Bachelor Thesis

An interview study to understand how currently available eMental Health interventions for informal caregivers handle stakeholder involvement
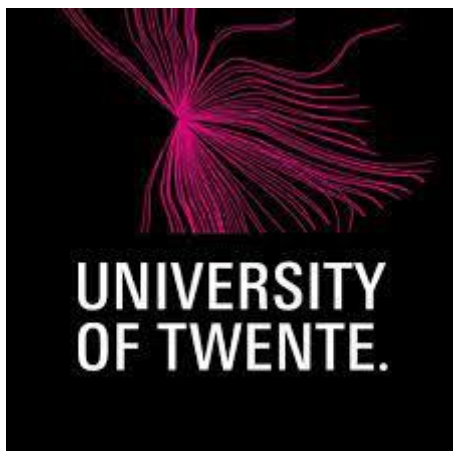
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Abstract

Objectives

To understand how currently available eMental Health interventions for informal caregivers handle stakeholder involvement during the development and implementation phase of their intervention.

Background

eHealth technologies lift the burden from the overstrained healthcare system and offer informal caregivers assistance and guidance in caring for their ill relatives or friends. These technologies facilitate self-management and aim to relief the psychological and physical demands that follow from continuous caregiving.

Methods

A qualitative semi-structured interview study was carried out to conduct a thematic analysis to answer the research question. Six companies that successfully launched an eMental Health intervention were interviewed.

Results

Needs of stakeholders were identified and translated into values of the eMental Health technologies. The most central needs and values are self-management skills, self-efficacy, trustworthiness and an easy usability. The key stakeholders of the interventions were the end-users that helped to shape the design and implementation process. Theories and implementation frameworks were considered by the majority of the companies and used sporadically to design and implement the interventions. A lack of stakeholder involvement beyond the end-users was established. Further, a limited amount of usability testing was conducted during and after the implementation.

Discussion

Involving stakeholders facilitates an effective, user-centered and tailored intervention to the target group. However, the interventions were hardly evaluated on effectiveness by the interviewed companies and therefore aggravate comparability between the interventions. Further, future studies should consider the success and effectiveness of an intervention when investigating the impact of stakeholder involvement.

1.Introduction

Nowadays, birth rates are declining while the average age of the population increases, inducing various consequences not only for the elderly but also for the younger members of society (Kanasi, Ayilavarapu, & Jones, 2016). This ageing society demands a higher need for care as well as more support for those suffering from chronic illnesses. The increasing prevalence rates of chronic illnesses combined with the increasing age pose a substantial challenge towards the healthcare systems (Janssen-Heijnen et al., 2005). In recent years, though, technological advancements are arising quicker than ever before and bear promising potential in helping to reduce the burden that is put onto the healthcare system. Modern technologies are being designed to support and manage the needs and demands of the patients and their caregivers. These technologies are used not only within the healthcare system itself, but hold a massive potential to be integrated into the social support system of the elderly and the ill.

One promising approach that aims to tackle this global issue lies in the domain of eHealth. eHealth is defined as the "use of technology to improve health, well-being and healthcare" (van Gemert-Pijnen et al., 2018) and makes use of innovative ideas to offer methods and solutions to maintaining and managing one's illness. Since the ageing population puts an enormous burden on the healthcare system in terms of preserving an adequate quality of patient care combined with a lack of financial resources, eHealth offers a propitous way of tackling these issues and faciliting the need for innovation within the healthcare system (Christie et al., 2018).

Developing and implementing these technological innovations holds many potential benefits such as cost-effectiveness, process optimization and an extended scope and impact (van Gemert-Pijnen et al., 2018; Ellis et al., 2021). Other advantages of using eHealth technologies in healthcare is the fact that it holds the potential to enhance the quality of care provided to the patients and to better the overall health and well-being of the patient (Li et al., 2013). Moreover, it can help healthcare experts to follow guidelines more diligently, while also enabling patients to access healthcare independent of time and setting (van Gemert-Pijnen et al., 2018). Lastly, the notion of empowerment is highly central in eHealth innovations. Not only does the patient feel to have more power and control over their illness, but he is also enabled to freely choose when and what aspects of healthcare to access (Risling et al., 2017). This patient-centredness is also beneficial outside the classic relationship between the patient and the healthcare professional, when for example family members or friends, so called "informal caregivers", are supportive or responsible for the healthcare of the patient. In particular, it facilitates the

involvement and commitment towards the management and supervision of one's health (Slev et al., 2016; van Gemert-Pijnen et al., 2018).

Particularly because of this ageing society and its consequential impact on the overload of the capacities of the healthcare facilities, informal caregiving is becoming increasingly prevalent and relevant for many family households. Informal caregiving is defined by having friends or family members caring for a person that is ill who is no longer capable of caring for himself (Chiao et al., 2015). Moreover, in comparison to the classic approach of healthcare, informal caregiving presents itself as an additional form of care that allows the chronically ill people to receive more attention and care by their friends and relatives (Pagliari et al., 2005). However, informal caregivers are often faced with challenges and obstacles of physical, psychosocial and economic nature to overcome. Consequently, the impact of their tasks and responsibilities on their mental and physical health are often undermined and overlooked (Li et al., 2022).

These challenges and barriers are often comprised of what is considered as caregiver burden, the "extent to which caregivers feel that their emotional or physical health, social life, and financial status have suffered as a result of caring" (Girgis et al., 2013). Moreover, despite this enormous burden, the needs of the informal caregivers often come secondary in comparison to the needs of the patients. Common tasks in informal caregiving comprise of household tasks, emotional support, personal care, organizing and scheduling, transportation, administration of medications, managing financial matters, shopping, meal preperation and mobility, while a majority of these tasks are being performed on a daily basis (Girgis et al., 2013; Wang et al., 2021). This extensive list of caregiving tasks stresses the complexity and scope of the responsibilities of informal caregiving which is underlined by findings from Schofield et al. (1997) who reported that more than 50% of informal caregivers carry out more caregiving tasks than they can personally handle and cope with, with also more than 50% stating having no personal time for themselves. Additionally, most primary caregivers are in the same age group as their elderly patients and therefore already face increased health problems which are often exacerbated by their role of a caregiver (Girgis et al., 2013).

Slev et al. (2016) illustrate other consequences for informal caregivers such as a high care burden, psychological problems as well as a decrease in social activities. Findings in other research support this by identifying significant problems of physical and psychological nature for informal caregivers of dementia patients. These comprise of increased depression and stress levels, increased social isolation and financial burden, as well as sleep disturbances (Peacock

& Forbes, 2003; Christie et al., 2018). Other physical consequences were reported by Stenberg et al. (2010), stating the most prevalent problems for informal caregivers to be fatigue, pain, sleep disturbances, loss of physical strength, loss of appetite, and weight loss. Another Australian study (Fisher & Briggs, 2000) found similar physical complaints from informal caregivers such as tiredness and exhaustion, problems in neck, back and shoulder as well as abnormal blood pressure and heart problems. In a study of informal caregivers that treat cancer patients (Grbich et al., 2001), fatigue was one of the main complaints mentioned by more than two thirds of respondents. As a result of experiencing fatigue as a caregiver, the fatigue levels will not only increase over the time of caregiving, but also adversely affect concentration abilities, motivation, relationships, the ability to perform usual activities as well as overall mood levels (Aranda & Hayman-White, 2001). Another interesting research finding illustrates the mutual dependencies of the problems experienced by informal caregivers: Due to the need for constant care of physical matters, the lack of sleep is further worsened through sleep disturbances which are highly correlating with depression, anger and anxiety (Flaskerud et al., 2000).

Various studies have also found supportive evidence for a decrease in social activities and social connectedness. This is explained by a central focus of the informal caregivers on the patient's needs and demands rather than their own (Slev et al., 2016). As a result, more than half of the respondents in Fisher et al.'s (2000) study reported a dramatic or major effect on their lives and decisions. Moreover, almost 50% reported adverse consequences for their holiday and vacation times, 30% for their travel time and planning, while another 15% and 25% reported insufficient time for socialising and hobbies, respectively. Consequently, these burdens resulted in social isolation and loneliness in one third of the informal caregivers, while one quarter experienced changes in family and other relationships as well as a sense of grief and loss. Lastly, about 11% reported insufficient time for personal relationships (Fisher et al., 2000). Caregivers that take initiative and go out to partake in social interactions and activities often give up because the concern for their patient overwhelms them when they are absent from home (Girgis et al., 2013). Even though the physical and psychosocial challenges of informal caregiving are often overwhelming and intense, it is common to see that informal caregivers do not seek help in form of therapy or treatment when necessary or when meeting the criteria for a certain psychitric illness (Vanderwerker et al., 2005).

In order to tackle these challenges and improve the quality of life of informal caregivers while also relieving the burden put onto the healthcare systems, eHealth interventions can be considered a promising technological approach designed to facilitate this goal. Hereby, the aim

of eHealth is to offer and provide support for informal caregivers in form of tools or strategies while also enabling them to continue to live their own lives outside the healthcare setting (Cunningham et al., 2013). Recent studies and meta-reviews have illustrated that eHealth interventions focused on supporting informal caregivers of people with dementia show substantial effectiveness in reducing the caregiver burden experienced by so many caregivers. For example, these internvetions can help by reducing depression, anxiety and stress as well as by improving positive aspects of caregiving, self-efficacy and confidence. Furthermore, eHealth interventions have a unique potential in terms of their large implementation scope since it is characterised by a low cost, low threshold of access and its possibility to integrate personalised and tailored design ideas (Boots et al., 2014; Jackson et al., 2016; Lee, 2015; Parra-Vidales et al., 2017; Scott et al., 2016; Tyack and Camic, 2017).

