close call, but do not downgrade the quality of evidence.

Summary: Unexplained heterogeneity is well below the threshold value of 60%. We downgraded quality of evidence by one level for imprecision, as the confidence interval overlaps a null effect, and fewer than 2000 participants were included in the meta analysis. We further downgraded quality of evidence for risk of bias, because articles with some concerns regarding risk of bias accounted for more than 60% of the weight for four domains. There may be some risk of publication bias, however we do not consider this sufficiently convincing to downgrade quality of evidence.

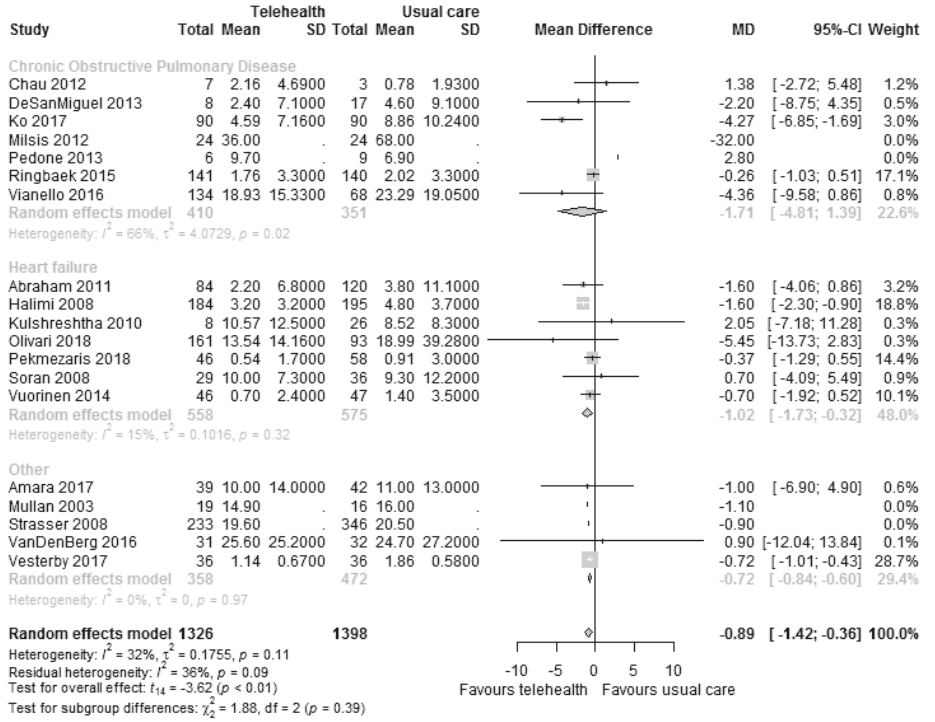
Overall judgement: Low quality of evidence

Length of condition-related hospital stay

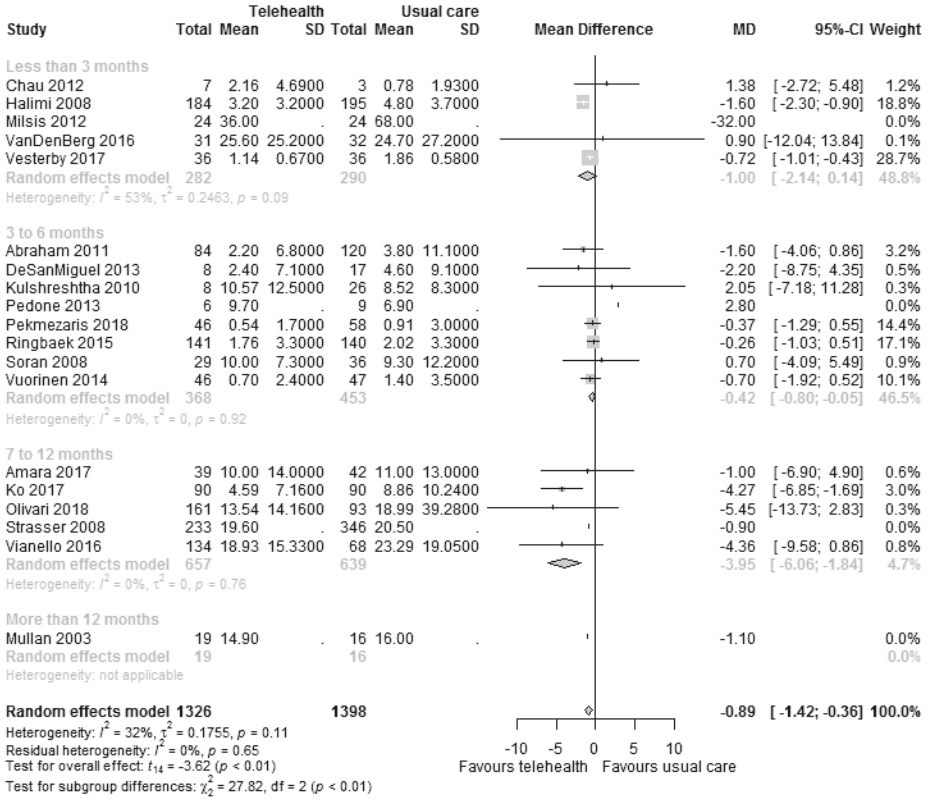
Inconsistency



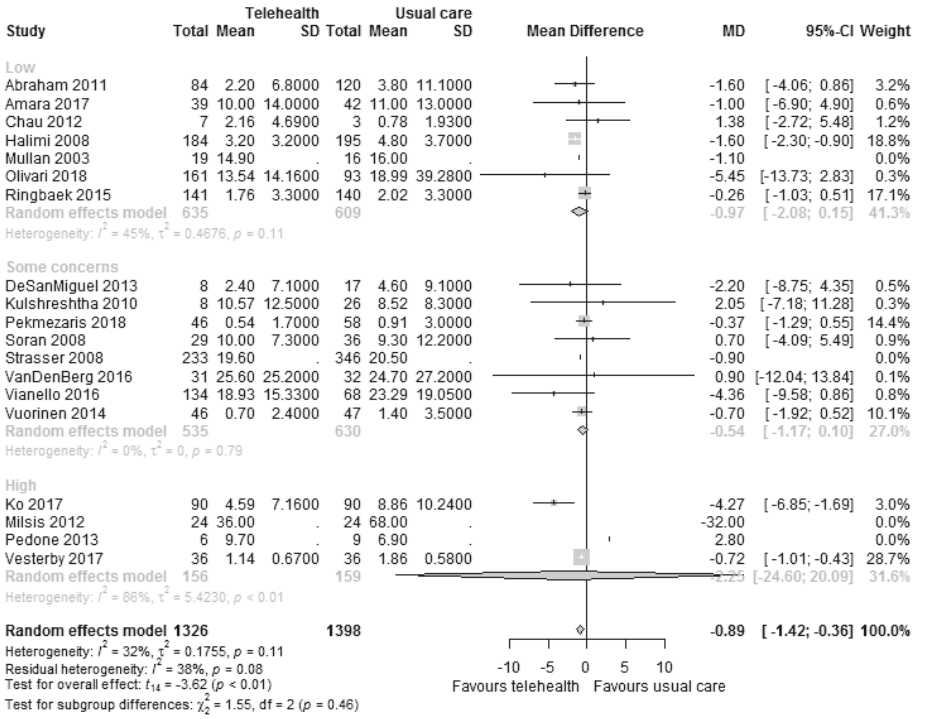
Multimedia Appendix 5. Figure 50. Forest plot for length of condition-related hospital stay for telehealth compared to usual care, stratified by telehealth type



Multimedia Appendix 5. Figure 51. Forest plot for length of condition-related hospital stay for telehealth compared to usual care, stratified by health condition



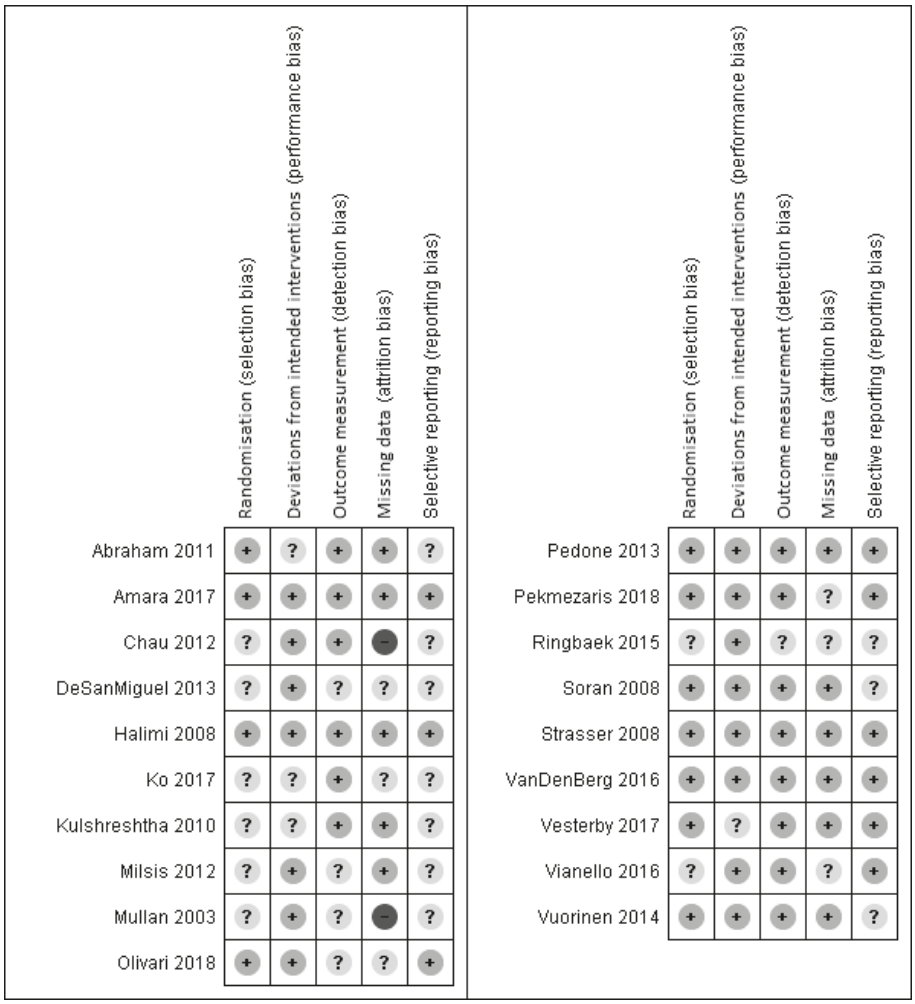
Multimedia Appendix 5. Figure 52. Forest plot for length of condition-related hospital stay for telehealth compared to usual care, stratified by length of follow-up



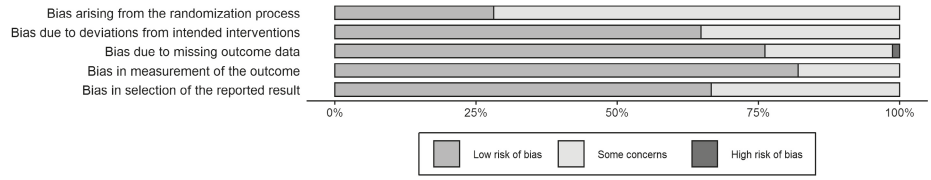
Multimedia Appendix 5. Figure 53. Forest plot for length of condition-related hospital stay for telehealth compared to usual care, stratified by risk of bias

Unexplained heterogeneity is below 15% for all analyses. Additionally, the majority of confidence intervals overlap, and variation in point estimates seems reasonable. Therefore, we do not downgrade for inconsistency.

Risk of bias



Multimedia Appendix 5 Figure 54. Risk of bias per domain per study reporting length of condition-related hospital stay



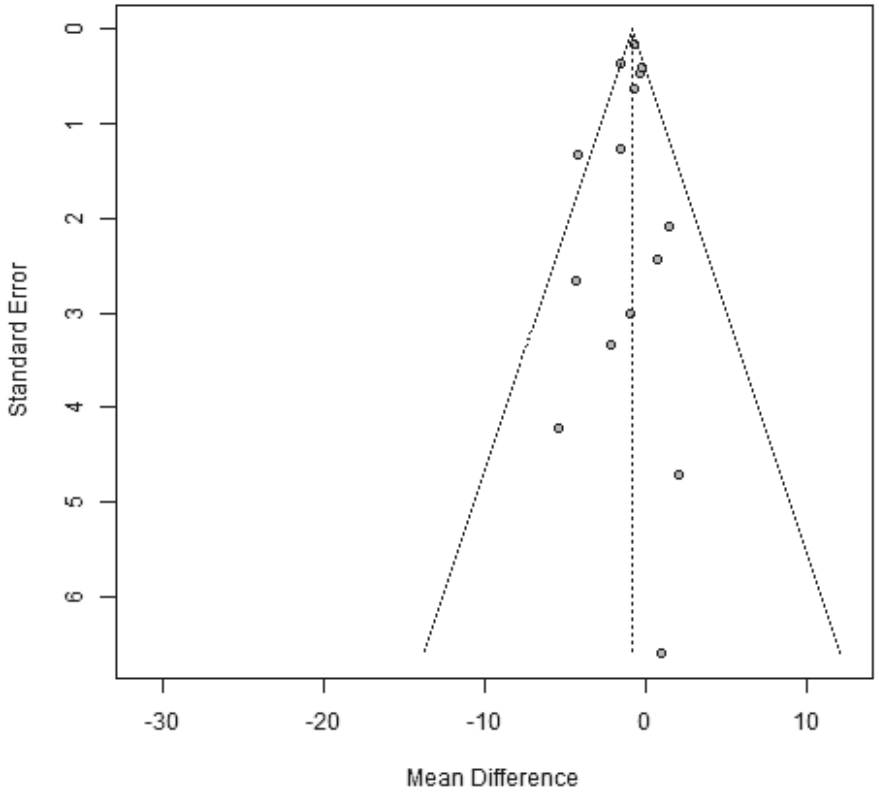
Multimedia Appendix 5. Figure 55. Weighted risk of bias summary per domain for length of condition-related hospital stay

More than 50% of the weight is accounted for by studies at low risk of bias in all domains except for randomization. Thus, we did not downgrade quality of evidence for risk of bias.

Imprecision

The confidence interval of the summary estimate does not overlap a null effect, and the analysis included more than 2000 participants, so there is no need to downgrade the quality of evidence for imprecision.

Publication bias



Multimedia Appendix 5. Figure 56. Funnel plot for length of condition-related hospital stay

Summary: Unexplained heterogeneity is below the threshold value of 60%, imprecision is limited owing to the large number of participants, the majority of studies has a low risk of bias, and risk for publication bias appears low.

Overall judgement: High quality of evidence

Multimedia Appendix 6 – Studies included in meta-analyses

1. Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet 2011;377(9766):658-66.
2. Al-Sutari MM, Ahmad MM. Effect of educational program on self-care behaviors and health outcome among patients with heart failure: An experimental study. International Journal of Evidence-Based Healthcare 2017;15(4):178-85.
3. Amara W, Montagnier C, Cheggour S, Boursier M, Gully C, Barnay C, et al. Early Detection and Treatment of Atrial Arrhythmias Alleviates the Arrhythmic Burden in Paced Patients: the SETAM Study. Pacing Clin Electrophysiol 2017;40(5):527-36.
4. Angermann CE, Störk S, Gelbrich G, Faller H, Jahns R, Frantz S, et al. Mode of action and effects of standardized collaborative disease management on mortality and morbidity in patients with systolic heart failure the interdisciplinary network for heart failure (INH) study. Circulation: Heart Failure 2012;5(1):25-35.
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Multimedia Appendix 7 – Hospitalization rates

Table 1. All-cause hospitalization rates as reported in the articles

	Telehealth		*Usual care*					
Author / year	**Rate**	**N**	**Rate**	**N**	**Rate difference (%)**	**Reported as**	**Health condition**	**Telehealth type**
Abraham 2011	0.32	270	0.44	280	−0.12 (−27.3%)	Rate per patient per 6 months	Heart failure	Device–based monitoring
Boriani 2017	86	437	90	428	−4 (−4.4%)	2–year rate per 100 patients	Heart failure	Device–based monitoring
Cross 2018a	2.7	116	11.2	117	−8.5 (−75.9%)	Rate per 100 participants per year	Inflammatory bowel disease	Mobile telemonitoring
Cross 2018b	0.9	115	11.2	117	−10.3 (−92%)	Rate per 100 participants per year	Inflammatory bowel disease	Mobile telemonitoring
Dario 2017	0.02	168	0.04	78	−0.02 (−50%)	Rate (not specified)	Type 2 diabetes	Device–based monitoring
Dewalt 2012	0.75	303	0.73	302	0.02 (+2.7%)	Rate of all–cause death or hospitalization per patient year	Heart failure	Structured telephone support
Sisk 2006	0.74	203	0.93	203	−0.19 (−20.4%)	Rate per patientyear	Heart failure	Structured telephone support
Ko 2017	1.75	90	2.59	90	−0.84 (−32.4%)	Rate per patientyear	COPD	Structured telephone support
Tompkins 2010	–	193	–	197	–	IRR (0.87)	Heart failure	Device–based monitoring
Wade 2011	1.21	164	1.19	152	0.02 (+1.7%)	Rate per patientyear	Heart failure	Device–based monitoring
Walker 2018	1.16	78	1.36	79	−0.2 (−14.7%)	Rate per patientyear	COPD	Device–based monitoring

Table 2. Condition-related hospitalization rates as reported in the articles

	Telehealth		*Usual care*					
Author / year	**Rate**	**N**	**Rate**	**N**	**Rate difference (%)**	**Reported as**	**Health condition**	**Telehealth type**
Böhm 2016	0.24	505	0.3	497	−0.06 (−20%)	Rate per patientyear	Heart failure	Device−based monitoring
Boriani 2017	56	437	58	428	−2 (−3.4%)	2−year rate per 100 patients	Heart failure	Device−based monitoring
Cordova 2016	35/10951	34	44/12012	33	−9 (−12.7%)	events / number of days in study	COPD	Device−based monitoring
Cross 2018a	9.8	116	16.4	117	−6.6 (−40.2%)	Rate per 100 patientyears	Inflammatory bowel disease	Mobile telemonitoring
Cross 2018b	14.4	115	16.4	117	−2 (−12.2%)	Rate per 100 patientyears	Inflammatory bowel disease	Mobile telemonitoring
Dario 2017	0.01	168	0.01	78	0	Rate (not specified)	Type 2 diabetes	Device−based monitoring
Dewalt 2012	0.27	303	0.3	302	−0.03 (−10%)	Rate per patientyear	Heart failure	Structured telephone support
Ko 2017	1.24	90	1.85	90	−0.61 (−33%)	Rate per patientyear	COPD	Structured telephone support
Pedone 2013	13	50	20	49	−7 (−35%)	Rate per 100 patientyears	COPD	Mobile telemonitoring
Phillips 2001	0.39	36	0.92	39	−0.53 (−57.6%)	Rate per patientyear	Spinal cord injury	Video consultations
Wade 2011	1.19	164	1.16	152	0.03 (+2.6%)	Rate per patientyear	Heart failure	Device−based monitoring

CHAPTER 5

Effectiveness of a mobile health and self-management app for high-risk patients with chronic obstructive pulmonary disease in daily clinical practice: mixed methods evaluation study

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ABSTRACT

Background

Mobile health and self-management interventions may positively affect behavioral change and reduce hospital admissions for patients with chronic obstructive pulmonary disease (COPD). However, not all patients qualify for these interventions, and systematic, comprehensive information on implementation- and compliance-related aspects of mobile self-management apps is lacking. Due to the tendency to target digital services to patients in stable phases of disease, it is especially relevant to focus on the use of these services in broad clinical practice for patients recently discharged from hospital.

Objective

This study aims to evaluate the effects of a mobile health and self-management app in clinical practice for recently discharged patients with COPD on use of the app, self-management, expectations, and experiences (technology acceptance); patients' and nurses' satisfaction; and hospital readmissions.

Methods

A prototype of the app was pilot tested with 6 patients with COPD. The COPD app consisted of an 8-week program including the Lung Attack Action Plan, education, medication overview, video consultation, and questionnaires (monitored by nurses). In the feasibility study, adult patients with physician-diagnosed COPD, access to a mobile device, and proficiency of the Dutch language were included from a large teaching hospital during hospital admission. Self-management (Partners in Health Scale), technology acceptance (Unified Theory Acceptance and Use of Technology model), and satisfaction were assessed using questionnaires at baseline, after 8 weeks, and 20 weeks. Use was assessed with log data, and readmission rates were extracted from the electronic medical record.

Results

A total of 39 patients were included; 76.4% (133/174) of patients had to be excluded from participation, and 48.9% of those patients (65/133) were excluded because of lack of digital skills, access to a mobile device, or access to the internet. The COPD app was opened most often in the first week (median 6.0; IQR 3.5-10.0), but its use decreased over time. The self-management element knowledge and coping increased significantly over time (P=.04). The COPD app was rated on a scale of 1-10, with an average score by patients of 7.7 (SD 1.7) and by nurses of 6.3 (SD 1.2). Preliminary evidence about the readmission rate showed that 13% (5/39) of patients were readmitted within 30 days; 31% (12/39) of patients were readmitted within 20 weeks, compared with 14.1% (48/340) and 21.8% (74/340) in a preresearch cohort, respectively.

Conclusions

The use of a mobile self-management app after hospital discharge seems to be feasible only for a small number of patients with COPD. Patients were satisfied with the service; however, use decreased over time, and only knowledge and coping changed significantly over time. Therefore, future research on digital self-management interventions in clinical practice should focus on including more difficult subgroups of target populations, a multidisciplinary approach, technology-related aspects (such as acceptability), and fine-tuning its adoption in clinical pathways.

Trial Registration: Clinicaltrials.gov NCT04540562; https://clinicaltrials.gov/ct2/show/NCT04540562.

INTRODUCTION

Background

Chronic obstructive pulmonary disease (COPD) affects over 250 million people worldwide [1] and almost 600,000 people in the Netherlands [2]. In 2020, it is expected to be the third leading cause of death worldwide [3]. COPD is a common disease characterized by persistent respiratory symptoms and airflow limitation due to airway and/or alveolar abnormalities [3]. The most common symptoms are dyspnea, chronic coughing, and sputum production [3-5]. An acute worsening of the symptoms is called an exacerbation [4,6]. Exacerbations lead to additional care [5] and often lead to hospital admission [7], with considerable costs involved [8].

Self-management interventions are also recognized to be important in reducing exacerbations [9] and hospital admissions [10,11], improving quality of life [9-11], and improving patients' control over their health [9]. Self-management skills can be beneficial for patients with COPD to manage their disease on a daily basis [12], for example, for medication use, breathing techniques, physical activity, and symptom recognition [13]. Effing et al [12] defined these interventions for patients with COPD as structured, personalized, and often multi-component, with goals of motivating, engaging, and supporting patients to positively adapt their health behaviors. Relevant features for self-management interventions include smoking cessation, recognition and treatment of exacerbation, increasing physical activity, nutrition advice, and management of dyspnea [14].

Mobile apps are increasingly being used to provide patients with health and self-management interventions, for example, for remote monitoring of patients' health status [15-17], self-report of symptoms or health status [16-18], education [16,19], and digital

support or feedback [15,17,18]. This is often combined with feedback from a health care professional or automated via the app [17-19]. Multiple reviews have analyzed the effectiveness of self-management interventions supported by mobile apps for patients with COPD on hospital admissions [15,18], exacerbations [15,16], length of hospital stay [18], behavioral outcomes [15,19], health-related outcomes [15,19], and quality of life [15]. The use of smartphones can be feasible in providing patients with self-management interventions [20,21] and to improve behavioral change [21]. A recent review reported the effects of smartphone interventions on exacerbations and showed that these interventions may decrease exacerbations, compared with usual care [16]. However, the findings remain inconsistent [17] due to heterogeneity among interventions [9,16,17,19,22], target populations [9,22,23], outcomes [9,22,23], and small sample sizes [16]. Further research and analysis on relevant apps for apps to support patients with COPD is necessary [24], as evidence is limited [15].

Until now, much attention has been given to the effects on clinical health outcomes [11,25-27] and hospital services [11,28,29]. Self-management behavior is also found to be important in reducing hospital admissions [30]. Factors affecting use in daily clinical practice, such as patients' satisfaction [31], technology acceptance [32,33], and health care professionals' satisfaction [34], were examined to a lesser extent. It also remains unclear which patients benefit most from these digital interventions [35,36]. It is suggested that it may be beneficial for patients experiencing frequent exacerbations [37]; nevertheless, stable patients with COPD are often the target population [38]. Patients experiencing a hospital admission due to an exacerbation may require a different approach, as they often experience feelings of distress during this time [39]. Additional evidence on this specific subpopulation is still needed [36], especially in combination with mobile health (mHealth) solutions [16]. Health care professionals' involvement is also essential for a successful self-management intervention in clinical practice [13].

Self-management interventions, which are increasingly supported by mobile apps in recent years, may improve disease management in patients with COPD and may decrease hospital admissions. However, not all patients qualify because of reasons such as socioeconomic status, internet access, and skills. Systematic, comprehensive information on implementation- and compliance-related aspects of mobile self-management apps is lacking. Additional evidence about the effectiveness of mobile self-management apps is needed, especially regarding factors affecting the use in clinical practice for high-use patients, such as those recently hospitalized due to an exacerbation.

Objectives

The objective of this study is to evaluate the effects of a mobile health and self-management app (*COPD app*) in clinical practice for patients with COPD, after discharge from the hospital, on app use, self-management, expectations and experiences (technology acceptance), patients' and nurses' satisfaction, and hospital readmissions.

METHODS

COPD app

The COPD app consisted of an 8-week health and self-management intervention, including the Lung Attack Action Plan, personalized medication overview, information about COPD, nutrition, physical activity, advantages of smoking cessation, weekly questionnaires monitored by nurses, and video consultation.

Pilot testing

Pilot testing was used to receive feedback on a prototype of the COPD app. A total of 6 patients, admitted to a large teaching hospital (Rijnstate, Arnhem) for a COPD exacerbation, were provided with a tablet and access to the app. Patients received assignments such as *Can you find and use the Lung Attack Action Plan*, *Can you find and open the questionnaire*, and *Can you find and read the information about nutrition*. We also asked their opinion about the information (eg, if they missed information elements), frequency of notifications they would prefer, the readability, the frequency of new information, and their sociodemographic characteristics. Before starting the feasibility study, results from the pilot testing were used to improve the COPD app.

Feasibility study–recruitment and eligibility criteria

Patients were recruited from a large teaching hospital (Rijnstate, Arnhem). To be eligible, patients must be older than 18 years, diagnosed for COPD by a physician, admitted to the hospital for a COPD exacerbation (generally considered high-risk patients), have access to a smartphone or tablet, have a working internet connection, being able to use a smartphone or tablet, and be proficiency in Dutch language. Patients with cancer or (severe) cognitive or psychiatric conditions were excluded. At least one hospitalization for COPD exacerbation in the year preceding this study was also a criterion for accrual, but it only applied during the first month (of the inclusion period) because the number of eligible patients was too low.

Study process

Patients were informed about the study by a pulmonary nurse and the researcher during hospital admission. Patients received the study information letter and were asked to sign

the informed form. They also received support to download apps. The *Patient Journey App* software (PJA version 4.0) [40] was used for the COPD app and *Facetalk* [41] for video consultation. The apps could be downloaded for free from the Google Play Store and the Apple App Store [41-43].

Intervention

The COPD app provided patients with an 8-week self-management program. The app had 3 views: timeline, information page, and contact page (see Multimedia Appendix 1). The start date was the date of discharge of each patient. The timeline was classified in 8 weeks, and each week included the Lung Attack Action Plan, personalized (daily and extra) medication overview, information and education, and questionnaires. The first week also included a video of a pulmonologist explaining the purpose of the app and additional information about the functionalities of the COPD app. After 8 weeks (until 20 weeks), patients remained accessible to the information in the app, but the questionnaires, medication overview, video consultation, and Lung Attack Action Plan (including contact request) were no longer accessible.

Timeline

The timeline consisted, in all weeks, of 5 elements: (1) *Lung Attack Action Plan*, (2) *Medication Overview*, (3) *Information and Education*, (4) *Questionnaires*, and (5) *Consultations*, in week 4 and 8 (see Multimedia Appendices 1 and 2).

Lung Attack Action Plan

The Lung Attack Action Plan was provided by the Lung Foundation (*Longfonds*) [44] and was digitalized in the COPD app. This action plan could help patients to recognize changes in their symptoms and guide them how to act upon these changes. The action plan consisted of different categories and colors: *I am doing well today* (green), *I feel worse* (yellow), *No improvement after 2 days* (orange), and *The situation is threatening* (red). All levels included advice about symptoms (eg, dyspnea, production of sputum, and coughing), medication, physical activity, and nutrition. Patients could access and use the Lung Attack Action Plan at any time using the COPD app. It was also possible to request contact with a pulmonary nurse after using the Lung Attack Action Plan. The nurse received a notification email and would contact patients within 2 working days.

Medication overview

Patients had access to an overview of their personal daily and extra medication.

Information and education

A total of 5 information categories were included in the timeline: the COPD app, the condition COPD, physical activity, nutrition, and advantages of smoking cessation. For each topic, a general page was accessible, including more specific topics. Patients were provided with information, in text and video, about the COPD app (eg, information about the different functionalities), COPD condition (eg, recognizing an exacerbation and accepting your lung condition), nutrition (eg, advice about protein-rich food), physical activity (eg, videos with exercises from a physiotherapist), and smoking cessation (eg, advantages of smoking cessation after 20 min and 1 month).

Questionnaires and monitoring

Patients were asked to fill out the weekly Clinical COPD Questionnaire (CCQ) and the Hospital Anxiety and Depression Scale (HADS) at weeks 1 and 8, using the app or via email. The results were monitored by nurses. The HADS was used to measure anxiety and depression The HADS is a 14-item screening list that consists of two 7-item subscales. The items are rated on a 4 point Likert scale (range 0-3) [45,46]. The CCQ is a self-administered questionnaire used to assess patients' clinical control. The CCQ is a 10-item scale with 3 domains: functional state, symptoms, and mental state, rated on a 7-point scale (0: no limitation to 6: totally limited). The CCQ score was calculated as the mean of the sum of all items [47]. The first CCQ was completed during hospital admission and repeated weekly. The nurses checked the scores weekly, and if a score was >2 and increased since the previous week, they contacted the patient.

Consultations

A video consultation was planned after 4 weeks with a pulmonary nurse, and a face-to-face consultation was planned after 8 weeks with a nurse practitioner or a pulmonologist. Patients could also request additional video consultations and telephonic consultations using the COPD app.

Information page

The information page contained an overview of the information elements: Lung Attack Action Plan, the COPD app, condition COPD, nutrition, physical activity, smoking cessation, and information about video consultation. The information elements were presented in a list format, with a search function. See Multimedia Appendices 1 and 3.

Contact page

The contact page presented 2 elements for patients: (1) the Lung Attack Action Plan and the option to request contact with a pulmonary nurse or (2) directly request telephonic

contact with a nurse. Nurses received an email and contacted the patients within 2 working days. See Multimedia Appendices 1 and 4.

Outcome measures

Use of the COPD app

Use of the COPD app is measured with log data. Use is reported as the number and percentage of patients and the number of times, described as page clicks, the app and the information items were opened. The number of times the Lung Attack Action Plan, contact request, and CCQ questionnaires were used is described with absolute and relative numbers.

Patient satisfaction

Patients completed questionnaires about satisfaction with app use, the information provided, and user-friendliness. This is assessed on a 7-point scale (1: totally disagree to 7: totally agree). Patients were also asked about their overall satisfaction on a scale of 1 to 10 (1: not satisfied at all to 10: very satisfied). See Multimedia Appendix 5 for the questionnaire.

