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## **Building bridges for meaningful ehealth: aligning people, technology and practice through collaboration and knowledge sharing**

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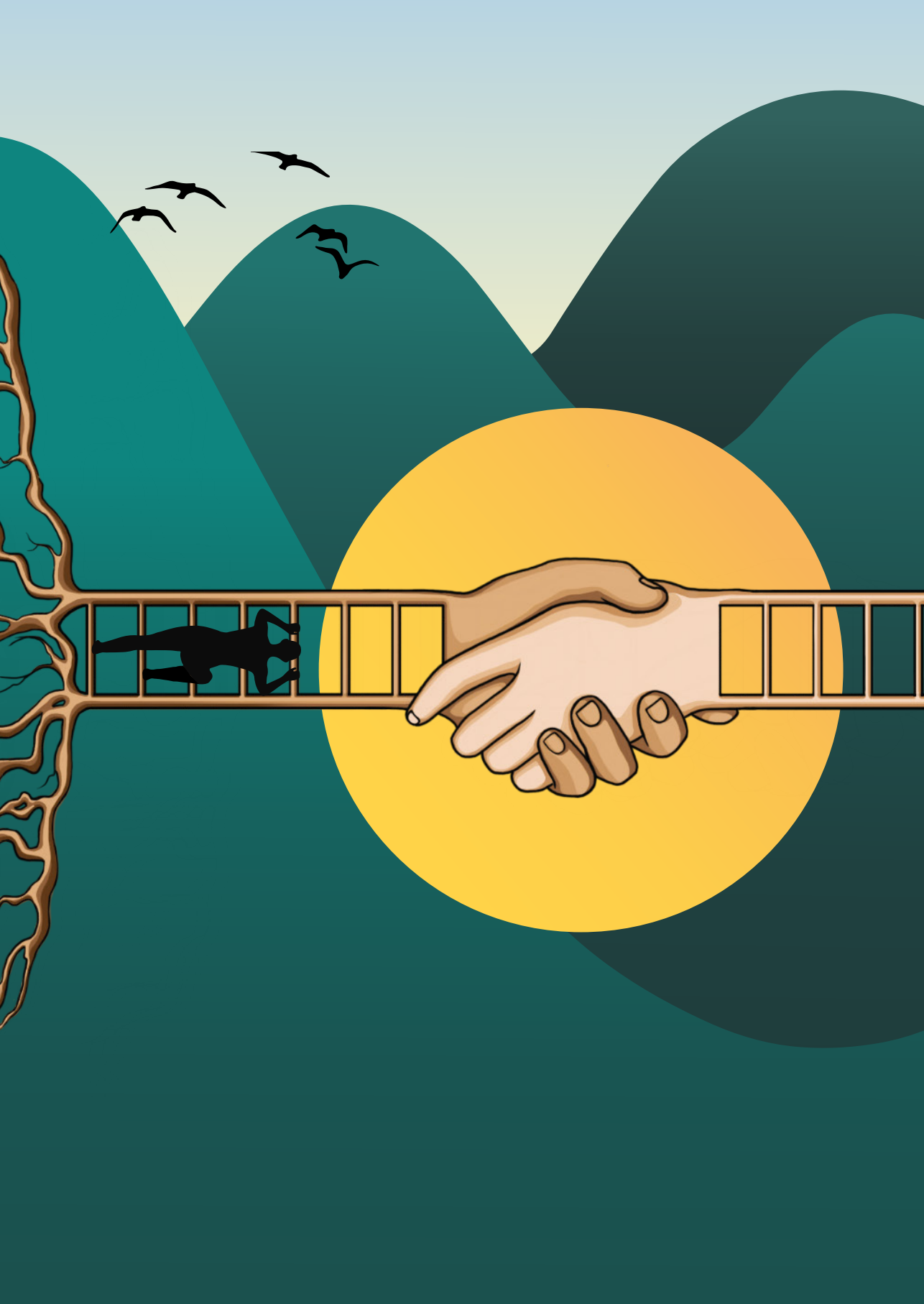
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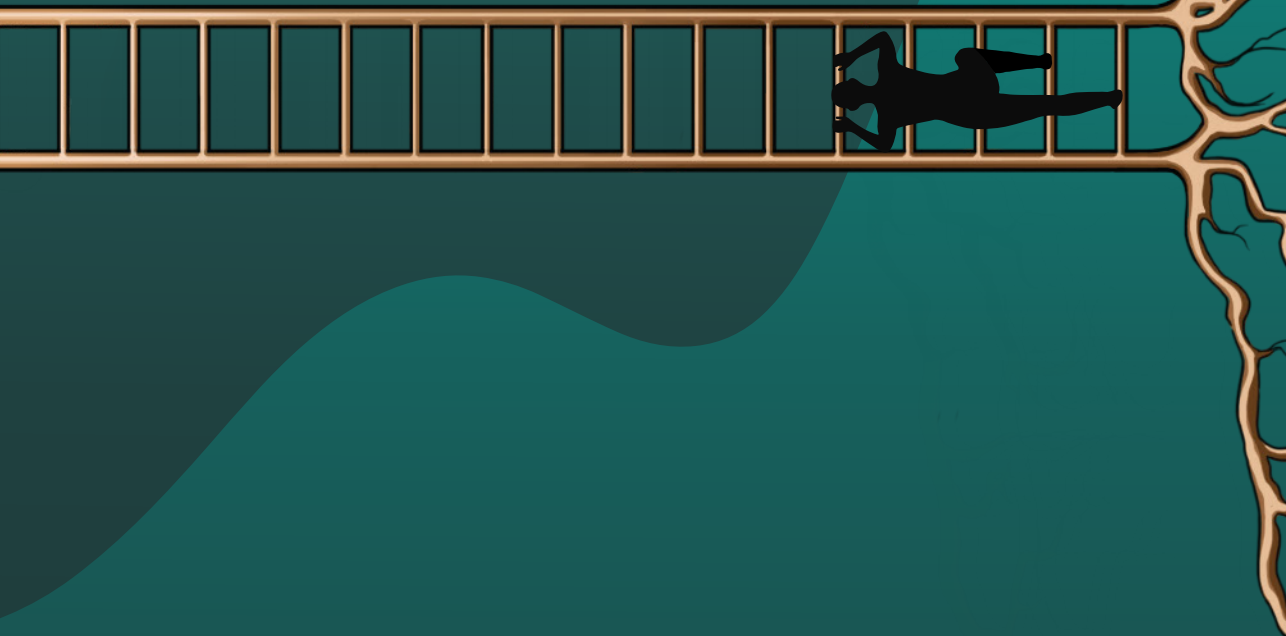
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# Chapter 1