However, in the past many eHealth interventions have failed to be adopted and successfully implemented in real life settings due to various reasons. One of the reasons is that the technology is being used differently to what the designers intended it to be, therefore lacking both effectiveness and efficiency of the intervention (van Gemert-Pijnen et al., 2018). Another reason for failed interventions is that errors are made during the design and implementation process in which key factors and variables are not considered salient enough by the designers (van Gemert-Pijnen et al., 2018; Greenhalgh et al., 2017). Since the design and implementation processes are interrelated by nature, errors in the design process – which precedes the stage of implementation - often make it impossible to obtain successful implementation in real life settings (Greenhalgh et al., 2017). For example, an often overlooked aspect of the design stage is the importance of stakeholder involvement (van Gemert-Pijnen et al., 2018). Stakeholders are individuals that in some form influence or are influenced by an eHealth technology, and therefore represent a very important target group for eHealth designers. Moreover, their needs and wishes are highly salient to consider in order to be able to create and develop a tailored intervention that meets the requirements of the necessary people involved (Birken et al., 2017). Only when a good fit between technology, context and user is established, the intervention has a likely chance to be successfully implemented and adopted by the stakeholders (van Gemert-Pijnen et al., 2018). Additionally, not all stakeholders are equally important in the design and implementation phase, requiring the developers to identify and create a map of key stakeholders with their personal needs and requirements as well as their objective power, legitimacy and urgency in relation to the intervention (van Gemert-Pijnen et al., 2018). In order to tackle the difficulties and obstacles often faced when developing eHealth interventions to be successfully implemented, particular frameworks have been developed to facilitate a systematic and strategic

development of eHealth interventions to ensure the most likely success of an intervention. Some examples of implementation frameworks to consider are the NASSS framework, the CFIR, and the CehRes Roadmap.

The first framework to consider is the NASSS (Non-adoption, Abandonment, Scale-Up, Spread, & Sustainability) framework which was developed by Greenhalgh et al. (2017) to produce an "evidence-based, theory-informed, and pragmatic framework to help predict and evaluate the success of a technology-supported health or social care program". The framework comprises 13 questions within six different domains as well as an additional domain which addresses the progress of interactions and adaptions over a prolonged time period. The six other domains are the condition, the technology, the value proposition, the adopter system and the wider institutional and societal context. The authors propose this framework not to be used as a checklist but rather as a reflexive guide for ideas and conversations. A special focus lies on the domain of value proposition in which the values for an intervention are based on the condition, the technology and the predicted adopters of a technology. In terms of stakeholder inclusion, it is only mentioned implicitly in the framework. Moreover, the areas of healthcare organisations, wider system and continuous embedding and adaptation are not considered in the value proposition. Therefore, it can be assumed that the framework is likely to be useful only to some extent in regard to guiding stakeholder involvement. In conclusion, the NASSS framework serves as a guideline that can be used by eHealth designers to explore the potential uptake and challenges of their technology. However, since only 13 questions are considered and stakeholder inclusion is not a central theme, it poses the question of how feasible and holistic the implementation framework is in relation to the success of an eHealth technology.

The Consolidated Framework For Implementation Research (CFIR) is another framework aimed at facilitating the success of eHealth implementation and was developed by Damschroder et al. (2009). It is comprised of the five main domains intervention characteristics, outer setting, inner, setting, characteristics of the individuals involved, and the process of implementation. Furthermore, each domain is composed of various constructs that translate to core variables and factors for each domain. For instance, evidence strength and quality is related to the intervention itself, while patient needs and resources are related to the domain of outer setting. On the other hand, the constructs culture and leadership engagement relate to the domain of inner setting, while planning, evaluating and reflecting relate to the process of the implementation. Each construct is explicitly defined with the overarching goal of providing a pragmatic structure to combine key constructs from established implementation theories. Generally, the framework is very elaborate and detailed in its approach to consider and integrate

the opinions of important stakeholders but lacks the link and connection between each domains and their individual constructs.

The CehRes Roadmap (van Gemert-Pijnen et al., 2011) is another framework developed to constitute a guideline for successful eHealth development, implementation and evaluation of an intervention. The authors used recent methods and models from the domains persuasive design, participatory development, human centred design as well as business modelling to create a five-phase model that supports and facilitates the development process of an eHealth technology. Persuasive design is a method that aims to influence the users' behavior by a product's characteristics and is based on social and psychological background theories. Participatory development is a people-oriented approach that stresses the importance of engaging relevant groups of people in the development of a project. Lastly, human-centred design relates to the focus of considering the insights and needs of users to create a useful and usable product. The five phases of the model can also be considered as stages since they are based and always related on the previous phases and comprise of the Contextual inquiry, Value specification, Design, Operationalization, and Summative evaluation. In terms of stakeholder salience, the CehRes Roadmap stresses the importance of a tailored and holistic design approach by ensuring that each phase is directly connected to stakeholder perspective, the context and the outcomes of previous phases. In comparison to the previously mentioned implementation frameworks, the CehRes Roadmap has the benefit of being the most holistic and iterative approach to facilitating successful implementation. Moreover, it puts the strongest salience on participatory development and stakeholder inclusion to reach this goal, as well as encompassing a complex and detailed business model and value map of important stakeholders.

In order to investigate how stakeholder involvement is influential for a successful implementation and uptake of an eMental Health intervention, an interview study was conducted. A total of seven interviews were performed with implementation experts of companies that successfully designed, implemented and launched eMental Health interventions. The aim of this thesis is understanding how currently available eMental Health interventions for informal caregivers handle stakeholder involvement. Therefore, the following exploratory sub-research questions have been defined:

1) To what extent are the needs of key stakeholders considered for a successful design and implementation of eMental Health technologies?

2) How are these needs related during the design and implementation phase to the values the eMental Health technologies propose?

3) How are implementation frameworks and theoretical models used to involve stakeholders in the design and implementation phase of eMental Health technologies?

2.Methods

An interview study was conducted to investigate and explore how stakeholder inclusion is used within the development and implementation process of eMental Health interventions. The chosen method was a qualitative semi-structured interview in order to conduct a comprehensive thematic analysis to answer the research question and the respective exploratory sub-questions. This method enabled the researchers for adequate comparison of key information between the interview partners, while retaining a flexible and efficient approach to extract as many insights about advantages, disadvantages, personal experiences and thoughts in regard to the process of designing and implementing eMental Health interventions.

The participants of the interviews were seven implementation experts of six different companies that successfully developed and implemented eMental Health interventions that target informal caregivers as their main target group. The countries in which the technologies were designed and launched are Belgium, Netherlands and Italy. However, all interviews were conducted in English language. The technologies were selected based on pre-defined inclusion criteria. To be considered for the interview study, the eMental Health intervention was required to be tailored and designed towards supporting the mental health of informal caregivers of patients with a chronic illness. Moreover, the technology itself was required to be accessible via the Internet and therefore needed to be designed for a website or application. Additionally, the technology needed to provide interactive feedback for the user instead of being merely text-based. Lastly, the interview partners needed to be part of the development process or sufficiently informed about the most salient aspects of the implementaton and design process of the interventions. *Table 1* describes the included companies in the interviews.

Table 1

Interview partners of eMental Health companies that participated in the interviews & pilot interviews

Name of the company of the interview study	Website	Description of the intervention	Job description of the interviewee	Country

Partner in Balans	partnerinbalans.nl	Providing digital modules tailored to informal caregivers of dementia patients	Postdoctoral Researcher	Belgium
Univeritsy Mecial Center Groningen	mantelzorg.nl	Mantelzorg Balans - Providing digital information and exercises tailed for informal caregivers.	Project Manager	Netherlands
Minddistrict	minddistrict.com	Providing digital self-help modules to informal caregivers to support them in their daily life.	Implementation and integration Manager	Netherlands
Transfore	transfore.nl/ ondersteuning-voor-naasten	Providing mental healthare to informal caregivers of forensically treated patients.	Strategic policy advisor	Netherlands
Nedap	nedap-healthcare.com/oplossingen/luna	Luna- a digital calendar application that helps informal caregivers to structure the daily life of their loved ones.	Product manager	Netherlands
Name of the company of the pilot study				
A Casa Ma non da Soli	portaledellacura.it/webinar/webinar-a-casa-ma-non-da-soli-1	A program for training targeted to families who have a member with some chronic condition. The program was conducted via the internet during the pandemic.	Assistant professor of sociology and economics	Italy
Minddistrict	minddistrict.com	Providing digital self-help modules to informal caregivers to support them in their daily life.	Account manager	Netherlands

An ethical approval (Appendix 3) was applied for and granted by the University of Twente prior to the interviews. An interview guide (Appendix 1) was then created to establish structural consistency among the interviews. The interview guide was developed within the scope of a PhD thesis and was based on the three common implementation frameworks: CehRes

Roadmap, CFIR, and NASSS. Moreover, it comprised 12 open-ended questions that cover the four domains of implementation and their relation to one another: technology, adopters, wider settings, and organisation. The first three questions of the interview guide query general base information about the company and their technology. The next five questions investigate the implementation process and the use of theoretical models and frameworks. Finally, the last four questions cover topics of potential influences on the implementation process, with a specific focus on stakeholder inclusion. An informed consent form (Appendix 2) was created and presented to each participant prior to the conduction of the interview. The informed consent form comprised information about the aim of the study, the right to withdrawal from the interview at any given time as well as a permission request to record the interview and use the collected data for scientific analyses. The interviews were conducted, transcribed and recorded online via Microsoft Teams. Necessary elements to conduct the interviews included a stable internet connection as well as a working microphone and camera. The coding software ATLAS.ti Windows (Version 22.0.10.0) was used to code all interviews.

The interviewees were approached on the basis of the inclusion criteria and contacted via Email to arrange an online video-call meeting to conduct the interview. At the start of the meeting, the aim and intention of the interview were revealed and clarified to the interviewee followed by a request to approve, sign and send back the informed consent form. Next, an audio-visual recording was started and the interview started following the questions from the interview guide. if necessary, nswers given by the interviewee were questioned further using prompts and follow-up questions,. After the completion of asking all questions within the interview guide, the interviewee was thanked for their time and participation and the recording was ended. The length of the interviews averaged around 60 minutes per interview. Minor language barriers and communication errors occurred due to the non-native nature of the participants in regard to the English language, but could be resolved with follow-up clarifications of questions and answers when applicable. Lastly, after the creation and revision of the interview transcript, the document was sent to the participants to allow for transparency and examination of their statements. All data was treated confidentially and anonymously, and deleted after the publication of the research study.