Self-management

The Partners in Health (PIH) scale was used to measure self-management [48,49]. The PIH is a 12-item scale, and the Dutch version consists of 2 subscales: (1) knowledge and coping and (2) recognition and management of symptoms, adherence to treatment. The Cronbach alphas of the subscales were .80 (knowledge and coping) and .72 (recognition and management of symptoms, adherence to treatment). The correlation between the subscales was 0.43. The items are rated on a 9-point Likert scale (0: low self-management and 8: high self-management). The first subscale consists of 7 items, and the second subscale consists of 5 items [49]. The total score for both subscales was calculated by taking the sum of the respective items.

Expectations and experiences with the COPD app

Questionnaires covering constructs of the Unified Theory of Acceptance and Use of Technology (UTAUT) [50] model were used to measure expectations (baseline) and experiences (weeks 8 and 20) with using the COPD app. The UTAUT consists of 4 constructs that influence behavioral intention and behavior: (1) performance expectancy, (2) effort expectancy, (3) social influence, and (4) facilitating conditions. A total of 8 questions were rated on a 7-point scale (1: totally disagree to 7: totally agree). See Multimedia Appendix 6 for the questionnaires.

Satisfaction of nurses

After all patients were included and completed the 8-week self-management program, we asked involved pulmonary nurses about their experience with the COPD app, video consultation, experience with monitoring the CCQ scores, and their satisfaction with for example efficiency and time investment.

Hospital readmissions

A hospital readmission was defined as admission for at least 24 hours. The number of hospital admissions was obtained from the electronic medical record (EMR) after 30 days, 8 weeks, and 20 weeks. This was compared with the readmission rate from the previous year, November 2017 to November 2018.

Other outcomes

Patients' age, Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage, and comorbidities were extracted from the EMR. Their marital status, education, internet use, smartphone or tablet skills, and need for support using a smartphone or tablet were assessed using a questionnaire.

Data collection

Use was assessed using log data, extracted from the app software, after 8 and 20 weeks. Patients completed a baseline questionnaire during hospital admission, covering aspects of self-management (PIH), expectations with the COPD app, internet use, smartphone or tablet skills, and sociodemographics. After 8 weeks and 20 weeks, a questionnaire was sent on self-management, experiences with the app, and (overall) satisfaction. After 30 days, 8 weeks, and 20 weeks, the readmission rate was assessed, and data were extracted from the EMR. See Table 1 for an overview of the outcomes and measurement time points.

Table 1. Outcomes and measurement time points.

Outcome	Measurement instrument	Baseline	30 days	Week 8	Week 20
Use of the COPD app	Log data	—[a]	—	—	—
Self–management	PIH[b] scale	●[c]	X[d]	●	●
Expectations with the COPD[e] app	Questionnaire (UTAUT[f] constructs)	●	X	X	X
Experiences with the COPD app	Questionnaire (UTAUT constructs)	X	X	●	●
Satisfaction (functionalities of the COPD app)	Questionnaire	X	X	●	X
Overall satisfaction	10–point scale	X	X	●	●
Readmissions	EMR[g]	X	●	●	●

[a]—: Weekly assessment from baseline until 20 weeks.
[b]PIH: Partners in Health.
[c]Outcome measurement.
[d]No outcome measurement.
[e]COPD: chronic obstructive pulmonary disease.
[f]UTAUT: Unified Theory of Acceptance and Use of Technology.
[g]EMR: electronic medical record.

Statistical analysis

Data analysis was performed using IBM SPSS V22.0. Descriptive statistics were used to report the baseline characteristics, app use, expectations and experiences, satisfaction, and number of readmissions. Changes in self-management over time were analyzed using a linear mixed model. Using a linear mixed model allowed for the inclusion of cases with missing data. The relation between app use and self-management was analyzed using linear regression. Normally distributed variables were reported as mean and standard deviation, and non-normally distributed data were reported with medians and interquartile ranges (25th-75th percentiles).

Approval and ethical considerations

The study was approved by the local ethical committee *Commissie Mensgebonden Onderzoek Arnhem–Nijmegen*.

RESULTS

Pilot testing

A total of 6 patients participated in the pilot testing of a prototype of the COPD app: 3 men and 3 women. The age range was 58-78 years. A total of 4 patients used the internet (almost) every day and 2 patients (less than) 1 day per week. Moreover, 3 patients used a smartphone or tablet (almost) every day, 1 patient multiple days per week, and 2 patients never. Furthermore, 3 out of 6 patients perceived their smartphone or tablet skills not good or not bad, 1 bad, and 1 good. In addition, 3 (out of 6) patients did not miss information items in the COPD app.

The information was categorized per day in the prototype, meaning that a new information item was presented daily. During the assignments and observations, we found that it was not easy for patients to find information because the timeline was very long. A total of 4 (out of 6) patients preferred to receive all information items in 1 overview, ordered by information category (eg, nutrition). On the basis of the findings, we categorized the information per category (eg, nutrition, physical activity) instead of per day. To increase ease of use, the 8-week program was classified per week instead of per day. Patients' opinion about the frequency of receiving a notification varied. Therefore, we decided to send a weekly reminder about the Lung Attack Action Plan and a reminder to fill out the weekly CCQ questionnaire.

Feasibility study–patient recruitment

Inclusion took place from November 19, 2018, to December 13, 2019. A total of 174 patients were assessed for eligibility. Moreover, 81 patients did not meet the inclusion criteria because they had no access to a smartphone or tablet (n=41), were not able to use a smartphone or tablet (n=19), no working internet connection (n=5), no proficiency in Dutch language (n=9), cancer, (severe) cognitive disability or psychiatric condition (n=7), or other reasons (n=24 eg, hospital admissions were too short, unclear diagnosis, or no reason was reported). In total, 28 patients declined to participate. Moreover, 2 patients signed the informed consent form, but they were excluded because the COPD app could not be installed on their smartphone or tablet. In total, 39 patients started the intervention. One patient died during the first 8 weeks, and 1 patient died before 20 weeks. Therefore, 39 patients were included in the analysis until 8 weeks, 38 patients were included in the analysis at week 8 and from week 8 to week 20, and 37 patients were included in the analysis at 20 weeks (Figure 1).

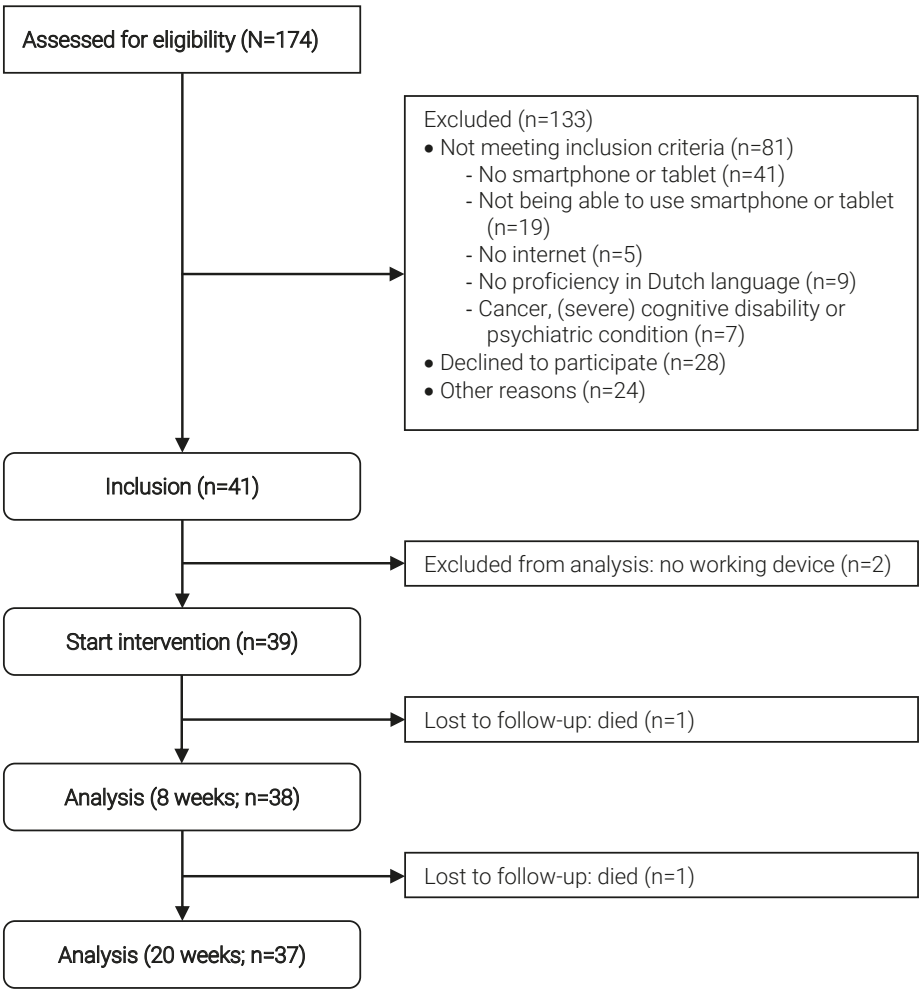

Figure 1. Flow diagram.

Baseline characteristics

The baseline characteristics of the population included in the feasibility study are presented in Table 2.

Table 2. Baseline characteristics (N=39).

Baseline characteristics	Patients
Gender, n (%)	
Women	30 (77)
Men	9 (23)
Age (years), mean (SD)	62.2 (6.7)
Severity classification, n (%)[a]	
Moderate (GOLD stage 2)	7 (18)
Very severe (GOLD stage 3+4)	32 (82)
Living with a partner, n (%)[a]	25 (68)
Having children, n (%)[a]	34 (92)
Children living at home, n (%)[a]	10 (30)
Education, n (%)[a]	
Low (primary school)	12 (32)
Middle (high school or vocational education)	22 (60)
High (higher vocational education or university)	3 (8)
Comorbidities, n (%)[a]	
Hypertension	7 (18)
Depression	3 (8)
Diabetes	2 (5)
Asthma	2 (5)
Heart disease	2 (5)
Reuma	2 (5)
Internet use (duration), n (%)[a,b]	
<6 months	2 (5)
6 months to 2 years	2 (5)
>2 years	2 (5)
>3 years	31 (84)
Frequency of internet use, n (%)[a]	
Almost every day	32 (86)
Multiple days a week	3 (8)
About 1 day a week	1 (3)
Never	1 (3)

Table 2. Continued.

Baseline characteristics	Patients
Smartphone or tablet skills, n (%)[a,b]	
Bad and/or very bad	7 (19)
Not good and/or not bad	16 (44)
Good and/or very good	13 (36)
Expects to need help with smartphone or tablet use, n (%)[a]	21 (58)

[a]Reported as valid percentage.
[b]Does not add up to 100% because of rounding.

Use

The use of the COPD app, questionnaires, and consultations is described in more detail below and is presented in Table 3.

Table 3. Overview of the use of the chronic obstructive pulmonary disease app functionalities (N=39).

Functionalities	Patients, n (%)
COPD[a] app use	
Week 1	39 (100)
Week 2	33 (85)
Week 3	32 (82)
Week 4–8	31 (79)
CCQ[b] questionnaires	
9 weekly CCQ questionnaires completed	29 (74)
8 weekly CCQ questionnaires completed	3 (8)
7 weekly CCQ questionnaires completed	4 (10)
<7 weekly CCQ questionnaires completed	3 (8)
HADS[c]	
Week 1: questionnaire completed	35 (90)
Week 8: questionnaire completed	33 (85)
Video consultation (week 4)	
Video consultation	17 (44)
Telephonic consultation	13 (33)
No video consultation	9 (23)
Face–to–face consultation (week 8)	

Table 3. Continued.

Functionalities	Patients, n (%)
Face–to–face consultation	27 (69)
Telephonic consultation	1 (2)
No face–to–face consultation (canceled)	11 (28)
Lung Attack Action Plan (week 1–8)	
Use Lung Attack Action Plan and request for contact	9 (23)
Contact with a nurse as a result of the use of the Lung Attack Action Plan	9 (100)
Contact page (week 1–8)	
Request for contact using contact page	3 (8)
Contact with a nurse as a result of the use of the contact page	3 (100)

[a] COPD: chronic obstructive pulmonary disease.
[b] CCQ: Clinical COPD Questionnaire.
[c] HADS: Hospital Anxiety and Depression Scale.

COPD app

The use of the COPD app varied widely across patients. The app was opened most often during the first week (median 6.0; IQR 3.5-10.0). However, use decreased over time. The app was opened by the majority of patients during the first 8 weeks, varying from 100% (39/39) in the first week to 79% (31/39) in week 8. Patients read information most frequently during the first week, especially regarding the functionalities in the COPD app (27/39, 69%), physical activity (24/39, 62%), the condition COPD, nutrition, and the Lung Attack Action Plan (22/39, 56%). See Multimedia Appendix 7 for detailed information.

Questionnaires (CCQ and HADS) and monitoring

In total, 29 patients filled out all the weekly CCQ questionnaires (in total 9 times including baseline), 3 answered the CCQ during 8 weeks, 4 answered the CCQ during 7 weeks, 1 answered the CCQ during 6 weeks, and 2 answered the CCQ during 2 weeks. A total of 35 patients filled out the HADS in week 1 (after discharge) and 33 after 8 weeks. Two patients reported that they did not want to fill out the questionnaires anymore during the study, and 1 patient died 7 weeks after discharge. The monitoring of the scores was used inconsistently, and therefore, the results do not offer a meaningful contribution.

Consultations

A total of 17 patients attended the planned video consultation 4 weeks after discharge. For 13 other patients, this was replaced by a telephonic consultation because of problems with the video consultation system (eg, technical issues or lack of skills from nurses or

patients); 2 patients did not want a video consultation; 1 patient visited the hospital instead; 1 patient's consultation was canceled because of hospital readmission; 1 patient left the digital waiting room because the nurse was too late; 1 patient was not available; and for 3 patients, a reason for cancelation was not reported.

A total of 27 patients attended their face-to-face consultation after approximately 8 weeks. For 11 other patients, the appointment was canceled because patients did not show up (n=5), because of readmission (n=3), two patients canceled the appointment, and 1 patient died. For 1 patient, this consultation was replaced by a telephonic consultation because the patients did not feel fit enough to come to the hospital.

In total, additional contact with a nurse was requested 19 times. A total of 9 patients used the Lung Attack Action Plan 15 times (13 times code yellow and 2 times orange), and 3 patients used the contact form 4 times to request contact with a nurse. See Multimedia Appendix 7 for more details on the use of the Lung Attack Action Plan.

Satisfaction

The COPD app was rated, on a scale of 1 to 10 (1: not satisfied at all to 10: very satisfied), with a 7.7 (SD 1.7) after 8 weeks and 7.0 (SD 2.4) after 20 weeks. Patients thought the app was easy to use and well-structured (26/28, 93%). Almost all patients reported that the Lung Attack Action Plan was easy to find (27/28, 96%) and easy to use (25/27, 93%), and more than half of the patients thought it actually helped them (18/27, 67%). The majority of patients also thought that the information was understandable (27/29, 93%), and all the patients (29/29, 100%) were satisfied with the information about nutrition. According to 33% (9/27) of patients, too much information was available in the COPD app. The majority of patients were satisfied with the video consultations (18/23, 78%) and thought it saved them time (19/29, 66%). See Multimedia Appendix 8 for more detailed information.

Self-management

Knowledge and coping increased significantly over time (P=.04). However, there was no significant change in the recognition and management of symptoms (P=.14). See Multimedia Appendix 9.

Relation between app use and self-management

No relation was not found between use of the app, the number of times the app was opened (mean page clicks during week 1-8), and the self-management elements *knowledge and coping* (P=.75) and *recognition management and adherence* (P=.92).

Expectations and experiences with the COPD app (technology acceptance)

Patients' expectations with the COPD app were relatively high. However, only 2 aspects improved over time. After using the app, more patients thought that it takes no effort to use it and that they had enough skills to use it. However, most aspects related to receiving support using the app decreased over time. See Multimedia Appendix 10 for more detailed information.

Satisfaction of nurses

The use of the COPD app and monitoring of the weekly questionnaires were evaluated with 3 nurses. They rated the COPD app, on a scale of 1 to 10 (1: not satisfied at all to 10: very satisfied), on average with a 6.3 (SD 1.2) Most of them were satisfied with the app (2/3, 67%) and the information provided (2/3, 67%) and thought that better care was provided using the COPD app (2/3, 67%). However, use of the COPD app did not save time (3/3, 100%). They received a lot of questions from patients (3/3, 100%), and they mentioned that it took them a lot of time to explain it and answer questions (2/3, 67%). They also reported:

> *Unfortunately not applicable for our target population, the app is good.*
> *How simple it seemed to use, how difficult it appeared to be for patients.*

Only 1 nurse would recommend the COPD app to more patients. The nurses would not recommend it to their colleagues.

The nurses were less satisfied with monitoring the results of the questionnaires and rated this with a 5.3 (SD 0.58), on a scale of 1 to 10 (1: not satisfied at all to 10: very satisfied). Only 1 nurse thought that monitoring the results of the questionnaires fitted well in their work process. They commented:

> *Plan more time for nurses to monitor the questionnaires.*
> *It is often unclear for patients what they have to fill out. Sometimes patients were surprised when they got a call, because they felt good.*

The nurses were less satisfied with the video consultations and mentioned the following:

> *This was very difficult, very unclear for patients, took a lot of time and often a telephonic consultation was needed.*
> *Many patients did not understand how to start a video consultation.*

Hospital readmissions

In total, 39 patients were included in the study. A total of 12 patients (12/39, 31%) were readmitted 22 times during the study period (20 weeks), of which 5 patients (5/39, 13%) were readmitted 1 time in the first 30 days. Within 8 weeks, 8 patients (8/39, 21%) were readmitted 11 times. In the total study period (until 20 weeks), there were 22 readmissions for 12 patients (12/39, 31%). The main reasons for readmissions was COPD exacerbations, and 1 time it was due to a patient's home situation.

In the year preceding the study, from November 2017 to November 2018, 340 patients were admitted 478 times to the hospital. In total, 48 patients (48/340, 14.1%) were readmitted 77 times within 30 days. There were 103 readmissions within 8 weeks for 61 patients (61/340, 17.9%), and 74 patients (74/340, 21.8%) were readmitted 129 times within 20 weeks.

DISCUSSION

Principal findings

In this study, a mobile self-management app for high-risk patients with COPD was evaluated in daily clinical practice. The COPD app was opened most often in the first week (median 6.0; IQR 3.5-10.0), but its use decreased over time (median 2.0; IQR 1.0-3.5 in week 8). Information, especially on physical activity (24/39, 62%), was read most often during the first week. The self-management element *knowledge and coping* increased significantly over time (*P*=.04), but a relation with app use was not found (*P*=.75). No significant change was found in *recognition and management of symptoms, adherence to treatment* (*P*=.14), or in relation with app use (*P*=. 92). Patients rated the COPD app on average with a 7.7 (SD 1.7) and nurses with a 6.3 (SD 1.2). Preliminary evidence about readmission rate showed that 13% (5/39) of patients were readmitted within 30 days, 21% (8/39) within 8 weeks, and 31% (12/39) within 20 weeks compared with 14.1% (48/340), 17.9% (61/340), and 21.8% (74/340), respectively, in a preresearch cohort.

Comparison with prior work

The use of mobile apps itself is not applicable to all patients [51,52]. In total, 37.4% (65/174) of all patients in our study had to be excluded because of lack of access to a mobile device or internet or skills to use it. This is in line with other findings of mHealth use in patients with COPD, in which only a minority owned a smartphone (23%) [53]. Technical issues and low compliance are recognized issues for digital interventions [54], and digital literacy among patients with COPD remains a challenge [52]. As a result of the pilot testing, the app we implemented was already simplified. However, digital literacy may still have been an issue during this study. Therefore, ease of use seems to be an essential element in

digital interventions for this patient population [20,27]. A total of 16.1% (28/174) of those possibly qualifying declined to participate, among other things, because it was too much of a burden or effort at the time. Patients may have experienced high levels of distress after experiencing an exacerbation [55], and therefore, they may be less willing to engage in a self-management intervention [38]. Therefore, these interventions are not applicable to all patients who are recently discharged from the hospital [38], as they may still feel (too) sick and/or are not able to focus on the intervention [34]. This emphasizes the importance of timing [39] and tailoring [56] an intervention.

Until now, the effects of self-management interventions on patients recently discharged from the hospital were scarcely evaluated [38] in combination with mobile apps. The direct effects [57] of app supported self-management and health interventions, for example, technology acceptance, self-management, and patients' and nurses' satisfaction are relevant for use in clinical practice. We found that the app was especially used during the first week after discharge. The Lung Attack Action Plan (9/39, 23%) and request for contact using the contact page (3/39, 8%) were used to a limited extent. However, the majority (29/39, 74%) completed the weekly CCQ questionnaires during the whole intervention period and the HADS in week 8 (33/39, 85%). Patients received frequent reminders by email, in the app and sometimes from nurses, to complete the questionnaires. The use of the COPD app and the Lung Attack Action Plan was more optional, rather at patients' own initiative. Receiving feedback can be important [56], and this may explain that the majority of patients completed the questionnaires, but that the use of the COPD app decreased over time. Low frequency of use can also be due to lack of self-management or technological skills [56].

Social support is seen as a facilitator for use [32,52]. The majority of the patients (28/37, 76%) expected to receive enough help using the COPD app. However, only 57% (17/30) of the patients indicated that they had received enough help (Multimedia Appendix 10). Tailored education can also facilitate use [52], but in this COPD app, only the medication overview was really personalized. Although the information items were aimed at high-risk patients with COPD, the information was generic. This might have contributed to the decrease in use. Tailored interventions [56], support [30], and patient engagement during development and implementation [56,58] may be beneficial for improved use.

A positive effect was found on knowledge and coping, which may partly be explained by the selection criteria for this study, as patients with cognitive disability and lack of skills with a mobile device were excluded. In addition, the provision of timely information using a mobile device can positively influence knowledge [59]. Self-management can also be enhanced by involving patients' partners, enhancing self-efficacy, and support from health

care professionals [30]. Although positive results on hospital readmissions were found in previous studies [6,18], these findings were inconsistent [15,28,60], which could be due to high methodological heterogeneity [16,19]. In our study, no large difference was observed, possibly due to low numbers. It would be interesting to verify the element of selection bias in view of the large percentage of patients that were excluded from this population.

Patients were satisfied with the COPD app, user-friendliness, and information. However, nurses addressed some concerns, for example, the increased workload and (lack of) integration in the work process. It is common that the degree of satisfaction between patients and health care professionals can differ. In general, patients report more favorable outcomes because mobile interventions are often provided as an extra service in addition to their usual care. For that same reason, health care professionals are generally less satisfied, especially because they often see it as an increase in workload [61]. The nurses in our study addressed concerns about the monitoring of the results of the questionnaires because they experienced a lack of integration in their work processes. Often a common pattern with the introduction of new innovations, this intervention was an addition to their current activities. Another reason might be that nurses had to work with different information technology systems that were not connected to the EMR. Lack of interoperability can be a barrier [58] for use, and this might explain the lack of monitoring of the first phase of the study. This improved after they received the scores in person by email. Health care professionals' adoption is essential to ensure success; therefore, they should be involved in the development and implementation process [56].

COPD management requires a multidisciplinary approach that is fragmented [24], and this approach is often not sufficiently supported by information technology [62]. Therefore, future research should focus on self-management interventions with a multidisciplinary approach tailored to individual patients recently discharged from the hospital. Pragmatic trials [63] can be used to determine, at a more rapid pace, which elements of self-management interventions are effective for which subgroups of patients with COPD recently discharged and which characteristics of mHealth solutions are adopted by both patients and health care professionals. Subsequently, a larger controlled study specifically involving this frail subgroup of patients should focus on the effects on clinical outcomes and hospital services use (eg, readmissions).

Limitations

Due to accrual issues, especially related to device availability and internet access, the COPD app was evaluated in a small sample, so we could not reach the power originally calculated for this trial. In addition, nurses found it difficult to comply with the contacting rules, so there were inconsistencies in the follow-up monitoring using the CCQ questionnaires.

Some patients were only contacted a limited number of times when they had a high score on the CCQ questionnaire. After approximately 20 patients, we decided to send nurses a notification by email with the scores, and they were asked to take up contact (if necessary). As a consequence of the team setting, only 3 nurses were involved in this study, and we have to be careful about the related outcomes. Preliminary evidence on readmission rates was provided based on an earlier cohort, but this was not a matched exercise. Therefore, definitive conclusions on this aspect cannot be drawn.

Conclusions

The integration and use of a mobile self-management app for recently discharged patients with COPD in clinical practice is affected by multiple factors and is only feasible for a relatively small number of patients after hospital discharge. Patients were very positive about the COPD app; however, its use decreased over time. The findings of this study showed a significant positive change in the self-management element knowledge and coping. Nurses expressed concerns about integration in their work processes and increased workload. Tailored interventions, patient support, and active adoption by professionals are important elements to ensure successful mHealth interventions. Therefore, future research on digital self-management interventions in clinical practice should focus on including more difficult subgroups of target populations, on a multidisciplinary approach, on technology-related aspects (such as acceptability), and on finetuning its adoption in clinical pathways.

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Abbreviations

CCQ: Clinical COPD Questionnaire
COPD: chronic obstructive pulmonary disease
EMR: electronic medical record
HADS: Hospital Anxiety and Depression Scale
mHealth: mobile health
PIH: Partners in Health
UTAUT: Unified Theory of Acceptance and Use of Technology

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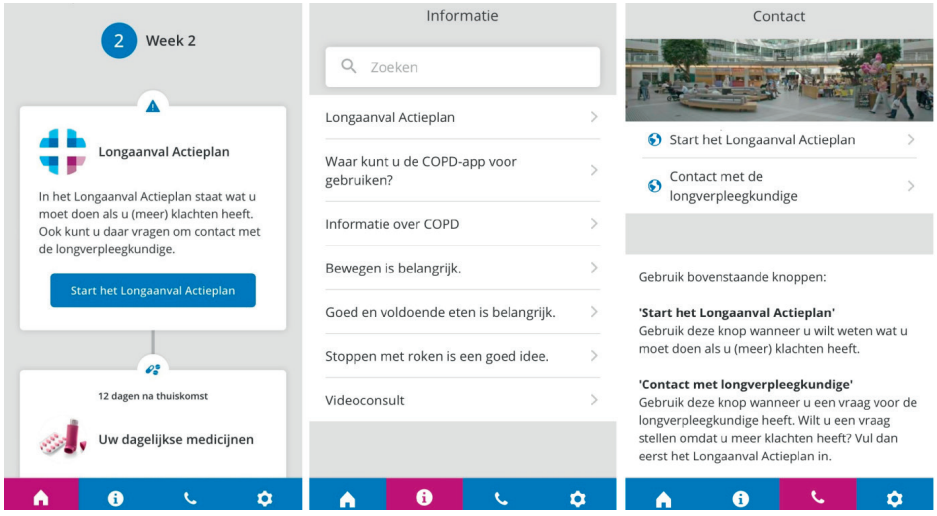
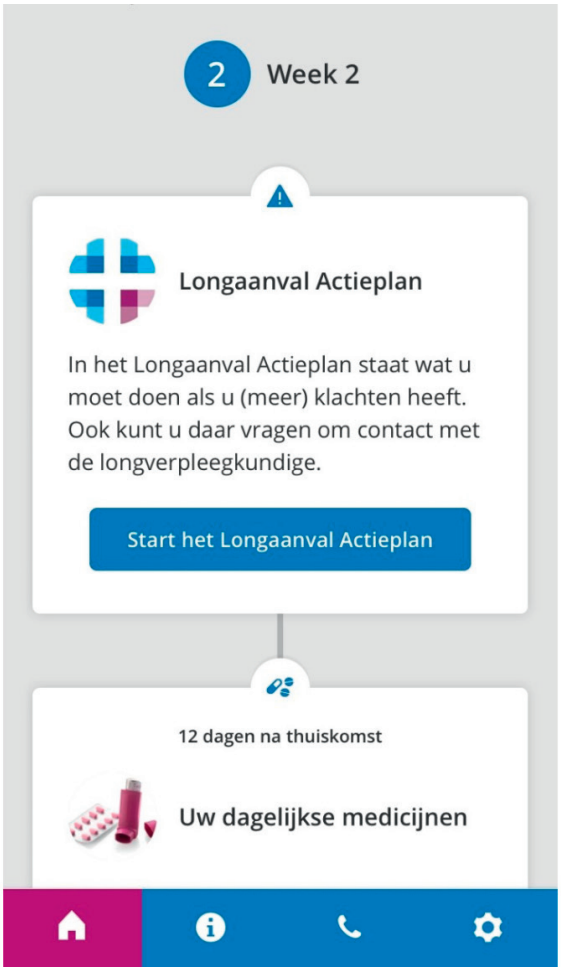
MULTIMEDIA APPENDICES

Multimedia Appendix 1 – COPD app



Multimedia Appendix 2 – Timeline (English translation)

COPD app – Timeline



English translation:

Week 2

Lung Attack Action Plan

In the Lung Attack Action Plan you can find what to do if you have (worsening) symptoms. You can also request contact with a pulmonary nurse.

Your daily medication

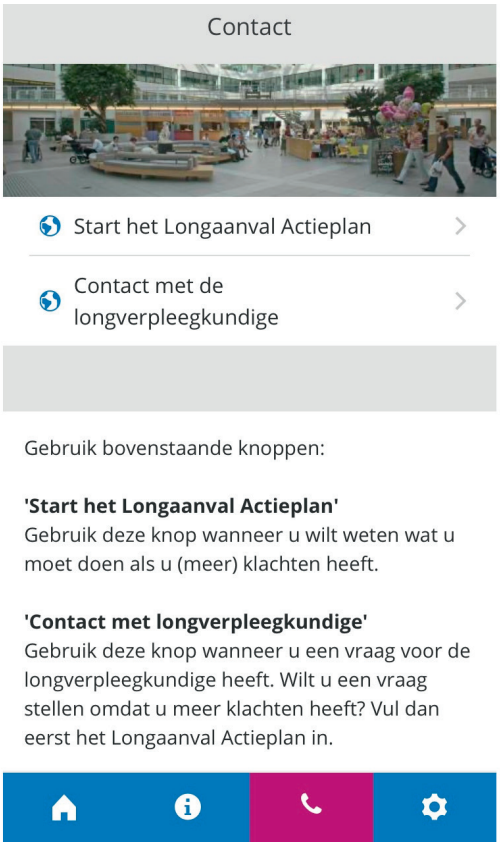
Multimedia Appendix 3 – Information page (English translation)

COPD app – Information page

English translation:
Information
Search
Lung Attack Action Plan
What to use the COPD app for?
Information about COPD
Physical activity is important
Good and enough nutrition is important
Smoking cessation is a good idea
Video consultation

Multimedia Appendix 4 – Contact page (English translation)

COPD app – Contact page



English translation:

Contact

- Start the Lung Attack Action Plan
- Contact with a pulmonary nurse

Use buttons above:

'Start the Lung Attack Action Plan'

Use this button if you want to know what to do when you have (worsening) complaints.

'Contact the pulmonary nurse'

Use this button if you have a question for the pulmonary nurse. Is your question related to worsening complaints? Use the Lung Attack Action Plan first.