## General introduction



*It is Wednesday morning, May 26<sup>th</sup> 2020. The country has been in lockdown already for two months due to the COVID-19 pandemic. Libraries are closed, and the social distancing measure is in effect everywhere. Vulnerable elderly individuals need to be extra protected, and it is advised not to visit grandparents. Social life has come to a standstill. This also holds true for 63-year-old Mrs. V from Leiden.*

*Her weekly bridge club is closed, and she has no family left. With only a landline, she feels disconnected from the outside world. As she looks at the local morning newspaper, an article catches her attention. It is about a local initiative called 'Blijf in Beeld' (ENG: 'Stay in Touch'). This initiative offers free smartphones to elderly villagers, donated by members from the community. Loneliness has been gnawing at her for weeks, growing stronger by the day. With the traumatic memory of a previous hacking incident still fresh in her mind, Mrs. V decides that it is time that she stops avoiding digital devices. She picks up the phone and dials the number listed at the bottom of the article.*

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This is the story of a 65-year-old woman who, after weeks of loneliness, feeling physically and digitally isolated from the rest of the world, decided to reach out to the founder of the 'Stay in Touch' initiative to obtain a smartphone. A volunteer, a digital buddy, listened to her fears and anxieties regarding all things digital. The buddy helped her become familiar with her new mobile phone and provided the necessary guidance.

Although, smartphones and digital tools seem commonplace, it turns out to be a completely different world for some people. A world that threatens to alienate them, if we are not careful.