The interview recordings and transcripts were revised by the researchers for errors and completeness. Next, a coding scheme was created inductively based on possible research directions that show promising and interesting potential to answer the research question and help to form exploratory sub-questions. General themes that emerged during the interviews were liberally created as a code and then assigned to the specific statements in the interview

transcripts. Next, the exploratory sub-research questions were defined and the codes were revised and condensed to match the content of the sub-question. The coding scheme was then deductively analysed to structure the codes into typologies. To ensure inter-coder reliability, the final coding scheme was checked by another researcher for an adequate match of created codes and their respective quotes.

3. Results

3.1. Structure and content of the coding scheme

During the analysis of the seven interviews, a total of 16 codes have been derived in order to quantify the information obtained in the interviews. In order to diversely answer the research question and the respective exploratory sub-research questions, four main codes have been defined. Firstly, the code "Approach to stakeholder involvement" was created to address the main research question and to obtain a general idea of how the companies consider stakeholder involvement in their design and implementation process. Therefore, the four subcodes were defined: "Identification of stakeholders", "Approach to stakeholder inclusion", "Training for coaches", and "Experiences and challenges with stakeholder involvement".

Secondly, in order to structure more detailed and in-depth information and to address the exploratory sub-research questions, three more codes were defined: In regard to the first exploratory sub-research question, the code "Needs of end-users" was created and divided into the three sub-codes "Practical needs", "Privacy needs", and "Technical needs".

In regard to the second exploratory sub-research question, the code "Values of intervention" was created and divided into three sub-codes, namely: "Practical values", "Personal values", and "Privacy values".

Lastly, in order to address the third exploratory sub-research question, the code "Implementation frameworks & theories" has been created and divided into the two sub-codes "Theoretical approach of stakeholder involvement" and "Experiences with frameworks & theories".

The following table (*Table 2)* describes the codes and frequencies with which each code appeared during all seven interviews.

Table 2

Defintion and prevalence of codes in the interviews

Name of the code	Name of the subcode	Definition of the code	Frequency
Approach to stakeholder involvement		Quotes that comprise stakeholder involvement in the design & implementation process	109
	Identification of stakeholders	Quotes that comprise acknowledged stakeholders of a company	21
	Approach to stakeholder inclusion	Quotes that comprise methods and criteria of involving stakeholders	62
	Training for coaches	Quotes that comprise the approach and methods of training coaches as stakeholders	7
	Experiences and challenges with stakeholder involvement	Quotes that comprise experiences, challenges and inferences from involving stakeholders	19
Needs of end-users		Quotes that comprise needs, wishes and demands of the end-users of a technology	33
	Practical needs	Quotes that comprise practical needs of end-users	15
	Privacy needs	Quotes that comprise privacy needs of end-users	10
	Technical needs	Quotes that comprise technical needs of end-users	8
Values of intervention		Quotes that comprise the values and qualities of an intervention	46
	Practical values	Quotes that comprise practical values of an intervention	19
	Personal values	Quotes that comprise personal values of an intervention	18

	Privacy values	Quotes that comprise privacy values of an intervention	11
Implementation frameworks & theories		Quotes that comprise acknowledged implementation frameworks and theories	33
	Theoretical approach of of stakeholder involvement	Quotes that comprise theoretical strategies to involve stakeholders during the design & implementation phase	13
	Experiences with frameworks & theories	Quotes that comprise experiences with implementation frameworks & theories that were made during the design & implementation phase	23

3.2. Description of the codes

3.2.1 Code "Approach to stakeholder involvement"

In regard to the main research question "The aim of this thesis is understanding how currently available eMental Health interventions for informal caregivers handle stakeholder involvement", the code "Approach to stakeholder involvement" was defined. In general, all interview partners deemed stakeholder involvement important and therefore also distinguished and included relevant stakeholders in the development and implementation of their eMental Health intervention. However, due to the diverse complexity and scale of the different interventions, a wide range of different approaches was used to address the involvement of relevant stakeholders. Moreover, all interviewees mentioned that involving stakeholders in the implementation and development phase is a difficult and complex process and can be challenging and demanding at times.

3.2.1.1 Sub-code "Identification of stakeholders"

"Identification of stakeholders" describes which groups, professionals and experts as well as which target groups were acknowledged in the interviews as relevant and meaningful stakeholders. Universally in all interviews, the implementation experts defined the informal caregivers as their main target group and end-users of their eMental Health technology. Therefore, the informal caregivers constitute the most important stakeholders for every intervention. One interviewee explicitly mentioned a second target group in the form of coaches who are professionals that help the informal caregivers become familiar with their tailored

programs and assist during the course of their intervention. Additionally, patients that receive care were mentioned across all interviews as important stakeholders, however, they were never considered as the target group of an intervention.

Other frequently mentioned stakeholders were considered experts in their specific domain who help to close the knowledge gap of the interviewed companies by adding valuable insights into specific areas of implementation and design. For instance, some of these experts that were mentioned in the interviews are clinicians and therapists that were approached to contribute to the design and effectiveness of an intervention. Another group of experts comprises of nurses, neurologists and social workers that also help to integrate their knowledge into the specific areas of intervention development. Moreover, similarly across all interviews, the companies employed internal as well as external project and case managers as well as integration and implementation managers. This facilitates not only the clinical effectiveness of the interventions, but also covers the economical point of view. However, this result has to be differentiated depending on the size and complexity of the company. Companies of larger scale were more likely to employ other, external experts from other companies to handle the economical area of expertise, while smaller companies were more inclined to employ individuals internally and make them part of their development and implementation team.

On the other hand, most interviewees also mentioned a close collaboration with external companies as their stakeholders. The main similarity in regard to the cooperation with other companies is that all websites and applications were developed, created and maintained by an external IT or technology company. It was striking that the lack of knowledge within the technical domain of implementation occurred across all eMental Health companies. It was therefore universally counteracted by employing a technical company to ensure optimal implementation in regard to the technological aspects of the intervention. Other companies that were collaborated with in a very similar approach are government and local municipality organisations. Lastly, the interviewees of companies that do not employ a free-of-charge business model mentioned a close collaboration with health insurance companies. This enables the eMental Health companies to appeal to clients of all social classes and provide equal accessibility to their target group.

Another important stakeholder of one of the companies, referred to as an indirect stakeholder, is their direct competition. The interviewee mentioned a frequent examination and comparison between the features and approaches of themselves and other, similar eMental Health interventions within their country in order to have an advantage over their competitors.

A last finding that was mentioned by two interviewees is that their company initially launched their technology without specifying and taking into account any stakeholders, but did so along the way of the evaluation and refinement processes.

The following quote is an extract of one of the conducted interviews:

"We always sort of saw the target group of Partner in Balans as being the the caregivers of people with dementia because yet that's the target group. But in the end, we're looking at the implementation. You have two target groups. You have the caregivers and you have the coaches because if the coaches aren't comfortable using the tool, then it won't get used and you won't reach your target group. So that's sort of been split up into two. Now when we did a lot of work on what did the coaches need to feel comfortable, you know, it turns out it's quite scary to use an online tool like this for the first time."

3.2.1.2. Sub-code "Approach to stakeholder inclusion"

"Approach to stakeholder inclusion" describes the method, strategies, and criteria in which the eMental Health organizations have approached and included their stakeholders. This theme comprised a wide range of approaches depending on the size and complexity of the organization and technology. A common method used by four of the six companies to engage their stakeholders is the use of interviews and focus groups. The interviewees mentioned that the interviews were conducted with groups of stakeholders to obtain information about their personal wishes and demands in regard to the technology. In particular, formal and informal caregivers as well as their patients were of main relevance in the interviews in order to extract their needs to be able to design a useful and tailored intervention.

In regard to the development of the interview guides, most companies used pre-existing interview guides that were adjusted to fit their intervention. One interviewee mentioned that their company developed and revised their own interview guide with a panel of informal and formal caregivers and experts in palliative care to achieve the most holistic and tailored outcome. On the other hand, another interviewee gave no specific information about the conduction of interviews.

In terms of usability and evaluation of the effectiveness of the technologies, two of six companies conducted usability testing and process evaluations. The interviewees elaborated that the usability tests and process evaluations were conducted in close relationship to the clinicians and informal caregivers to identify which features of the technology are useful and meaningful for the end-users, and which features are impractical and inefficient. One

interviewee mentioned that after identifying the weak and inefficient features, they either adjusted and improved these features or excluded and eliminated them entirely from the technology.

Another approach to involve relevant stakeholders is the use of questionnaires and was employed by four out of the seven companies. It became apparent during the interviews that the questionnaires were solely used for the evaluation of the intervention, but were never integrated during the design or development phases of the intervention. The questionnaires were conducted mainly with the informal caregivers after the intervention to obtain useful feedback for the effectiveness and to collect improvement points for the intervention.

Lastly, one interviewee stated that they employed a pilot study in the early phase of their intervention in order to see how effective their technology is, which flaws and weaknesses can be identified, and which aspects to improve upon. The other six companies did not conduct a pilot study or similar effectiveness methods prior to the launch of the interventions.

An extract of one interview concerning the approach to involving stakeholders is:

"Before doing the interviews, we had our interview schedule reviewed by a panel of informal caregivers and by an expert in palliative care and another, well, our colleague at [another organization]. So based on that, we arrived at the interview scheme. Then we had the interviews with the informal caregivers and with the care professionals. So they were involved in that."

3.2.1.3. Sub-code "Training for coaches"

Other relevant stakeholders that were identified through the interviews are the previously mentioned coaches. Coaches perform in real life coaching by helping and assisting the informal caregivers to familiarise themselves with the offered intervention programs as well as aid and give guidance during the course of the intervention. Only one company employed such coaches. Particularly, one overaching theme was the training that was necessary for the coaches to be confident, knowledgable and efficient at their job. The interviewee stated that in order to tackle the effectiveness and self-efficacy of the coaches, they developed and operated tailored training programs for the coaches. Moreover, it was stated that meetings were held every couple months with the coaches to observe and debrief the progress made by the coaches. In particular, the meetings address the experiences and challenges faced and are used to answer any questions or uncertainties of the coaches in regard to their work. In regard to the training programs, the interviewee mentioned they try to limit the maximum amount of coaches to 10

total coaches per session. This limit in partipants is employed in order to be most effective at teaching the required skills and knowledge as well as to establish and sustain an interactive working environment.