Multimedia Appendix 5 – Questionnaire: patient satisfaction

Patient Satisfaction Questionnaire

Usability (7-point scale, 1: totally disagree to 7: totally agree)

1. Log in to the app is easy
2. The COPD app is well-structured

Lung Attack Action Plan (7-point scale, 1: totally disagree to 7: totally agree)

3. The Lung Attack Action Plan is easy to find in the app
4. The Lung Attack Action Plan is easy to use
5. The Lung Attack Action Plan helped me

Information (7-point scale, 1: totally disagree to 7: totally agree)

6. I prefer to receive my information via video instead of text
7. I am satisfied with the information I received about the condition COPD (for example about functioning of the lungs and lung exacerbations)
8. I am satisfied with my, daily and extra, medication overview in the app
9. I am satisfied with the information about breathing technique(s)
10. I am satisfied with the information about nutrition
11. I am satisfied with the information about physical activity
12. If applicable, I am satisfied with the information about the advantages of smoking cessation
13. There is too much information available in the COPD app
14. I prefer to receive more frequent reminders in the app, regarding new information or questionnaires
15. I missed information about (multiple answers possible):
    - ☐ The condition COPD
    - ☐ Lung exacerbations
    - ☐ Breathing techniques
    - ☐ Nutrition
    - ☐ Physical activity
    - ☐ Smoking
    - ☐ Otherwise, namely: _____
    - ☐ I did not miss information

16. In general, how satisfied are you with the COPD app?

Rate from 1 to 10
1 = very unsatisfied
10 = very satisfied

1 2 3 4 5 6 7 8 9 10

17. Do you have suggestions to improve the COPD app?

Video consultation (7-point scale, 1: totally disagree to 7: totally agree)

18. I am satisfied with video consultation
19. I could hear and see the nurse clearly during video consultation
20. I had problems using video consultation
21. By using video consultation, I saved time because I did not have to come to the hospital

Multimedia Appendix 6 – Expectations and experiences with the COPD app

Questionnaire: expectations and experiences with the COPD app

Expectations (7-point scale, 1: totally disagree to 7: totally agree)

1. By using the app, I will have more control over my condition COPD
2. By using the app, I will better recognize complaints and symptoms of my condition COPD
3. By using the app, I will know better what to do when my complaints and symptoms get worse
4. It will take no effort to use the COPD app
5. People in my direct environment (eg, family and friends) will stimulate me to use the COPD app
6. I have enough skills (with the tablet or smartphone) to use the COPD app
7. I will get enough help using the COPD app
8. I intend to use the COPD app

Experiences (7-point scale, 1: totally disagree to 7: totally agree)

9. By using the app, I have more control over my condition COPD
10. By using the app, I recognize complains and symptoms of my condition COPD better
11. By using the app, I know better what to do when my complaints and symptoms get worse
12. It takes no effort to use the COPD app
13. People in my direct environment (eg, family and friends) stimulated me to use the COPD app
14. I have enough skills (with a smartphone or tablet) to use the COPD app
15. I get enough help using the COPD app
16. I intend to keep using the COPD app

Multimedia Appendix 7 – Use of the COPD app

Table 4. Use of the COPD app (N=39)

Use	Week								
	1	2	3	4	5	6	7	8	9–20[a]
COPD app									
Pageclicks, Median (IQR)	6.0 (3.5 – 10.0)	3.0 (2.0 – 5.0)	2.0 (2.0 – 5.0)	2.0 (1.0 – 3.5)	2.0 (1.0 – 4.5)	2.0 (1.0 – 3.0)	2.0 (1.0 – 3.0)	2.0 (1.0 – 3.5)	3.0 (1.0 – 6.0)
App opened, n (%)	39 (100)	35 (90)	33 (84)	32 (82)	31 (79)	31 (79)	31 (79)	31 (79)	30 (79)
Information									
About the app									
Pageclicks, Median (IQR)	2.0 (0.0 – 5.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)
Information opened, n (%)	27 (69)	7 (18)	3 (8)	1 (3)	2 (5)	1 (3)	0 (0)	0 (0)	6 (16)
Subpage: about the app									
Pageclicks, Median (IQR)	2.0 (0.0 – 4.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)
Information opened, n (%)	22 (56)	5 (13)	3 (8)	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)	6 (16)
About COPD									
Pageclicks, Median (IQR)	1.0 (0.0 – 3.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 5.0)
Information opened, n (%)	22 (56)	7 (18)	8 (21)	2 (5)	4 (10.3)	4 (10)	1 (3)	1 (3)	15 (39)
Subpage: about COPD									
Pageclicks, Median (IQR)	0 (0.0 – 2.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 4.0)
Information opened, n (%)	16 (41)	7 (18)	7 (18)	1 (3)	3 (8)	4 (10)	1 (3)	1 (3)	15 (39)
Nutrition									
Pageclicks, Median (IQR)	1.0 (0.0 – 6.0)	0 (0.0 – 1.0)	0 (0.0 – 2.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 1.0)
Information opened, n (%)	22 (56)	12 (31)	12 (31)	9 (23)	3 (8)	6 (15)	3 (8)	1 (3)	12 (32)

Table 4. Continued.

Use	Week								
	1	2	3	4	5	6	7	8	9–20[a]
Subpage: nutrition									
Median (IQR)	0.0 (0.0 – 3.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)
Information opened, n (%)	17 (44)	9 (23)	9 (23)	8 (21)	3 (8)	5 (13)	3 (8)	1 (3)	9 (24)
Physical activity									
Pageclicks, Median (IQR)	1.0 (0.0 – 3.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 1.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)
Information opened, n (%)	24 (62)	30 (77)	11 (28)	6 (15)	2 (5)	4 (10)	1 (3)	4 (10)	8 (21)
Subpage: physical activity									
Pageclicks, Median (IQR)	0.0 (0.0 – 1.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)
Information opened, n (%)	11 (28)	9 (23)	7 (18)	3 (8)	2 (5)	2 (5)	1 (3)	3 (8)	5 (13)
Smoking cessation (pageclicks)									
Pageclicks, Median (IQR)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)
Information opened, n (%)	7 (18)	5 (13)	0 (0)	1 (3)	2 (5)	3 (8)	1 (3)	1 (3)	4 (11)
Subpage: smoking cessation									
Pageclicks, Median (IQR)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)
Information opened, n (%)	7 (18)	3 (8)	0 (0)	1 (3)	1 (3)	1 (3)	1 (3)	1 (3)	1 (3)
Lung Attack Action Plan									
Pageclicks, Median (IQR)	1.0 (0.0 – 1.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)
Information opened, n (%)	22 (56)	3 (8)	2 (5)	0 (0)	0 (0)	2 (5)	0 (0)	1 (3)	6 (15)
Video consultation									

Table 4. Continued.

Use	Week								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9–20[a]**
Pageclicks, Median (IQR)	0.0 (0.0 – 1.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)
Information opened, n (%)	12 (31)	2 (6)	3 (8)	1 (3)	3 (8)	1 (3)	0 (0)	1 (3)	3 (8)

[a] Mean week 9 – 20, n=38

Multimedia Appendix 8 – Patient satisfaction

Table 5. Patient Satisfaction (N=38)

Satisfaction statements	Week 8, n (%)[a]
User–friendliness	
Log in to the COPD app is easy	27 (93)
The COPD app is:	
…easy to use	26 (93)
…well–structured	26 (93)
Lung Attack Action Plan	
…is easy to find	27 (96)
…is easy to use	25 (93)
…helped me	18 (67)
Information	
The information in the COPD app is understandable	27 (93)
I prefer receiving my information via video instead of text	16 (57)
I am satisfied with the information I received about:	
…the condition COPD	23 (82)
…my daily and extra medication	24 (86)
…breathing techniques	25 (89)
…nutrition	29 (100)
…physical activity	26 (93)
… the advantages of smoking cessation	19 (95)
There is too much information available in the COPD app	9 (33)
I prefer to receive more frequent reminders in the app, regarding new information or questionnaires	16 (57)
Video consultation	
I am satisfied with video consultation	18 (78)
I could hear and see the nurse clearly during video consultation	16 (70)
I had problems using video consultation	11 (38)[b]
By using video consultation, I saved time because I did not have to come to the hospital	19 (66)[b]

[a] Valid percentage of patients that (totally) agree (≥5 on 7-point scale).
[b] yes/no question

Multimedia Appendix 9 – Self-management

Table 6. Self-management (N=38)

PIH domains	Baseline	8 weeks	20 weeks	Change over time
	EMM[a] (95% CI)	EMM[a] (95% CI)	EMM[a] (95% CI)	*P*–value[b]
Knowledge and coping	5.2 (4.8 – 5.6)	5.6 (5.3 – 6.0)	5.9 (5.5 – 6.3)	*P*=.04
Recognition and management of symptoms, adherence to treatment	7.0 (6.6 – 7.3)	7.2 (6.9 – 7.5)	7.4 (7.1 – 7.6)	*P*=.14

[a] Estimated Marginal Means (EMM), Confidence Interval (CI)
[b] Lineair Mixed Model

Multimedia Appendix 10 – Expectations of and experiences with the COPD app

Table 7. Expectations and Experiences with the COPD App

Expectations and Experiences	Baseline (N=39), n (%)[a]	8 weeks (N=38), n (%)[a]	20 weeks (N=37), n (%)[a]
More control over my treatment	27 (73)	18 (56)	20 (67)
Better able to recognize symptoms and complaints	31 (84)	23 (72)	21 (70)
Know what to do when my complaints get worse	31 (84)	23 (72)	23 (77)
It takes no effort to use the COPD app	27 (73)	26 (84)	26 (90)
People in my direct environment stimulate me to use the COPD app	29 (78)	14 (45)	12 (40)
I have enough skills to use the COPD app	25 (68)	26 (87)	25 (83)
I will get enough help using the COPD app	28 (76)	17 (57)	13 (45)
I intend to use/keep using the COPD app	34 (94)	19 (63)	20 (69)

[a] Valid percentage of patients that (totally) agree (≥5 on 7-point scale, 1: totally disagree to 7: totally agree)

CHAPTER 6

Video consultation as an adequate alternative to face-to-face consultation in continuous positive airway pressure use for newly diagnosed patients with obstructive sleep apnea: randomized controlled trial

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ABSTRACT

Background

The effectiveness of continuous positive airway pressure (CPAP) is dependent on the degree of use, so adherence is essential. Cognitive components (eg, self-efficacy) and support during treatment have been found to be important in CPAP use. Video consultation may be useful to support patients during treatment. So far, video consultation has rarely been evaluated in thorough controlled research, with only a limited number of outcomes assessed.

Objective

The aim of the study was to evaluate the superiority of video consultation over face-to-face consultation for patients with obstructive sleep apnea (OSA) on CPAP use (minutes per night), adherence, self-efficacy, risk outcomes, outcome expectancies, expectations and experiences with video consultation, and satisfaction of patients and nurses.

Methods

A randomized controlled trial was conducted with an intervention (video consultation) and a usual care group (face-to-face consultation). Patients with confirmed OSA (apnea-hypopnea index >15), requiring CPAP treatment, no history of CPAP treatment, having access to a tablet or smartphone, and proficient in the Dutch language were recruited from a large teaching hospital. CPAP use was monitored remotely, with short-term (weeks 1 to 4) and long-term (week 4, week 12, and week 24) assessments. Questionnaires were completed at baseline and after 4 weeks on self-efficacy, risk perception, outcome expectancies (Self-Efficacy Measure for Sleep Apnea), expectations and experiences with video consultation (covering constructs of the unified theory of acceptance and use of technology), and satisfaction. Nurse satisfaction was evaluated using questionnaires.

Results

A total of 140 patients were randomized (1:1 allocation). The use of video consultation for OSA patients does not lead to superior results on CPAP use and adherence compared with face-to-face consultation. A significant difference in change over time was found between groups for short-term (*P*-interaction=.008) but not long-term (*P*-interaction=.68) CPAP use. CPAP use decreased in the long term (*P*=.008), but no significant difference was found between groups (*P*=.09). Change over time for adherence was not significantly different in the short term (*P*-interaction=.17) or long term (*P*-interaction=.51). A relation was found between CPAP use and self-efficacy (*P*=.001), regardless of the intervention arm (*P*=.25). No significant difference between groups was found for outcome expectancies (*P*=.64), self-efficacy (*P*=.41), and risk perception (*P*=.30). The experiences were positive,

and 95% (60/63) intended to keep using video consultation. Patients in both groups rated the consultations on average with an 8.4. Overall, nurses (n=3) were satisfied with the video consultation system.

Conclusions

Support of OSA patients with video consultation does not lead to superior results on CPAP use and adherence compared with face-to-face consultation. The findings of this research suggest that self-efficacy is an important factor in improving CPAP use and that video consultation may be a feasible way to support patients starting CPAP. Future research should focus on blended care approaches in which self-efficacy receives greater emphasis.

Trial Registration: Clinicaltrials.gov NCT04563169; https://clinicaltrials.gov/show/NCT04563169

INTRODUCTION

Telemedicine is increasingly used to support self-management in chronic diseases and is defined as the use of information and communication technology to deliver health care at a distance [1], but so far we see little evidence in this field. Nevertheless, telemedicine solutions are used for patients with obstructive sleep apnea (OSA) for example, for monitoring, education, and consultation [2]. OSA is considered a chronic disease [1,3]; it is a sleep disorder that affects at least 2% to 4% of the adult population [4] and is characterized by repeated episodes of full or partial occlusion of the upper airway during sleep [4,5]. This condition can have multiple effects on patients' health such as cognitive dysfunction [4], decrease in health-related quality of life [4,6], increase in cardiovascular disease risk, and sleepiness during the daytime [6]. The severity is often determined with the apnea-hypopnea index (AHI) [4], which represents the number of apneas and hypopneas per hour [4] and is classified as mild (5 to 15 per hour), moderate (15 to 30 per hour) or severe (>30 per hour) [7]. Continuous positive airway pressure (CPAP) is the preferred treatment [6], especially for moderate to severe OSA [5]. CPAP prevents the airway from narrowing or collapsing by applying a positive pressure via a nasal mask during sleep [8] and is tailored to each patient [9]. As the effectiveness of CPAP is dependent on use [5,10], treatment adherence is essential. Cognitive components, mainly based on the social cognitive theory [11], are becoming increasingly important in predicting CPAP use [12-14]. Support during treatment [15], tailored interventions [16], and closer follow-up [17] can also positively affect adherence.

Video consultation may be a useful way to support patients [1,17,18] during treatment and is defined as a "technology used to realize a real-time visual and audio patient assessment at a distance" [19]. Video consultation has been beneficial in chronic conditions (eg, diabetes [20,21] and cancer [19,22]) and in care for OSA patients [17,18]. The use for OSA patients may be promising, especially since physical examination is not always needed [1], and CPAP use can already be monitored remotely [23]. However, the evidence on the effectiveness for OSA patients is still limited [24]. Previous studies were narrowly focused, with mainly adherence [18,25] and satisfaction [17,18,26] being assessed. Although cognitive components, (eg, self-efficacy and outcome expectancies) are found to be important elements for CPAP use [13,14,27], there is a lack of evidence about these effects on video consultation for OSA patients. Previous research on OSA patients also mainly evaluated the use of video consultation for initial contact with health care professionals focused on diagnosis, treatment plans [18,26], or for training purposes [17]. The use of video consultation may be particularly relevant during follow-up (after an initial face-to-face contact) for newly diagnosed patients, since support during treatment is important [15] and successful CPAP use is often determined at an early stage of treatment [28].

Only a limited number of randomized controlled trials (RCTs) were conducted [17,25,26,29], with only one fully powered trial [29]. In a study by Smith et al [25], video consultation was used by nurses for patients who were nonadherent during the first 3 months of treatment. One group of patients received specific information (n=10) about CPAP and one group (n=9) generic information. Both adherence and satisfaction were higher in the intervention group (P=.003). Isetta et al [29] conducted a multicenter RCT with patients receiving access to either a telemedicine program (n=69) with video consultations or usual care (hospital visits, n=70). Although the telemedicine approach was assumed to be more cost-effective, CPAP adherence was equivalent after 6 months [29]. Video consultation was also used for initial contact before starting treatment, with mixed results. The use of video consultation for training purposes did not lead to a difference in knowledge [17]. Also, no significant differences in satisfaction and CPAP adherence were found after 14 days for new OSA patients starting CPAP treatment [18]. Adherence rates were found to be higher after 6 months for patients who received their initial consultation face-to-face than via video consultation. However, statistically significant difference was not reported [26].

Video consultation is often found to be as effective as face-to-face consultation in terms of CPAP use [18,29]. Previous studies often focused on newly diagnosed patients before the start of treatment [17,18,26], with generally small sample sizes [17,25,26]. Patients are satisfied with video consultation [17,18,25], and it may be a promising way to deliver more convenient care with indirect benefits for patients (eg, less travel time) [24]. Additionally, remote monitoring [30] and patient support treatment [31] can positively affect CPAP

use [30,31]. Therefore, it may be expected that video consultation in combination with remotely monitoring CPAP use, consultation with nurses, and the indirect benefits of video consultation (eg, less travel time) [24] may improve CPAP use. Cognitive components (eg, self-efficacy) are also found to be important elements for CPAP use [13,14,27], but evaluation in combination with video consultation is lacking [24]. More evidence about the technology being used and health care professionals' perceptions is also needed to ensure successful implementations [17]. Such knowledge is essential because the use of video consultation is increasing, but evidence is still lacking and powered studies are needed [24].

Therefore, the objective of this paper is to evaluate the superiority of video consultation versus face-to-face consultation for patients with OSA on CPAP use (minutes per night), CPAP adherence, self-efficacy, risk perception, outcome expectancy, video consultation expectations and experiences with technology, and the satisfaction of patients and nurses.

METHODS

Study design

We conducted a nonblinded RCT with an intervention group (video consultation) and a usual care group (face-to-face consultation), with 1:1 allocation.

Recruitment and participants

Patients were recruited from a large teaching hospital (Rijnstate, Arnhem). To be eligible to participate, patients had to be older than 18 years, be diagnosed with moderate or severe OSA (AHI >15), require CPAP treatment, have no history of CPAP treatment, have access to a tablet or smartphone, and be proficient in the Dutch language. Exclusion criteria were having a psychiatric or cognitive disorder.

Study process

Prior to the study, a letter was sent to patients to confirm their appointments (eg, sleep study and consultation with the pulmonologist) including information about the study. During the first face-to-face consultation with the pulmonologist, patients received their treatment plan and information about the study (including information letter and informed consent form). This was followed by instruction about their CPAP treatment. After this consultation, the researcher provided patients with additional information about the study, and they were asked to sign the informed consent form. For reasons of clinical necessity, patients started treatment the same day.

Randomization

After patients signed informed consent and completed the baseline questionnaire, they were randomized by the researcher to the intervention or usual care group using the software program Research Manager (Cloud9 Software) with block size of 10. The researcher informed the patients about their allocation, and the intervention group received additional information about the video consultation app (Facetalk, Qconferencing) [32]. All participants received a copy of the informed consent form, and a follow-up appointment was planned directly.

Intervention

The video consultation app Facetalk [32] could be downloaded (for free) from Google Play [33] or the App Store [34]. The first video consultation with a nurse was planned for 1 week after the start of CPAP. Patients received an email with the date, time, and a link to start the video consultation in the app. Three focus points were discussed during the consultations: (1) adherence (>6 hours per night), (2) rest AHI <5 (or <10 if age over 70 years), and (3) (improvements in) symptoms. If these objectives were achieved after 1 week, a new consultation was planned for 3 weeks later (4 weeks after the start). If these objectives were not achieved, video consultations were planned for weekly (until 4 weeks after starting CPAP treatment). After 4 weeks, patients received a questionnaire. See Multimedia Appendix 1 for the study process.

Usual care

The usual care group followed the same care process but with face-to-face consultation instead of video consultation. Patients received a confirmation letter with the day and time of their next consultation.

Outcome measures

Primary outcome

The primary outcome was CPAP use (minutes per night), monitored remotely with Encore Anywhere (Philips). Conforming to the initial protocol, CPAP use was assessed during the first 4 weeks (short-term). Additionally, we assessed CPAP use after week 4, week 12, and week 24 (long-term).

Secondary Outcomes

CPAP adherence

CPAP adherence was defined as CPAP use for at least 5 nights per week for at least 4 hours per night [15,35] and was assessed during the first 4 weeks (short-term) and week 4, week 12, and week 24 (long-term).

Treatment self-efficacy, risk perception, and outcome expectancies

The Self-Efficacy Measure for Sleep Apnea (SEMSA) [13] was used to measure cognitive components: self-efficacy, risk perception, and outcome expectancies. The SEMSA is a 26-item scale [13] with subscales: self-efficacy and outcome expectancies each have 9 questions rated on a 4-point scale from not at all true to very true and risk perception has 8 questions rated on a 4-point scale from very low to very high. The mean of the nonmissing item responses was calculated for risk perception, outcome expectancies, and self-efficacy. For the purpose of this study, the SEMSA was translated back (from English into Dutch) and forth (from Dutch into English) by Taalcentrum-VU [36]. In this study, the statements from the published paper were used [13].

Relation between self-efficacy, risk perception, outcome expectancies, and CPAP use

The relations between CPAP use and self-efficacy, risk perception, and outcome expectancies were assessed. Also, the differences between the intervention and usual care group were analyzed.

Expectations and experiences with video consultation

Questions covering constructs of the unified theory of acceptance and use of technology (UTAUT) model [37] were used to measure expectations and experiences with the use of the video consultation system. The UTAUT consists of 4 constructs that influence behavioral intention and behavior—performance expectancy, effort expectancy, social influence, and facilitating conditions [37]. A total of 9 questions were rated on a 7-point scale (1=totally disagree to 7=totally agree).

Satisfaction

Patient satisfaction was evaluated with questions about the consultations and information received. Additionally, the intervention group answered questions about the video consultation system. All questions were rated on a 5-point scale (from 1=totally disagree to 5=totally agree). Nurses' experiences were evaluated using a questionnaire with questions about the video consultation system, satisfaction, and organizational benefits (eg, time and efficiency).

Other parameters

Patient age, marital status, education, experience with internet and internet use, tablet or smartphone skills, and support (with tablet or smartphone use) were assessed via a questionnaire at baseline. Data about comorbidities, AHI, number of consultations, symptoms, and results of the Epworth Sleepiness Scale [38] were obtained from the electronic medical record. This scale is a self-administered questionnaire to examine the perception of daytime sleepiness that has 8 questions about how likely it is to doze off in different situations ranging from 0 to 3. A total score for this scale is calculated by taking the sum of the 8 items. A total of 11 to 12 is considered mild, 13 to 15 moderate, and 16 to 24 severe excessive daytime sleepiness [39]. In this study, a total score of >10 is considered excessive daytime sleepiness.

Sample size calculation

Since there is no determined clinically relevant difference for CPAP use [40], we assumed that a difference of 1 (SD 2.0) hour per day of average CPAP use (primary outcome) is clinically significant [13,29]. Using a *t* test, alpha of .05, and 80% power, 63 subjects per group (a total of 126) were needed. Correcting for 10% dropout, 70 patients were recruited for each group.

Statistical analysis

Data analysis was performed using SPSS (version 22.0, IBM Corp). Descriptive statistics were used to report the baseline characteristics, experiences, expectations, and satisfaction. Linear mixed models were used to analyze differences in CPAP use over time for the intervention and usual care group (interaction term: time × group). All available CPAP use data were used in the analysis, according to the intention-to-treat principle. Differences in adherence over time between groups was analyzed using generalized estimating equations. The relation between CPAP use and risk perception, outcome expectancies, and self-efficacy was analyzed with a linear regression. Normally distributed variables were reported as mean and standard deviation, and statistical differences were tested using an independent samples *t* test. Nonnormally distributed data were reported with medians and interquartile range (25th to 75th percentiles), and differences between groups were analyzed with Mann-Whitney *U* tests.

Approval and ethical considerations

All participants signed a written informed consent form prior to inclusion in the study. The study was approved by the regional medical research ethics committee Commissie Mensgebonden Onderzoek Arnhem–Nijmegen and registered at Clinicaltrials.gov [NCT04563169].

RESULTS

Recruitment and participants

Patients were included from January 2, 2019, until June 26, 2019. In total, 222 patients were screened for eligibility, and 50 patients did not meet the inclusion criteria: no tablet or smartphone (n=17), no proficiency in the Dutch language (n=10), AHI <15 (n=10), history of CPAP treatment (n=5), no OSA (n=4), psychiatric or cognitive disorder (n=3), and age <18 years (n=1). In total, 28 patients declined to participate, and 4 patients were not informed about the study for other reasons: 2 patients were not referred to the researcher due to logistical errors, 1 patient followed a different care process (there was no consultation with the pulmonologist that same day), and 1 patient had had CPAP for try out for a short period.

In total, 140 patients were randomized, and 70 patients were allocated to the intervention group and 70 patients to the usual care group. During the intervention period, 2 patients discontinued the intervention: 1 preferred face-to-face consultation, and 1 had no working device. Four patients stopped CPAP treatment during the intervention period (first 4 weeks). In total, 10 patients were lost to follow-up in the intervention group (n=9 stopped CPAP treatment and n=1 died) and 3 in the usual care group (n=3 stopped CPAP treatment). See Figure 1 for the CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

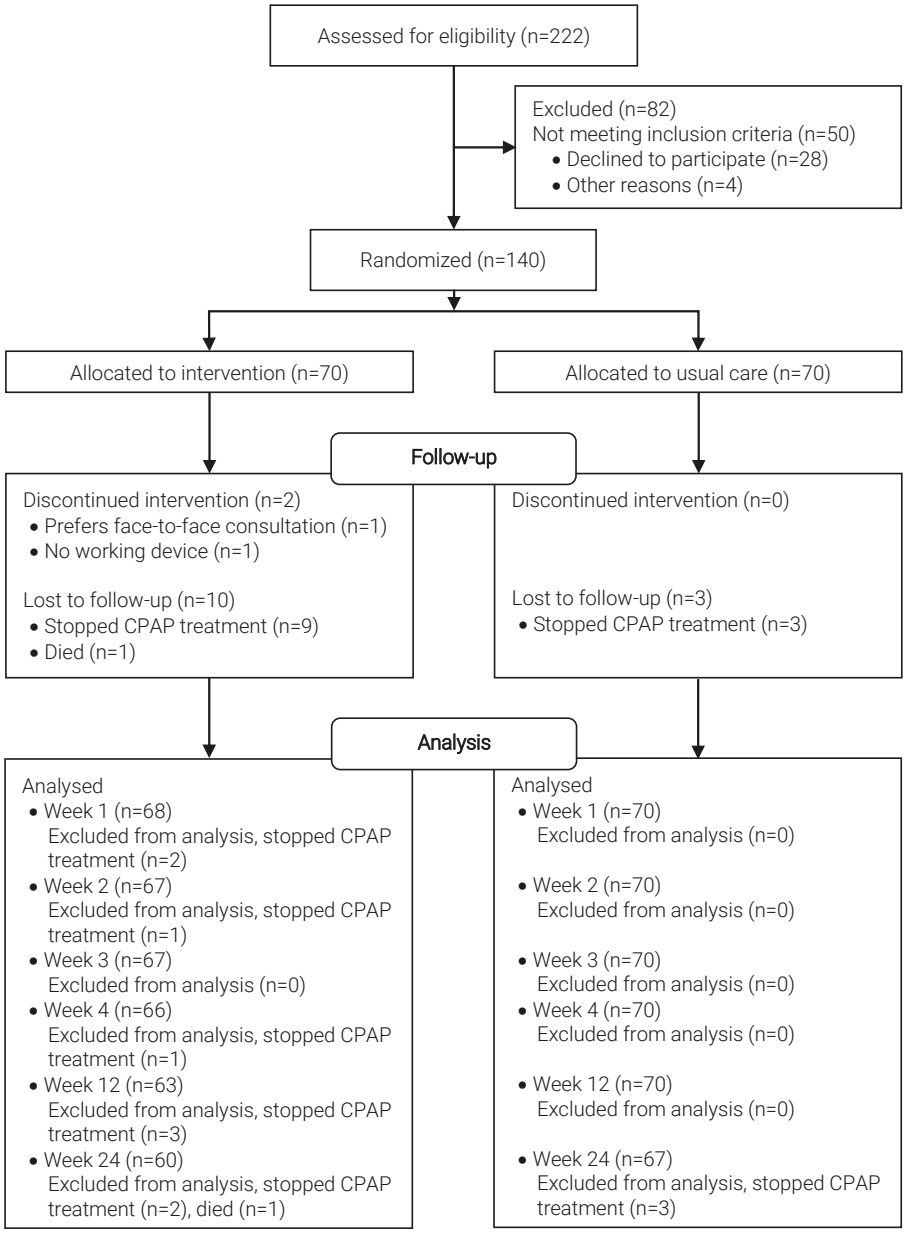

Figure 1. CONSORT flow diagram.

Baseline characteristics

Both groups had similar baseline characteristics (Table 1), only outcome expectancies (*P*=.048) and risk perception (*P*=.02) appeared to be significantly different between groups.

Table 1. Baseline characteristics (n=140)

Characteristics	All patients (n=140)	Intervention (n=70)	Usual care (n=70)	*P* value
Gender, women, n (%)	29 (21)	12 (17)	17 (24)	.30
Age (years), mean (SD)	53.3 (12.1)	52.3 (12.4)	54.3 (11.9)	.40
AHI[a], median (IQR)	31.0 (21.5–45.0)	31.0 (22.0–46.0)	30.5 (20.0–42.0)	.96
Living with a partner, n (%)	110 (79)	59 (84)	51 (73)	.10
Education, n (%)	—[b]	—	—	.22
Low	8 (6)	3 (4)	5 (7)	—
Middle	89 (64)	41 (59)	48 (69)	—
High	43 (31)	26 (37)	17 (24)	—
Internet use: duration, n (%)	—	—	—	>.99
< 6 months	3 (2)	1 (1)	2 (3)	—
1–2 years	1 (1)	1 (1)	0 (0)	—
>2 years	1 (1)	1 (1)	0 (0)	—
>3 years	135 (96)	67 (96)	68 (97)	—
Internet use: frequency, n (%)	—	—	—	.31
(almost) every day	128 (91)	66 (94)	62 (89)	—
Multiple days a week	9 (6)	4 (6)	5 (7)	—
≤ 1 day per week	3 (2)	0 (0)	3 (4)	—
Tablet or smartphone skills, n (%)	—	—	—	.91
Quite bad or bad	5 (4)	2 (3)	3 (4)	—
Not good or not bad	23 (16)	11 (16)	12 (17)	—
Quite good	27 (19)	14 (20)	13 (19)	—
Good	55 (39)	26 (37)	29 (41)	—
Very good	30 (21)	17 (24)	13 (19)	—
Expects to need help with tablet or smartphone use, n(%)	26 (19)	11 (16)	15 (22)	.41
Comorbidities, n (%)	—	—	—	—
Obesity (BMI >30)	97 (69)	51 (73)	46 (66)	.36
Hypertension	48 (34)	24 (34)	24 (34)	>.99
Hypercholesterolemia	21 (15)	8 (11)	13 (19)	.24
Heart disease	20 (14)	11 (16)	9 (13)	.63

Table 1. Continued.

Characteristics	All patients (n=140)	Intervention (n=70)	Usual care (n=70)	*P* value
Diabetes	14 (10)	7 (10)	7 (10)	>.99
ESS[c] score, n (%)	—	—	—	.19
Total score ≤ 10	105 (79)	56 (84)	49 (74)	—
Total score > 10	28 (21)	11 (16)	17 (26)	—
SEMSA[d] constructs	—	—	—	—
Outcome expectancies, mean (SD)	2.78 (0.62)	2.88 (0.57)	2.67 (0.65)	.048
Self–efficacy, median (IQR)	3.00 (2.56–3.56)	3.00 (2.56–3.33)	3.00 (2.56–3.67)	.40
Risk perception, median (IQR)	2.00 (1.54–2.50)	2.31 (1.63–2.63)	1.88 (1.50–2.31)	.02

[a] AHI: apnea-hypopnea index.
[b] Not applicable.
[c] ESS: Epworth Sleepiness Scale.
[d] SEMSA: Self-Efficacy Measure for Sleep Apnea.