## Digital transformation

The current Dutch healthcare system is facing many challenges due to an aging population, increased prevalence of chronic diseases and advancements in medical treatment and technology placing a strain on the system in terms of finances and workforce shortages (1). To address the challenges, 'Het Integraal Zorgakkoord' (2023 -2026) (ENG: Integrated Care Agreement) was recently established in the Netherlands. This agreement, signed by the Ministry of Health, Welfare and Sport and a large number of parties in the Dutch healthcare sector aims to ensure the availability, affordability, accessibility, and appropriateness of healthcare both in the present and in the future. An important pillar within the agreement centres around the use and integration of eHealth within the digital transformation of healthcare. eHealth refers to the delivery or enhancement of health services and information through the internet and related technologies (2). As such, eHealth steers away from the traditional healthcare provision and offers alternative and innovative ways in providing healthcare, including remote and digital care. Originally introduced in 1999 as a term referring to internet-based medicine which provides information on symptoms and treatments, eHealth has since evolved with the introduction of

modern technologies. It now encompasses a wide range of digital health technologies, including electronic health records, clinical decision support systems, telemedicine, health apps, wearables, and sensors. Providing a myriad of opportunities, it is considered essential for addressing the existing healthcare challenges at both national and global levels.

### **Role and benefits of eHealth**

The widespread uptake and use of mobile phones and internet access globally have made mobile phones a powerful platform for delivering personalized health in a for patient convenient way. This form of eHealth has particularly gained traction in the treatment and management of chronic lung conditions such as asthma, and Chronic Obstructive Pulmonary Disease (COPD) (3-5). Managing these chronic diseases is a multidisciplinary process, requiring close collaboration between healthcare professionals and active engagement of patients themselves. As such, technologies like remote monitoring devices and mobile apps can offer ongoing individual self-care support, facilitate regular monitoring for better health outcomes and stimulate patients in changing undesired behaviour into desired behaviour, such as adhering to a medication regimen (3).

### **Lack of widespread adoption and implementation**

While the past decade is marked by an ongoing exponential growth of eHealth technologies, a substantial portion of these technologies pose health claims which are not supported by sufficient research to validate their effectiveness, safety, or impact on health outcomes. eHealth that is sufficiently evidence-based may still be challenged by poor uptake into practice. Hence, while there is an exponential growth in digital health technologies, only a small portion of them find their way into practice and benefit patients. This discrepancy between research and development efforts and practical application is characterized by low adoption rates, limited scalability, and inadequate integration into existing healthcare and reimbursement systems (6).

During the COVID-19 pandemic telemedicine and remote patient monitoring have proved instrumental in maintaining access to care, mitigating the spread of the virus, and optimizing resource utilization and as such has raised awareness on the usage and benefits of eHealth. However, while the COVID-19 pandemic has propelled the use of telemedicine, it has also exposed important gaps in effective integration of telehealth within the current health system (7). Hence, though initially marked as the turning point in the digitalization of healthcare, enabled by regulatory changes that enabling greater access and reimbursement and an increased user and provider willingness (8), its long term impact remains debatable and most importantly limited to the use of telemedicine (9-11).

Extensive literature before and after the COVID-19 pandemic has highlighted the reasons behind the failure of widespread eHealth adoption and implementation. As a result, research focus has shifted from primarily developing innovative digital health solutions to understanding the conditions necessary for successful implementation

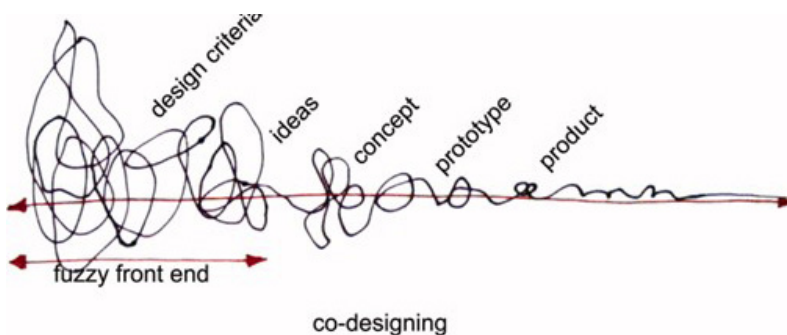
(6,12). Considering this, this dissertation identified five challenges pertaining to the development, implementation and evaluation of eHealth solutions that require attention. These challenges can be metaphorically depicted as gaps that must be bridged to facilitate widespread implementation of eHealth in healthcare settings in order to be meaningful.