This interview quote relates to the idea behind employing and training coaches:

"So yeah, but it's sort of two branches on that I work the most on, on like really setting up the training. So the coaches feel better equipped like we've added intervision as well. So every couple months we open up a session across organizations to talk to coaches about how it's going."

3.2.1.4. Sub-code "Experiences and challenges with stakeholder involvement"

Another theme that was crystallised during the interviews was the experiences and challenges in regard to involving stakeholders. Universally, all interviewees mentioned various obstacles, challenges and problems that were encountered during the process of designing and implementing their technologies.

In regard to meeting the needs and wishes of their stakeholders, two interviewees elaborated on difficulties in relation to identifying the most important needs of their stakeholders. One challenge that was directly mentioned was communicating, understanding and then correctly interpreting the needs and wishes of the interviewed stakeholders. Moreover, it posed a further challenge to select and distinguish between the most salient and relevant needs. On the other hand, another company was less concerned about the correct identifcation and interpretation of the needs of the stakeholders, but was instead particularly critical about being able to meet those needs and applying and implementing them correctly in their intervention. This interviewee mentioned that this is because their particular technology is evolving and changing constantly in terms of the features and usability since the launch of the technology. Thus, she also expressed the necessity to be aware and conscious about not taking advantage of any relevant stakeholders in this regard. Similarly, another interviewee also expressed ethical concerns in regard to involving and addressing stakeholders - and in particular end-users - to be of high relevance within the design and implementation process. However, no further specified information was given about these ethical considerations.

Another challenge that was mentioned by two interviewees was the conduction of interviews with the stakeholders. Particularly, since the majority of interviews were conducted in groups and focus groups, it emerged difficult to select the ideal size of the interview groups. It was mentioned that in the beginning, the interview sessions were not as productive and

efficient. Interview sessions with too little participants did not yield enough relevant and diverse information to be extracted, while interview sessions with too many participants lacked interactivity. Both interviewees stated that the ideal size of focus and interview groups was established during the course of conducting many interviews in a trial and error approach.

Another finding that depicted a challenge for one company was the shift from an offline to an online environment due to the outbreak of the pandemic. The interviewee elaborated that online encounters with their stakeholders were lacking a lot of personal interaction and the human touch. Moreover, it was stated that it also impaired the perception of impressions that one can gain more appropriately and accurately in physical meetings. On the other hand, though, three companies mentioned benefits that resulted from the change to an online environment. In particular, it was stated that their technologies resulted in an increased reachbility for the end-users as well as more flexibility in terms of the usage of the technology and the involvement of relevant stakeholders.

A quote from one of the interviews that resemble some of the challenges faced is:

"And to find a product that can really meet all your needs and also not, you know, take advantage of anyone […] I find it quite a complicated context. And yeah, PartnerInBalans is always changing. If you ask me how it looks like in a year, It'll probably be different again."

3.2.2 Code "Needs of end-users"

In regard to the first exploratory sub-research question "To what extent are the needs of key stakeholders considered for a successful design and implementation of eMental Health technologies?", the code "Needs of end-users" has been defined. Generally, all interviewed companies deemed the identifcation of the needs of important stakeholders salient. Consequently, all companies also considered and identified the respective needs of their stakeholders. In order to answer the first and the second exploratory sub-research question ("How are these needs related during the design and implementation phase to the values the eMental Health technologies propose?"), only the needs of the end-users, i.e. the informal caregivers, will be considered. A wide range of stated needs of the end-users were identified within the interviews. They were often personal wishes and demands to help the informal caregivers cope and deal with specific challenges and obstacles. The needs can be distinguished into the three themes of "Practical needs", "Privacy needs", and "Technical needs".

3.2.2.1 Sub-code "Practical needs"

The most commonly mentioned needs within the interviews can be categorised under the theme of "Practical needs". These comprise needs that are considered as objectives that want to be reached and achieved by the informal caregivers. Universally, all interviewees mentioned that they identified practical needs of their end-users.

One need of end-users that was mentioned by one interviewee is the provision of support in the earlier stages of disease recognition. It was elaborated by the interviewee that they address the importance of acquiring the required knowledge, insights and skills for caregiving as early as possible. Consequently, they also offer the informal caregivers help in regard to preparing and learning the new knowledge and skills from the beginning. In fact, it was stated to be common for informal caregivers to delay the acquisition of these skills for too long. As a result, they often underestimate the progressive nature of a disease and are quickly overwhelmed to learn the new caregiving insights when stress, fatigue and sleep deprivation have acculumated over the course of intensive caregiving. The interviewee stressed that a lot of their end-users regret not taking advantage of the offered support and help earlier and therefore identified this as one of the main needs of their end-users. Two other interviewees also addressed the provision of support systems. However, the focus of their statements was not on the most adequate timing of support provision. Instead, they elaborated that the support should be provided by a professional. In fact, both interviewees stated that acquiring skills, knowledge, and other valuable insights about caregiving can be most beneficial if conveyed through assistance and guidance from a care professional (e.g. formal caregivers).

Another established need that was mentioned in two interviews is the need for support in regard to time-management and setting boundaries for the informal caregivers. It was elaborated that the caregivers are often overwhelmed by the extensive list of tasks they have to perform to care for their patients. Moreover, they would therefore often struggle to allow themselves to find some time for their own personal needs and interests. Thus, it was stated to be important to recognise this need and offer support towards the informal caregivers in regard to managing and distinguishing between their own personal time and the caregiving activities.

Lastly, in three of the seven interviews it was mentioned that the technologies should be easily accessible and findable for the end-users. In particular, it was stated that a well-marketed technology will not only increase the findability for the end-users, but will also appeal and attract attention of clinicians. Consequently, the clinicians become aware of such an existing

eMental Health technology and can recommend the intervention to their patients with informal caregivers.

For instance, one interviewee stated the following in regard to practical needs of end-users:

"There's this paradox where, right after the diagnosis, people don't really feel like they need a lot of support and help that they can manage. They have time and then later on when things progress and get progressively harder, they wish that they had taken advantage of that time to prepare and accepted some of the help that was offered at that time. Because to organize it just later when you're completely overwhelmed and stressed and strictly sleep deprived. It's just that much harder. [...] The caregivers needed something that would help them adjust in that early phase and where we really could also share with them, like: "You have the time now, you know, we don't want to scare anyone, but this is the time to sort of prepare and learn the new skills that you might need later on." So that was sort of the need where it came from"

3.2.2.2 Sub-code "Privacy needs"

Other needs of end-users that could be crystallised through the conduction of the interviews relate to the domain of privacy. Four of the seven interviewees stated that their end-users demand a secure and safe to use technology. In fact, it was stressed that their data should be handled and stored securely. Moreover, many users wish to operate the technologies anonymously. It was elaborated that the personal data and progress of the informal caregivers as well as their patients shall be treated anonymously, with no possibility to identify them.

Lastly, it was mentioned by three interviewees that their end-users state trustworthiness as a need. On the one hand, trustworthiness was specified by one interviewee in regard to the information provision of their technology. For instance, it was mentioned that the display of information and knowledge should be transparent by including references and quotes to the used literature. Another interviewee elaborated on this theme that in order to achieve this trustworthy relationship with their clients, the trust can be accomplished and maintained by having and retaining a good relationship with their end-users.

The following quote is used to illustrate how one company addresses the privacy needs of their end-users:

"I think it's always good to have, or always important to have the good relationship [with our clients] because it's all a trust thing. They bought something and they have expectations. And if you make sure that the relationship is good, then they trust you and they are more open to use our [intervention]. And that's what's been really important."

3.2.2.3 Sub-code "Technical needs"

The last theme of needs that could be identified through the interviews are related to the technical aspects of the technology. All interviewees mentioned and identified similar technical needs of their end-users. One of the main extracted needs in this regard is an easy to use technology. It was elaborated by multiple interviewees that their end-users demand a simple, straightforward and easy to use product. Considering the fact that most informal caregivers are middle-aged, their technological skills and knowledge are often limited. Therefore, the technology should be designed in a simplistic and uncomplicated manner and should leave no space for the end-user to interpret any steps or features of the technology incorrectly.

Furthermore, another technical need that was crystallised through the interviews is the usability of the technology via different technological devices. In fact, two interviewees mentioned that their end-users desire the technology to be accessible and usable through different platforms. For instance, it was mentioned that the technology should function properly on common technical devices such as a smartphone, a laptop and computer, as well as a tablet.

One interviewee stated the following in regard to the technical needs of their end-users:

"Yeah, I think the tool is quite easy to use. It's really simple. You have a main page which is always feasible, and there are three modules like information exercises and the memory part. That's quite easy. That's also what we heard in the usability."

3.2.3 Code "Values of intervention"

In order to address the second exploratory sub-research question "How are these needs related during the design and implementation phase to the values the eMental Health technologies propose?", the code "Values of intervention" has been defined to identify the values and qualities that are central to the eMental Health technologies. All interviewed companies have defined and integrated certain qualities in their intervention that they deem important and valuable for their end-users. The characteristics of these values differ slightly depending on the type of technology and the size of the company. However, certain core-values could be identified and were resembling within all interviews. The most commonly mentioned and regarded as important values are the facilitation of self-management and self-efficacy. Self-management in this regard comprises the general idea of supporting the informal caregivers with insights and knowledge on how to find a balance between caregiving for their patients and managing their own well-being and responsibilities outside of caregiving. On the other hand, self-efficacy relates to the approach of assisting and helping the informal caregivers to gain

knowledgable insights and acquire skills and expertise in order to be and feel confident and well-prepared for upcoming caregiving tasks.