CPAP use

The use of video consultation does not lead to superior results on CPAP use compared with face-to-face consultation. A significant difference in change over time was found between groups for short-term (weeks 1 through 4) CPAP use (*P*-interaction=.008). However, the specific time points (week 1: *P*=.62; week 2: *P*=.15; week 3: *P*=.33, and week 4: *P*=.20) were not significantly different. See Multimedia Appendix 2 and Multimedia Appendix 3 for more detailed information on short-term CPAP use.

No significant difference in change over time for long-term CPAP use (week 4, week 12, and week 24) was found between groups (*P*-interaction=.68). CPAP use decreased for both groups in the long term (*P*=.008), but no significant difference was found between the intervention and usual care group (*P*=.09). See Table 2 and Figure 2 for change in CPAP use over time (week 4, week 12, and week 24).

Table 2. Long-term continuous positive airway pressure use (minutes per night).

Week[a]	Intervention		Usual care	
	EMM[b] (SE)	95% CI	EMM (SE)	95%CI
Week 4	334.3 (16.3)	302.1–366.5	371.4 (15.8)	340.1–402.7
Week 12	311.5 (16.8)	278.4–344.6	348.6 (16.2)	316.5–380.7
Week 24	295.2 (17.8)	260.0–330.4	332.7 (17.3)	298.1–366.5

[a] Linear mixed model.
[b] EMM: estimated marginal mean.

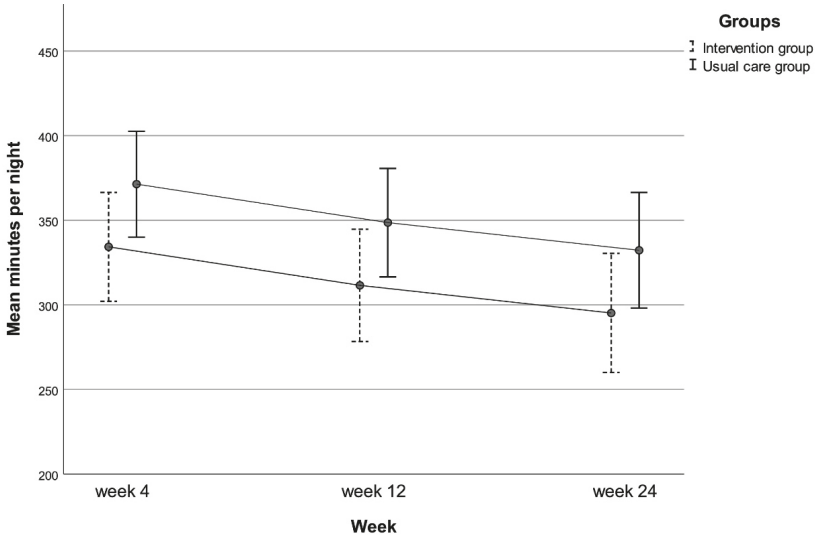

Figure 2. Long-term continuous positive airway pressure use: change over time.

CPAP adherence

The use of video consultation does not lead to superior results on CPAP adherence compared with face-to-face consultation. No significant difference was found between both groups for short-term (*P*=.95) and long-term (*P*=.12) CPAP adherence. Also, no significant difference in change over time between the intervention and usual care group was found for short-term (*P*-interaction=.17) and long-term (*P*-interaction=.51) CPAP adherence. See Multimedia Appendix 4 and Multimedia Appendix 5 for the short-term and long-term adherence rates per week.

Self-efficacy, risk outcomes, and outcome expectancies

No significant difference between groups was found for the SEMSA constructs: outcome expectancies (*P*=.64), self-efficacy (*P*=.41), and risk perception (*P*=.30). See Multimedia Appendix 6.

Relation between self-efficacy, risk perception, outcome expectancies, and CPAP use

After 4 weeks, a relation was found between CPAP use and self-efficacy (*P*=.001), meaning that patients with higher levels of self-efficacy showed higher CPAP use. There was no relation between CPAP use and risk perception (*P*=.34) or outcome expectancies (*P*=.76). Also, the difference between the intervention and usual care group was not significant (*P*=.25).

Expectations and experiences with video consultation

Patients expressed positive expectations for the use of video consultation. After 4 weeks, 76% (48/63) indicated that video consultation had a positive effect on control over their treatment, and 75% (47/63) indicated that it positively affected the treatment itself. The majority (58/63, 92%) implied it did not cost them effort, 95% (60/63) reported that they had enough skills to use a tablet or smartphone and that they received enough support (53/63, 84%). Although, 64% (44/69) expected to be stimulated by people in their direct environment to use video consultation, only 25% (16/63) were actually stimulated. Almost all patients (60/63, 95%) intended to keep using video consultation. See Multimedia Appendix 7.

Satisfaction with consultation

Patients in both groups were satisfied with the consultations. On average, the intervention group rated the consultations with an 8.5 and the usual care group with an 8.3 on a scale of 1 to 10 (1=not at all satisfied to 10=very satisfied). Patients indicated (intervention group versus usual care group) that health care professionals understood their problems (59/63, 94%, vs 58/68, 85%) and listened to them (60/63, 95%, vs 61/68, 90%). Almost all patients understood the content of the consultation (61/63, 97%, vs 62/68, 91%), could easily express their feelings (59/63, 94%, vs 62/68, 91%), and were satisfied with the information they received (58/63, 92%, vs 60/68, 88%). However, more patients with video consultation reported that they did not miss important information (56/63, 89%, vs 43/68, 63%). See Multimedia Appendix 8.

Satisfaction with video consultation

The majority (56/63, 89%) of the patients were very satisfied with video consultation, the quality of the video (50/63, 79%), and sound of the system (45/63, 71%). It also saved them time (61/63, 97%) and provided better access to health care professionals (43/63,

68%). Almost all patients felt safe about their privacy and confidentiality (61/63, 97%) and preferred a video consultation over a face-to-face consultation (51/63, 81%). According to almost half (28/63, 44%) the patients, face-to-face consultation can be replaced by video consultation. See Multimedia Appendix 9.

Nurse satisfaction

Nurses (n=3) rated the use of video consultation on average with a 7.3 (SD .57) on a scale of 1 to 10 (1=not at all satisfied to 10=very satisfied). They were all satisfied with privacy and confidentiality and quality of the sound and video and would recommend its use to colleagues and patients. Two nurses agreed that its use fits in their work process. However, only one nurse was completely satisfied with the information she could provide. They did not think that the use of video consultation helped them save time or work more efficiently.

The nurses reported that use of video consultation is not suitable for new patients, and they prefer to use it during follow-up:

> *It is not suitable for a first consultation after starting CPAP because you cannot provide enough information.*
> *Not for new patients because providing information and checking the device and sleep mask is difficult using video consultation.*

The nurses also experienced some technical problems:

> *Sometimes there were log-in problems and I had to call the patient first by phone.*
> *Sometimes it took long before there was a connection. This costs more time.*

They also provided suggestions for improvement and described advantages of video consultations:

> *Plan the video consultations one after the other and not alternating with face-to-face consultations.*
> *It is a good alternative for follow-up consultations. It is more patient friendly than a face-to-face consultation.*
> *Saves time for patients.*

DISCUSSION

Principal findings

In this RCT, we evaluated the superiority of video consultation over face-to-face consultation for newly diagnosed OSA patients. For CPAP use, we found a significant difference in change over time between groups in the short term (*P*-interaction=.008). However, the specific time points (week 1: *P*=.62; week 2: *P*=.15; week 3: *P*=.33, and week 4: *P*=.20) were not significantly different. No significant difference in change over time was found for long-term CPAP use (*P*-interaction=.68). No significant difference in change over time between groups was found for short-term (*P*-interaction=.17) or long-term (*P*-interaction=.51) CPAP adherence. Self-efficacy appeared to have a statistically significant effect on CPAP use in both groups (*P*=.001) regardless of the intervention arm (*P*=.25). No significant difference between groups was found for outcome expectancies (*P*=.64), self-efficacy (*P*=.41), or risk perception (*P*=.30). The experiences with video consultation were very positive. Almost all patients (60/63, 95%) intended to keep using video consultation. Patients in both groups rated the consultations on average with an 8.4. All nurses (n=3) were satisfied with privacy and confidentiality aspects and quality of the sound and video. However, they expressed some recommendations for improvement (eg, to use video consultation only in follow-up).

Comparison with prior work

Unfortunately, change over time was not evaluated in previous controlled studies [18,26,29], but this evaluation is as such a likely pattern. In our study, a significant difference in CPAP use between video consultation and face-to-face consultation was not found. Parikh et al [18] reported statistically equivalent CPAP use for new OSA patients (mean average use minutes per day 305.31 vs 340.55, *P*=.15). In a multicenter RCT, no statistically significant difference was found for CPAP use after 6 months (telemedicine mean use 4.4 [SD 2.0] hours per day vs face-to-face 4.2 [SD 2.0] hours per day, *P*=.83) and adherence (telemedicine 65% vs usual care 57% compliance, *P*=.33) [29]. Based on these findings, it appears that CPAP use is equivalent to using video consultation.

Where previous studies mainly focused on CPAP use, adherence, and satisfaction with video consultation [17,18,25,26,29], we additionally evaluated the combination of cognitive components (self-efficacy, outcome expectancies, and risk perception), experience with the technology (using the UTAUT model), and satisfaction of patients and nurses. This combination of outcomes has received little attention until now. Cognitive components are found to be increasingly important in predicting CPAP use [13,14,27]. Our results show that use of CPAP is higher in patients with high levels of self-efficacy (*P*=.001) regardless of the intervention arm (*P*=.25). In order to improve self-efficacy, it is necessary to positively influence patient perceptions. Patients may benefit from a self-management approach

[27,41,42] with tailored education to change their perceptions about CPAP use and subsequently improve self-efficacy [43]. Lai et al [44] provided patients with additional education to enhance, for example, self-efficacy. This increased CPAP use compared with patients receiving usual care (*P*<.001). Stepnowsky et al [41] showed that a self-management program with information about OSA- and CPAP-related issues led to high self-efficacy scores (4.5 [SD 0.6]; scale 0 to 5) and CPAP adherence (5.5 [SD 2.3] mean hours per night). Because self-efficacy scores can be affected by the time that patients are treated, scores should be assessed regularly in order to be useful in clinical practice [14].

However, limited evidence was available about the effect of video consultation for newly diagnosed patients starting CPAP. Most previous RCTs were small, with sample sizes varying from 19 to 40 patients [17,25]. Only Isetta et al [29] evaluated CPAP compliance with a fully powered sample size. Although almost half of the patients (40%) in this study had insufficient digital skills, technology aspects were not evaluated [29]. In our study, 9% (20/222) were unable to participate because of lack of access to a mobile device or due to psychiatric or cognitive disorder. During the intervention, 2 patients (2/70, 3%) discontinued the video consultation intervention because of preference for face-to-face consultation or problems with their mobile device. The use of video consultation is evolving rapidly in clinical practice, but digital services are not applicable to all patients and digital health literacy remains a challenge [45]. This is especially due to lack of awareness or knowledge or unwillingness to change [46] and emphasizes the importance of personalized interventions rather than a one-size-fits-all approach.

The assessment of UTAUT components and self-efficacy can also be used to indicate technology use [47]. To our knowledge, no previous studies have identified technology acceptance for OSA patients using video consultation. Patients in our study had positive experiences with the use of video consultation and were satisfied with the video consultation system and consultations in general. Previous studies also reported high satisfaction scores [17,18,25,26], mostly regarding communication with a health care professional [18] and privacy and security factors [17]. Although most patients would recommend the use of video consultations to others, not all patients in our study are convinced that all visits can be replaced by video consultations. This is in line with findings from previous research [17].

The involvement of health care professionals is essential to achieve successful implementation of technology [48], but this is often not evaluated [17]. We found that nurses (n=3) preferred to start with a face-to-face consultation because education about the sleep mask and adjustments are often required during the first follow-up appointment with the nurse. The applicability of technology use may be dependent on the population [49], and

for OSA patients, the use of video consultation in a blended care setting might therefore be beneficial. We found that the nurses were satisfied with video consultation and especially with the quality of the system, privacy and confidentiality. They would recommend it to colleagues and patients. Nurses also reported technical problems (eg, problems with Wi-Fi connections). Technological issues are often seen as a barrier [50], and it is important to take technical elements into account [48,51,52] during implementation. Another point for improvement is integration in existing health care processes (eg, planning). To achieve successful implementation, it can be beneficial to involve professionals during the implementation process itself [50].

Video consultation can be seen as a promising app to support OSA patients during treatment. Still, evidence was lacking and previous research was not strong enough in design or focused on a limited number of outcomes. With the evaluation of a broad range of outcomes affecting CPAP use and implementation of video consultation in clinical practice, this RCT adds value to current knowledge.

However, proper evaluation in this field is challenging because research often lags behind the rapid development of technology [53]. The use of pragmatic trials may be promising [54] to evaluate different elements of eHealth solutions in a hospital setting and can, for example, be used to get (more) rapid insights in relevant implementation outcomes such as feasibility, impact on an organization, and acceptance and adoption by health care professionals and patients. Future research should focus on blended care approaches in which self-efficacy especially receives greater emphasis. For organizations to be able to implement video consultation on a larger scale, integration in existing health care processes and technology acceptance by patients and professionals is necessary.

Limitations

Several limitations should be considered. Risk perception and outcome expectancies were significantly different at baseline, despite randomization. For a limited number of patients (7/66, 11%, in the intervention group and 6/70, 9%, in the control group), video consultations or face-to-face consultations were replaced with a telephonic consultation due to technical problems in the intervention group and because patients in the control group could not come to the hospital. The protocol process were not strictly followed because patients failed to attend their scheduled appointment (no show, sick, on holiday) or there were organizational inaccuracies such as wrongly scheduled appointments. The percentage of patients that followed the process exactly as described (Multimedia Appendix 1) was higher in the intervention group (approximately half) than in the usual care group (approximately one-third). However, all patients received the intervention (type of consultation) they were allocated to except for the 2 patients who discontinued the intervention (Figure 1). Another

limitation is that only 3 nurses were involved in the evaluation. Therefore, a firm conclusion on professional aspects cannot be drawn.

Conclusion

Support of OSA patients with video consultation does not lead to superior results on CPAP use and adherence compared with face-to-face consultation. The findings of this research show that a significant difference in change over time was found between groups for short-term CPAP use (but not on specific time points), but not for long-term CPAP use. Levels of self-efficacy were positively related to CPAP use in both groups. Patients were very satisfied with video consultation and reported positive experiences.

Therefore, the findings of this research suggest that self-efficacy is an important factor in improving CPAP use and that video consultation may be a feasible way to support patients starting CPAP. The integration in health care processes and tailoring video consultation use to patient and professional needs is essential to ensure successful use. A blended care setting, in which an initial video consultation is combined with face-to-face consults, may be beneficial. To our knowledge, this is the first RCT that examined the effects of video consultation on CPAP use over time for newly diagnosed OSA patients in combination with cognitive components and experience with technology use. Future research should focus on blended care approaches in which self-efficacy receives greater emphasis.

Acknowledgments

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Abbreviations

AHI: apnea-hypopnea index
CONSORT: Consolidated Standards of Reporting Trials
CPAP: continuous positive airway pressure
OSA: obstructive sleep apnea
RCT: randomized controlled trial
SEMSA: self-efficacy measure for sleep apnea
UTAUT: unified theory of acceptance and use of technology

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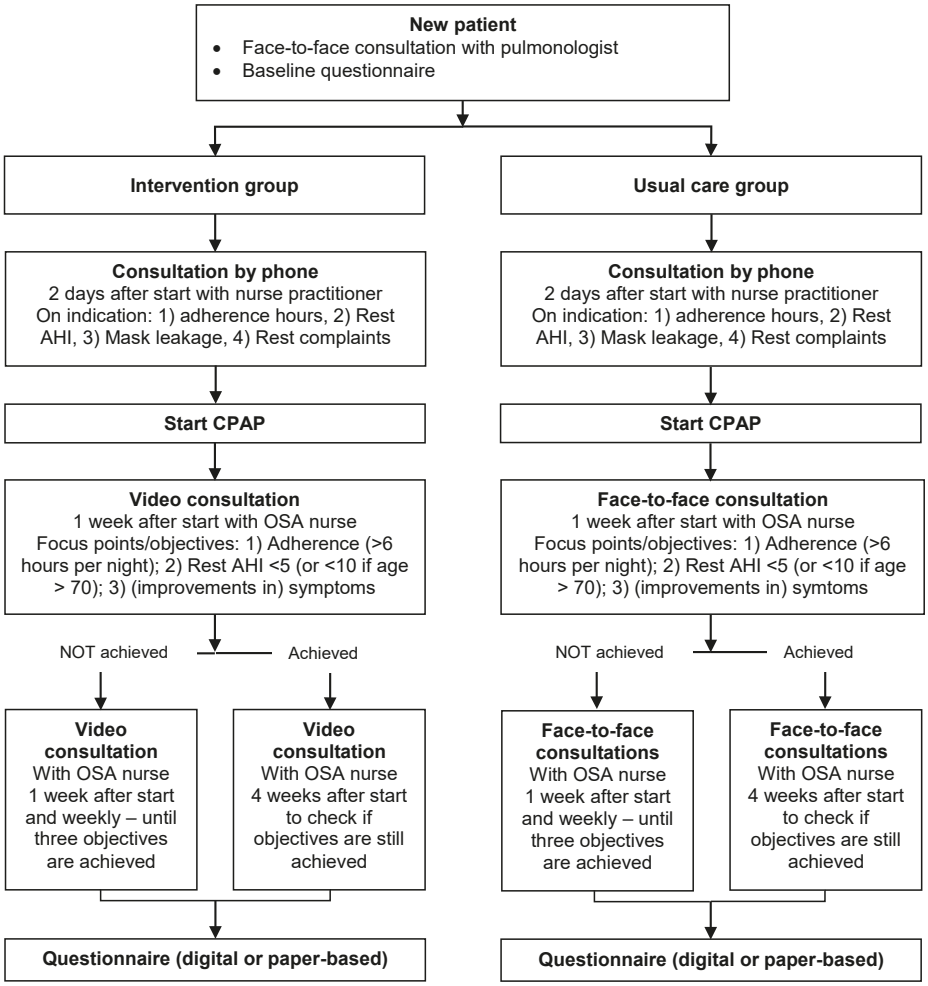
MULTIMEDIA APPENDICES

Multimedia Appendix 1 – Study process



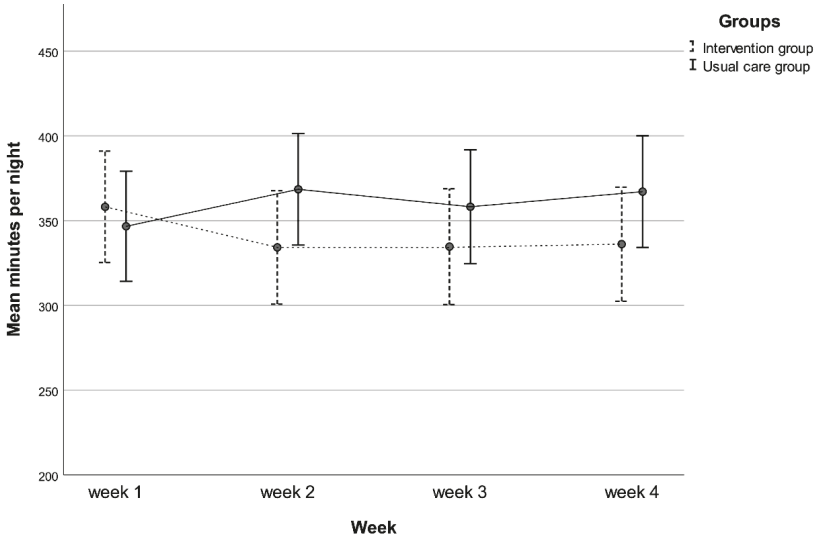
Multimedia Appendix 2 – Short-term CPAP use

Table 3. Short-term CPAP use (minutes per night)

Week[a]	Intervention		Usual care	
	EMM (SE)	95% CI	EMM (SE)	95%CI
Week 1	358.2 (16.7)	325.2 – 391.1	346.7 (16.4)	314.2 – 379.1
Week 2	334.2 (16.9)	300.8 – 367.7	368.5 (16.6)	335.6 – 401.4
Week 3	334.7 (17.3)	300.6 – 368.8	358.2 (17.0)	324.7 – 391.7
Week 4	336.2 (17.0)	302.6 – 369.8	367.2 (16.7)	334.2 – 400.1

[a] Linear mixed model

Multimedia Appendix 3 – Short-term CPAP use: change over time



Multimedia Appendix 4 – Short-term CPAP adherence

Table 4. Short-term CPAP adherence (CPAP use 5 ≥ nights ≥ 4 hours per night)

Week[a]	Intervention (%)	Usual care (%)
Week 1	77%	78%
Week 2	78%	78%
Week 3	78%	78%
Week 4	81%	82%

[a] Generalized estimating equations

Multimedia Appendix 5 – Long-term CPAP adherence

Table 5. Long-term CPAP adherence (CPAP use 5 ≥ nights ≥ 4 hours per night)

Week[a]	Intervention (%)	Usual care (%)
Week 4	78%	85%
Week 12	65%	75%
Week 24	63%	73%

[a] Generalized estimating equations

Multimedia Appendix 6 – Self-efficacy measure for sleep apnea constructs: self-efficacy, risk perception, and outcome expectancies.

Table 6. Self-efficacy Measure for Sleep Apnea (SEMSA) constructs, after 4 weeks

SEMSA constructs	Intervention	Usual care	*P* value
Outcome expectancies, mean (SD)[a]	2.89 (.56)	2.84 (.65)	.64
Self–efficacy, median (IQR)[b]	3.00 (2.89 – 3.44)	3.22 (2.71 – 3.67)	.41
Risk perception, median (IQR)[b]	1.75 (1.50 – 2.31)	1.63 (1.31 – 2.44)	.30

[a] Independent samples t-test
[b] Mann-Whitney U test

Multimedia Appendix 7 – Expectations and experiences with video consultation

Table 7. Expectations and experiences with video consulation (intervention group)

Statements based on Unified Theory of Acceptance of Technology	Expectation: baseline (N=70)[a], n (%)	Experience: after 4 weeks (N=66)[a,b], n (%)
I will have more control over my treatment using video consultation	46 (66)	
I have more control over my treatment using video consultation		48 (76)
The use of video consultation will have a positive effect on my treatment	48 (69)	
The use of video consultation had a positive effect on my treatment		47 (75)
It will not cost me effort to use video consultation	57 (81)	
It did not cost me effort to use video consultation		58 (92)
People in my direct environment will stimulate me to use video consultation	44 (64)	
People in my direct environment stimulated me to use video consultation		16 (25)
I have (tablet/smartphone) skills to use video consultation	64 (91)	
I had (tablet/smartphone) skills to use video consultation		60 (95)
I will receive enough support to use video consultation	60 (86)	
I received enough support to use video consultation		53 (84)
I intend to use video consultation	66 (94)	
I will keep using video consultation		60 (95)

[a]Number and valid percentage of patients that agree or totally agree (≥5 on 7-point scale, 1: totally disagree to 7: totally agree)
[b] n=4 patients lost to follow-up and n=3 patients did not complete the questionnaire

Multimedia Appendix 8 – Patient satisfaction with consultation

Table 8. Patient satisfaction with consultation, after 4 weeks

Satisfaction statements	Intervention (N=66)[a,b], n(%)	Usual care (N=70)[a,c], n(%)
The health care professional understood my problems	59 (94)	58 (85)
The health care professional listened to me during the (video/face–to–face) consultations	60 (95)	61 (90)
It was easy to express my feelings during the (video/face–to–face) consultations	59 (94)	62 (91)
I am satisfied with the information that I received during the (video/face–to–face) consultations	58 (92)	60 (88)
I did not miss important information during the (video/face–to–face) consultations	56 (89)	43 (63)
The explanation that I received during the (video/face–to–face) consultations helped me	55 (87)	58 (85)
I understood the content of the (video/face–to–face) consultations	61 (97)	62 (91)
I felt comfortable during the (video/face–to–face) consultations	60 (95)	62 (91)

[a] Number and valid percentage of patients that agree or totally agree (≥5 on 7-point scale, 1: totally disagree to 7: totally agree)
[b] n=4 patients lost to follow-up and n=3 patients did not complete the questionnaire
[c] n=2 patients did not complete the questionnaire

Multimedia Appendix 9 – Patient satisfaction with video consultation

Table 9. Patient satisfaction with video consultation, after 4 weeks

Satisfaction with video consultation statements	Intervention (N=66)[a], n(%)
I save time because of video consultation	61 (97)[b]
I felt safe about my privacy and confidentiality	61 (97)[b]
I would recommend video consultation to patients in a similar situation	57 (91)[b]
I am (very) satisfied with the use of video consultation	56 (89)[b]
I prefer a consult with video consultation than face–to–face	51 (81)[b]
I am satisfied with the quality of the video	50 (79)[b]
I am satisfied with the quality of the sound	45 (71)[b]
I have better access to my health care professionals because of video consultation	43 (68)[b]
I think that a video consultation can replace all consultations in the hospital	28 (44)[c]

[a] n=4 patients lost to follow-up and n=3 patients did not complete the questionnaire
[b] Number and valid percentage of patients that agree or totally agree (≥5 on 7-point scale, 1: totally disagree to 7: totally agree)
[c] Yes/No/Maybe question: percentage of patients that answered 'yes'

CHAPTER 7

Remote continuous monitoring with wireless wearable sensors in clinical practice, nurses perspectives on factors affecting implementation: a qualitative study

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**The last two authors contributed equally*

ABSTRACT

Background

Continuous monitoring using wireless wearable sensors is a promising solution for use in clinical practice and in the home setting. The involvement of nurses is important to ensure successful implementation. The aim of this paper is to provide an overview of 1) factors affecting implementation of continuous monitoring using wireless wearable sensors by evaluating nurses' experiences with its use on the nursing ward, and 2) nurses' expectations for use in the home setting.

Methods

Semi-structured interviews were conducted with 16 nurses from three teaching hospitals in the Netherlands, covering constructs from the Consolidated Framework for Implementation Research (CFIR). A deductive approach of directed content analysis was applied. One additional construct was added using the Unified Theory for Acceptance of Technology (UTAUT). The quotes and domains were rated including valence (positive, neutral, negative) and strength (strong: -2, +2, neutral 0, and weak: -1, +1).

Results

Data was collected on 27 CFIR constructs and 1 UTAUT construct. In the experience of at least 8 nurses, five constructs had a strong positive influence on implementation on the nursing ward including: relative advantage (e.g., early detection of deterioration), patient needs and resources (e.g. feeling safe), networks and communications (e.g. execute tasks together), personal attributes (e.g. experience with intervention), implementation leaders (e.g., project leader). Five constructs had a strong negative influence: evidence strength and quality (e.g. lack of evidence from practical experience), complexity (e.g. number of process steps), design quality and packaging (e.g., bad sensor quality), compatibility (e.g, change in work) and facilitating conditions (e.g, Wi-Fi connection). Nurses expected continuous monitoring in the home setting to be hindered by compatibility with work processes and to be facilitated by staff's access to information. Technical facilitating conditions (e.g. interoperability) were suggested to be beneficial for further development.

Conclusions

This paper provides an overview, including relative importance, of factors influencing implementation of continuous monitoring, based on nurses' experiences with use on nursing wards, and perspectives for use in the home setting. Implementation of continuous monitoring is affected by a wide range of factors. This overview may be used as a guideline for future implementations.

Keywords: Continuous monitoring, Wireless Technology, Nurses

Contributions to the literature

- Nurses have firm views on barriers and facilitators of implementation of continuous monitoring with wireless wearable sensors on nursing wards as well as in the home situation, and play a crucial role during implementation
- Implementation of continuous monitoring using wireless wearable sensors in clinical practice is complex and affected by a wide range of factors such as compatibility with work processes, complexity of the intervention, technical conditions, patient needs and nurses' personal experiences.
- This knowledge on intervention, process and professional characteristics is useful for future implementation of wireless wearable sensors on the nursing ward and in the home setting.

BACKGROUND

Patients' vital signs are monitored during hospitalization to detect clinical deterioration. Vital signs are monitored continuously on Intensive Care Units (ICU), while patients on clinical wards are generally monitored intermittently [1, 2], often every 4 [3], or 6 to 8 hours [2]. Several parameters are measured during these routine observations including heart rate, respiratory rate and blood pressure. These measurements are usually conducted in person by nursing staff, which can be time consuming [2]. A Modified Early Warning Score (MEWS), a scoring system incorporating all intermittent measurements and other observations, is often used to facilitate detection of clinical deterioration on nursing wards [4].

Continuous monitoring of vital signs using wireless wearable sensors in nursing wards is a promising solution and may lead to earlier detection of deterioration in patients [5], early interventions [6], reduction in length of stay, and number of ICU days [2]. It may also contribute to patient safety [7], improve patient mobility [7], and reduce workload for nurses [8]. Many different wearable sensors are available [1]. Some provide funtionality similar to that of monitors on the Intensive Care Unit. These tend to be cumbersome devices. Other sensors measure a limited number of vital signs, such as heart reate and respiratory rate, but come in more manageable forms, such as adhesive patches that can be attached to a patient's chest. These are more suitable for monitoring on the nursing ward, and may als obe suitable for use in the home setting [9]. The implementation and use of these sensors will affect hospital staff and their work. Therefore, the involvement of nursing staff, who are

often responsible for the monitoring of patients, is essential for successful implementation in clinical practice [3, 5].

Implementation of technology in clinical practice, for example continuous monitoring, is a complex process [10-12] and can be affected by technical, social and organizational factors [12, 13]. The engagement of stakeholders is valuable throughout the whole process including development and evaluation [10]. Lack of their involvement is found to be a barrier for implementation [3] and therefore it is important to obtain their input [14]. Previous studies found that nurses are positive about the possible benefits of continuous monitoring such as signaling early deterioration, but they also see disadvantages for example less patient contact [15] and technical issues [16]. Recent evidence on the use of wireless sensors in daily clinical practice is limited [3]. Some positive and negative factors affecting implementation of continuous monitoring with wireless wearable sensors were reported in previous studies [3, 9, 15], but systematic information on the relative importance of a broad range of factors affecting implementation from the perspective of nurses is limited. Also, insight into nurses expectations on future developments for continuous monitoring using these sensors in the home setting, which may change nurses' roles, is lacking.

The aim of this paper is to provide a overview of 1) factors affecting implementation of continuous monitoring using wireless wearable sensors by evaluating nurses' experiences with its use on the clinical ward, and 2) nurses' expectations for its use in the home setting.

METHODS

Sampling procedure and participants

A qualitative study, with a generic approach, was conducted. Purposive sampling was used to select hospitals in the Netherlands where continuous monitoring with wireless wearable sensors, further referred to as *continuous monitoring,* was used. In total, 3 teaching hospitals were included, through the authors' network. Contact persons e.g. department heads or managers in the hospitals were approached by e-mail or telephone to invite hospital nurses to participate in the study. The criterium was that they were involved in continuous monitoring using sensors on the nursing ward. After agreement, semi-structured interviews were scheduled with each of these nurses individually, no preparation was requested.

Data Collection Procedure

The contents of semi-structured interviews were based on the Consolidated Framework for Implementation Research (CFIR). This framework describes constructs organized in 5

domains: 1) Intervention Characteristics, e.g. evidence strength & quality and complexity, 2) Outer Setting, e.g. cosmopolitanism and patient needs & resources, 3) Inner Setting, e.g. compatibility and networks & communication, 4) Characteristics of Individuals, e.g. knowledge & beliefs and other personal attributes and 5) Process, e.g. champions and reflecting & evaluating [11]. The interview guide can be found in Additional file 1.