## Challenges

### Challenge one: misalignment with user needs

The limited adoption of eHealth solutions can be partly attributed to the lack of active involvement of end-users, such as patients, during the initial stages of design and development (6, 13). This can result in poor usability, poor user experience and, most importantly, misalignment with user needs (6, 14, 15). Recognizing the importance of end-user engagement in eHealth development, there has been a growing emphasis on co-creation and patient involvement in eHealth development (13, 16). However, in practice, patients are primarily involved during later stages when advanced prototypes or finished products already exist (17). During these stages, users are asked to test the prototypes or products, focusing mainly on usability, user-friendliness, and interaction with the user interface. Although this approach helps refine the eHealth technology and ensures certain aspects, such as understandable information and user-friendly navigation, it does not necessarily guarantee that the prototype effectively addresses users' problems or fulfils their unmet needs.

The initial design phase, often referred to as the “fuzzy front-end” research, aims to uncover the central challenges, understand the context, explore unmet needs in detail to then ideate potential solutions that align with those user needs (18, 19). The ideas generated during this phase are subsequently developed into concepts and prototypes, which are further refined based on user feedback (18) (see [Figure 1](#)).

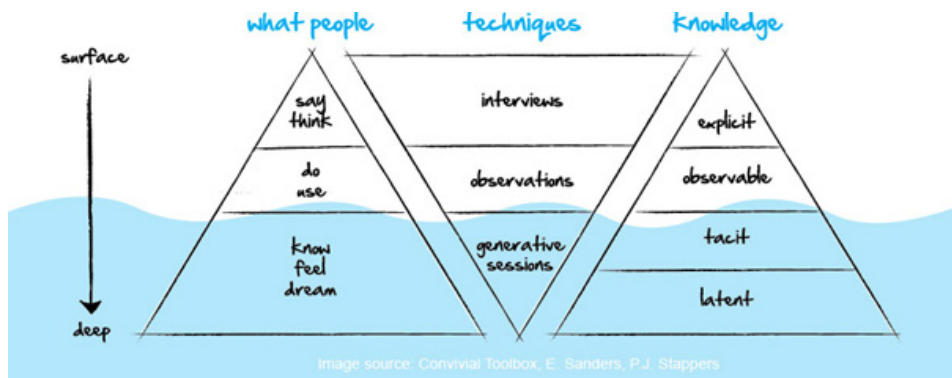


**Figure 1.** Design process adopted from co-design process by Sanders and Stappers (20)

One strategy to actively involve users in the design process is known as participatory design. This approach is based on the notion that users are regarded as “experts by experience” or experts of their “lifeworld” (21). It acknowledges that their

knowledge is equally valuable in a collaborative design process as the expertise of designers, developers, and researchers. Participatory design employs various tools and techniques to tap into users' knowledge and foster mutual understanding throughout the design process (22).

Within participatory design 'knowledge' is theoretically conceptualized into various levels of knowledge; explicit, observable, tacit and latent knowledge (see Figure 2). Explicit and observable knowledge – what people say and do – is the most accessible layer of knowledge and can be explored using conventional qualitative research techniques like interviews and observations. Deeper levels of knowledge such as tacit and latent knowledge respectively refer to knowledge that people can act upon but cannot readily express in words (like riding a bike or why something is funny) and knowledge people are not aware of yet (like knowing where to drive to, based on experience as a passenger) (23). Desires, needs, motivations and experiences are generally concealed in these deeper layers and require participatory design tools, such as creative and reflective exercises, to be elucidated (24). Consequently, employing participatory tools to effectively identify user needs and uncover deeper levels of knowledge is essential for developing eHealth interventions that address unmet user needs.