3.2.3.1 Sub-code "Practical values"

One theme that was crystallised through the conduction of the interviews are the qualities and values in regard to the practicality aspects of the interventions. All interviewees stated an integration of a variety of practical values within their technologies.

One value that was central to all interviewed companies is a simple and easy to use intervention. It was mentioned that it was highly important during the design, usability and process evaluation phases to guarantee that the user is able to use, navigate and access all the relevant features of the technology. In fact, one interviewee stated their company employed a simplistic, straight-forward web-adaptable website that could be accessed through all technical devices. The idea behind this approach was to ensure that the technology remains operative for the user at all times since maintenance issues such as updates and incompatibility problems in regard to different operating systems can be bypassed.

Another practical value that was employed in all eMental Health technologies is the information provision of relevant caregiving knowledge and skills. In line with the previously mentioned values regarding the usability of the technology, it was again emphasised that the way the information is displayed to the user is enforced in a very straight-forward and easy manner. It was mentioned by three interviewees that the information provision is carried out in an organised manner by grouping the relevant information blocks and features into different categories. Another interviewee elaborated on this by explaining that their technology categorises various caregiving topics and provides clickable links to these subjects. The user will then be presented a concise, very simplistically written and easily understandable text that informs the reader about their particular field of interest. The same interviewee claimed that there is a lot of caregiving information on the internet that can be easily accessible, however, much information is unreliable and incorrect. Therefore, the interviewee elaborated that in their particular technology the users are being directed to respectable and reliable sources which have been pre-selected by the company.

Another interviewee also regarded their technology as straightforward and intuitive based on end-user feedback, but mentioned that their technology also entails some more complex and advanced elements. In fact, it was stated that the basic features and elements are visualised and accessible in a very simple and easy to understand manner for everyone.

However, their technology also contains a more advanced layer with features that are not always obviously accessible or visible to their less experienced and less technical-affine users.

Lastly, the theme of accessibility was mentioned as a represented value in four technologies. It was elaborated by several interviewees that their technology should be easily attainable and avoid complex procedures until their end-users can access and use their technology. One interviewee specifically stressed the importance of offering their technology free of charge. She elaborated that this was possible through funding from the Dutch government, and therefore deemed it highly important to use this as an advantage and offer access to their intervention to informal caregivers of all social classes who may not otherwise be able to use it. She further explained that they conducted usability testing with people of lower educational status in order to ensure that the information provision is understandable and simple enough for all of their clients. Furthermore, their technology can be accessed without the necessity to create an account. However, it was stated that the creation of an account is recommended to benefit from additional features such as monitoring and saving of made progress.

One interviewee stated the following in regard to practical values of their technology:

"We wanted to hand over information to them in an easy manner and link them to one specific source. That is quite good, like for example to the government. Or if you want to know something about your testimony. You will click here and then you have one link so they don't have to find all that information for themselves. And also we categorized it according to what they need. Well, take into account with respect to regulations, what should you be aware of the illness procedure? How does it look like? What do you do if someone dies? What do you need to do? So we wanted to, on the one hand already give them all these topics and information on these topics just to show them this is what might you may encounter during this process. And then if you may encounter it, we have a very easily written text in which we direct to good sources. So we did everything to make it as easy as possible for them."

3.2.3.2 Sub-code "Personal values"

The most frequently mentioned qualities and values that are central to the eMental Health technologies of the interviewed companies are in relation to the personal and human-centred domain. All companies implemented personal values and it was crystallised through the interviews that the main focus and salience of offering qualities and values to the customers lie on the personal realm. These implemented values aim to benefit the end-users to feel more confident in their abilities and manage their own personal lives.

One theme that was mentioned before as one of the core qualities of the technologies is the facilitation of self-management. Particularly, it became apparent during the interviews that informal caregivers often struggle to balance their informal caregiving responsibilities with their own personal needs, desires and obligations. For instance, one interviewee stressed that the goal of their intervention and approach is to make the informal caregivers feel acknowledged about their caregiving situation. It was underlined that problems and challenging situations can quickly arise with the nature of giving informal care for a close person with a chronic illness. Therefore, their goal is to help the informal caregivers accept and acknowledge the situation and help them to become more aware of their own wellbeing. It was further elaborated that constant caregiving can quickly result in a predominant and fixated focus on the wellbeing and needs and demands of their patients. Consequently, the health and wellbeing of the informal caregivers tends to be considerably undermined and neglected. Furthermore, this theme was also present in another interview. It was stated as a value of the company's technology to assist the informal caregivers to set their own boundaries in regard to their own personal life and the caregiving life. The interviewee elaborated that informal caregivers often use all their energy and emotions towards caring for their family members, while neglecting caring for themselves. It was therefore reasoned to be one of their main goals to tackle this problem by helping the caregivers to find an equilibrium between the needs of the caregivers and the needs of their patients.

Another theme that was established was the value of facilitating self-efficacy and confidence in the informal caregivers in regard to handling their situation and managing their skills. One interviewee stated that their company implemented personas within the technology with which the informal caregivers can identify. For example, these personas consist of different, fictional persons that find themselves in similar caregiving situations and have to deal with various realistic challenges and problems in their lives. It was elaborated that these provided personas help the informal caregivers to find resemblence to their own personal situation and to identify themselves with one of these personas. It was stated that the idea behind the personas is not only to improve the self-efficacy and self-confidence of their end-users, but also helps to lower the taboo topic and stigmatisation that informal caregivers are often exposed to in a polite and respectful manner.

Another key value that was mentioned in almost all interviews is trustworthiness of the intervention. Two interviewees specified that in order to achieve a trustful image and relationship with their customers, it is important to ensure the reliability of the sources used to provide information in the technologies. Moreover, another interviewee elaborated on this topic

by mentioning that their users should be provided with a safe space in which they feel comfortable and secure. In order to achieve this goal, it was amplified that the transparency of sources and literature is pervasive.

Lastly, one interviewee stated that a positive work attitude and an energetic and genuine approach in regard to the relationship with the clients is essential. She illustrated that working closely with her clients, her positivity and energy towards them is highly regarded and she receives very postive feedback about it. Furthermore, she elaborates that this positive attitude translates and rubs off onto her clients. Generally, she concludes that this motivation to be genuinely interested and authentic about her work fuels not only her joy about her job, but also improves and facilitates adherence of the informal caregivers to the intervention.

The following example quote of one the interviews underlines the idea and notion behind personal values of one company:

"[...] being so explicit about it and also lowering the taboo, I won't say the taboos will be completely gone, but we make it explicit. We make it explicit in a way, hopefully in a, in a respectful way. But we talk about these things and we say people gotta deal with the same issues or with comparable issues. It's never the same, but comparable issues, emotional problems, yeah. [...] In Holland, there is a saying: "Calling the beast by the name." Be explicit about it and not sugarcoating."

3.2.3.3 Sub-code "Privacy values"

The last theme that was crystallised through the conduction of the interviews were the values in regard to privacy. Four of the seven companies explicitly mentioned privacy as a value for their customers. However, two of the four interviewees did not provide more specified information about how these privacy values were implemented in their technology. One interviewee mentioned that their technology can be used completely anonymously. She elaborated that the end-user has the choice to create an account to benefit from features such as progress monitoring, but stating that providing the email address would be sufficient to do so. If desired, the customer has the option to add further personal information. However, she stressed that it is also possible to use their technology without having to create an account and provide an email address, resulting in the choice to adopt the intervention completely anonymously.

Another interviewee also stated that their technology can be used entirely anonymously. He added that it is particularly benefical for those clients that do not want to expose their

identity. Moreover, it was elaborated that some informal caregivers do not want other people to know that they invest personal time in informing themselves and aquiring new knowledge and skills through interventions for caregivers.

The following interview extract presents an idea of what privacy values are important for one organization:

"Well, I think the value is to do it in your own way when you want it. You can do it anonymous or you don't have to tell anyone who you are. And, I think that those are values where you don't want people to know that you invest in this, doing this. This is the value."

3.2.4 Code "Implementation frameworks & theories"

In regard to the third exploratory research sub-question "How are implementation frameworks and theoretical models used to involve stakeholders in the design and implementation phase of eMental Health technologies?", the code "Implementation frameworks & theories" has been created and sub-divided into the two codes "Theoretical approach of stakeholder involvement" and "Experiences with frameworks & theories" in order to gain extensive insights about how stakeholders were involved with the use of theoretical background.

3.2.4.1 Sub-code "Theoretical approach of stakeholder involvement"

During the design and implementation process of the eMental Health technologies, all interviewed companies have made use of certain theories and frameworks that helped them follow a guideline for the development process, or was used to generate ideas and get inspired about considerations regarding the implementation phase. Every interviewee stated relevant information that theories and implementation frameworks were used and applied in the development of their intervention.

However, only four out of the seven interviewees could state the theories and frameworks by its name since not all of them were knowledgeable in this specific domain, or were not involved in the theoretical background application at the time of the intervention development. The theories and frameworks that were mentioned during the interviews are the CehRes roadmap including the Business Model Canvas, the Consolidated Framework for Implementation Research (CFIR), the Acceptance & Commitment Theory (ACT), the Diffusion of Innovation Theory, the Medical Research Council framework, and the Intervention Mapping Technique.

Firstly, the Acceptance & Commitment Theory (ACT) (Hayes et al., 2004) is an action-oriented approach to therapy in which patients learn to embrace that their deep inner emotions are reasonable responses to particular events and stimuli. Furthermore, they learn that these emotional responses should not inhibit them from going forward and looking ahead in their lives instead of avoiding, ignoring, rejecting and struggling with them. With this knowledge, patients learn to accept and embrace these difficulties and commit to behaviour change.

Secondly, the Diffusion of Innovation Theory (Kaminski et al., 2011) was considered. The theory was designed to offer support and facilitate insights for the adoption of a new idea, product philosophy within society. The target group of an innovation is first seperated into five groups which are categorised by the sequence in which they adopt the new innovation. The theory states that the group of people who first adopt and spread the product are called the "innovators". If the product receives some form of approval, it will spread to the larger parts of society. The next group to show interest and adopt the new product are called the "early innovators". The "early majority" is the next group to adopt the product, followed by the "late majority". Lastly, "laggards" and "non-adopters" are considered as the final two groups. The theory aims with this division of groups to offer a guideline that can be used to identify how each group of society might be persuaded by the launch and spread of a product, and can be applied to help the facilitation of the implementation process of a product.