The interviews were conducted by the first author (LK). At the start of the interview, all respondents were informed about the purpose of the interview and verbal consent for audio recording was obtained. The first 10 interviews in the first hospital were conducted face-to-face in a room on the nursing ward with only the respondent and interviewer present. The other interviews, 3 interviews in two hospitals each, were conducted by telephone due to COVID-19 circumstances. The interviews lasted on average 31.5 minutes (range 19 – 44 minutes). Data were collected between December 2019 and July 2020. Ethical approval for this study was asked for and waived by the Medical Research Ethics Committee Arnhem-Nijmegen (registration 2019-5489). The study fell outside the remit of the law for Medical Research Involving Human Subjects Act and was approved by the local ethical committee.

Data Analysis

The first author (LK) transcribed all interviews verbatim. Transcripts were anonymized and not returned to the participants. The first two authors (LK, GMP) independently selected text fragments ('quotes') and coded all interviews using Atlas.ti version 8. If quotes did not fit in the CFIR framework, the Unified Theory of Acceptance and Use of Technology (UTAUT), in particular facilitating conditions [17], was used for other specific technological aspects. A deductive approach of directed content analysis [18] was applied. Although, we did not develop questions for all CFIR constructs, some topics came up during interviews nonetheless. These topics were coded to the corresponding CFIR construct.

Subsequently, the first two authors (LK, GMP) rated the valence and strength of each quote using CFIR criteria (see Additional file 2). The valence could be positive, negative or neutral. The valence for the total could also be mixed (both positive and negative). The strength indicated whether a construct had a weak (-1 or +1), strong (-2 or +2), or neutral (0) influence on implementation [19]. The first two authors rated each CFIR construct on valence and strength, and a case memo [20] was written (Additional file 3). Inconsistencies in coding and rating between the two assessors were discussed and if no agreement was reached, assessed by a third assessor (CD). Saturation of the data was analyzed (post hoc) and confirmed, so more interviews would not lead to additional new factors. Feedback on the findings was not elicited from participants. For the reporting of this paper, we used the COREQ guidelines.

RESULTS

Study population

In total, 16 interviews were conducted with nurses from three teaching hospitals. Their characteristics are presented in table 1.

Table 1. Characteristics of the 16 participating nurses

Characteristics	Nurses (N=16)
Gender, women, n(%)	16 (100)
Age, mean (SD), range (min–max)	34.1 (11.2), 22–56
Work experience	
0 – 4 years	3 (19)
5 – 9 years	4 (25)
10 – 14 years	4 (25)
>=15 years	5 (31)

Intervention

The intervention, in the three hospitals, consisted of continuous monitoring using wireless wearable sensors on nursing wards and was used for bariatric patients after surgery (in hospital 1), for patients who had heart- or heart-valve surgery and for unstable patients and vulnerable elderly (in hospital 2), and for patients with pulmonary, neurological, gastrointestinal, and liver diseases (hospital 3). Two out of three hospitals used the biosensor from 'Philips'[21], with a battery duration of 4 days, to measure heart rate and respiratory rate. The third hospital used a sensor from 'Sensium'[22], with a duration of 4-5 days, to measure heart rate, respiratory rate and temperature.

Experiences with continuous monitoring on the nursing ward and in the home setting

In total, we selected 1068 quotes covering 27 CFIR constructs and 1 UTAUT construct. A total overview of the rating of all quotes from all respondents can be found in Additional file 4 (nursing ward) and 5 (home setting). By quantifying the findings, the most prevailing results are presented below.

On the nursing ward, 19 CFIR constructs and 1 UTAUT construct were identified by at least 8 nurses. Of these,10 constructs had a positive influence, 5 mixed and 5 had a negative influence on implementation of continuous monitoring on the nursing ward. In the home setting, seven constructs were identified by at least 8 nurses, 2 were projected to have a

positive influence, 2 a negative influence and, 3 were mixed. Results that were mentioned by the at least 8 (out of 16) nurses are described below and presented in table 2.

Table 2. Continuous monitoring on the nursing ward and expectations use in the home setting (N=16)

CFIR and UTAUT constructs	**Experiences: on the nursing ward**		**Expectations: use in the home setting**	
	Total rating[a]	Total N nurses (no. of quotes[b])	Total rating[a]	Total N nurses (no. of quotes[b])
I. Intervention characteristics				
Evidence strength and quality	–2	14(36)	–1	8(18)
Relative advantage	+2	15(61)	+2	10(16)
Trialability	Mixed	8(15)	–[c]	–
Complexity	–2	16(100)	NA[d]	NA
Design quality and packaging	–2	15(39)	–	–
II. Outer setting				
Patient needs & resources	+2	10(25)	Mixed	15(44)
III. Inner setting				
Networks & communications	+2	15(32)	NA	NA
Tension for change	+1	13(18)	NA	NA
Compatibility	–2	13(39)	–2	16(97)
Relative priority	Mixed	16(39)	NA	NA
Goals and feedback	+1	16(20)	NA	NA
Learning climate	+1	16(79)	NA	NA
Available resources	Mixed	16(42)	Mixed	9(14)
Access to information and knowledge	+1	16(48)	+2	13(21)
IV. Characteristics of individuals				
Knowledge and beliefs	Mixed	9(12)	Mixed	12(26)
Other personal attributes	+2	12(19)	NA	NA

Table 2. Continued.

CFIR and UTAUT constructs	Experiences: on the nursing ward		Expectations: use in the home setting	
	Total rating[a]	Total N nurses (no. of quotes[b])	Total rating[a]	Total N nurses (no. of quotes[b])
V. Process				
Formally appointed internal implementation leaders	+2	10(26)	–	–
Champions	+1	14(34)	–	–
Reflecting and evaluating	Mixed	15(33)	–	–
UTAUT				
Facilitating conditions	–2	8(31)	–	–

[a] Minus sign (-) means a negative influence on implementation, positive sign (+) means positive influence on implementation, 'mixed' means both negative and positive influence on implementation
[b] In total, 1068 quotes were selected of which 5 quotes were coded to two constructs
[c] "–" construct was not mentioned by nurses
[d] Not applicable (NA): mentioned by 1 – 7 nurses

Intervention characteristics

Evidence strength and quality

Experience on the nursing ward

This domain refers to respondents' practical experiences on the nursing ward and perceptions of the available evidence (e.g. from use in practice) for continuous monitoring. Statements about the importance of evidence strength and quality of continuous monitoring on the nursing ward were mentioned by almost all respondents (14/16, 88%), with a strong negative influence on implementation. Respondents referred especially to the lack of available evidence to substantiate the use of continuous monitoring with a limited number of vital signs (e.g., heart-rate and respiratory rate) in their patient population. Gathered evidence based on practical experiences was also found to be a negative influence, especially because measurements of vital signs by the sensor often did not correspond with measurements with another monitoring device used in daily practice. Technical issues (e.g., system was not working or not reliable) were also mentioned. Despite a negative sentiment, two nurses mentioned positive experiences with regards to early detection of deterioration (see Additional file 4).

> *"We need to gain trust in the idea that heart rate and respiratory rate together provides sufficient information to conduct interventions. That is still difficult for me."*

Expectations for continuous monitoring in the home setting
Half of the nurses (8/16, 50%) were not convinced there is enough available evidence for continuous monitoring in the home setting. This was caused by predominantly negative experiences based on use on the nursing ward, and they also still need to gain trust in the system and the new way of working (see Additional file 5).

> *"We are not even close to monitoring patients at home. Even here [on the nursing ward] it has not worked 100% of the time."*

Relative advantage
Experience on the nursing ward
Many advantages for continuous monitoring were mentioned by almost all nurses (15/16, 94%) including data availability, patient safety, early discharge, higher turnover, (higher) quality of measurements, and support of clinical view. Early detection of deterioration (12/16, 75%) and time and efficiency (10/16, 63%) were also seen as advantages, as the intervention saves them time measuring vital signs regularly and thus routine rounds.

> *"You have a continuous sight on the patient. I think that is most important, you can detect early deterioration"*

Expectations for continuous monitoring in the home setting
Nurses (9/16, 56%) foresee many advantages for the use of continuous monitoring in the home setting including data availability, early discharge, higher turnover or lower cost, early deterioration, time or efficiency benefits, and patient safety.

> *"The advantage is that people don't need to spend the night here in the hospital. I think this also saves healthcare costs."*

Trialability

Experience on the nursing ward

This domain includes statements on the ability to pilot the intervention. On the one hand conducting a pilot was perceived positively (3/16, 19%) because it was possible to gain experience with continuous monitoring. On the other hand it was perceived negatively (3/16, 19%) because the pilot setting led to additional tasks and duplications in registration because multiple systems were used.

> *"We conducted a pilot on the nursing ward…I think for a certain number of patients. Based on that pilot we wanted to see if it would be meaningful."*

Complexity

Experience on the nursing ward

Complexity refers to the perceived difficulty of the intervention. All nurses (16/16, 100%) brought up aspects related to the high degree of complexity of the intervention, and in total complexity was seen as a (strong) negative influence on implementation. The negative rating was especially due to the duration of the intervention (13/16, 81%) in terms of extra time required for example to attach and activate the sensor, perceived difficulty (8/16, 50%), and the number of procedural steps (8/16, 50%).

> *"First we had to open the system, search for the patient in the system. That will already take approximately 5 minutes, so it takes extra time."*

Design quality and packaging

Experience on the nursing ward

The design quality and packaging includes statements regarding the quality of the sensor (e.g, flexibility and attachment to the body), the system (e.g. scanning and connection with sensor) and data availability (e.g. gaps in data availability). The majority of the nurses (13/16, 81%) was not satisfied with the quality of the sensor for example because of detachment of the sensor from the patient's body. They were also not satisfied with the quality of the system (3/16, 19%), and data availability (3/16, 19%). Positive elements about the quality of the sensor were only mentioned by a small number of nurses (5/16, 31%), for example good attachment of the sensor to the body and flexibility of the sensor

> *"Our target population was sweating a lot after surgery, and we noticed the sensor would come off…"*

Outer setting

Patient needs and resources

Experience on the nursing ward

This construct includes factors affecting patients as a result of continuous monitoring on the nursing ward, this was seen as a positive influence on implementation. One third of the nurses (5/16, 31%) perceived that patients on the nursing ward felt safer when they were monitored continuously and that they were not burdened by the sensor (5/16, 31%). Only, a minority (3/16, 19%) mentioned that the sensor may be inconvenient for some patients, for example because of skin irritation.

> *"There were also patients that felt safe: 'so you monitor my values 24 hours per day. So even if you are not in my room, you monitor me'. That gave patients a feeling of safety."*

Expectations for continuous monitoring in the home setting

The majority of the nurses (10/16, 63%) mentioned that the intervention can be beneficial for patients because they can recover in their own home. Although, 31% (5/16) of the nurses expect that continuous monitoring will make patients feel safe at home, but according to the majority (10/16, 63%) early discharge with continuous monitoring might also cause patients to feel insecure or anxious because they don't receive care in the hospital. Adequate patient information is considered a facilitator (2/16, 13%).

> *"I think that people will recover better at home. I also think they will sleep better in their own bed, because that is more pleasant."*

Inner setting

Networks and communication

Experience on the nursing ward

This domain includes nurse preferences for- and experiences with communication about the implementation of the intervention. For example most nurses (10/16, 63%) were positive about executing a task together with a colleague. They perceived this as a facilitating factor to practice the use of the sensor. Nurses were also positive about both formal communication (8/16, 50%), for example planned information meetings, and informal communication (5/16, 31%) with colleagues.

> *"During the planned meetings we could get together and share experiences, we also had frequent mail contact but the moments together were the most pleasant."*

Tension for change

Experience on the nursing ward

Tension for change encompasses statements on the need to change the current situation of monitoring on the nursing ward, for example the use of the MEWS. Although, according to 31% (5/16) changing the current situation would be beneficial e.g. measuring the respiratory rate by a device instead of manually, 50% (8/16) did not feel the need to change the current situation. They were satisfied with the current monitoring and especially the use of the Modified Early Warning Score (MEWS).

> *"These check-ups, the MEWS, are really useful during acute situations. You can really compare with other check-ups or with deteriorating patients, so I am used to working with the MEWS and I think it is quite nice."*

Compatibility

Experience on the nursing ward

This domain includes the degree to which the intervention is compatible with existing work processes and systems [11]. Multiple (sub)categories were distinguished including compatibility with work process and the use of systems, change in work and perceived risks. Compatibility with work processes was rated negatively by most nurses (12/16, 75%). This can be explained by increased workload (4/16, 25%). For example, in case of deteriorating vital signs nurses needed to check the patients and, if necessary, perform extra check-ups. Some sensor limitations were also not compatible with work processes, according to 6 nurses (6/16, 38%). For example, the sensor could not measure certain vital signs such as blood pressure. Also, it could not be used for patients with a pacemaker, when diagnostic tools such as a CT scan were used, or while the patient was taking a shower. Almost half of the nurses (7/16, 44%) thought that with continuous monitoring their work would not change and would not be affected, especially because they think their clinical view is still needed in addition to continuous monitoring. Six nurses (6/16, 38%) reported risks of continuous monitoring including lack of clinical view (4/16, 25%).

> *"So at some point you could see a deviation in a patient, which you couldn't see with your clinical view alone, but to really be sure how the patient was doing you still had to go and take the measurements. So that was an additional task…"*

Expectations for continuous monitoring in the home setting

Compatibility was perceived as a negative influence on implementation of continuous monitoring in the home setting. Half of the nurses (8/16, 50%) thinks that continuous monitoring in the home setting will negatively change their work. According to 44% (7/16)

this will have a negative effect on their relation and contact with patients because there will be less personal contact due to patients' shorter stay in the hospital. In total, 50% (8/15) is negative about compatibility with work processes. Nurses expect workload to increase (5/16, 31%) if they have to monitor patients in the home setting in addition to taking care of patients on the nursing ward. Almost all nurses (15/16, 94%) think that continuous monitoring in the home setting involves risks including lack of clinical view, occurrence of complications in the home setting, when complications remain unnoticed (for too long) and technical issues (e.g., Wi-Fi connection or defect sensor). Nurses also expect that for certain patients who have low health literacy and coping mechanism the use of the sensor can be a risk.

> *"There are definitely risks in the home setting. There must always be somebody who can take action if a patient calls or when you receive an alarm with the measurement of this patient. These are the the measurement of this patient, who is responsible to take action? There are quite a number of challenges [regarding monitoring in the home setting]."*

Relative priority

Experience on the nursing ward

This is defined as the degree to which nurses perceived continuous monitoring to be a priority in the organization and their department. Although the responses varied, most nurses (11/16, 69%) thought that the implementation of continuous monitoring would be a priority for the hospital. However, the priority on the nursing ward itself varied during implementation, 19% (3/16) considered it a priority during implementation, 19% (3/16, 19%) thought it was not a priority. All three hospitals conducted a pilot, 19% (3/16, 19%) mentioned that the priority decreased due to the unsuccessful pilot and that there was a lack of priority (6/16, 38%) on the nursing ward after the pilot.

"I think priority is high, because a lot of manpower and money is dedicated to it."

Goals and feedback

Experience on the nursing ward

All respondents (16/16, 100%) could explain the aim of the intervention i.e. early detection of deterioration and the prospect of early discharge with continuous monitoring in the home setting.

> *"Eventually, the goal is to discharge a patient early and monitoring them at home"*

Learning climate

Experience on the nursing ward

Learning climate refers to the degree to which nurses feel it was possible to give input, whether their input was valued, sufficient opportunity was given to try out the new intervention, sufficient time was available for learning, and how they felt about making mistakes. It was possible to give input (9/16, 56%) and the input was valued (12/16, 75%). Almost all nurses (12/16, 75%) had enough time for training. However, their perceptions varied about the possibility to test the intervention and whether they felt safe to try the intervention and make mistakes.

> *"It was a pilot and it was no direct risk for the patient. We also performed the normal checks, so you had a good view of the patient and patient safety was not at risk".*

Available resources

Experience on the nursing ward

This domain refers to the available resources and time for implementation. Nurses' experiences varied, 81% (13/16) thought there were sufficient additional resources such as a dedicated project team and technical support. The majority (11/16, 69%) did not receive extra time for the intervention and 37% (6/16) reported that there were not enough human resources available during implementation, especially dedicated nurses were lacking.

> *"There was a project team with supervisors and researchers and somebody from the technical department."*

Expectations for continuous monitoring in the home setting

In total, 38% (6/16) thought that the current staffing is insufficient to handle the additional tasks for continuous monitoring in the home setting, and that extra human resources (4/16, 25%) would be beneficial for implementation.

> *"If you also have patients here, you don't have time for the patients at home. You need an extra person per shift, responsible for monitoring [in the home setting]"*

Access to information and knowledge

Experiences on the nursing ward

Access to information and knowledge included for example access to a manual as a guide and a training on how to execute tasks. Overall, this was rated positively by almost all nurses (15/16, 94%), especially a manual was perceived to be helpful. In total, 63% (10/16)

was also positive about the training. However, four nurses (4/16, 25%) were less satisfied, reasons being that a lot of information was given at once during the training and they felt that there was insufficient opportunity to practice during the training.

> *"The manual was changed frequently, with new tips and things. That was very useful"*

Expectations for continuous monitoring in the home setting
In total, 75% (12/16) of the nurses think that information, for example a decision tree, or training would be beneficial for continuous monitoring in the home setting.

> *"I think we need a manual on what to do with which complaints. It needs to be unequivocal."*

Characteristics of individuals

Knowledge and beliefs

Experiences on the nursing ward
This domain included statements on nurses' beliefs about and attitudes towards continuous monitoring. Nurses were predominantly positive (7/16, 44%) about continuous monitoring on the nursing ward. In total, 25% (4/16) was not positive about the intervention.

> *"I think it is a very nice development. When I see it in practice, I think it could be possible…there are a lot of patients that could just go home"*

Expectations for continuous monitoring in the home setting
Nurses' beliefs (attitudes) towards continuous monitoring in the home setting varied, 56% (9/16) was positive about continuous monitoring in the home setting and they think it is a positive development. However, 38% (6/16) was less enthusiastic about the development, especially because of the change in providing care.

> *"I think this is a logical development in the sense that you always keep considering how care can be organized differently, you evolve with the time, technology develops rapidly, and I can understand that you start thinking about how you can monitor people at home, does that result in early discharge, and what can be done safely."*

Other personal attributes

Experience from use on the nursing ward

This domain includes personal characteristics affecting implementation for example competence, age, employment and experience with the intervention. In total, 75% (12/16) mentioned personal characteristics that will contribute to the implementation, for example (younger) age (2/16, 13%). Also, according to 63% (10/16) experience with the new intervention tasks will be beneficial, for example to execute tasks correctly and at a more rapid pace.

> *"The more often you do it, the easier it will become and you will get into a routine."*

Process

Formally appointed internal implementation leaders

Experience from use on the nursing ward

Six nurses from all three hospitals mentioned that a formally appointed internal implementation leader, often a project leader, was appointed to coordinate the intervention project. This was seen as positive by 44% (7/16) of the nurses because of the support and motivation they received.

> *"The project leader was accessible, and visible on the nursing ward….I think that is important especially at the start, that somebody is always available to answer your questions"*

Champions

Experience from use on the nursing ward

Champions were mostly referred to as "key users", a group of nurses with specific involvement and focus on this project. Champions were reported to be present in all three hospitals and their presence was appreciated by more than half (10/16, 63%) all nurses, for example for practical support.

> *"We had key-users who helped us attaching and connecting the sensor."*

Reflecting and evaluation

Experience from use on the nursing ward

Over half of the nurses (9/16, 56%) was positive about the evaluation of the intervention implementation. They reported that evaluations, conducted during or after the implementation period, were completed in (team) meetings or that evaluation forms were used. This provided them with insights into the status of the implementation project. Almost 40% (6/16) was not involved in an evaluation or would have preferred an evaluation.

"We discussed it each day in the daily evaluation. How is it going, is the connection working, are the check-ups good, do you notice differences, do you feel positively or negatively about it. A lot of attention was paid to it."

Facilitating conditions (UTAUT)

Experience from use on the nursing ward

Facilitating conditions include the degree to which nurses perceive that technical infrastructure is adequate to support the intervention. This was considered negatively by half of the nurses (8/16, 50%). This was mainly due to a bad Wi-Fi connection (7/16, 44%), and the reason the pilot was discontinued in two hospitals. Lack of interoperability with already existing systems, for example with the Electronic Medical Record (EMR), was also seen as a negative aspect by 25% (4/16).

"The Wi-Fi was a problem. Sometimes the sensor did not connect and we had to restart the whole system. So that was the reason it did not work out."

Suggestions and technical conditions for further development of continuous monitoring on the nursing ward and in the home setting

Suggestions for further development

In total, 12 nurses (12/16, 75%) made suggestions for further development of continuous monitoring in the hospital and the home setting. Seven nurses (7/16, 44%) mentioned that they need additional parameters for continuous monitoring inside and outside the hospital, for example blood pressure or oxygen saturation. Other suggestions for improvement of continuous monitoring in the home setting include: agreements upon responsibilities for continuous monitoring in the home setting (3/16, 19%), personalized target values of vital parameters to prevent false alarms (2/16, 13%) and a dedicated contact person (2/16, 13%).

Conditions for continuous monitoring

To ensure successful intervention, interoperability with already existing systems (e.g. EMR) is perceived as important by nurses (8/16, 50%), this could contribute to (future) implementation and save time. Other conditions for continuous monitoring include properly working and reliable technology (network, sensor etc) (6/16, 38%), which will also lead to (extra) added value of this intervention. In addition, patients' home situation should be ready (1/16, 6%) and patients should have skills (2/16, 13%) to handle the sensor, before continuous monitoring can be implemented at home.

DISCUSSION

Principal findings

In total, we identified 27 constructs from the CFIR framework and 1 construct from the UTAUT model influencing implementation of continuous monitoring on nursing wards. Five constructs, mentioned by the majority of nurses (at least 8), in their experience had a strong positive influence on implementation. These constructs included relative advantage (e.g., early detection of deterioration), patient needs and resources (e.g., feeling safe), networks and communications (e.g. execute tasks together), personal attributes (e.g. experience with intervention), implementation leaders (e.g., project leader). Five constructs had a strong negative influence on implementation, including evidence strength and quality (e.g. lack of evidence from practical experience), complexity (e.g. number of procedural steps), design quality and packaging (e.g., bad sensor quality), compatibility (e.g., change in work) and facilitating conditions (e.g., Wi-Fi connection). Nurses expected continuous monitoring in the home setting to be hindered by compatibility with work processes and systems (e.g., change in work) and evidence strength and quality (e.g., lack of available evidence), and to be facilitated by access to knowledge and information (e.g., training) and perceived advantages of the implementation (e.g., data availability). Technical facilitating conditions, for example interoperability with already existing systems, were suggested to be beneficial for further development.

Comparison with other studies

Only a limited number of earlier studies evaluated nurses' perspectives of continuous monitoring with wireless wearable devices [3, 9]. In a randomized controlled trial (RCT), health care professionals' experiences with- and expectations for use of a wearable device on a general ward were assessed using interviews. Several findings from this study were comparable with our study such as positive aspects including early detection of clinical deterioration, feelings of safety and shorter hospital stay and negative aspects for example less patient contact and not being able to measure all vital signs with one sensor. However, the results of this RCT also indicate that continuous monitoring can have both positive and negative effects on workload and time spent [8]. The findings of an observational cohort study on continuous monitoring with a wearable device on a general ward, described that the majority of nurses (74%, n=17) did not think that using the wearable device would be time saving [23].

Continuous monitoring was perceived as complex especially due to extra time required for the intervention and the number of procedural steps to activate the sensor for example attachment and connection of the sensor. This experience could also be a result of the pilot study setting, since this set up led to temporary duplications in registration and additional

tasks as multiple systems were used. Nurses also reported that the amount of current staffing was insufficient to monitor patients on the nursing ward and simultaneously in the home setting and that additional (human) resources are necessary for the use of continuous monitoring in the home setting.

Integration of- and compatibility with work processes and changed roles for professionals are found to be important for implementation of interventions using information- and communication technology [24], such as continuous monitoring. We found that nurses' lack of direct observation and relying on their "clinical view" was perceived as a (possible) risk for continuous monitoring. They also expected that its use in the home setting will have a negative effect on their contact with patients for example because of early discharge. Nurses in several previous studies were also worried about decrease in patient contact [8, 15] and therefore lack of assessment of deterioration [15]. The use of technology may change nurses' profession and their contact and relationship with patients, especially regarding remote care and monitoring. According to Peplau's theory of interpersonal relations, contact between patients and nurses consists of different phases (orientation, identification, exploitation, and resolution) in which nurses can take on different roles, such as counsellor, technical expert and, resource person for example to provide information [25]. The introduction of technology, such as sensor devices, may change the delivery of care, for example because patients are monitored remotely from home. This may also require a change in nurses' roles because physical and face-to-face contact is more limited.

The success of an intervention is obviously affected by technology aspects and integration with current systems, including the hospital information technology infrastructure. This includes for example interoperability with the EMR [1], which is important for long-term use [1]. This was confirmed by nurses in our study, because lack of a highly reliable Wi-Fi network was mentioned as a reason to discontinue the intervention. It was also found to be a barrier in a previous pilot study of continuous monitoring on a nursing ward [26]. Wi-Fi related issues can also cause data loss [27]. Therefore, prior to the implementation of a technology, it is recommended to ensure a well-functioning and reliable hospital Wi-Fi infrastructure [1]. Other technical issues included lack of evidence for the use of continuous monitoring as nurses sometimes experienced deviating measurements in comparison with another monitoring device used in daily practice. Evaluation of validation and feasibility of these devices is still ongoing [9] and therefore pragmatic evaluation of new technologies, or new versions of existing technologies, is required. This is especially relevant since the development of technology is evolving at a rapid pace, and currently multiple sensors, with different specifications, are available for continuous monitoring [9].

Nurses' personal characteristics may also affect the uptake of technology in clinical practice. eHealth literacy, "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem" requires skills [28] and access to digital tools [29]. Nurses' digital competencies can be affected by age and experience and may be improved by training and education [30]. Nurses in our study also highlighted that information (e.g., manual and decision tree) and training is needed especially for continuous monitoring in the home setting. Also, technical support can facilitate technology use [31]. Another important aspect for successful digital interventions is technology acceptance. The UTAUT model can be used to assess both the intention for technology use and the actual use [17] and includes the potential moderating factors age, experience and also gender and voluntariness of use. Other personal characteristics may also influence eHealth acceptance such as knowledge about - and experience with IT and work experience [32]. In future research, additional attention should be paid to the impact of nurses' eHealth literacy, digital skills, and technology acceptance on interventions supported by technology.

Although several studies evaluated the perspectives and experiences of continuous monitoring from nurses' perspectives [8, 15, 23, 26], there is limited information available about factors that influence implementation on different general wards and expectations for use of wireless wearable sensors in the home setting. Our overview, therefore, adds to the current body of knowledge by structured application of both CFIR and UTAUT frameworks. Future research is needed to confirm the use of this overview in developing, implementation and evaluating interventions on a larger scale.

Strengths and Limitations

One strength of our study is that a wide range of factors were structurally assessed with focus on both experience from use of continuous monitoring on nursing wards and expectation of its use in the home setting. Additionally, we interviewed nurses from different teaching hospitals in which continuous monitoring was used in different populations and received comparable views on the use of the sensor. As indicated in the methods, not all constructs of the CFIR framework were used for the semi-structured interviews, but the included constructs were based on a selection made by the authors taking into consideration the intervention (continuous monitoring), the setting (hospital) and the respondents (nurses). However, topics related to other constructs (e.g., trialability, patient needs & resources and other personal attributes) came up during the interviews and were coded as belonging to these topics.

This study has some limitations. Ten interviews were conducted face-to-face, while 6 interviews had to be conducted by telephone, due to COVID-19 circumstances. We do not

think that this influenced the results, because a semi-structured interview was used and no additional notes were taken into account for data analyis, for example about non-verbal behavior. The first author conducted all interviews, and the transcripts were anonymized. Data analysis was conducted by the first two authors independently, of which one was not involved in the interviews. The preunderstanding of authors was not used in the analysis. Furthermore, the number of nurses per hospital varied and continuous monitoring using wireless wearable sensors was conducted on different nursing wards in each hospital. Also, nurses' personal characteristics (e.g., age, work experience and experience with the intervention) may have differed. Because saturation was confirmed (post hoc), we believe that all factors influencing implementation in this setting have been identified. The sample size was insufficient to look into differences between answers given by nurses with different characteristics. Future research is needed on the effect of nurses' personal characteristics such as age, work experience, and (digital) skills on implementation of digital interventions such as continuous monitoring. Despite these limitations, this is to the best of our knowledge, the first qualitative study to identify and score constructs influencing the implementation of continuous monitoring on nursing wards and to classify perceptions on its use in the home setting.

Conclusions

This paper provides an overview of factors influencing the implementation of continuous monitoring on nursing wards including their relative importance, and provides insight in nurses' perception of factors affecting its use in the home setting. This may be used as guidance for future implementations and evaluations.

List of abbreviations:

CFIR: Consolidated Framework for Implementation Research
EMR: Electronic Medical Record
MEWS: Modified Early Warning Score
UTAUT: Unified Theory of Acceptance and Use of Technology

Declarations

Ethics approval and consent to participate

Ethical approval for this study was asked for and waived by the Medical Research Ethics Committee Arnhem-Nijmegen (registration 2019-5489). The study fell outside the remit of the law for Medical Research Involving Human Subjects Act and was approved by the local ethical committee.

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ADDITIONAL FILES

Additional file 1 – Interview guide and CFIR constructs

Additional file 1 – Table 1. Interview guide

Domains	Questions
I. Innovation characteristics	
A. Intervention source[a]	–[b]
B. Evidence strength and quality	• Do you think there is enough evidence that the sensor will work in the home setting?
C. Relative advantage	• According to you, what is the advantage of using the sensor on the nursing ward? And in the home setting? • Do you think there are other ways to achieve this goal (continuous monitoring in the home setting)? • What are, according to you, the (dis)advantages for patients on the nursing ward/in the home setting?[b]
D. Adaptability[c]	• In what way could the sensor be adapted to support your work?
E. Trialability[d]	–
F. Complexity	• Hospital 1: Rate every task on a scale from 1: difficult to 10: easy, and explain this by mentioning barriers and facilitators? Were you able to execute this task alone? • Hospital 2 and 3: Which tasks did you execute to enable monitoring with the sensor? On a scale from 1: difficult to 10:easy, how difficult were these tasks? • Hospital 2 and 3: Were there any barriers or facilitators? If yes, which?[e] • Were you able to execute the tasks alone or were you dependent on others? • Is it taken into account that extra time is needed for all these tasks? In other words, did you receive extra time for these tasks? • One a scale from 1: difficult to 10: easy, how easy do you think it is to deliver care for patients using the sensor in the home setting? Do you think you need additional training, skills or information/knowledge?
G. Design quality and packaging	What is your opinion on the quality of the sensor?
H. Cost[a]	–
II. Outer setting	

Domains	Questions
A. Patient needs & resources[d]	–
B. Cosmopolitanism	• How do you think this care should be organized in the home setting?[f]
C. Peer pressure[a]	–
D. External policy & incentive[a]	–
III. Inner setting	
A. Structural characteristics[a]	–
B. Networks & communications	• What helped you the most: information via the project organization or supervisor in planned meetings, or unplanned information, for example during a coffee break or with a colleague?
C. Culture[d]	–
D. Implementation climate	
1. Tension for change	• Do you think the current monitoring method (*e.g. MEWS*) should be changed? • How can you see the (deviating) values? How are patients monitored in the current situation?[f]
2. Compatibility	• Do you think your relation with patients will change with continuous monitoring using the sensor? • How is continuous monitoring going to help you with your work? Do you think you can do your job better? • Do you think continuous monitoring will change your work on the nursing ward/in the home setting? • Do you think there are risks for using the sensor in the home setting?
3. Relative priority	• Is the use of the sensor a high priority in the hospital? • And at the nursing ward?
4. Organizational incentives & rewards[a]	–
5. Goals and feedback	• Did you hear, in advance, what the aim is of using the sensor? What is the aim according to you?
6. Learning climate	• Was sufficient input asked from you? By whom? And was your input valued? • Do you think there were enough possibilities to test ('try–out') the sensor? • Was there enough time (training)? • Were you worried about making mistakes?