**Figure 2.** Different research techniques access various levels of knowledge (image adopted from Sleswijk Visser et al., 2005)

While participatory design plays a pivotal role in the active involvement of end-users and stakeholders, the use of participatory design tools often remains limited to a single phase, is poorly substantiated or lacks methodological reasoning (17, 25). To support researchers in the use of participatory design it is imperative to substantiate and report on participatory design choices and establish a more comprehensive understanding of eHealth development methods (26). The creation of a knowledge base in this area requires more in-depth case studies that elucidate and reflect upon the specific applications of participatory design tools and methods.

## Challenge two: user non-adherence and disengagement

A significant challenge encountered in the use and uptake of eHealth is non-adherence, referring to the extent that users use or keep using the intervention in the desired way (27, 28). One key factor contributing to non-adherence is the lack of user engagement with the technology or engagement for a brief time (29, 30). Engagement encompasses a broader set of psychological and behavioural factors related to individual's interaction and involvement with digital health technologies (31). As such, it reflects the level of interest, motivation, and connection users have with the technology (32).

To enhance user-engagement gamification principles are increasingly being integrated into the design of eHealth, aiming to make the digital health technology more appealing, motivating and engaging for users. These game design elements can be very specific, such as the inclusion of “badges” or “levels” in the interface, or they can be more comprehensive, such as incorporating a storyline to clarify personal behaviour change goals or stimulate enduring play (33). Persuasive game design has been applied in behaviour change-based eHealth interventions as means to encourage people to modify their behaviour (34), for instance by influencing people's attitudes to certain behaviour or by building new skills within the game world that can be applied in real-life situations (35).

While engagement plays a significant role in the adoption of and adherence to eHealth intervention, it is important to note that disengagement does not always imply non-adherence. The duration or frequency of use required to achieve the desired (behavioural) outcomes (e.g. increased medication adherence) may vary among different technologies and user groups (27). This is particularly true with digital health technologies that target behaviour change as the desired outcome. In such cases, disengagement from eHealth may be justified if the desired behaviour change has been accomplished, through for example the formation of a habit (36). Non-engagement in these instances is not a consequence of, for example, losing interest.

## Challenge three: missing those who benefit most

While the technology itself plays an essential role in engagement to and use of eHealth solutions specific user characteristics are equally important (29). Studies investigating demographic factors associated with lower eHealth usage have found that older adults, individuals with chronic diseases living alone, and those with lower income and/or education were less likely to use eHealth solutions (37). Another study showed that having a lower socio-economical position, indicated by lower levels of education and income, was associated with limited access to digital technologies and digital healthcare services (38). Consequently, individuals with lower socio-economic position are more likely to have lower levels of digital health literacy and health literacy compared to those with higher socio-economic position. Considering the association between limited health and digital literacy with lower eHealth usage and the recognized role of (digital) health literacy in reducing health inequality,



researchers and policymakers have focused on promoting (digital) health literacy as a means to address the digital divide.

The so-called 'digital divide' in which digital health systems and technologies are predominantly accessed and used by individuals with a higher education and higher health literacy, is of particular concern as people with lower education and fewer resources generally have an increased risk of developing chronic conditions and more often need ongoing medical care (39). Hence, while current healthcare is shifting and increasingly relies on remote healthcare and digital healthcare technologies and services, individuals with limited access to digital technologies may experience challenges in obtaining timely and reliable health information, seeking appropriate medical advice, or miss out on opportunities to adopt healthy behaviours. Consequently, this growing digital divide has the potential to widen health inequities and exclude digitally disadvantaged individuals (40, 41). This issue is not new. In fact, the WHO has recognized the digital divide, with risk of digital exclusion and unequal access, as one of the biggest challenges posed by the digital transformation of healthcare (42, 43).

While access within the digital transformation is often seen from the dimensions of material access, referring to the physical access to digital technologies such as computers, smartphones, and internet connectivity, access is considered a multifaceted phenomenon that encompasses various dimensions of access, including, material access, skills access and motivational access (44). This means that, even if access is available, disparities may still exist if people do not possess the proper competence to use the digital health technologies and services needed to effectively to use the technology (skills access). The emergence of diverse digital health technologies necessitates individuals to navigate through portals, actively engage with apps, remain motivated to use self-monitoring devices, interpret collected data, assess information reliability, and effectively communicate with digital health systems. This additional set of skills and abilities has been conceptualized into eHealth literacy. Shedding light on and addressing eHealth literacy needs of individuals is paramount to providing appropriate support and to develop eHealth that fit people's eHealth literacy needs (45, 46). The eHealth Literacy Questionnaire (eHLQ) is increasingly used globally as comprehensive person-centred instrument to measure eHealth literacy. However, despite the ongoing digital transition in the Netherlands a comprehensive Dutch person-centred instrument to measure eHealth literacy is lacking.