Thirdly, the Medical Research Council framework (Craig et al., 2008) was considered in the implementation process of one technology. This framework was developed especially for complex interventions and aims to guide researchers to identify relevant and adequate research methodologies in the implementation process. The framework focuses on the evaluation of different requirements that are central to the design and planning phase of an eHealth intervention. Moreover, it can be used to investigate the effectiveness of an intervention before it is launched onto the market.

Fourthly, the Intervention Mapping Technique (Bartholomew et al., 1998) was mentioned in the interviews. It is a framework that was particularly designed for the development of eHealth interventions. Moreover, it is based on the three problem-solving themes "Needs assessment", "Program development", and "Evaluation". The theory is comprised of five steps that are intended to aid the development of eHealth interventions: 1) creating a matrix of proximal program objectives, 2) selecting theory-based intervention methods and practical strategies, 3) designing and organising a program, 4) specifying adoption and implementation plans, and 5) generating program evaluation plans (Bartholomew et al.,

1998).

Lastly, one company mentioned that they did not use a specific theory or framework in their implementation process, but created and developed their own tailored method suitable for their specific intervention themselves. Another company, however, stated that they did not use a particular theory or framework at all during the design and implementation phase of their intervention.

In conclusion, it can be summarised that five of seven companies employed a theoretical model or framework that considers stakeholders prior or during their design and implementation phase. On the other hand, two companies did not employ such theories and frameworks.

The following is an extract of one interview that refers to the use of such theories and frameworks:

"I went back and forth between all of the frameworks so many times. There's so many of them. They're also similar. But you're still afraid of choosing the wrong one somehow. So I talked to a professor in Germany. She recommended the CFIR framework to me. So the consolidated framework for Implementation Research. And it basically covered the areas I was thinking of and seemed comprehensive and the fact that it included a few more I hadn't thought of. So I've sort of stuck with that one since then."

3.2.4.2. Sub-code "Experiences with frameworks & theories"

In order to be able to evaluate the use of implementation frameworks and theories, all interviewees were asked about their personal experiences and insights about the use and integration of these theories and frameworks during the design and implementation process of their intervention.

In general, adverse events considering the integration of these theories were mentioned slightly more frequently than positive experiences. One problem that occurred for multiple companies is the fact that an inadequate amount of stakeholders was included in the implementation and design phase of the intervention. It was stated that not enough stakeholders were considered despite the extensive guidelines that the implementation frameworks and theories in relation to stakeholder involvement provide. Moreover, two interviewees elaborated that they failed to integrate and convince some stakeholders from the healthcare sector about becoming part of their intervention. Another theme that was mentioned in the interviews is the fact that economic-related problems occurred for some companies. In fact, it deemed a

challenge to integrate all necessary requirements and considerations into the development of a financing and business model.

On the other hand, six interviewees contributed positive and benefial experiences in regard to the use of theories and frameworks to the interviews. One interviewee stated that the use of the Business Model Canvas allowed and guided their company to develop an appropriate and holistic business model. Consequently, it allowed the company to implement their eMental Health technology effectively and launched the intervention without any major challenges or unexpected and surprising events. Another interviewee also specified that the application of theories was effectively used by following a sequence of steps that was pre-determined by the theories to guide the implementation process. As a result, no major problems occurred during the implementation and launch of their technology. Additionally, three interviewees stated that their company was satisfied with the integration of such theories and frameworks. In fact, it was elaborated that in particular the collaboration with the customer and other relevant companies was positive and satisfactory.

In summary, it became apparent during the interviews that both negative and positive experiences were made by the different companies during the implementation and design of their eMental Health technologies. While most theories aim to guide the developers by offering a structural and methodological approach to the implementation of technologies, the guidelines proposed in the theories are held general and sometimes superficial. Consequently, the interviewed companies faced some challenges in regard to applying the theories and frameworks as they were not detailed and elaborate enough to be tailored and applied to the specific technology.

The following quote is an extract of one of the interviews in regard to the experiences made with the consideration of theories and frameworks:

"When it comes to financing an eHealth intervention it's really not easy and we spent a lot of time trying to sort of map this context and where does [the technology] fit into it. Because for example, if you would go, like, we thought our municipality would be a great place like the local government, you know, to implement because they know all the health care organizations, they have money that is specifically for prevention that the municipalities mandate from the governmentor let's say from above. But wait until you go to the municipality they love it, but they say well this isn't an intervention, this is treatment. So you would need to go to the health insurer. They go to the health insurer. You do the whole talk again and they go, "Oh, love it! Interesting." It fits all of our themes and stuff on self-management and online tools and stuff.

*But this is clearly prevention. So you need to go through this again and no one wants to pay for it.***"**

4. Discussion

4.1 Main findings

The above stated results can be summarised into the most central outcomes of our interview study. Firstly, involving external stakeholders such as experts and other companies can help to close the knowlede gap in the implementation and design process of an eHealth intervention. It was established that the companies that launched an eMental Health technology would often lack the necessary skills and knowledge in certain domains of implementation and design of an intervention. They would therefore seek help from other, external companies and experts to help to apply and integrate the relevant expertise and knowledge to their intervention. Indeed, obtaining expert knowledge from external stakeholders is a practical approach to facilitate and improve the success and effectiveness of an intervention and can help to bridge the knowledge gap between technology planning and strategic management (Peykani et al., 2022).

Moreover, it was established that assessing the needs of the technologies' end-users was beneficial to design a tailored and user-centered intervention. In fact, the established needs were largely used and applied to the design and proposition of the values of an eMental Health intervention. The most central needs that were identified and translated into the values of a technology are self-management skills, self-efficacy, trustworthiness and an ease of use. As a result of considering and applying these user needs in the design phase of the intervention, the values proposed in the technologies facilitate and offer their users support in reaching their goals (Asbjørnsen et al., 2020). However, some difficulties occurred identifying and interpreting the needs precisely during the interview conduction with the stakeholders. Even though the companies that faced these challenges were using implementation frameworks as a guide to address their stakeholders' needs, the existing frameworks only offered limited support. As a matter of fact, the common frameworks for implementation address stakeholder involvement, however, they are superficially and abstractly constructed to be generalisable and applied to a wide range of interventions (Christie et al., 2018). In this specific context, the companies lacked support in form of a more specific guide that could help them to efficiently analyse the needs of their stakeholders.

Another finding regarding the needs assessment of the companies' stakeholders is the primary focus on their end-users. While many companies mentioned their close collaboration

with stakeholders of external companies and organisations, the inquiries about identified needs of their stakeholders was almost exclusively related to the needs of their end-users – the informal caregivers. While the needs of their end-users are most salient for the design and tailoring of the intervention, investigating and identifying the needs of other stakeholders are also highly beneficial for the implementation process and sucess of an intervention (van Gemert-Pijnen et al., 2011). Thus, it can be concluded that a more holistic approach in regard to the needs assessment of stakeholders would have possibly resulted in a more effective and successful intervention.

Furthermore, a lack of pilot and usability testing during the implementation process was particularly striking. Only one of six companies conducted a pilot study, while only two of the six companies investigated and conducted usability testing before the intervention was launched onto the market. Consequently, the interviewees were able to give little to no information about the effectiveness of their eMental Health technology. This result is not only unexpected, but also surprising since various research stresses the importance of usability testing to ensure an effective and tailored product to the target group (Lyles et al., 2014; Bastien, 2010; van Gemert-Pijnen et al., 2011). Moreover, this iterative process allows an intervention to have flaws and weaknesses identified and eliminated, while enabling the intervention to be tailored and adjusted in the early phases of development (Bastien, 2010; van Gemert-Pijnen et al., 2011). By following the guidelines of implementation frameworks that address and guide usability testing - for example the CehRes roadmap (van Gemert-Pijnen et al., 2011) - the interviewed companies could have increased the effectiveness and market launch potential of their intervention.

Another central theme that emerged was the ineffective use of questionnaires and interviews during the implementation and design process of the interventions. While four out of six companies did conduct questionnaires and interviews, the application of both methods was limited solely to the target group and their patients. In other words, only informal and formal caregivers and their patients were interviewed and given questionnaires, while other stakeholders were not considered by any of the companies. Addtionally, in particular questionnaires were only administered after the launch of the intervention to receive feedback about the usability of their product, but not during the design process. This result contrasts the guidelines proposed by van Gemert-Pijnen et al. (2011), who state that all relevant stakeholders should be analysed through a contextual inquiry that entails the conduction of interviews and questionnaires. Moreover, it allows the intervention developers to obtain important information about the requirements and needs of relevant stakeholders as well as the context, strenghts and

weaknesses of their technology. By failing to adhere to these guidelines, even though some companies referred to using the CehRes roadmap (van Gemert-Pijnen et al., 2011) in their implementation process, the interviewed companies were unable to extract the maximum amount of relevant information from the stakeholders.

Lastly, generally speaking, stakeholder inclusion was highly beneficial for the interviewed companies. They gained extensive information and insights about the needs and requirements of their target group that facilitated the design process of a tailored intervention that meets their expectations. However, the approach of involving stakeholders was often unstructured and disorganised. Moreover, the interviewed companies only distinguished between their end-users and other relevant stakeholders in regard to stakeholder salience, but made no further indications about the levels of importance and relevance of other stakeholders. By following the guidelines of relevant implementation frameworks, a distinguishment of stakeholder relevance could have yielded a more holistic overview and perhaps led to a more optimised and tailored intervention.