Domains	Questions
Readiness for implementation	
1. Leadership engagement	–
2. Available resources	• Do you think the hospital has enough resources (technical and human resources) available to support the use of the sensor?
3. Access to knowledge and information	• What did you think of the training? • Do you think you need training, additional knowledge or skills?[e]
IV. Characteristics of individuals	
A. Knowledge & beliefs	• The aim is to use continuous monitoring for patients in the home setting. What do you think about that?
B. Self–efficacy	• Did you feel confident enough to communicate about this (continuous monitoring) with patients?[f]
C. Individual stage of change[d]	–
D. Individual identification with organization[d]	–
E. Other personal attributes[d]	–
V. Process	
A. Planning[d]	–
B. Engaging[a]	–
1. Opinion leaders	• Were you motivated by people (in the hospital) to use the sensor? If yes, by whom?
2. Formally appointed internal implementation leaders	• Were there people coordinating the project – the use of the sensor? • Was this beneficial? If no, did you miss something?
3. Champions[d]	–
4. External change agents[d]	–
C. Executing[d]	–
D. Reflecting & evaluating	• Was the project evaluated with you? What did you think about this?

[a] no results available
[b] -: no question formulated
[c] answers to questions were coded in different factors
[d] results are available for this factor
[e] question was missing in 1 interview
[f] question was not posed to all respondents

Additional file 2 – Criteria used to assign ratings

Additional file 2 - Table 1. Criteria used to assign ratings to quotes [19]

Rating	Criteria
–2	The construct is a negative influence in the organization, an impeding influence in work processes, and/or an impeding influence in implementation efforts. The majority of interviewees (at least two) describe explicit examples of how the key or all aspects (or the absence) of a construct manifests itself in a negative way.
–1	The construct is a negative influence in the organization, an impeding influence in work processes, and/or an impeding influence in implementation efforts. Interviewees make general statements about the construct manifesting in a negative way but without concrete examples: • The construct is mentioned only in passing or at a high level without examples or evidence of actual, concrete descriptions of how that construct manifests; • There is a mixed effect of different aspects of the construct but with a general overall negative effect; • There is sufficient information to make an indirect inference about the generally negative influence; and/or • Judged as weakly negative by the absence of the construct.
0	A construct has neutral influence if: • It appears to have neutral effect (purely descriptive) or is only mentioned generically without valence; • There is no evidence of positive or negative influence; • Credible or reliable interviewees contradict each other • There are positive and negative influences at different levels in the organization that balance each other out; and/or different aspects of the construct have positive influence while others have negative influence and overall, the effect is neutral.
+1	The construct is a positive influence in the organization, a facilitating influence in work processes, and/or a facilitating influence in implementation efforts. Interviewees make general statements about the construct manifesting in a positive way but without concrete examples: • The construct is mentioned only in passing or at a high level without examples or evidence of actual, concrete descriptions of how that construct manifests; • There is a mixed effect of different aspects of the construct but with a general overall positive effect; and/or • There is sufficient information to make an indirect inference about the generally positive influence.

Rating	Criteria
+2	The construct is a positive influence in the organization, a facilitating influence in work processes, and/or a facilitating influence in implementation efforts. The majority of interviewees (at least two) describe explicit examples of how the key or all aspects of a construct manifests itself in a positive way. Missing Interviewee(s) were not asked about the presence or influence of the construct; or if asked about a construct, their responses did not correspond to the intended construct and were instead coded to another construct. Interviewee(s) lack of knowledge about a construct does not necessarily indicate missing data and may instead indicate the absence of the construct.

Additional file 3 – Memo template example

C. Relative Advantage

RATING: OVERALL +2 (ANALYST ONE +2, ANALYST TWO +2)

RATING – Continuous monitoring in the home setting: OVERALL +2 (ANALYST ONE +2, ANALYST TWO +2)

SUMMARY: Relative advantage was (mainly) a positive construct and multiple example were mentioned.
RATIONALE: Relative advantage for continuous monitoring at the nursing ward included.
DATA:

Respondent 1:
Quote 1:33: "*And for patients ofcourse, because the patient is also, I think it is safer because we don't do check-ups everytime here*"

- Valence and strenght: positive, +2
- Subcategory: Patient safety

Quote 1:35: "*If there is risk for the patient, that you notice that or at least receive an alarm, so I think you will get there earlier. Could be.*"

- Valence and strength: positive, +2
- Subcategory: Early deterioration

Quote 1:36. "*I think it is easier, it will take less time to do the same check-ups*".

- Valence and strenght: Positive, +2
- Subcategory: Time/efficiency

Etc…

Continuous monitoring on the nursing ward

Table C1. Total number of quotes and rating per respondent

Respondents	Total No. quotes	Rating – No. quotes				
		–2	**–1**	**0**	**1**	**2**
1	7	–	–	–	–	7
2	5	–	–	–	1	4
3	10	–	–	2	3	5
4	–	–	–	–	–	–
5	2	–	–	–	–	2
6	3	–	–	1	1	1
7	1	–	1	–	–	–
8	3	–	–	–	–	3
9	2	–	–	–	–	2
10	3	–	–	–	–	3
11	1	–	–	–	1	–
12	4	–	–	–	–	4
13	4	–	–	–	1	3
14	5	–	–	–	1	4
15	8	2	–	–	–	6
16	3	–	–	–	2	1
Total	61 (n=15)	2 (n=1)	1 (n=1)	3 (n=2)	10 (n=7)	45 (n=13)

Table C2. Ratings (neg/neutral/pos) per subcategory

Categories	No. respondents (no. quotes)			
	Total	**Negative (–1 or –2)**	**Neutral (0)**	**Positive (+1 or +2)**
Early deteriorating	12 (22)	–	–	12 (22)
Time and efficiency	11(21)	1(2)	2(3)	10(16)
Continuous monitoring – data availability	7(7)	1(1)	–	6(6)
Patient safety	4(7)	–	–	4(7)
Quality (measurement/support clinical view)	2(2)	–	–	2(2)
Early discharge and (higher) turnover	1(1)	–	–	1(1)

Continuous monitoring in the home setting

Table C4. Total number of quotes and rating per respondent (continuous monitoring in the home setting)

Respondents	Total No. quotes	Rating – No. quotes				
		–2	**–1**	**0**	**1**	**2**
1	–	–	–	–	–	–
2	1	–	–	–	–	1
3	1	–	–	–	–	1
4	–	–	–	–	–	–
5	1	–	–	–	–	1
6	1	–	–	–	–	1
7	1	–	–	1	–	–
8	4	–	–	–	–	4
9	–	–	–	–	–	–
10	2	–	–	–	2	–
11	–	–	–	–	–	–
12	2	–	–	1	1	–
13	1	–	–	–	–	1
14	2	–	–	–	–	2
15	–	–	–	–	–	–
16	–	–	–	–	–	–
Total	16 (n=10)	–	–	2	3	11

Table C5. Ratings (neg/neutral/pos) per subcategory

Category	No. respondents (no. quotes)			
	Total	**Negative (–1 or –2)**	**Neutral (0)**	**Positive (+1 or +2)**
Continuous monitoring – data availability	4(4)	–	–	4(4)
Early discharge and cost benefits	3(3)	–	–	3(3)
Early discharge and (higher) turnover	3(4)	–	–	3(4)
Early deteriorating	2(2)	–	–	2(2)
Time and efficiency	2(2)	–	2(2)	–
Patient safety	1(1)	–	–	1(1)

Additional file 4 – Continuous monitoring on the nursing ward: ratings assigned to CFIR and UTAUT constructs

Additional file 4 – Table 1. CFIR and UTAUT domains and ratings for continuous monitoring on the nursing ward

CFIR domains	Total rating[a]	Total N (no. of quotes[b])	Negative (–1 or –2)	Neutral (0)	Positive (1 or 2)
I.Intervention characteristics					
Evidence Strength and quality	**–2**	**14(36)**	**14(31)**	**1(1)**	**3(4)**
Evidence from practical experience		14(26)	13(21)	1(1)	3(4)
Available evidence for continuous monitoring		2(10)	2(10)	–[c]	–
Relative advantage	**+2**	**15(61)**	**2(3)**	**2(3)**	**14(55)**
Early detection of deterioration		12(22)	–	–	12(22)
Time/efficiency		11(22)	1(2)	2(3)	10(17)
Continuous monitoring (data availability)		7(7)	1(1)	–	6(6)
Patient safety		4(7)	–	–	4(7)
Quality (measurements/support clinical view)		2(2)	–	–	2(2)
Early discharge and (higher) turnover		1(1)	–	–	1(1)
Trialability: pilot setting	**Mixed**	**8(15)**	**3(5)**	**5(6)**	**3(4)**
Complexity	**–2**	**16(100)**	**15(87)**	**1(1)**	**6(12)**
Duration		13(59)	13(59)	–	–
Perceived difficulty (intricacy)		13(29)	8(17)	1(1)	6(11)
Number of procedural steps		9(12)	8(11)	–	1(1)
Design quality and packaging	**–2**	**15(39)**	**14(32)**		**5(7)**
Quality sensor		14(29)	13(22)	–	5(7)
Data availability		3(6)	3(6)	–	–
Quality system		3(4)	3(4)	–	–
II. Outer setting					
Patient needs & resources	**+2**	**10(25)**	**3(5)**	–	**10(20)**
Patient comfort (sensor burden)		8(14)	3(5)	–	5(9)
Feeling safe		5(6)	–	–	5(6)

CFIR domains	Total rating[a]	Total N (no. of quotes[b])	Negative (–1 or –2)	Neutral (0)	Positive (1 or 2)
Patient mobility		2(2)	–	–	1(2)
Information for patients		2(2)	–	–	2(2)
Patient – attitude towards intervention		1(1)	–	–	1(1)
III. Inner setting					
Networks and communication	**+2**	**15(32)**	–	**1(1)**	**15(31)**
Execute task together		10(15)	–	–	10(15)
Formal communication		9(9)	–	1(1)	8(8)
Informal communication		5(6)	–	–	5(6)
Formal and informal communication is necessary		2(2)	–	–	2(2)
Tension for change:	**+1**	**13(18)**	**8(13)**	–	**5(5)**
Need to change current situation		13(18)	8(13)	–	5(5)
Compatibility	**–2**	**13(39)**	**13(26)**	**7(8)**	**4(5)**
Compatibility with work process		12(21)	12(19)	1(1)	1(1)
Sensor limitations		6(10)	6(10)	–	–
Workload		4(5)	4(5)	–	–
(false) alarms		4(5)	3(3)	1(1)	1(1)
Responsibility for tasks		1(1)	1(1)	–	–
Change in work		10(11)	–	7(7)	3(4)
Clinical view		4(4)	–	4(4)	–
Addition to (current) work		2(2)	–	–	2(2)
Use of technology		2(2)	–	–	2(2)
Contact with specialist		1(1)	–	1(1)	–
Change in tasks		2(2)	–	2(2)	–
Risk		6(7)	6(7)	–	–
Lack of clinical view		4(5)	4(5)	–	–
Technology		2(2)	2(2)	–	–
Relative priority	**Mixed**	**16(39)**	**11(17)**	**1(1)**	**14(21)**
Nurses/nursing ward		12(19)	10(13)	1(1)	4(5)
Priority during implementation		7(8)	3(3)	1(1)	3(4)
Priority after implementation/pilot		7(8)	6(7)	–	1(1)

CFIR domains	Total rating[a]	Total N (no. of quotes[b])	Negative (–1 or –2)	Neutral (0)	Positive (1 or 2)
Priority decreased		3(3)	3(3)	–	–
Hospital		14(18)	3(4)	–	11(14)
Specialist(s)		2(2)	–	–	2(2)
Goals and feedback	**+1**	**16(20)**	–	–	**16(20)**
Learning Climate	**+1**	**16(79)**	**10(20)**	–	**16(59)**
Feeling safe to try/making mistakes		14(23)	6(8)	–	11(15)
Time for training		13(16)	1(1)	–	12(15)
Input was valued		12(12)	–	–	12(12)
Possible to test intervention		11(15)	7(9)	–	5(6)
Possible to give input		10(13)	1(2)	–	9(11)
Leadership engagement	**1**	**2(3)**	**2(2)**	**1(1)**	–
Available resources	**Mixed**	**16(42)**	**13(20)**	–	**13(22)**
Available human resources during implementation		16(31)	6(9)	–	13(22)
Extra time for intervention		11(11)	11(11)	–	–
Access to information and knowledge	**+1**	**16(48)**	**4(6)**	**3(4)**	**15(38)**
Manual		10(21)	–	1(1)	9(20)
Training		15(27)	4(6)	3(3)	10(18)
IV. Individual characteristics					
Knowledge and beliefs: attitude towards intervention	**Mixed**	**9(12)**	**4(5)**	–	**7(7)**
Individual stage of change: change in enthusiasm	**Mixed**	**3(3)**	**2(2)**	–	**1(1)**
Individual identification with organization	**+2**	**1(1)**	–	–	**1(1)**
Other personal attributes	**+2**	**12(19)**	**2(2)**	**1(1)**	**12(16)**
Experience with executing (new)task		10(14)	–	1(1)	10(13)
(Younger) age		2(2)	–	–	2(2)
Part–time employment		2(2)	2(2)	–	–
Competence (communication)		1(1)	–	–	1(1)
V.Process					
Planning	**–2**	**4(4)**	**4(4)**	–	–
Engaging:					

CFIR domains	Total rating[a]	Total N (no. of quotes[b])	Negative (–1 or –2)	Neutral (0)	Positive (1 or 2)
Opinion leaders – experts (medical professionals)	**+1**	**3(4)**	**–**	**–**	**3(4)**
Formally appointed internal implementation leaders	**+2**	**10(26)**	**–**	**6(7)**	**7(19)**
Champions	**+1**	**14(34)**	**2(2)**	**10(14)**	**10(18)**
External change agents	**+1**	**3(4)**	**–**	**1(1)**	**3(3)**
Reflecting and evaluating	**Mixed**	**15(33)**	**6(7)**	**4(5)**	**9(21)**
UTAUT					
Facilitating conditions	**–2**	**8(31)**	**8(31)**	–	–
(Wi–Fi) Connection		7(26)	7(26)	–	–
Interoperability		4(5)	4(5)	–	–

[a] Minus sign (-) means a negative influence on implementation, positive sign (+) means positive influence on implementation, 'mixed' means both negative and positive influence on implementation

[b] In total, 1068 quotes were selected of which 5 quotes were coded to two constructs

[c] "–": construct was not mentioned by nurses

Additional file 5 – Continuous monitoring in the home setting: ratings assigned to CFIR and UTAUT constructs

Additional file 5 –Table 1. CFIR and UTAUT domains and ratings for continuous monitoring in the home setting

CFIR domains	Total rating[a]	Total N (no. of quotes[b])	Negative (–1 or –2)	Neutral (0)	Positive (+1 or +2)
I.Intervention characteristics					
Evidence strength and quality	**–1**	**8(18)**	**8(18)**	**–[c]**	**–**
Available evidence for continuous monitoring in the home setting		8(18)	8(18)	–	–
Relative advantage	**+2**	**10(16)**	–	**2(2)**	**9(14)**
Continuous monitoring (data availability/access)		4(4)	–	–	4(4)
Early discharge: (higher) turnover		3(4)	–	–	3(4)
Early discharge: cost		3(3)	–	–	3(3)
Early deterioration		2(2)	–	–	2(2)
Time/efficiency		2(2)	–	2(2)	–
Patient safety		1(1)	–	–	1(1)
Complexity	**–2**	**7(8)**	**7(8)**	–	–
Perceived difficulty (intricacy)		5(5)	5(5)	–	–
Duration		2(2)	2(2)	–	–
Number of procedural steps		1(1)	1(1)	–	–
II. Outer setting					
Patient needs & resources	**Mixed**	**15(44)**	**12(17)**	**1(1)**	**14(26)**
Patient feeling safe		13(19)	10(13)	–	5(6)
Recovery in own home		11(18)	–	1(1)	10(17)
Patient comfort/burden		3(4)	3(4)	–	–
Information for patients		2(2)	–	–	2(2)
Treatment adherence		1(1)	–	–	1(1)
Cosmopolitanism	**1**	**3(6)**	**–**	**2(2)**	**2(4)**
III. Inner Setting					
Culture	**0**	**2(2)**	–	**2(2)**	–
Change in culture		2(2)	–	2(2)	–

CFIR domains	Total rating[a]	Total N (no. of quotes[b])	Negative (–1 or –2)	Neutral (0)	Positive (+1 or +2)
Compatibility	**–2**	**16(97)**	**16(72)**	**12(24)**	**1(1)**
Change in work		14(22)	8(10)	9(12)	–
Contact with patient		13(16)	7(9)	7(7)	–
Change in tasks		3(4)	–	3(4)	
Clinical view		1(1)	1(1)	–	–
Responsibility		1(1)	–	1(1)	–
Compatibility with work process		11(23)	8(14)	6(8)	1(1)
Time/workload		6(11)	5(10)	1(1)	–
Responsibility for tasks		5(7)	2(2)	4(5)	–
(false) alarms		2(2)	–	2(2)	–
Applicability patient population		2(2)	1(1)	–	1(1)
Sensor detachment		1(1)	1(1)	–	–
Risks		15(52)	15(48)	3(4)	–
Complications		9(18)	8(16)	2(2)	–
Clinical view		8(13)	8(13)	–	–
Patient population: health skills/ coping		6(9)	6(9)	–	–
Applicability to patient population		4(5)	4(4)	1(1)	–
Technology		3(3)	2(2)	1(1)	–
Responsibility		3(3)	3(3)	–	–
Sensor detachment: lack of data availability		1(1)	1(1)	–	–
Available resources	**Mixed**	**9(14)**	**6(8)**	**1(1)**	**4(5)**
Human resources available		6(8)	6(8)	–	–
Human resources needed		5(6)	–	1(1)	4(5)
Access to information and knowledge	**+2**	**13(21)**	–	**1(1)**	**12(20)**
Information (e.g. decision tree) or training is needed		13(21)	–	1(1)	12(20)
IV. Characteristics of individuals					
Knowledge and beliefs	**Mixed**	**12(26)**	**6(8)**	**1(1)**	**9(17)**
Attitude towards continuous monitoring in the home setting		12(26)	6(8)	1(1)	9(17)

CFIR domains	Total rating[a]	Total N (no. of quotes[b])	Negative (–1 or –2)	Neutral (0)	Positive (+1 or +2)
Other personal attributes	**+2**	**6(7)**	–	–	**6(7)**
Experience with executing (new) task		3(4)	–	–	3(4)
Work experience		3(3)	–	–	3(3)

[a] Minus sign (-) means a negative influence on implementation, positive sign (+) means positive influence on implementation, 'mixed' means both negative and positive influence on implementation

[b] In total, 1068 quotes were selected of which 5 quotes were coded to two constructs

[c] "–": construct was not mentioned by nurses

CHAPTER 8

Strengthening the evidence base for eHealth in clinical practice: performing research with standalone or interoperable systems

Laura Kooij & Wim H van Harten

ABSTRACT

There is a gap between eHealth research and its widespread uptake in clinical practice as a consequence of the characteristics of technology and the way research is conducted with standalone or EMR-interoperable systems. Scientific evidence comparing the two approaches is scarce. Therefore, differences in, and consequences of research on eHealth with standalone systems and with interoperable systems (especially with electronic medical record [EMR]) are described using cases from clinical practice. Although standalone systems in laboratory settings do not reflect the complexity of real-life, for research in clinical practice they may be suitable to assess usability or feasibility at a small scale. Realizing interoperable eHealth solutions is a challenging, time- and resource intensive process and requires large(r) investments, as it is often complicated by a myriad of interfering factors. However, it is a more sustainable option in the long run, and generated evidence reflects the real world clinical setting and may facilitate widespread use. The decision for either a standalone or interoperable systems affects the research design, implementation and adoption of the eHealth technology. Apart from using a decision framework, it is recommended to include the technology design with an a priori assessment.

BACKGROUND

eHealth is changing healthcare, reflecting the societal trend towards digitalization but also as a possible contribution in delivering patient-centered and cost-effective care [1]. eHealth, the use of technology to improve health, well-being and healthcare [2] is a broad term encompassing e.g., telehealth, telemedicine, mobile health (mHealth) and Electronic Medical Records (EMR) [3]. The COVID-19 pandemic highlights the importance of the use of eHealth to provide care from a distance [4], for example by using video consultation or remote monitoring.

Market- and technology push are very strong in this field and the use of eHealth solutions is especially promoted as it may lead to reduction in hospital visits and hospitalizations. Telehealth was so far predominantly introduced and evaluated for chronic conditions, especially heart failure and Chronic Obstructive Pulmonary Disease (COPD), with only small to moderate effects [5]. Widespread use of eHealth services remains challenging [6]. Mobile devices and wearables are, for example widely used in everyday life. However their application in healthcare is often lagging behind or mainly found in niches involving innovative, early-adopter providers.

Decision-making on implementing innovative technology in healthcare should be based on sufficient and adequate evidence; however, this approach has its own pace of- and tradition in generating evidence and of market entry. Proper scientific evaluation is needed for appropriate budget allocation and a coverage decision to implement eHealth solutions in hospital organizations, as well as for professionals to gain confidence in adopting it in practice [7]. Partly as a consequence of the sometimes implicit characteristics of digital technology, eHealth seems often to be stuck between the rapid evolving field of information technology (IT) and the medical environment [8]. There remains a gap between research and uptake in clinical practice [9], and many initiatives remain in the pilot phase [10]. Both implementation and diffusion on a large scale and its translation in transformation of care are not accomplished yet or at least delayed.

Combining implementation and research in complex care settings

A first issue related to the uptake of eHealth can be explained using the innovation S-curve (see figure 1). The development of an innovative technology starts from a new angle and often with a lower initial quality or performance level, then accelerates, especially when the need for further innovation of the existing technology is declining or simply not possible, followed by maturity and eventually the next decline phase [11, 12]. Adopting innovative digital health with lower quality levels (with or without a proper evidence base) will not easily be accepted in clinical practice. To be successful in the healthcare setting, an upcoming

technology should rather provide direct added value or be likely to provide that soon [13, 14]. As technology push is often strong and digital solutions commonly enter the market without a proper research base, formal implementation in terms of coverage may be even more challenging.

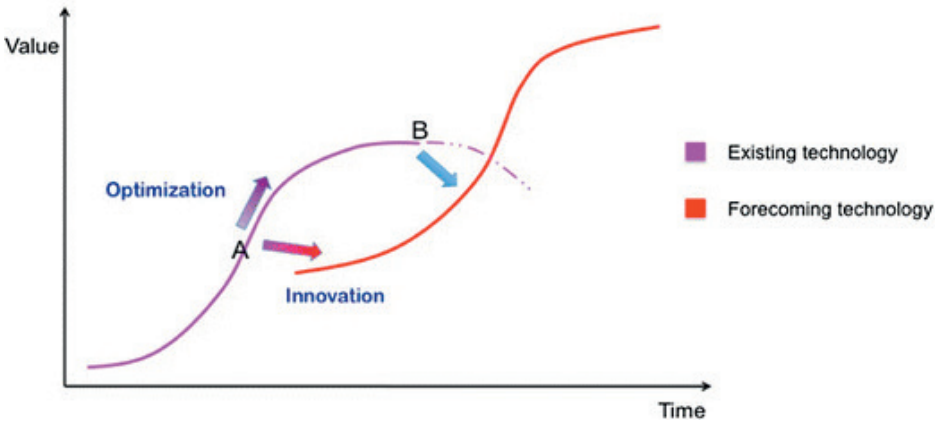

Figure 1. Innovation S-Curve [12]

A second issue lies in the rapid pace of technology development and new versions or generations entering the market. Conducting decent medical research takes time, especially since the randomized controlled trial is still seen as the gold standard [15]. Therefore, published results may be outdated once the study is finished [9]. Efficiency of the research and development (R&D) process might be increased by using different research designs such as experimental (e.g., stepped-wedge), adaptive or factorial designs [9] and pragmatic trials [15, 16]. Although treatment and patient related outcomes are preferable, it is also important to assess other proximal outcomes [17], especially since these outcomes are more directly affected by the intervention [9, 18] and technology use. More pragmatic approaches and trial designs are thus needed to speed up and increase the numbers of findings of research and to actually support decisions on uptake in daily clinical practice [9, 15]. Third, the decision to perform research using standalone or interoperable systems is often underexposed, but certainly relevant, because it adds dynamics that affect the research design, the pace of research and of possibilities of adoption.

eHealth evidence development: using standalone or interoperable systems?

eHealth services can be implemented using either standalone or interoperable systems. Clinicians commonly prefer the least possible numbers of clicks of integrated systems and balance this against perceived added value and speed of implementation of standalone features. Standalone systems are easier to study in a lab like setting (e.g., academic

environment) or even in clinical practice, because they run relatively independent of primary hospital IT systems such as the EMR. Increasingly, connectivity is added through portal technology [19] and other applications. It is used on a daily basis and considered the primary system for healthcare professionals. The advantage of using innovative eHealth solutions interoperable with existing information systems, for example for research, has the advantage of exact reflection of clinical practice. However, it is also more complex due to dependencies of various internal stakeholders and of planning that is often dominated by the hospital's operational priorities. The dependency on, or lack of interoperability with, primary hospital information systems is often not evaluated nor clarified a priori in research projects. Working with completely functional IT mock-up systems could be a solution in the research and development (R&D) phase. However, this is usually too expensive and cumbersome. IT systems that are operational in daily clinical practice such as the EMR in hospitals, often lack innovative features since these are developed for 'standard' use on a large scale. Innovations within these systems are commonly only provided in case of high demand from larger numbers of organizations or professionals. The dependency on the R&D planning of large software suppliers, for which competition is often limited, can be a barrier for innovative health care organizations. Technology start-up companies often fill this gap and are leading in providing innovative and often standalone eHealth solutions. This emphasizes the relevance for decision-making on using standalone or interoperable systems in hospital settings. The use and applicability of standalone versus interoperable systems in combination with conducting research will be explored using cases from clinical practice.

Overall, the use and impact of eHealth can be evaluated: using standalone systems in a laboratory setting (e.g., academic environment), standalone systems in a clinical setting or using interoperable systems especially with the EMR, that operates by definition in the clinical setting.

Scarcely scientific evaluation has been done comparing the use of standalone and interoperable systems. Therefore, the aim of this viewpoint is to provide guidance on using standalone versus interoperable systems in eHealth evidence development, taking the pace of IT development into account. We use experiences from our own practice to provide support in deciding on the appropriate research environment.

R&D using standalone versus EMR-interoperable systems

Standalone systems

New eHealth solutions are often provided by small firms and start-ups, with generally a vulnerable position [20] in a competing market, but also with higher levels of flexibility. Standalone systems can be evaluated in a so-called laboratory setting, for example in

an academic setting, with limited outside influences. However, when a study runs out of funding [16] it may not be possible to test the intervention in clinical practice using the real world EMR environment. By exception, it is possible to proceed from a laboratory setting to daily practice without much ado, more often the complexity of the real life setting requires additional adaptations or investments. Standalone systems are not, or in limited extent, dependent on an organizations' technical infrastructure and therefore less complex to implement and perform research upon.

Case 1: For the evaluation of a standalone video consultation system, without integration into the hospitals' primary information system (the EMR), only Internet connection (Wi-Fi, 4G) was required. Single sign-on was not possible and, therefore, the video consultation system was used for the consultations in combination with the EMR for registration (for care professionals) and to plan the consultations (for support staff). The support staff was working in two different systems and experienced lack of compatibility with standard work processes, which may lead to increase in workload. The implementation costs were a combination of fixed costs for hardware (e.g, mobile devices) and variable costs (e.g., product licenses). This approach, using a standalone system, offered the possibility to test its use in clinical practice, to clarify users' satisfaction and technology acceptance [21] without doing large investments.

Case 2: In another study, we evaluated the use of a standalone mobile health and self-management application for high-risk patients with COPD. Although, patients were satisfied with the app, we found that it was only applicable to small part of the population [22]. Using a standalone system was a pragmatic way to gain useful insights at a more rapid pace and to support decision-making about upscaling. This study revealed that lack of compatibility with standard work processes is a barrier for healthcare professionals.

Interoperable systems

Interoperability is necessary to achieve integration between eHealth systems and services from third parties with already existing systems. This can be challenging since collaboration between multiple organizations is required [23]. The interoperability framework is used to clarify this field (figure 2), and used to illustrate interoperability of different systems within one organization. Agreements on multiple levels are needed: legal and regulatory, policy, care process, information, applications and IT infrastructure [23, 24]. *Legal and regulatory* agreements are always a precondition for implementation in clinical practice. Integration of an eHealth tool in an organizations' information and technical infrastructure should also be in line with a care organizations' *policy* for example regarding data processing and data protection [24]. Lack of integration in a *care process* is seen as a barrier in previous studies [8, 25] and can hamper the enthusiasm of users (doctors and nurses). Determining which

information should be transferred between these systems and with which level of detail is important to decide how information is being exchanged with use of the new application. Technical specifications about the *new application(s)* are also necessary to assess the level of complexity (e.g. regarding technology standards) in order to achieve interoperability on *application* and *IT infrastructure* level (see figure 2).

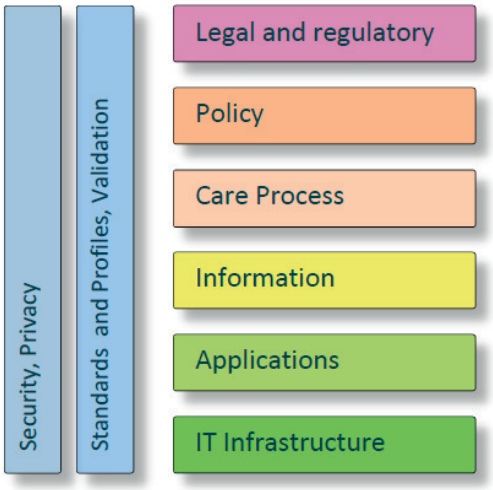

Figure 2. Interoperability framework [24]

Interoperability may have a positive effect on the implementation and uptake of eHealth [25, 26], and may provide a sustainable solution to achieve upscaling. Implementation of interoperable eHealth solutions is complex, especially in research on possibly disruptive digital technology that can interfere with the hospitals' investments and version update agenda. Therefore, support from senior management can be essential as various stakeholders are involved [25] and financial resources are required. Large (EMR) software suppliers, with often a monopoly position, can delay the process. The EMR is frequently updated with new releases and planned updates. This can be a precondition to achieve interoperability, and may also require alignment with the investment calendar of the organization, which/what may delay the implementation process.

Case 3: For the introduction of remote monitoring using a wireless sensor in a nursing ward, integration in the hospitals' infrastructure was necessary to present the data in the ward monitor that was connected to the EMR. For interoperability, a connection between these systems needed to be achieved, with considerable software and hardware costs involved. It proved time- and resource-intensive to cover the six domains of the interoperability framework satisfactorily, including formal agreements on e.g. integration in the care

process (who is responsible for which action), exchange of information (what information is needed) and integration in the infrastructure (see figure 2). This required additional updates in other technology and software domains such as for Wi-Fi coverage on the nursing ward, hardware updates, purchase of mobile devices, and increase in maintenance costs for the hospital organization. Ultimately, it will contribute to compatibility with work processes, because of the connection between the new devices and the EMR.