The third access dimension, motivational access, relates to the personal motivation, attitudes, and willingness to engage with digital technologies. People with lower social-economic positions or limited health literacy are seldomly actively involved in eHealth development, resulting in interventions that fail to meet their needs, motivation, attitude towards eHealth and eHealth literacy needs (47, 48). Involving individuals with low socio-economic positions or limited health literacy in participatory design seems logical to develop eHealth interventions that address their (unmet) needs. However, effective involvement of these groups in participatory design is often hindered by

barriers such as difficulties understanding study content, challenges with abstract thinking, language or literacy issues, anxiety towards research or the research team, feelings of stigmatization, and limited exposure to technology and the internet (49-51). Studies that do succeed in involving socio-economically disadvantaged groups often limit their involvement to later development stages, such as assessment of an app or patient portals on usability or readability of health information. To our knowledge there currently is no clear methodology for involving people with low socio-economic position or limited health literacy in the participatory design process of an eHealth intervention. Therefore, there is a need for best practice examples and guidance on how to effectively involve people with limited health literacy.

Hence, to ensure that eHealth benefits all people in need and is accessible in terms of skills and motivation, it is essential to involve socio-economically disadvantaged groups throughout all stages of development using participatory design. By doing so we can help bridge the gap between those who have access to digital health technologies and those that do not, rather than creating a range of interventions that are largely unused by those who could benefit the most.

#### **Challenge four: limited evidence on the effectiveness of eHealth**

The lack of evidence on the effectiveness of eHealth solutions presents a significant challenge to their widespread adoption and implementation of eHealth. Generally, practice and clinical decision making nowadays is based on evidence-based medicine. Therefore, demonstrating the effectiveness and clinical benefits of eHealth interventions has become a crucial aspect of the transition towards digital healthcare (52). It plays a vital role in distinguishing useful and beneficial eHealth interventions from potentially harmful ones, and even influences reimbursement decisions (53).

Randomized controlled trials (RCTs) based on the fundamentals of creating two comparable groups to assess the true effect of an intervention, lie at the top of the scientific evidence pyramid. However, despite its robust evidence, there is growing uncertainty as whether the plethora of RCT evidence on eHealth actually translates into improvements in patient outcomes and care. One reason and challenge is formed by the fact that RCTs typically focus on well-defined, homogeneous populations, employ blinding techniques, follow specific protocols, and incorporate controlled clinical elements. These measures aim to ensure comparability between groups and attribute any differences in outcomes to the intervention itself. Paradoxically, these strict criteria limit the external generalizability of study findings, meaning that they may not readily apply to real-world practice or the broader population. They run the risk of overlooking the complexity of contextual factors that exist in everyday healthcare settings, creating a disconnect between research outcomes and practical application. Hence, there is an increasing need for real-world evaluation and generation of real-world evidence in terms of the effectiveness of eHealth technologies.

## Challenge five: disconnection between evidence and application in practice

The generation and application of evidence is essential for the adoption of eHealth and its impact on healthcare and society. However, there is often a disconnection between the generation of evidence and its application in practice, leading to a 'knowledge-to-action' gap (54). This gap has been recognized as one of the significant challenges of our time and has prompted a global call for knowledge translation, which involves 'the synthesis, dissemination, exchange, and application of knowledge in an effort to improve health services and products and strengthen the healthcare system' (55).