4.2 Comparison to similar studies

These results are consistent with the findings of Kujala et al. (2020) who investigated common challenges and opportunities in regard to the implementation of eHealth services for self-management. Their main findings comprise of a poor match between the technologies and the associated stakeholders. In fact, it was found that the technologies would often suffer from technical issues, usability problems as well as a lack of functionalities. For example, users of the technologies stated that the registration process was impractical, the technology operated at a slow pace with occasional delays, and that the features of the technology were missing functionalities. Moreover, a misfit between the technology and the work tasks of health professionals was identified. These findings are in line with outcomes of the conducted interviews. First, although the lack of usability testing was crystallised in the interviews, the adverse consequences were difficult to identify and define by the companies since very little evaluation of the effectiveness and success of their interventions was performed. Second, the mismatch between the stakeholders' needs and the technology emphasises the importance of considering the requirements and demands of relevant stakeholders. As a result, the outcomes of the study by Kujala et al. (2020) help to underline that usability testing is essential for eHealth technologies to ensure a flawless and tailored product for the target group. Moreover, usablity testing largely facilitates the adherence to the intervention as a result of eliminating the relevant factors that hamper and discourage the use of a technology (Kujala et al., 2020). Finally, it can be concluded that extensive and effective stakeholder involvement largely benefits the

identifation of stakeholder needs and values. Consequently, it also promotes a larger adherence to the intervention as well as a more user-centered and tailored product.

Another study by Cresswell & Sheikh (2013) investigated the different factors that influence the implementation and adoption of eHealth technologies in organisational settings. The results mainly underline the identified shortcomings of the implementation process of the interviewed companies in our study. Firstly, in regard to technical considerations of an intervention it was found that the features that facilitate the uptake and adoption of a technology are: easy usability, early benefits, a good fit within organisational processes, as well as an easy adaptation to integrate changing needs of stakeholders. Moreover, it was identified that an on-going involvement of relevant stakeholders and the use of usability testing in the design phase of an intervention promotes that the intervention is valued and adhered to by professionals and patients (Cresswell et al., 2013). In comparison to the outcome of the interview study, some resemblance is identified in regard to the needs of the end-users and the proposed values of the technologies. In fact, a majority of the interviewed companies identified the users' needs of an easy usability and translated this into a simplistic and straight-forward design of their technology. Additionally, all companies established the importance of involving their key stakeholders in the design and implementation phase of their intervention. Nevertheless, the consideration of the stakeholders and their needs was limited and could have been extended as proposed by Cresswell et al. (2013), who claim that a successful implementation should respond to and fulfill the needs and requirements of all relevant stakeholders. The interviewed companies in our study only, however, only limited their needs assessments to a small group of stakeholders, primarily their end-users. A more adequate assessment of stakeholders and their respective needs could have therefore led to more effective and tailored interventions.

4.3 Strenghts & Limitations

Strengths of this study are a holistic approach to the interview conduction in which the researchers were able to obtain a clear overview of the background of each company, how they operate and what processes were made during the design and implementation phase of each intervention. In fact, the interview guide surpassed the mere interests of the research questions and allowed the researchers to integrate and contextualise additional information about the company into their research.

However, the study also had some limitations. Firstly, the conducted interview study yielded only a limited amount of information about stakeholder involvement. Out of the seven interviews, two interviews were pilot interviews to test and improve the interview guide.

Although the interview guide was considerably in-depth and extensive, only six companies in total were interviewed. Furthermore, the countries in which the technologies operate were only highly developed, Western European countries. Therefore, it is highly questionable how generalisable and applicable these results are to other parts of the world.

Secondly, not all interviewees had adequate knowledge about all the topics they were inquired about in the interviews. While some statements were vague and superficial, it also posed a challenge for some interviewees to specify, exemplify and provide more in-depth information about particular topics of interest. Moreover, some interviewees stated that they were not part of a particular process in the implementation phase and therefore lacked the relevant knowledge, while others referred to a colleague within their company that is more profound in the relevant domain.

Next, all interviews were conducted in a foreign language for both partners of the interview. While the English level of most interviewees was adequate, some language barriers occurred that hampered the flow of the interviews. Even though all questions were sufficiently answered, the information could have yielded a more rich and extensive outcome if conducted in the respective native language of the interview partners.

Another aspect to critise is the fact that all interviews were conducted in an online face-to-face meeting. A physical meeting would have been more personal for both interview partners. Moreover, it is likely that trust and engagement would have been facilitated by a meeting in real life, and therefore possibly produced more detailed and extensive results. Furthermore, the researchers experienced minor connection issues during the conduction of the online interviews. As a result, certain statements were cut out and required to be repeated upon request by the researchers which impaired the flow of the interview.

Lastly, it could have been useful to have inquired the companies about the success of their intervention. Since this theme was not considered in the interview guide, it poses a further challenge to generalise the findings and compare the different technologies in regard to the success and impact of involving relevant stakeholders.

4.4 Conclusion

The results of our study highlight the importance of stakeholder involvement for a successful design and implementation of an eMental Health intervention. In particular, assessing the specific needs and requirements of stakeholders is essential to develop features and values of an intervention. Moreover, stakeholders shape the design and implementation

process with their insights and allow the intervention to be effective, user-centered and tailored to their specific users and other stakeholders. While a list of theories and implementation frameworks already exist to guide intervention developers in the design and implementation process of their technologies, an even greater focus should be emphasised onto the involvement of relevant stakeholders. While most frameworks and theories do entail information and guidelines about stakeholder involvement, the importance and relevance of it may not be highlighted and emphasised enough. Even though this interview study yielded informative insights about the approach in which stakeholders were involved and which challenges had to be overcome, the results have to be considered with caution. Due to the small number of interviewed companies it poses a challenge to generalise these findings and apply them more universally to the eHealth sector. Consequently, in order to make reliable statements about the effectiveness of stakeholder involvement, more qualitative research needs to be conducted on this theme. Future research could also take into account the success and effectiveness of an intervention as a variable to make more reliable statements about the influence of stakeholder involvement and to allow for more adequate comparability.

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Appendix 1: Interview guide

Interview guide for semi-structured interviews with Implementation Specialists at eHealth organisations delivering web-based interventions to improve mental well-being of informal caregivers

Space for mutual introductions

Ok, let's start with a couple of general questions:

1) How would you describe your technology/service in a couple of sentences? (What is it, what does it do? What are the most important things to say about it?)

2) Tell me about the creative process? How did the idea come to life? (Specific need to address, ties with academia, tested for efficacy?)

3) What about the values it incarnates? (Value based design, value specification, value proposition)

Ok, thank you. Now, I would like to ask you some questions about implementation

4) What is your role in the organisation? Who else is involved in implementation (formally or informally)?

5) In which stage it is?

6) Did you follow an implementation plan?

7) Did you follow a framework or theory to guide implementation (how did you chose this one?)

8) Did Covid interfere with your implementation? (How?)

Great, now the idea is that I will present to you several general themes. I will ask you to reflect on how these themes influenced the implementation of the technology.

9) Attributes of the technology itself? Hardware? How do you deal with updates and technical support?

10) Organisational context? (Relationships with local organisations, specific implementation knowledge, etc)

11) Wider context? (Socio-political, economical, healthcare)

12) Stakeholder involvement? (Who are they, how they were identified, what is the specificity of dealing with caregivers, were they involved in design/distribution, other phases, what was the added value, describe the process, what challenges did you encounter?)

As a last question, can you think of any other technologies that I might want to involve in my case study? Is there someone else you think I would benefit from talking to?

Thank you, the interview is finished. As part as a short follow up, I will fill in a Business Model Canvas regarding your intervention and share it with you, would you be willing to complete it?

Appendix 2: Informed consent

Informed consent form for research with human participants

Dear Participant

Thank you for your permission to be interviewed.

This research is being conducted by Sofia Bastoni from the University of Twente, as part of the ENTWINE ITN Consortium (https://entwine-itn.eu).

The purpose of this interview is to understand how eHealth innovations and technologies to support Informal Care are successfully implemented in practice. Think about how implementation was handled within your organisation, what was needed for the implementation of your innovation, what stage of implementation does your innovation find itself in, who are your key stakeholders, how the technology was conceived and how does your context operate. We are interested in your professional opinion and findings, therefore there are no right or wrong answers. In connection with the duration of this assignment, we also wanted to ask if you are available for a short follow up (via email). The interview will last approximately 45 minutes, but you have the right to stop the interview at any time and without giving any explanation.

For the sake of processing this interview, we would like to record the meeting. If you are not comfortable with video recordings, you can turn off your camera at any point. With those recording(s) we can transcribe and quote the interview. All names, places and dates will be made anonymous. The recordings are stored securely according to the UT data management system for transcription of the interview. After the transcriptions, the recording will be destroyed. Some of the information or experience you will share may be confidential and you might not want it to be used for research purposes. If you do not wish for us to share certain information you can let us know so that we can handle it discreetly. The anonymised transcript

will be shared with you once completed and you can also indicate that we cannot use certain information later.

This research project has been reviewed and approved by the BMS Ethics Committee. No specific risks are envisioned with the participation to this study. Ethical procedures for scientific research, conducted by the Ethics Committee of the Faculty of Behavioral, Management and Social Sciences (BMS) of the University of Twente require that the interviewees explicitly agree to the interview and how the information will be used in their interviews. This consent form is necessary for us to ensure that you understand the purpose of your involvement and that you agree to the terms of your participation.

Therefore, please read the attached consent form and then sign this form to confirm that you agree to the following.**Consent Form for "Successfully implemented technologies to support informal care: multiple case study"**

YOU WILL BE GIVEN A COPY OF THIS INFORMED CONSENT FORM

Please tick the appropriate boxes

Taking part in the study	**Yes**	**No**
I have read and understood the study information dated 17/02/2022, or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	□	□
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time without having to provide a reason.	□	□
I understand that taking part in the study involves participating to a video recorded online interview for the duration of 45 minutes approximately and a short follow up in the form of email exchange. The recordings will be transcribed and deleted right after. I will receive the transcription and will have the possibility to retract any information that I am not comfortable with sharing.	□	□

Use of the information in the study

I understand that information I provide will be used for scientific publication ☐ ☐
purposes. The interview (s) will be analysed, and the result will be reported to
describe the implementation of eHealth solutions to support informal care.
Furthermore, the publication will be part of the researchers' doctoral dissertation.
No other use is envisioned for the data.