Case 4: We evaluated nurses' experience in three hospitals that implemented continuous monitoring using wireless wearable sensors at a nursing ward. The majority of the nurses mentioned that lack of compatibility with present work processes was a barrier for implementation. Also the duration of the intervention involving extra tasks due to workarounds related to lack of integration and lack of facilitating conditions (such as Wi-Fi connection) were seen as barriers for implementation. In two out of three hospitals, the intervention was discontinued due to technical issues [27].

Comparing eHealth research with standalone or EMR-interoperable systems

Various frameworks can be used as a guideline for implementation and evaluation of eHealth interventions, such as the Consolidated Framework for Implementation Research [28], CeHRes roadmap [29] and the NASSS (non-adoption, abandonment, scale-up, spread, sustainability) framework [30]. As is clarified in these frameworks, eHealth implementation is a complex process [28-30] and successful implementation can be facilitated or hindered by a set of interacting factors [20, 30].

A key element in implementation is the technology and the setting in which it can be used. Assessment of the need for interoperability with the current information infrastructure is an important factor to successfully implement eHealth initiatives in care settings and to support decision-making about the technology setup for research purposes [31]. The HOT-Fit model by Yusof et al. [32, 33] is used to further explain the use of standalone versus and interoperable systems, because in this model the interaction of relevant factors such as technology, human and organization is illustrated. Also, technology is subdivided into different elements.

The HOT-FIT model [32, 33] is based on the Delone and McLean Information System success model [34] and the IT-organization fit model [35] and combined with human and organization factors (see figure 3). The technology domain consists of system quality, information quality and service quality. System quality refers often to system performance including for example reliability, flexibility (eg, adaptation to healthcare environment and integration with other systems). Information quality refers to the quality of the information processed by the system. Service quality involves service or technical support [32, 33]. The advantages and

disadvantages of standalone versus EMR-interoperable systems are summarized in table 1, based on the HOT-fit model [32, 33] and on the cases that we provided.

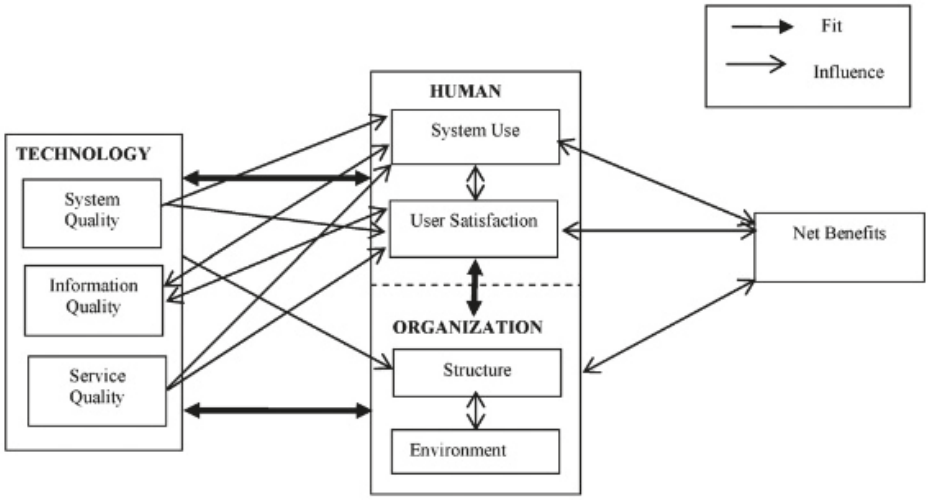

Figure 3. HOT-Fit model [32, 33]

Table 1. Advantages and disadvantages of standalone vs. EMR-interoperable systems

Variables	Standalone	EMR–interoperable
Technology		
System quality	Lack of interoperability with other systems (–[a])	Interoperability with other systems (+[b])
	Vulnerable (–)	Reliable (+)
	Tailored to specific use (+)	Use adapted to EMR interoperability (+/–[c])
	Usability (+)	Usability (+/–) standardization (–) interoperability (+)
	Privacy and security: lack of compatibility with existing system(s) (+/–)	Privacy and security: compatibility with existing (high) EMR privacy and security standards (+/–)
Information quality	Fragmented (–), but quality for specific technology (+)	Comprehensive overview (+)
Service quality	Additional services needed (+/–)	Extension of already existing agreements (+/–)
Human		

Table 1. Continued.

Variables	Standalone	EMR–interoperable
Compatibility with (existing) work processes	Isolated process (–)	Integrated in care processes (+)
Technology use	Tailored (+)	Standardization (+/–)
Organization		
Top management support	Needed in limited extent (+)	Needed/conditional (–)
Cost	Relatively lower (+)	Relatively higher (–)
Additional factors		
Ease to scale up	Complex (–) unless standalone is sustainable	Lower complexity (+)
Software supplier	Flexible, in area of expertise (+)	Less flexible, aimed at standardization (–)
	Tailored to (specific) needs (+)	Adaptation to clinical practice setting (+)
Resources needed for implementation	Relatively low (+)	Relatively high (–)
Time to launch[d]	Relatively low (+)	Relatively high (–)

[a]"+": Advantage
[b]" –": Disadvantage
[c]"+/–": Advantage and/or disadvantage
[d] Dependent on agreements within or with (external) organizations

Overall, standalone systems will be beneficial in isolated processes, with lack of dependency on existing care process and systems. These systems are often tailored to specific wishes and needs from organizations or healthcare professionals, leading to increased usefulness and quality of information for a specific domain. However, they lack interoperability and are often vulnerable especially when produced and serviced by small start-up companies. Privacy and security standards need to be achieved for both standalone and (EMR) interoperable systems. However, the privacy and security standards for interoperable systems are often higher because of the impact of these systems on already existing systems, and infrastructure where standalone systems operate separately from an organizations' infrastructure. Due to the lack of interoperability, additional service(s) are needed to ensure service quality. Standalone systems provide good solutions to move forward with new initiatives but with risk of failure on the long-term. Interoperable systems meet certain reliability standards, enable a complete information overview, but require standardization with existing systems, which may reduce usefulness for specific domains. The implementation of interoperable systems is more time-, resource- and cost intensive, but a more sustainable solutions on the long-term (see table 1).

Implications for research

Standalone systems can be used for conducting research: 1) relatively independently from hospital IT systems, 2) to assess technology usability, feasibility, and users' acceptance on a small scale, 3) with fixed budget and resource allocation, and, 4) as a proof of principle or as a prophase for interoperable use with existing infrastructure.

Interoperable systems, especially with EMR, can be used for conducting research: 1) to approximate technical real-world conditions in complex hospital care settings, 2) to assess a broad range of outcomes reflecting daily clinical practice and, 3) to realistically estimate budget impact or cost effectiveness for broader implementation in clinical practice, 4) to enable large-scale use by most providers that are not early adopters.

Conclusions

The use of eHealth can be evaluated using standalone systems in a laboratory- or clinical setting or with interoperable systems. Standalone systems in laboratory settings do not reflect the complexity of real-life. This type of evaluation may be suitable for research conducted relatively independent from complex care settings, to assess feasibility against relatively low cost. Realizing EMR- interoperable eHealth solutions is a challenging, time and resource intensive process and requires large(r) investment, as it is often complicated by a myriad of interfering factors such as technology, organizational and individual factors. However, it is a more sustainable option and can be used to assess a broad range of outcomes to predict success at a wider scale in daily clinical practice. The decision for either a standalone or interoperable systems is relevant because it may affect research design, time to launch, implementation and adoption of the technology and even the intervention outcomes. It is recommended to include the technology design in implementation frameworks with assessment a priori.

Abbreviations

COPD: chronic obstructive pulmonary disease
EMR: electronic medical record
IT: information technology
mHealth: mobile health
R&D: research and development

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CHAPTER 9

General discussion

GENERAL DISCUSSION

This dissertation aimed to increase our understanding of digital transformation in hospital care by reporting on the implementation and evaluation of eHealth in clinical practice. We evaluated the effects of eHealth on patients, healthcare professionals, and hospital organizations using different approaches and technologies. In this final chapter, we present the main findings and reflect on methodological considerations and recommendations for healthcare policy and future research.

Status of evidence on eHealth

Many healthcare professionals in different healthcare settings care for patients with a chronic disease. This highlights the importance of communication and information exchange between professionals. Shared care may improve integration and is defined as "the joint participation of GPs and hospital consultants in the planned delivery of care for patients with a chronic condition, informed by an enhanced information exchange over and above routine discharge and referral letters" [1]. The use of information technology (IT) to support shared care is promising. In **Chapter 2**, we conducted a systematic literature review on the effectiveness of IT-supported shared care in patients with chronic disease on provider or professional (proximal), process (intermediate), health, clinical, and financial (distal) outcomes. Thirteen eligible publications were identified, including 11 (cluster) randomized-controlled trials, a controlled trial, and a pre-post feasibility study. The interventions were supported by four different IT applications: 1) an electronic decision support system, 2) electronic health records (EHRs), 3) an IT platform combined with a call center, and 4) electronic communication applications. IT-supported care had a positive effect on provider or professional (proximal) outcomes such as general practitioners' satisfaction and confidence. Positive effects on intermediate (process) and distal outcomes (e.g., cost). were also reported, but varied.

The effectiveness of IT-supported shared care was only evaluated to a limited extent. However, proximal outcomes appeared to be relevant to the assessment and are responsive to the evaluated effects [2, 3]. To evaluate eHealth, more pragmatic approaches are needed [4] that evaluate proximal outcomes [2].

In the Netherlands, the use of eHealth and the number of patient portals are increasing [5, 6]. The implementation of a patient portal significantly affects a hospital organization and involves multiple stakeholders. In **Chapter 3**, a qualitative study was conducted in which barriers and facilitators were assessed among stakeholder groups (N=21) from three hospitals: 1) healthcare professionals, 2) managers, and 3) IT professionals. Barriers and facilitators were examined on six levels: 1) innovation (the patient portal), 2) individual

professional, 3) patient, 4) social, 5) organizational, and 6) economic and political context [7]. For data analysis, these levels were combined with technical and portal characteristics [8]. Similarities (e.g., perceived usefulness) and differences (e.g., positive attitudes of medical professionals) were found between the stakeholder groups. The main barriers to patient portal implementation were lack of resources, financial difficulties, and guaranteeing privacy and security. The main facilitators were perceived usefulness, positive attitude, and management support. These findings suggest that implementation in a hospital organization is affected by multiple factors at different levels: micro level (stakeholders' attitudes), meso level (operational factors such as resources and management support), and macro level (governmental commitment). This is supported by previous studies that also identified factors affecting the implementation of eHealth at different levels, such as the innovation, the outer context, the process, the organization [9].

In **Chapter 3**, we provided a comprehensive overview of barriers and facilitators to the implementation of patient portals at multiple levels, showing that the implementation process is not only technical but also affects the organization and hospital staff. Patients are important users of eHealth so their perspectives and adoption can influence the success of an intervention. Patients' perspectives on development of a patient portal were evaluated in previous research [10, 11]. Patients were satisfied [10] and perceived the portal as easy to use [11]. However, the effects of patient portals on health or clinical outcomes remain inconclusive [12, 13]. Knowing which factors affect successful implementation of eHealth interventions is important as this can support transfer of these interventions to other settings [14].

The use of eHealth may also lead to organizational advantages, such as reduction of hospital services. In **Chapter 4**, we conducted a systematic review to determine the effect of telehealth on all-cause and condition-related hospitalization. Telehealth is healthcare provided over a distance using information and communication technology [15] and may help to solve the problem of rising healthcare costs by reducing the demand for hospital services. In total, 129 articles were included in the meta-analysis and these articles described different telehealth types, including device-based monitoring, structured telephone support, mobile telemonitoring, video consultation, web-based monitoring, and interactive voice response for various conditions. Compared with usual care, telehealth reduced mean all-cause (-5.7%) and condition-related hospitalizations (-23.4%), all-cause hospital days (-17.7%) and condition-related hospital days (-39.8%) and reduced risk of all-cause hospitalizations (-4.8%) and condition-related hospitalizations (-15.6%).

In Chapter 2 and Chapter 4, we revealed heterogeneity in the eHealth interventions among IT applications, patient populations, and outcome measures in IT-supported shared care.

Heterogeneity has also been reported in patient engagement [16], web-based interventions [17], tailored information in eHealth interventions [18], patient portals [12], implementation strategies [19], and factors affecting outcomes of eHealth interventions [20] in other systematic reviews. This is also reflected in the definitions of eHealth, which include broad terms like medical informatics [21], digital technologies [22], and technology [23], which may explain the variability.

In this first part of the General Discussion, we have summarized the effects of IT-supported shared care and eHealth in clinical practice. Some of these findings are relevant to clinical practice but the effectiveness of IT-supported shared care is still not completely defined. Studies investigating shared care and eHealth were mostly heterogeneous in terms of interventions, study populations, and IT applications. The perspectives of multiple stakeholders can affect implementation success and should therefore be considered. A more pragmatic and focused approach, for example by evaluating proximal outcomes [2], may help to determine the value of eHealth in clinical practice.

Implementation and evaluation of eHealth in clinical practice

In this next section, we describe the effects of eHealth on patients (Chapters 5 and 6) and nurses (Chapters 5–7).

In **Chapter 5**, we conducted a mixed methods evaluation study on the effectiveness of a mobile health and self-management app for high-risk Chronic Obstructive Pulmonary Disease (COPD) patients. A prototype was pilot tested with six patients and the findings were used to optimize the app. The COPD app consisted of an 8-week program including a Lung Attack Action Plan [24], education, medication overview, video consultation, and questionnaires. We assessed app use, self-management (using the Partners in Health Scale [25, 26]), expectations and experiences (based on Unified Theory Acceptance and Use of Technology [UTAUT] model [27]), satisfaction, and readmission rates.

In total, 39 patients were included in the study. App use decreased over time but the self-management element 'knowledge and coping' increased significantly over time (P=.04). The mean patient rating on a 10-point scale was 7.7 (SD 1.7) after 8 weeks and 7.0 (SD 2.4) after 20 weeks. Most patients thought the app was easy to use, well structured, that the information was understandable and were satisfied with the information they received. The UTAUT model [27] was used to evaluate expectations of and experiences with the app and most patients reported positive expectations and experiences.

In **Chapter 6**, we conducted a randomized-controlled trial to evaluate the superiority of video consultation over face-to-face consultation in patients with obstructive sleep apnea

(OSA) on continuous positive airway pressure (CPAP) use. CPAP adherence, self-efficacy, outcome expectations, risk perception, expectations and experiences with technology, and satisfaction were also assessed. In total, 140 patients were randomized (1:1). Video consultation did not increase CPAP use and adherence compared with face-to-face consultation. Also, no significant difference between groups was found for outcome expectancies (*P*=.64), self-efficacy (*P*=.41), and risk perception (*P*=.30). However, a significant relationship was found between CPAP use and self-efficacy, regardless of the intervention arm (*P*=.001). Patients' experiences with video consultation were positive. Patients (intervention group versus usual care group) were satisfied with the consultations and indicated that healthcare professionals understood their problems (59/63, 94% vs 58/68, 85%) and listened to them (60/63, 95% vs 61/68, 90%). Patients also thought that video consultations saved them time (61/63, 97%) and provided better access to healthcare professionals (43/63, 68%).

We also evaluated the satisfaction of three nurses in **Chapter 5** and three nurses in **Chapter 6**. Overall, they were satisfied with video consultation but did not think it saved them time because patients asked additional questions (Chapter 5) and the new technology did not integrate with existing systems. In both studies, a 'standalone' system was used, meaning that it was not integrated with existing systems such as EMRs. Such a standalone system may lead to additional tasks such as double registration.

Nurse involvement is important for the successful implementation of eHealth in clinical practice [28]. In **Chapter 7**, we evaluated factors affecting the implementation of continuous monitoring with wireless wearable sensors in clinical practice and expectations of use in a home setting from a nurse's perspective. The Consolidated Framework for Implementation Research (CFIR) [29] was used to conduct semi-structured interviews with 16 nurses. This framework consists of five domains: intervention, outer setting, inner setting, individual characteristics, and process. The CFIR framework [29] and one additional factor from the UTAUT model [27] were also used to analyze the data. Five constructs had a strong positive influence on implementation according to most nurses: relative advantage, patient needs and resources, networks and communications, personal attributes, and implementation leaders. Five constructs had a strong negative influence on implementation according to most nurses: evidence strength and quality, complexity, design quality and packaging, compatibility, and facilitating conditions. Nurses believed that continuous monitoring in the home setting would be facilitated by access to knowledge and information and by perceived advantages of the implementation. They believed it would be hindered by compatibility with work processes and systems and by strength and quality of evidence.

Introducing eHealth to clinical practice may change the work of healthcare professionals [9, 20] so it is important to obtain their input [30]. In Chapter 7, we showed that implementation of eHealth may be affected by factors related to the intervention, outer setting, inner setting, process, and individual. The adoption of eHealth can also be influenced by usefulness, ease of use, and technical issues [31-33]. Training can help with the use and adoption of eHealth [34] and was perceived positively in our study on continuous monitoring on nursing wards (Chapter 6). Attention should also be paid to enhancing motivation [35], self-efficacy [36], digital health literacy [37], and technology acceptance [32]. Support from healthcare professionals may help to increase and improve the use of eHealth among patients [38, 39].

Some implications of these findings are discussed in the next section, followed by recommendations for improving practice and policy.

Discussion and implications

Access to digital health

We found that 'one size does not fit all', meaning that eHealth has to be adapted to suit different populations and different patients. In Chapter 5, a mobile health and self-management app for recently discharged COPD patients was considered feasible by only a small number of patients. Most patients (76.4%) had to be excluded, half of these (48.9%) because they did not have digital skills, access to a mobile device, or access to the internet. This accessibility issue may be explained by a lack of digital health literacy or eHealth literacy. This is defined as the ability to seek, find, understand, and appraise health information from electronic sources and apply this knowledge to addressing or solving a health problem. Digital health literacy can be affected by health status, educational background, and the technologies that are used [40]. Older people and people with a lower socioeconomic status often have lower digital health literacy [41] and are less likely to use eHealth [42]. It appears that the populations that are most in need of eHealth are not able to access it [42]. Lack of access to eHealth and the lack of skills needed to use it can exclude those patients that need it the most [43]. This highlights a need to continuously improve digital health literacy [40], for example by tailoring interventions to patients' specific skills and needs [44].

Uptake and upscaling of eHealth: redesign of care processes

Many initiatives do not make it past the pilot phase [45]. Implementing new interventions in clinical practice or upscaling existing ones is challenging because it involves multiple stakeholders and factors – as we found during implementation of patient portals (Chapter 3) – and continuous monitoring (Chapter 7). Previous research has also identified a wide range of factors affecting eHealth implementation [9, 20, 31]. Frequently reported facilitators are perceived usefulness and ease of use [31] and common barriers are lack

of compatibility with work processes, complexity of the intervention, and technological issues [9, 20, 31]. These factors should be assessed in individual healthcare organizations because eHealth interventions are often context-specific [31, 46].

Compatibility (i.e. alignment between the eHealth intervention and the organization [9]) is important for success of eHealth interventions. Compatibility can refer to work processes such as integration of eHealth into clinical practice. Lack of compatibility can increase workload, disrupt work processes, and confuse responsibilities [9, 20]. Lack of integration or interoperability of the new technology with existing systems can also be a barrier to eHealth implementation [31, 32, 47]. For example, we found that the COPD app (Chapter 5) and continuous monitoring (Chapter 7), both standalone systems, increased workload. Introducing new technology can change work processes, which may increase workload [20]. Integrating eHealth into usual clinical care may increase its use [48] but healthcare processes need to be adapted to it and sufficient resources are needed for this adaptation [49]. We discuss the importance of decision-making on using standalone or interoperable systems below (Chapter 8).

Variability in eHealth interventions

We evaluated a range of technologies in our studies, and found a wide variation among studies (Chapters 2 and 4). eHealth interventions involve many technologies (e.g., video consultation, patient portal, mHealth, wearables) aimed at different users (e.g., patients, medical doctors, nurses), for which different outcomes can be evaluated (e.g., clinical, process, health services outcomes). More transparency about what 'the intervention' entails, including scope, proper research design for each phase [50], and outcome measures may help make findings transferable to other contexts.

Recommendations for practice/policy

Transformation of care requires upscaling and integrating eHealth into clinical practice and comes with many challenges at different levels. To help overcome these challenges, we have provided recommendations for practice and policy at the micro, meso, and macro levels.

Micro level – Patients and healthcare professionals

The involvement of patients and healthcare professionals is important during the development, implementation, and evaluation of eHealth. Our findings (Chapters 2, 5, and 6) show that proximal outcomes provide useful insights into the effects of eHealth on its users, such as technology acceptance and self-efficacy. Tailoring interventions to each patient's digital health literacy can also be useful [44].

- *Therefore, we recommend 1) identifying characteristics of patients and healthcare professionals that may influence use, such as technology acceptance, self-efficacy, and digital health literacy, before using the intervention; 2) adjusting implementation strategies according to these characteristics; and 3) evaluating proximal outcomes to identify the direct effects of eHealth interventions.*

Meso level: Organizational aspects

Multiple factors can influence eHealth implementation, and these are partly context-specific [31, 47]. Common factors include compatibility with work processes, and sufficient finances and technology aspects [20, 31, 32, 51].

These factors may be a precondition for successful implementation and should be considered before the intervention is implemented and not only after. To improve implementation, factors affecting implementation should be assessed as early as possible [20]. Different implementation frameworks are available [14, 29, 52] which can be used as a guideline.

- *More pragmatic evaluations are needed that focus on the applicability in hospital care settings to assess the direct (proximal) effects of the intervention and to support transferability of findings.*

Macro level: Governmental policy and finances

The availability of financial resources is often considered a barrier to eHealth success [20]. For example, initial investments are needed to install a new system [53]. These initial investments might bring economic benefits by reducing the use of hospital services, such as hospital admissions. So far, the reported effects of eHealth on hospital services have been limited (Chapter 4) and methodologically firm studies on possible savings are scarce or even lacking. Therefore, implementing eHealth requires considerable investments from organizations with uncertain benefits. The government needs to offer investments and reimbursements [9, 20] to support sustainable use of eHealth in clinical practice.

- *We recommend that the diffusion and upscaling of eHealth is supported not only by investments for implementation but also by reimbursement to support long-term use.*
- *We also recommend investing more broadly into sound methodological studies on the cost benefit and cost effectiveness of digital health services.*

Conducting eHealth research in clinical practice

More evidence is needed to make decisions about innovative technology in healthcare, to allocate budget appropriately, and for professionals to gain confidence using this

technology in clinical practice [54]. There is a gap between research on interventions and their uptake in clinical practice [2], and eHealth seems to be stuck between the rapidly evolving field of IT and the more conservative medical environment.

In **Chapter 8**, we focused on an issue we were confronted with in various stages of our research: the matter of using standalone versus interoperable systems in eHealth research and -evidence development. The use of eHealth can be evaluated using 1) standalone systems in a laboratory setting (e.g., academic environment), 2) standalone systems in a clinical setting, and 3) systems that are interoperable with the EMR in a clinical setting. Deciding which digital features and technology to use during research is important because these can influence research design, research pace, and adoption possibilities.

Standalone systems are not, or in limited extent, dependent on an organization's technical infrastructure so are less complex to implement and to perform research upon. Interoperable systems can reflect actual clinical practice but are more complex because they are dependent on various internal stakeholders and on planning that is often dominated by the hospital's operational priorities. According to the interoperability framework, agreements are needed on multiple levels, including legal and regulatory, policy, care process, information, applications, and IT infrastructure [55, 56]. We compared the use of standalone and interoperable systems when conducting research using clinical cases as examples (including the studies presented in Chapters 5–7). Based on these findings, we presented the following implications for research:

Standalone systems can be used for conducting research: 1) relatively independently from hospital IT systems, 2) to assess technology usability, feasibility, and users' acceptance on a small scale, 3) with fixed budget and resource allocation, and, 4) as a proof of principle or as a prophase for interoperable use with existing infrastructure.

Interoperable systems, especially with EMR, can be used for conducting research: 1) to approximate technical real-world conditions in complex hospital care settings, 2) to assess a broad range of outcomes reflecting daily clinical practice and, 3) to realistically estimate budget impact or cost effectiveness for broader implementation in clinical practice, 4) to enable large-scale use by most providers that are not early adopters.

We also used the HOT-FIT model to report differences between standalone and EMR interoperable systems [57, 58]. This model presents the interaction of relevant factors such as technological factors (system quality, information quality, and service quality), human factors, and organizational factors. Overall, standalone systems are better for isolated processes because they limetly depend on existing care processes and systems.

Because, they are not interoperable additional services are needed to ensure service quality. Standalone systems are good for starting new initiatives but have a risk of failure in the long-term. Interoperable systems meet certain reliability standards and offer a complete information overview, but need to be standardized to existing systems, which may reduce usefulness in specific domains. The implementation of interoperable systems requires more time, resources, and costs but is a more sustainable solution in the long-term (see Chapter 8, Table 1).

Standalone systems in laboratory settings do not reflect the complexity of real-life. They may be suitable for research (in clinical practice) conducted relatively independently from complex care settings to assess feasibility at relatively low cost. Establishing eHealth solutions that are interoperable with EMRs requires more investment and is more complex. However, these systems can be used to assess many outcomes so can predict success on a wider scale in clinical practice, making them a more sustainable option. Deciding which technology to use is important and may affect implementation and adoption. This is discussed in the next section.

Evaluation of eHealth effects: technology acceptance

Multiple models are available for measuring technology acceptance; the functional UTAUT model is often used [59]. To investigate the expectations of and experiences with eHealth, we evaluated acceptance of a COPD app (Chapter 5) and video consultations (Chapter 6) using statements based on the UTAUT model. In both studies, statements related to social support were lower than the patients expected. In response to the statement *people in my direct environment will stimulate me to use the COPD app*, 78% of the patients expected people to stimulate them to use the COPD app but only 45% actually reported getting support. Similarly, 64% expected to be stimulated to use video consultations, but only 25% experienced this. The majority (76%) of patients using the COPD app expected to get enough help from the app, but only 57% got enough help. Previous research also found that social support was lower than expected [10]. These findings suggest that social support is important for technology acceptance [60, 61] and can be influenced by caregivers as well as personal acquaintances [60].

Adoption and adherence are also relevant to technology use. Adoption refers to the decision to start using a new technology [62] and adherence refers the use of the intervention as intended [63] or the extent to which the intervention is used [64]. In Chapter 5, we found that most patients were content using the COPD app, indicating good technology acceptance. However, use of the app decreased over time, suggesting a lack of adherence. Therefore, it is important to consider acceptance, adoption, and adherence for long-term use.

Recommendations for future research

For healthcare to change, more research on eHealth is needed in real-life settings. Based on our findings, we provide recommendations for future research below.

Randomized-controlled trials have been the gold standard in clinical research [4]. However, to keep up with the rapidly evolving field of IT, different research approaches are needed to evaluate eHealth in clinical practice [2]. More pragmatic approaches and trial designs may speed up and increase our understanding of how eHealth affects clinical practice [2, 4].

Multiple models and frameworks are available for the implementation of eHealth in clinical practice, including the CFIR framework [29], the Nonadoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework [14], and the CeHRes roadmap [52]. We also provided a comprehensive overview of barriers and facilitators for implementing eHealth in clinical practice (Chapter 2), as well as factors specific to nursing wards and the home setting (Chapter 7). These overviews may help to determine which elements are important for implementation of eHealth in a specific organization.

Transformation of care requires a shift not only in research approaches but also in accepted outcome measurements. Clinical research has often focused on evaluating clinical outcomes; to better understand the implementation of eHealth, more attention needs to be paid to cognitive and socio-psychological outcomes because these may provide useful information on the effects of eHealth technology in clinical scenarios. Future research should focus more on technology acceptance, for which the UTAUT model [27] is frequently used [65]. However, this model needs to be updated to differentiate between patients and healthcare professionals and include additional factors such as years of experience [32].

Transferring eHealth findings is challenging because eHealth use is influenced by multiple interdependent aspects including technology, organizations, and social/individual aspects [51]. Future research should include a more comprehensive evaluation of eHealth, addressing a wide range of outcomes and being transparent about successes and failures. This may improve the transferability of findings.

Concluding remarks

The aim of this dissertation was to contribute to the knowledge of digital transformation in hospital care by evaluating the use of eHealth in clinical practice and the effects it has on patients, healthcare professionals, and hospital organizations. We have provided important information on IT-supported shared care and eHealth in clinical practice together with an evaluation of different uses and different outcomes. Our findings are relevant to

healthcare professionals, policy makers, and researchers, and create a basis for future implementations and research.

Transformation of care requires collaboration among healthcare professionals from different organizations, for which the use of technology is inevitable. Until now, evidence on IT-supported shared care was limited and the reported effects of eHealth in clinical practice have been mixed because of the variety of interventions, technologies, and users. In addition, a wide range of outcomes have been evaluated. The introduction of eHealth into clinical practice has changed the healthcare profession and healthcare professionals are now facing changes to their daily tasks, responsibilities, and contact with patients. A wide range of factors can influence implementation of eHealth in clinical practice and these need to be considered to achieve sustainable digital transformation. Healthcare organizations need to invest sufficient resources (human/technology) in new technologies without knowing whether this will pay off (for example by reducing demand for hospital services). The implementation of eHealth is complex because it is affected by many factors at different levels and by different stakeholders. The main challenges to integrating eHealth in clinical practice include ensuring compatibility with work processes, integrating innovative technologies with existing systems, and tailoring interventions to individual user characteristics. We found that eHealth can improve the delivery of patient-friendly care services, but the effects on health outcomes remain uncertain. The aim of digital care transformation is to ensure high quality, accessible, and affordable care, which is especially relevant to patients with chronic disease. Implementing eHealth would involve major changes to a complex environment as care pathways will need to be redesigned rather than just providing an extra optional service.

Pragmatic research approaches are required to minimize the gap between the clinical situation and IT, and to evaluate the use of eHealth in a real-life setting. These approaches may support the transferability of findings and help to transform healthcare using eHealth.

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CHAPTER 10

Summary
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SUMMARY

Worldwide, the population is ageing. This has increased the demand for healthcare, raising concerns about the growing burden on healthcare systems and increasing care expenses. Chronic diseases have increased in prevalence due to demographic trends and behavioral factors. Patient-centeredness is an important aspect of high-quality care, and means that patients are actively involved in their own care and have timely access to information. This is particularly relevant to patients with chronic diseases as they are responsible for the daily management of their condition. Using skills and knowledge to manage your own disease is also part of self-management. Multiple healthcare professionals care for a patient with chronic disease, therefore, coordination and integration are very important. Shared care can improve on those aspects especially as general practitioners and hospital consultants both participate in caring for patients with a chronic condition.

Healthcare needs to change to face the present challenges and to ensure that high-quality, accessible and affordable care is provided. The use of information technology (IT) in healthcare, or eHealth, is a promising solution.

The World Health Organization (WHO) defines digital health as *the field of knowledge and practice associated with the development and use of digital technologies to improve health.* This definition includes eHealth, which can be defined as *an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve healthcare locally, regionally, and worldwide by using information and communication technology.* eHealth is a brood term encompassing a variety of technologies including the Electronic Medical Record (EMR), patient portal, mobile health (mHealth), telehealth, and telemedicine. eHealth may improve accessible, coordinated and high-quality care by allowing information to be shared among healthcare professionals and by facilitating patient-centered care. Although, eHealth has potential, more knowledge is needed on how it will affect clinical practice.