The Knowledge-to-Action (KtA) framework offers a conceptual framework to aid in knowledge translation and the use of this evidence by healthcare professionals in their decision making regarding the adoption of health policies, practices, or programs (56). This framework consists of two interconnected components: the Action Cycle and the Knowledge Creation funnel. The Action Cycle encompasses the activities required to apply evidence-based knowledge into practice. It involves tailoring interventions to suit the local context, identifying and evaluating barriers and facilitators to implementation, and ensuring the effective application of evidence-based practices (57). On the other hand, the Knowledge Creation funnel represents the simultaneous process of generating tools and key messages that support the Action Cycle. It involves a funnel-like process translating scientific results into core messages that are actionable and easily understandable by stakeholders and decision-makers. Principles of science communication and data visualization play a valuable role in this knowledge creation process. However, there is currently a lack of guidance on how to practically implement the knowledge creation funnel (58).

### Building bridges – why this dissertation

To conclude, while eHealth is promising in facing current healthcare challenges, measures should be undertaken to bridge the gaps that challenge the development, implementation, and evaluation. Addressing these gaps is crucial for the development of meaningful eHealth solutions that align with user needs, promote user engagement and adherence and ensure equal access to eHealth. In addition, to reach its full potential effort should be directed at generating evidence on effectiveness, and facilitating knowledge translation and dissemination, thereby bridging the gap between research and practice and strengthening the wide-spread adoption and implementation of eHealth.

## Outline of this dissertation

This dissertation addresses the above-mentioned challenges in eHealth development, evaluation, and implementation. Through real-world examples and case studies it demonstrates how these challenges can be addressed and metaphorical gaps can be bridged.

The dissertation consists of three parts. Part 1 focuses on the challenges in eHealth development (**Challenge one, two and three**) and demonstrates, through three case studies, how these challenges can be tackled. The first case study showcases how participatory design can be utilized to involve end-users and other stakeholders in designing the innovative game 'Ademgenoot' to motivate people with asthma to adhere to their medication regimen (**chapter 2**). It shows how behaviour change and persuasive game design theory can be combined to create a fun and engaging game. In the second case study we focus our participatory design efforts on people with limited health literacy and provide an approach on how one can design with and for people with asthma and limited health literacy employing participatory design tools (**chapter 3**). **Chapter 4** presents the third case study, the Hospital Hero app, which demonstrates how participatory design can be employed to involve children and other stakeholders in the development of an app aimed at reducing preprocedural stress and anxiety among children visiting the hospital.

**Part 2** continues with the evaluation of eHealth and addresses challenges related to generating evidence on effectiveness (**Challenge four**). We do so by presenting a protocol for a real-world pragmatic RCT to assess the effectiveness of a smart asthma inhaler, the ACCEPTANCE study (**chapter 5**). The protocol demonstrates how real-world evidence can be collected and provides an approach to identify which patients benefit most from the smart inhaler program. We continue our exploration on effectiveness studies by presenting a Cochrane systematic review and meta-analysis on integrated disease management for people with COPD, which are complex interventions that are pooled to generate an overall estimate of effect on multiple clinical and process outcomes (**chapter 6**). By doing so we touch upon the complexity of systematically pooling and evaluating real-world RCTs of complex interventions, the challenges of heterogeneity and the importance of contextual factors.

In **Part 3** we provide tools that can be helpful in working towards more equitable eHealth, addressing prerequisites in eHealth development such as understanding people's eHealth literacy needs (**Challenge three**) and supporting the translation of knowledge into practice (**Challenge five**). We present the Dutch version of the eHLQ and discuss its translation, cultural adaption, and validity assessment (**chapter 7**). In **chapter 8** we present a systematic, practical, and easy-to-implement tool for effective knowledge creation, and its use in a case study on chronic respiratory diseases in low- and middle-income countries. A detailed overview of the chapters, study aim and used design or research methods is provided in **Table 1**.

The closing chapter, **chapter 9**, reflects on the separate studies, places them into a larger context, identifies important lessons learned, and concludes with some final insights.