The aim of this dissertation is to contribute to the knowledge of digital transformation in hospital care by developing and implementing eHealth solutions in clinical practice and to evaluate the effect of these changes on patients, healthcare professionals, and hospital organizations.

In **Chapter 1,** this background information and the aim of the dissertation is provided.

In **Chapter 2** a systematic literature review was conducted focused on the effectiveness of IT-supported shared care interventions in chronic disease in terms of provider or professional, process, health or clinical and financial outcomes. Also, an inventory of the IT applications' characteristics that support such interventions was provided. Thirteen publications were selected, including 11 (cluster) RCTs, a controlled trial, and a pre-post feasibility study. Four main categories of IT applications were identified: 1) electronic decision support tools, 2) electronic health records, 3) IT platform with a call-center, and 4) electronic communication applications. Positive effects were found for decision support-based interventions on financial outcomes. Electronic health record use improved some clinical outcomes and the use of an IT platform with a call-center resulted in fewer readmissions. The use of electronic communication applications showed positive results in terms of primary care physicians' satisfaction and confidences. As IT was only a small part of the intervention, it is hard to determine its real added value in shared care. The included studies showed a large heterogeneity in the included populations, outcome measures and IT applications used. Therefore, a firm conclusion could not be drawn.

In **Chapter 3**, a qualitative study was conducted to assess barriers and facilitators to patient portal implementation among the various stakeholders within hospital organizations in the Netherlands. A total of 2 university medical centers, 3 teaching hospitals, and 2 general hospitals were included. For each, 3 stakeholders were interviewed: 1) medical professionals, 2) managers, and 3) IT employees. In total, 21 semi-structured interviews were conducted using the Grol and Wensing model, which describes barriers to and facilitators for change in healthcare practice at 6 levels: 1) innovation (the patient portal); 2) individual professional; 3) patient; 4) social context; 5) organizational context; and 6) economic and political context. For data analysis, these levels were combined with technical and portal characteristics from McGinn et al. The main barriers to patient portal implementation were 'lack of resources', 'financial difficulties', and 'guaranteeing privacy and security'. The main facilitators were 'perceived usefulness', 'positive attitude', and 'management support'. To conclude, patient portal implementation is a complex process and is not only a technical process, but also affects the organization and its staff. Barriers and facilitators occurred at various levels and differed among hospital types, and stakeholder groups in terms of several factors. Our findings underscore the importance of involving multiple stakeholders in portal implementations.

In **Chapter 4**, a systematic review and meta-analysis was conducted to evaluate the effects of telehealth on the hospital services use, i.e. hospitalizations, and to compare the effects between telehealth types and health conditions. Telehealth is health care provided over a distance using information and communication technology. Peer-reviewed randomized-controlled trials reporting the effect of telehealth interventions compared with usual

hospital care were included. We included 127 RCTs in the meta-analysis. Compared with usual care, telehealth reduced the risk of all-cause hospitalization (–4.8%) and condition-related hospitalizations (–15.6%). Telehealth also leads to reductions in the mean all-cause hospitalization (-5.7% less than usual care) and condition-related hospitalizations (-23.4% less than usual care). Overall, all-cause hospital days and condition-related hospital days per patient decreased significantly (-17.7% and -39.8%, respectively). For hospitalized patients, the mean stay for any cause could potentially be reduced (-5.7%) and for condition-related hospitalizations even more (-30.5%). The effects were similar between telehealth types and health conditions. The effects of telehealth are small to moderate and appear to be stronger for condition-related outcomes than for all-cause outcomes.

In **Chapter 5** the effects of a mobile health and self-management app for, recently discharged, patients with chronic obstructive pulmonary disease (COPD) were evaluated. This COPD-app consisted of an 8-week health and self-management intervention, including the Lung Attack Action Plan, personalized medication overview, information (about COPD, nutrition, physical activity, advantages of smoking cessation), weekly questionnaires monitored by nurses, and video consultation. A prototype of the app was pilot tested with 6 patients with COPD. In the feasibility study, self-management (Partners in Health Scale), expectations and experiences the app (based on Unified Theory Acceptance and Use of Technology [UTAUT] model), and satisfaction were assessed using questionnaires at baseline, after 8 weeks, and 20 weeks. Use was assessed with log data, and readmission rates were extracted from the electronic medical record (EMR). In the feasibility study, a total of 39 patients were included; 76.4% of patients had to be excluded from participation, and 48.9% of those patients were excluded because of lack of digital skills, access to a mobile device, or access to the internet. Overall, patients were satisfied with the app, but its use decreased over time. The self-management element knowledge and coping increased significantly over time (P=.04). Preliminary evidence about readmission rate showed that 13% of patients were readmitted within 30 days, 21% within 8 weeks, and 31% within 20 weeks compared with 14%, 18%, and 22%, respectively, in a preresearch cohort. The use of a mobile health and self-management app, after hospital discharge, seems to be feasible only for a small number of patients with COPD. This chapter showed that tailored interventions, patient support, and active adoption by professionals are important elements to ensure successful mHealth interventions.

In **Chapter 6**, we conducted a randomized-controlled trial to evaluate the superiority of video consultation over face-to-face consultation in patients with obstructive sleep apnea (OSA) on continuous positive airway pressure (CPAP) use. CPAP use was monitored remotely, with short-term (weeks 1 to 4) and long term (week 4, 12 and week 24) assessments. Participating patients completed questionnaires at baseline and after 4 weeks on self-

efficacy, risk perception, outcome expectancies (Self-Efficacy Measure for Sleep Apnea), expectations and experiences with video consultation (covering constructs of the UTAUT model), and satisfaction. Nurse satisfaction was evaluated using separate questionnaires. A total of 140 patients were randomized (1:1 allocation). The use of video consultation for OSA patients does not lead to superior results on CPAP use compared with face-to-face consultation. For CPAP use, we found a significant difference in change over time between groups in the short term (*P*-interaction=.008). No significant difference in change over time was found for long-term CPAP use (*P*-interaction=.68). Also, no significant difference in change over time between groups was found for short-term (*P*-interaction=.17) or long-term (*P*-interaction=.51) CPAP adherence. A relation was found between CPAP use and self-efficacy (*P*=.001), regardless of the intervention arm (*P*=.25). The experiences were positive, and 95% (60/63) intended to keep using video consultation. Overall, patients and nurses (n=3) were satisfied with the video consultation system. The findings of this research suggest that self-efficacy is an important factor in improving CPAP use and that video consultation may be a feasible way to support patients starting CPAP.

Nurses' perspectives on eHealth implementation were evaluated more extensively in a qualitative study in **Chapter 7**. The aim is to provide an overview of 1) factors affecting implementation of continuous monitoring using wireless wearable sensors by evaluating nurses' experiences with its use on the nursing ward, and 2) nurses' expectations for use in the home setting. Semi-structured interviews were conducted with 16 nurses from three hospitals in the Netherlands, covering constructs of the Consolidated Framework for Implementation Research (CFIR). The CFIR constructs were also used for data analysis together with one additional construct from the UTAUT. Data was collected on 27 CFIR constructs and 1 UTAUT construct. In the experience of at least 8 nurses, five constructs had a strong positive influence on implementation of continuous monitoring on the nursing ward including: 'relative advantage' (e.g., early detection of deterioration), 'patient needs and resources' (e.g. feeling safe), 'networks and communications' (e.g. execute tasks together), 'personal attributes' (e.g. experience with intervention), 'implementation leaders' (e.g., project leader). In the experience of 8 nurses, five constructs had a strong negative influence: 'evidence strength and quality' (e.g. lack of evidence from practical experience), 'complexity' (e.g. number of process steps), 'design quality and packaging' (e.g., bad sensor quality), 'compatibility' (e.g., change in work) and 'facilitating conditions' (e.g, Wi-Fi connection). Nurses expected implementation of continuous monitoring of patients in the home setting to be hindered by 'compatibility' with work processes and systems (e.g., change in work) and 'evidence strength and quality' (e.g., lack of available evidence), and to be facilitated by 'access to knowledge and information' (e.g., training) and 'perceived advantages' of the implementation (e.g., data availability). Technical 'facilitating conditions', for example interoperability with already existing systems, were suggested to

be beneficial for further development. The overview provided in this paper, may be used as guidance for future implementations and evaluations.

There is a gap between eHealth research and widespread uptake in clinical practice, partly because of the characteristics of technology and the way research is conducted. In **Chapter 8**, we discussed how standalone and interoperable systems are used in eHealth evidence development in order to keep up with the pace of IT developments relevant to clinical practice. The use of eHealth can be evaluated using: standalone systems in a laboratory setting (e.g., academic environment), standalone systems in a clinical setting or with interoperable systems (especially with the EMR). Deciding which technology to use in hospital settings is relevant. Therefore, differences in, and consequences of research on eHealth with standalone systems and EMR-interoperable systems were described using cases from clinical practice. Standalone systems in laboratory settings do not reflect the complexity of clinical practice. Standalone systems in clinical practice may be suitable for research conducted relatively independent from complex care settings, to assess its feasibility against relatively low cost. Realizing (EMR) interoperable eHealth solutions is a challenging, time and resource intensive process. It requires large(r) investment, as it is often complicated by a myriad of interfering factors such as technology, organizational and individual factors. However, it is a more sustainable option and can be used to assess a broad range of outcomes to predict success at a wider scale in daily clinical practice. The decision for a standalone or interoperable systems is relevant, because it may affect research design, implementation and adoption of the technology.

In **Chapter 9**, the main findings and implications are discussed, followed by recommendations for improving practice and policy and future research. We found that 'one size does not fit all', meaning that eHealth has to be adapted to suit populations and different patients. It is also needed to continuously improve digital health literacy, defined as the ability to seek, find, understand, and appraise health information from electronic sources and apply this knowledge to addressing or solving a health problem.

Implementing new interventions in clinical practice or upscaling existing ones is challenging because it involves multiple stakeholders and factors. These factors should be assessed in individual healthcare organizations, because eHealth interventions are often context-specific. Compatibility (i.e. alignment between the eHealth intervention and the organization) is important for success of eHealth interventions. Integrating eHealth into usual clinical care may increase its use but healthcare processes need to be adapted to it and sufficient resources are needed for this adaptation.

Transformation of care requires upscaling and integrating eHealth into clinical practice and comes with many challenges at different levels. To help overcome these challenges, we have provided recommendations for practice and policy at; the micro level (e.g., identifying patient's and healthcare professional's characteristics that may influence use); meso level (e.g., more pragmatic evaluations are needed that focus on applicability in hospital care settings) and; macro level (e.g., need for reimbursements to support long-term use and investing more into sound methodological studies on cost effectiveness of digital health services).

Future research should include a more comprehensive evaluation of eHealth, addressing a wide range of outcomes and being transparent about successes and failures. Transformation of care requires a shift in research approaches (e.g., more pragmatic trials) and in accepted outcome measurements, more attention needs to be given to cognitive and socio-psychological outcomes. This may provide useful information on the effects of eHealth technology in clinical practice.

In this dissertation we have provided important information on IT-supported shared care and eHealth in clinical practice, together with an evaluation of different uses and different outcomes. Our findings are relevant to healthcare professionals, policy makers, and researchers, and create a basis for future implementations and research. We found that eHealth can improve the delivery of patient-friendly care services, but the effects on health outcomes remain uncertain. Implementing eHealth would involve major changes to a complex environment (e.g. hospitals), as care pathways will need to be redesigned rather than just providing an extra optional service. Pragmatic research approaches are required to minimize the gap between the clinical situation and IT, and to evaluate the use of eHealth in a real-life setting. This approach may help to transform healthcare using eHealth.

SAMENVATTING

Wereldwijd is er sprake van vergrijzing en stijgt de zorgvraag. Dit zorgt voor een toenemende druk op de gezondheidszorg en zorguitgaven. Er is ook een toenemende prevalentie van mensen met chronische ziekten ten gevolge van demografische trends en gedragsfactoren. Patiëntgerichte zorg is een belangrijk aspect van hoge kwaliteit van zorg, dit betekent dat patiënten actief betrokken zijn bij hun eigen zorg en tijdig toegang tot informatie hebben. Dit is met name relevant voor patiënten met een chronische ziekte, zij zijn namelijk zelf verantwoordelijk voor de dagelijkse regie over hun aandoening. Het gebruik van vaardigheden en kennis hierbij is ook een onderdeel van zelfmanagement. Verschillende zorgverleners zorgen samen voor patiënten met een chronische ziekte en daarom is coördinatie en integratie van zorg erg belangrijk. 'Shared care' kan bijdragen aan een verbetering van deze aspecten, met name omdat huisartsen en artsen uit ziekenhuizen samen zorgen voor patiënten met een chronische aandoening.

Verandering in de gezondheidszorg is noodzakelijk om deze uitdagingen aan te kunnen gaan en om ervoor te zorgen dat toegankelijke, betaalbare en hoge kwaliteit zorg geleverd kan worden. Het gebruik van informatie technologie (IT) in de gezondheidszorg, of eHealth, is een veelbelovende oplossing.

De Wereldgezondheidsorganisatie definieert digitale gezondheid als *"het gebied van kennis en praktijk geassocieerd met de ontwikkeling en gebruik van digitale technologieën om zorg te verbeteren."* Hieronder valt ook eHealth, dit is een brede term en omvat verschillende technologieën zoals het Elektronisch Patiënten Dossier (EPD), patiëntportaal, 'mobile health', telehealth, en telemedicine. eHealth kan zorgen voor verbetering van toegankelijke, gecoördineerde en hoge kwaliteit van zorg, door informatie-uitwisseling tussen zorgverleners mogelijk te maken en door patiëntgerichte zorg te faciliteren. eHealth is veelbelovend, echter is meer kennis nodig over het daadwerkelijke effect op de klinische praktijk.

Het doel van dit proefschrift is bijdragen aan de kennis over digitale transformatie in de ziekenhuiszorg, door het ontwikkelen en implementeren van eHealth toepassingen in de klinische praktijk en door het evalueren van de effecten van deze veranderingen op patiënten, zorgverleners en ziekenhuisorganisaties.

In **hoofdstuk** 1 staat deze achtergrondinformatie en het doel van het proefschrift beschreven.

In **hoofdstuk 2** is een systematisch literatuuronderzoek uitgevoerd naar de effectiviteit van shared care interventies, met ondersteuning van IT, voor patiënten met chronische ziekten. In dit literatuuronderzoek is gekeken naar de effecten op professionals, proces, gezondheid of klinische en financiële uitkomsten. De kenmerken van de IT applicaties zijn ook geïnventariseerd. Er zijn 13 publicaties geselecteerd, inclusief 11 (cluster) gerandomiseerde gecontroleerde studies (RCT), een gecontroleerde studie en een voor- en na haalbaarheidsstudie. Vier categorieën IT applicaties werden vastgesteld: 1) elektronische beslissingsondersteuning tools, 2) elektronische gezondheidsdossiers, 3) IT platform met een call-center en 4) elektronische communicatie applicaties. Positieve effecten werden gevonden voor interventies met beslissingsondersteuning op financiële uitkomsten. Het gebruik van een elektronisch gezondheidsdossier kan leiden tot verbetering van sommige klinische uitkomsten. Het gebruik van een IT platform resulteerde in minder heropnames. Het gebruik van elektronische communicatie applicaties kan resulteren in meer tevredenheid en vertrouwen van huisartsen. De toegevoegde waarde van IT in shared care interventies was moeilijk vast te stellen, omdat IT vaak slechts een klein deel van de interventie was. De studies waren heterogeen op het gebied van geïncludeerde populaties, uitkomstmaten en de IT applicaties die werden gebruikt. Daarom kan er nog geen duidelijke conclusie getrokken worden over de effectiviteit van shared care interventies met ondersteuning van IT.

In **hoofdstuk 3** is een kwalitatieve studie uitgevoerd met als doel het vaststellen van de belemmerende en bevorderende factoren van patiëntportaal implementatie vanuit verschillende stakeholders uit Nederlandse ziekenhuizen. Er werden twee universitaire medische centra, 3 top klinische ziekenhuizen en 2 algemene ziekenhuizen geïncludeerd. In elk ziekenhuis werden 3 stakeholders geïnterviewd: 1) medisch professionals, 2) managers, en 3) IT medewerkers. In totaal zijn 21 semigestructureerde interviews uitgevoerd met gebruik van het model van Grol en Wensing. Dit model beschrijft belemmerende en bevorderende factoren voor verandering in de gezondheidzorg op 6 niveaus: 1) innovatie (het patiënt portaal); 2) individuele professional; 3) patiënt; 4) sociale context; 5) organisatorische context; en 6) economische en politieke context. Voor het analyseren van de data werd dit model gecombineerd met technische en portaal kenmerken van McGinn et al. De belangrijkste bevorderende factoren waren: 'perceived usefulness' (bijvoorbeeld de informatie toegankelijkheid voor patiënten), de 'positieve attitude van individuen' en 'steun van het management' (zoals een strategisch plan voor eHealth en patiëntportalen). De belangrijkste belemmerende factoren zijn: 'gebrek aan resources' (zoals gebrek aan personeel), 'financiële bezwaren' (bijvoorbeeld kosten en gebrek aan vergoedingen), en het 'garanderen van privacy en beveiliging' (zoals strenge regels). Concluderend, de implementatie van patiëntportalen is een complex proces. Het is niet alleen een technisch proces, maar de implementatie heeft ook invloed op de organisatie en het personeel.

Belemmerende en bevorderende factoren zijn gevonden op verschillende niveaus, ook zijn er verschillen gevonden tussen type ziekenhuizen en stakeholdergroepen. Onze bevindingen onderstrepen het belang om verschillende stakeholders te betrekken bij de implementatie van patiëntportalen.

In **hoofdstuk 4** is een systematisch literatuuronderzoek en een meta-analyse uitgevoerd om de effecten van telehealth op het gebruik van ziekenhuisdiensten, oftewel ziekenhuisopnames en opnameduur, te evalueren. Daarnaast zijn de effecten tussen de typen telehealth en aandoeningen vergeleken Telehealth betekent het leveren van zorg op afstand met gebruik van informatie- en communicatietechnologie. Gerandomiseerde gecontroleerde studies (RCT) gepubliceerd in vaktijdschriften, waarin de effecten van telehealth interventies vergeleken werden met reguliere zorg, zijn geïncludeerd. We hebben in totaal 127 RCTs geïncludeerd in de meta-analyse. In vergelijking met reguliere zorg, zorgt telehealth voor een lager risico op ziekenhuisopnames voor alle oorzaken (-4.8%) en voor aandoening specifieke ziekenhuisopnames (-15.6%). Telehealth heeft, in vergelijking met reguliere zorg, ook gezorgd voor minder opnames gerelateerd aan alle oorzaken (-5.7%) en gerelateerd aan de aandoening (-23.4%). Ook zijn het aantal ziekenhuis dagen per patiënt, gerelateerd aan alle oorzaken (-17.7%) en de aandoening (-39.8%), significant afgenomen. Voor patiënten met een opname kan een gemiddeld verblijf voor alle oorzaken mogelijk worden verlaagd (-5.7%) en nog meer voor aandoening gerelateerde opnames (-30.5%) De effecten waren vergelijkbaar voor de typen telehealth en aandoeningen. De gevonden effecten van telehealth op ziekenhuisopnames en opnameduur, waren klein tot gemiddeld.

In **hoofdstuk 5** zijn de effecten van een mobiele gezondheid en zelfmanagement app voor onlangs ontslagen patiënten met COPD (een longziekte) geëvalueerd. De COPD-app bestond uit een 8 weken durende gezondheid en zelfmanagement interventie, inclusief; het Longaanval Actieplan, gepersonaliseerd medicatieoverzicht, informatie (over de aandoening COPD, voeding, lichamelijk activiteit, voordelen van stoppen met roken), wekelijkse vragenlijsten gemonitord door verpleegkundigen en videoconsult. Een prototype van de app is getest met 6 COPD patiënten. In de daaropvolgende haalbaarheidsstudie zijn zelfmanagement (Partners in Health Scale), verwachtingen en ervaringen met de app (Unified Theory of Acceptance and Use of Technology [UTAUT] model), en tevredenheid vastgesteld door middel van vragenlijsten op baseline, na 8 weken en na 20 weken. Het gebruik van de app is vastgesteld met log data. Heropnames zijn uit het EPD gehaald. In totaal zijn 39 patiënten geïncludeerd; 76.4% van de patiënten zijn uitgesloten van deelname, en 48.9% van deze patiënten zijn uitgesloten vanwege gebrek aan digitale vaardigheden, toegang tot een mobiel apparaat, of toegang tot het internet. In het algemeen waren patiënten tevreden met de app. Echter werd het gebruik minder na verloop van tijd. Het zelfmanagement element ‘knowledge and coping’ was significant toegenomen

na verloop van tijd (*P*=.04). Voorlopig bewijs over heropnames laat zien dat 13% van de patiënten een heropname had binnen 30 dagen, 21% binnen 8 weken, en 31% binnen 20 weken, in vergelijking met 14%, 18% en 22% in een historisch cohort. Het gebruik van een mobiele gezondheid en zelfmanagement app lijkt haalbaar voor slechts een klein aantal patiënten met COPD na ontslag uit het ziekenhuis. Het aanbieden van interventies op maat, ondersteuning voor patiënten en actieve adoptie door professionals zijn belangrijke elementen voor succesvolle mHealth interventies.

In **hoofdstuk 6**, is een gerandomiseerd gecontroleerd onderzoek (RCT) uitgevoerd. Het doel van dit onderzoek was om te evalueren of het gebruik van videoconsult beter is dan face-to-face consulten in het ziekenhuis voor patiënten met obstructief slaap apneu (OSA), die gebruik maken van een slaapmasker. Het gebruik van het slaapmasker werd op afstand gemonitord, met beoordelingen op korte termijn (week 1 tot 4) en lange termijn (week 4, 12 en 24). Vragenlijsten werden ingevuld door patiënten op baseline en na 4 weken om de volgende uitkomsten te meten: zelf-effectiviteit ('self-efficacy'), risico perceptie, uitkomstverwachtingen (Self-Efficacy Measure for Slaap Apnea), verwachtingen en ervaringen met video consult (met gebruik van constructen van het UTAUT model) en tevredenheid van patiënten. Tevredenheid van verpleegkundigen werd ook geëvalueerd met gebruik van vragenlijsten. In totaal, zijn 140 patiënten gerandomiseerd (1:1 allocatie). Het gebruik van videoconsult voor OSA patiënten leidt niet tot betere resultaten, in vergelijking met face-to-face consulten, voor gebruik van het slaapmasker. Een significant verschil voor het gebruik van het slaapmasker werd gevonden tussen de groepen op korte termijn (*P*-interaction=.008), maar niet op lange termijn (*P*-interactie=.68). Verandering na verloop van tijd voor therapietrouw was niet significant verschillend op korte termijn (*P*-interactie=.17) of lange termijn (*P*-interactie=.51). Een relatie werd gevonden tussen gebruik van het slaapmaker en zelf-effectiviteit (*P*=.001), ongeacht de interventie arm (*P*=.25). De ervaringen waren positief en 95% (60/63) was van plan om videoconsult te blijven gebruiken. In het algemeen waren patiënten en verpleegkundigen (n=3) tevreden met het videoconsult systeem. De resultaten uit dit onderzoeken suggereren dat zelf-effectiviteit een belangrijke factor is in het verbeteren van het gebruik van een slaapmasker en dat videoconsult een haalbare manier is om patiënten, die beginnen met gebruik van een slaapmasker, te ondersteunen.

In **hoofdstuk 7** is een kwalitatief onderzoek uitgevoerd. Doel van dit onderzoek was het genereren van een overzicht met factoren die implementatie van continue monitoring met gebruik van draadloze draagbare sensoren (verder continue monitoring genoemd) beïnvloeden. Om dit vast te stellen zijn de ervaringen van verpleegkundigen met het gebruik van continue monitoring op de afdeling en hun verwachtingen voor gebruik in de thuissituatie (van patiënten) geëvalueerd. Semigestructureerde interviews zijn uitgevoerd

met verpleegkundigen uit drie Nederlandse ziekenhuizen, hierbij is gebruik gemaakt van het Consolidated Framework for Implementation Research (CFIR). CFIR werd ook gebruikt voor data analyse, in combinatie met een component uit het UTAUT model. Data is verzameld van 27 CIR componenten en 1 UTAUT component. Volgens tenminste 8 verpleegkundigen, hadden 5 componenten een positieve invloed op implementatie op de verpleegafdeling namelijk: 'relative advantage' (zoals eerdere waarneming van achteruitgang), 'patient needs and resources' (zoals veilig voelen van patiënten), 'networks and communications' (bijvoorbeeld het samen uitvoeren van een taak), 'personal attributes' (zoals ervaring met de interventie), 'implementation leaders' (bijvoorbeeld aanwezigheid van een projectleider). Vijf componenten hadden een sterke negatieve invloed op implementatie, volgens tenminste 8 verpleegkundigen, namelijk: 'evidence strength and quality' (bijvoorbeeld gebrek aan bewijs vanuit praktische ervaringen), 'complexity' (zoals aantal proces stappen), 'design quality and packaging' (zoals slechte sensor kwaliteit), 'compatibility' (zoals verandering in werk) en 'facilitating conditions' (zoals Wi-Fi verbinding). Verpleegkundigen verwachten dat continue monitoring in de thuissituatie belemmerd zal worden door 'compatibility' met werkprocessen en systemen (zoals verandering in werk) en 'evidence strength and quality' (zoals gebrek aan beschikbaar bewijs), en bevorderd zal worden door beschikbare kennis en informatie (bijvoorbeeld training) en 'perceived advantages' van de implementatie (zoals beschikbaarheid van data). 'Facilitating conditions', zoals interoperabiliteit met bestaande systemen, kunnen bijdragen aan verdere ontwikkeling. Het overzicht, in dit paper, kan gebruikt worden als leidraad voor toekomstige implementaties en evaluaties.

Er is een kloof tussen onderzoek en gebruik van eHealth in de klinische praktijk, deels vanwege de kenmerken van technologie en vanwege de manier waarop onderzoek wordt uitgevoerd. In **hoofdstuk 8**, beschrijven we hoe standalone (d.w.z. zelfstandig werkende systemen) en interoperabele systemen gebruikt worden voor de evaluatie van eHealth om op deze manier mee te kunnen gaan met de snelheid van IT ontwikkelingen, die relevant zijn voor de klinische praktijk. Het gebruik van eHealth kan geëvalueerd worden met gebruik van standalone systemen in een lab setting (zoals academische omgeving), standalone systemen in een klinische setting of met interoperabele systemen (met name met het EPD). Besluitvorming over het gebruik van deze systemen in ziekenhuizen is relevant. Daarom zijn verschillen in, en consequenties van, eHealth onderzoek met standalone systemen en met interoperabele systemen beschreven met gebruik van voorbeelden uit de dagelijkse praktijk. Standalone systemen in een lab setting zijn geen goede weerspiegeling van de complexiteit van de dagelijkse praktijk. Het gebruik van standalone systemen in de klinische praktijk kan geschikt zijn voor onderzoek dat relatief onafhankelijk van de dagelijkse praktijk wordt uitgevoerd, hiermee kan de haalbaarheid van de technologie vastgesteld worden tegen relatief lage kosten. Het realiseren van (EPD) interoperabele eHealth oplossingen is een uitdaging en kost veel tijd en middelen. Het vraagt om grote(re) investeringen, daarbij wordt

het vaak beïnvloedt door verschillende factoren zoals technologische, organisatorische en individuele factoren. Echter, is het een duurzamere oplossing omdat het ook ingezet kan worden om een breed scala aan uitkomsten te evalueren. Dit kan gebruikt worden om succes op een grote schaal in de dagelijkse klinische praktijk te voorspellen. Besluitvorming over gebruik van een standalone of interoperabele systemen is relevant, omdat dit effect kan hebben op het onderzoeksdesign, de implementatie en adoptie van technologie.

In **hoofdstuk 9** zijn de belangrijkste bevindingen en implicaties van het proefschrift beschreven, gevolgd door aanbevelingen voor praktijk en beleid en voor toekomstig onderzoek. Een belangrijke bevinding uit dit proefschrift is dat eHealth aangepast moet worden aan de verschillende populaties en verschillende patiënten. Het is hierbij belangrijk om 'digital health literacy' constant te verbeteren. Dit is gedefinieerd als "de mogelijkheid om gezondheid informatie uit elektronische bronnen te zoeken, vinden, begrijpen en te beoordelen en om deze kennis te gebruiken bij het adresseren of oplossen van een gezondheidsprobleem" [vertaling van Engelse definitie].

De implementatie van nieuwe interventies of het opschalen van bestaande interventies in de klinische praktijk is een uitdaging omdat er meerdere stakeholders betrokken zijn en omdat dit wordt beïnvloedt door meerdere factoren. Deze factoren moeten in elke afzonderlijke zorgorganisatie vastgesteld worden, omdat eHealth interventies vaak context-specifiek zijn. Compatibiliteit (dat wil zeggen de aansluiting van de eHealth interventie op de organisatie) is een belangrijk aspect voor het succes van een eHealth interventie. De integratie van eHealth in de reguliere klinische zorg kan het gebruik vergroten. Zorgprocessen moeten hier wel op aangepast worden en hiervoor zijn voldoende middelen nodig.

Zorgtransformatie vereist opschaling en integratie van eHealth in de klinische praktijk, dit gaat gepaard met uitdagingen op verschillende niveaus. Om deze uitdagingen aan te gaan, hebben we verschillende aanbevelingen gedaan voor praktijk en beleid op; micro niveau (bijvoorbeeld vaststellen van de kenmerken van patiënten en zorgprofessionals die eHealth gebruik kunnen beïnvloeden); meso niveau (bijvoorbeeld het uitvoeren van meer pragmatische evaluaties gericht op de toepasbaarheid in ziekenhuizen) en; macro niveau (bijvoorbeeld de noodzaak van vergoedingen om gebruik op de lange termijn te ondersteunen en investering in methodologische studies gericht op kosteneffectiviteit van digitale zorgdiensten).

Een aanbeveling voor vervolgonderzoek is om uitgebreidere evaluaties van eHealth uit te voeren, waarin aandacht wordt besteed aan een breed scala van uitkomstmaten. Ook is transparantie over successen en mislukkingen belangrijk. Zorgtransformatie vraagt ook om een andere aanpak van onderzoek, bijvoorbeeld door het uitvoeren van meer pragmatisch

onderzoek en door acceptatie van (andere) uitkomstmaten. Dit betekent ook meer aandacht voor cognitieve en socio-psychologische uitkomsten, dit kan namelijk nuttige informatie opleveren over de effecten van eHealth technologie in de klinische praktijk.

In dit proefschrift hebben we belangrijke informatie verstrekt over shared care interventies met ondersteuning van IT en implementatie van eHealth in de klinische praktijk, in combinatie met evaluatie van verschillende toepassingen en uitkomstmaten. Onze bevindingen zijn relevant voor zorgprofessionals, beleidsmakers en onderzoekers en leggen een basis voor toekomstige implementaties en onderzoek. We hebben gevonden dat eHealth de kan zorgen voor een verbetering van patiëntvriendelijk zorg, maar dat de effecten op gezondheiduitkomsten onduidelijk blijven. De implementatie van eHealth vraagt om grote veranderingen in een complexe omgeving. Herontwerp van zorgpaden is noodzakelijk, in plaats van alleen een extra optionele dienst toevoegen (aan een zorgpad). Pragmatische onderzoeksmethoden zijn nodig om de kloof tussen de klinische situatie en IT te verkleinen en om het gebruik van eHealth in de praktijk de evalueren. Deze aanpak kan bijdragen aan het realiseren van zorgtransformatie met gebruik van eHealth.

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