Chapter title	Research aim	Dissertation aim	Design or research method	Design or research phase	Deliverable	Stakeholders involved
Part 1 - Participatory Design						
2. Design of the persuasive game Ademgenoot.	To design a persuasive game to motivate people with mild asthma to adhere to their medication regimen.	To demonstrate how participatory design techniques, in combination with behaviour change and persuasive game theory, can be applied to develop an engaging game.  To demonstrate how stakeholders can be involved in early stages of eHealth development.	Participatory design approach, generative techniques, semi structured interviews, persona creation, brainstorming, paper prototyping, WhatsApp prototyping, think-aloud exercise.	Define, create, prototype, user experience evaluation.	Prototype of a persuasive game based on automatic data logging using an electronic adherence monitoring device.	People with mild asthma, practice nurses, expert behaviour change, expert persuasive game design, patient advocates, smart inhaler developers, designers.
3. Designing with and for people with asthma and limited health literacy.	To demonstrate the application and tailoring of participatory design activities to fit the needs and skills of people with limited health literacy.	To explore how participatory design activities can be applied among people with limited health literacy.	Participatory design approach, brainstorming, co-creating stories, experience prototyping, think-aloud exercise.	Define, create, prototype, user experience evaluation.	Prototype of a medication adherence eHealth intervention.	People with asthma and limited health literacy, practice nurses, health literacy experts, smart inhaler developers, designers.
4. Design and pilot study of the Hospital Hero app	To design and evaluate an application to reduce procedural stress and anxiety among children visiting the hospital.	To demonstrate how participatory design can be combined with service design to develop and app based on the child's experience journey  To illustrate how gamification and storytelling can be used to create an engaging serious game.	Participatory design, service design, experience journey mapping, paper prototyping, usability testing, pilot study, mixed method.	Define, create, prototype, evaluation on user experience in practice.	Hospital Hero smartphone application.	Children (between 4 and 12 years) visiting the outpatient clinic, healthcare professionals, educational content experts, app developers, designers.

Chapter title	Research aim	Dissertation aim	Design or research method	Design or research phase	Deliverable	stakeholders involved
<b>Part 2 - Effectiveness Assessment</b>						
5. Protocol for a cluster RCT on a smart asthma inhaler programme	To investigate the effectiveness of a smart inhaler asthma self-management programme on medication adherence and clinical outcomes in adults with uncontrolled asthma, to evaluate its acceptability, and to identify subgroups who would benefit most based on patient characteristics.	To illustrate collection of long-term real-world eHealth intervention within a cluster RCT.  To provide an approach on how to identify which patients benefit most, based on patient characteristics.  To illustrate patient participation in the design and execution of a RCT.	Cluster RCT, pragmatic trial, patient involvement.	Protocol for an effectiveness evaluation.	Protocol for the evaluation of the effectiveness and cost-effectiveness of a smart asthma inhaler programme in primary care in the Netherlands.	Smart inhaler developers, patient advocates.
6. Cochrane review update	To compare the effectiveness of integrated disease management (IDM) programmes versus usual care for people with COPD on various clinical outcomes.	To shed light on the methodological challenges of complex health interventions, such as eHealth and the importance of contextual factors.	Systematic review, meta-analysis, Risk of Bias Grading, GRADE approach.	Synthesis and appraisal of all empirical evidence.	Various (eHealth and non-eHealth based) complex health interventions.	

Chapter title	Research aim	Dissertation aim	Design or research method	Design or research phase	Deliverable	stakeholders involved
<b>Part 3 - Tools and Instruments</b>						
7. Translation and validity assessment eHLQ	To translate and culturally adapt the original eHLQ into a Dutch version, and to examine validity of the translated instrument.	To provide an instrument to identify people's eHealth literacy needs and inform future digital health technology development and assessment.	Validity argument approach, cognitive interviewing, confirmatory factor analysis, invariance testing, multigroup comparison.	Instrument translation, cultural adaptation, and validity assessment.	Dutch version of the eHLQ.	People engaging with digital health technology or digital health services now or in the future, developer of the original instrument, translators, bilingual representatives, questionnaire administrator.
8. Systematic approach to knowledge creation	To provide researchers a systematic approach for putting knowledge creation into practice.	To provide a step-by-step tool on how to create knowledge to inform evidence-based decision making .  To demonstrate how to apply the tool into practice.	Framework design, case study demonstration.	Tool development.	Step-by-step instruction tool.	Science communication experts, UX designer.

RCT = randomized controlled trial; eHLQ = eHealth Literacy Questionnaire

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## Chapter 1

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