I understand that personal information collected about me that can identify me, ☐ ☐
such as [e.g., my name or where I live], will not be shared beyond the study team.

I agree that my information can be quoted in research outputs. ☐ ☐

I agree that my company name can be used for quotes. ☐ ☐

☐ ☐

Future use and reuse of the information by others

I give the researchers permission to keep my contact information and to contact ☐ ☐
me for future research projects.

Signatures

Micol Bronzini   17/02/22

Name of the Interviewee	Signature	Date

I have accurately read out the information sheet to the potential participant and,
to the best of my ability, ensured that the participant understands to what they are
freely consenting.

Sofia Bastoni   17/02/22

Name of the Researcher	Signature	Date

**Study contact details for further information: Sofia Bastoni, University of
Twente Drienerlolaan 5, 7522 NB, Enschede, The Netherlands. Email:
s.bastoni@utwente.nl Phone: +31 53 489 5284)**

**Contact Information for Questions about Your Rights as a Research
Participant**

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the Secretary of the Ethics Committee of the Faculty of Behavioural, Management and Social Sciences at the University of Twente by ethicscommittee-bms@utwente.nl

Appendix 3: Ethical approval

UNIVERSITY OF TWENTE.

FACULTY BMS

220018 REQUEST FOR ETHICAL REVIEW

Request nr:	220018
Researcher:	Bastoni, S.
Supervisor:	Gemert - Pijnen, J.E.W.C. van
Reviewer:	Klooster, P.M. ten
Status:	Approved by commission
Version:	2

1. START

A. TITLE AND CONTEXT OF THE RESEARCH PROJECT

1. What is the title of the research project? (max. 100 characters)

   Successfully implemented technologies to support informal care: multiple case study

2. In which context will you conduct this research?

   PhD project

3. Date of the application

   18-01-2022

5. Is this research project closely connected to a research project previously assessed by the BMS Ethics Committee?

   Yes

please provide the ethic request number(s) for the research project(s):

   211229

B. CONTACT INFORMATION

6. Contact information for the lead researcher

   6a. Initials:

   S.

   6b. Surname:

   Bastoni

   6c. Education/Department (if applicable):

   BMS-PGT

   6d. Staff or Student number:

   76683507

6e. Email address:

    s.bastoni@utwente.nl

6f. Telephone number (during the research project):

    +31534895284

6g. If additional researchers (students and/or staff) will be involved in carrying out this research, please name them:

    2 students: to be assigned

6h. Have you completed a PhD degree?

    No

7. Contact information for the BMS Supervisor

    7a. Initials:

        J.E.W.C.

    7b. Surname:

        van Gemert - Pijnen

    7c. Department:

        BMS-PGT

    7d. Email address:

        j.vangemert-pijnen@utwente.nl

    7e. Telephone number (during the research project):

        +31534896050

8. Is one of the ethics committee reviewers involved in your research? Note: not everyone is a reviewer.

    No

C. RESEARCH PROJECT DESCRIPTION

9a. Please provide a brief description (150 words max.) of the background and aim(s) of your research project in non-expert language.

    This project aims to deepen cases of successfully implemented technologies to support informal caregivers. Informants were recruited in a prior stage to recommend examples of technologies they have come across. At this stage, contact people within the technology organizations identified during the previous stage will be interviewed. The qualitative data will be analyzed though thematic analysis.

9b. Approximate starting date/end date of data collection:

        Starting date: 2022-01-22

        End date: 2022-04-29

9c. If applicable: indicate which external organization(s) has/have commissioned and/or provided funding for your research.

        Commissioning organization(s):

```
Not applicable
```

Funding organization(s):

Grant number:

2. TYPE OF STUDY

Please select the type of study you plan to conduct:

```
I will be collecting new data from individuals acting as respondents,
interviewees, participants or informants.
```

4. RESEARCH INVOLVING THE COLLECTION OF NEW DATA

A: RESEARCH POPULATION

20. Please provide a brief description of the intended research population(s):

```
At this stage of the research, professionals in the field of ehealth
technologies for caregivers will be interviewed.
```

21. How many individuals will be involved in your research?

```
We expect to interview 15 at most 20 individuals
```

22. Which characteristics must participants/sources possess in order to be included in your research?

```
There are no specific socio-demographic inclusion criteria for
interviewees at this point. However, interviewees will be
professionals in the field of eHealth for informal caregivers in
Europe.
```

23. Does this research specifically target minors (<16 years), people with cognitive impairments, people under institutional care (e.g. hospitals, nursing homes, prisons), specific ethnic groups, people in another country or any other special group that may be more vulnerable than the general population?

```
No
```

24. Are you planning to recruit participants for your research through the BMS test subject pool, SONA

```
No
```

B. METHODS OF DATA COLLECTION

25. What is the best description of your research?

- ```Interview research```

26. Please prove a brief yet sufficiently detailed overview of activities, as you would in the Procedure section of your thesis or paper. Among other things, please provide information about the information given to your research population, the manipulations (if applicable), the measures you use (at construct level), etc. in a way that is understandable for a relative lay person.

```
At this stage, interviewees will answer open questions about the
eHealth technology or innovation their company developed. The
```

questions will inquire the implementation process and planning, its relevant stakeholders, its wider context, the creative process and value proposition of the innovation. No personal questions or data regarding the individual will be collected except for their contact information and position. The interviewees will receive a copy of the transcription. As a follow up, the interviewees will be asked to check and edit (if necessary) a graphical summary of the interview (following the Business Model Canvas).

How much time will each participant spend (mention the number of sessions/meetings in which they will participate and the time per session/meeting)?

Approximately 45 minutes (each interviewee will take part in one single session) plus a maximum of 15 mins for the asynchronous follow up.

C: BURDEN AND RISKS OF PARTICIPATION

27. Please provide a brief description of these burdens and/or risks and how you plan to minimize them:

No particular risks or burdens are envisioned. The interview will be as brief as possible, on a voluntary participation basis and scheduled at the best convenience of interviewees.

28. Can the participants benefit from the research and/or their participation in any way?

No

29. Will the study expose the researcher to any risks (e.g. when collecting data in potentially dangerous environments or through dangerous activities, when dealing with sensitive or distressing topics, or when working in a setting that may pose 'lone worker' risks)?

No

D. INFORMED CONSENT

30. Will you inform potential research participants (and/or their legal repsentative(s), in case of non-competent participants) about the aims, activities, burdens and risks of the research before they decide whether to take part in the research?

Yes

Briefly clarify how:

The purpose of the study will be briefly disclosed during the recruitment of the participants (most likely through an introductory email) and deepened through the informed consent and information sheet before the interview.

32. How will you obtain the voluntary, informed consent of the research participants (or their legal repsentatives in case of non-competent participants)?

Signed

33. Will you clearly inform research participants that they can withdraw from the research at any time without explanation/justification?

Yes

Attachment: informed-consent_Multiple Case Study Bastoni_14012022_ML.pdf

34. Are the research participants somehow dependent on or in a subordinate position to the researcher(s) (e.g. students or relatives)?

> No

35. Will participants receive any rewards, incentives or payments for participating in the research?

> - No

36. In the interest of transparency, it is a good practice to inform participants about what will happen after their participation is completed. How will you inform participants about what will happen after their participation is concluded?

> - Participants will receive the researcher's contact details, so that they can contact the researcher if they have questions/would like to know more.
> - Participants will receive oral/written information about what the researcher(s) will do with the collected data.
> - Participants who indicate they are interested will receive a summary of the research results.
> - Other (Please specify):
>   > Participants will be given a copy of the interview transcript so that they can review it and possibly withdraw information they are not comfortable with sharing. They will be given the choice to just being audio recorded instead of video.

E. CONFIDENTIALITY AND ANONYMITY

37. Does the data collected contain personal identifiable information that can be traced back to specific individuals/organizations?

> Yes

38. Will all research data be anonymized before they are stored and analysed?

> No

39. Will you make use of audio or video recording?

> Yes

> • What steps have you taken to ensure safe audio/video data storage?
>   > Only the researchers involved in the project will have access to recording.

> • At what point in the research will tapes/digital recordings/files be destroyed?
>   > The files will be destroyed right after transcription, which will take place shortly after the interviews have taken place.

5. DATA MANAGEMENT

> - I have read the UT Data policy.
> - I am aware of my responsibilities for the proper handling of

data, regarding working with personal data, storage of data,
        sharing and presentation/publication of data.

6. OTHER POTENTIAL ETHICAL ISSUES/CONFLICTS OF INTEREST

40. Do you anticipate any other ethical issues/conflicts of interest in your research project that have not
been previously noted in this application? Please state any issues and explain how you propose to deal
with them. Additionally, if known indicate the purpose your results have (i.e. the results are used for e.g.
policy, management, strategic or societal purposes).

        No other ethical issues are invisioned

7. ATTACHMENTS

        informed-consent_Multiple Case Study Bastoni_14012022_ML.pdf

8. COMMENTS

        -

9. CONCLUSION

Status: Approved by commission

The BMS ethical committee / Domain Humanities & Social Sciences has assessed the ethical aspects of
your research project. On the basis of the information you provided, the committee does not have any
ethical concerns regarding this research project. It is your responsibility to ensure that the research is
carried out in line with the information provided in the application you submitted for ethical review. If you
make changes to the proposal that affect the approach to research on humans, you must resubmit the
changed project or grant agreement to the ethical committee with these changes highlighted.

Moreover, novel ethical issues may emerge while carrying out your research. It is important that you re-
consider and discuss the ethical aspects and implications of your research regularly, and that you proceed
as a responsible scientist.

Finally, your research is subject to regulations such as the EU General Data Protection Regulation (GDPR),
the Code of Conduct for the use of personal data in Scientific Research by VSNU (the Association of
Universities in the Netherlands), further codes of conduct that are applicable in your field, and the obligation
to report a security incident (data breach or otherwise) at the UT.

Informed consent form template for research with human participants

Dear Participant
Thank you for your permission to be interviewed.

This research is being conducted by Sofia Bastoni from the University of Twente, as part of the ENTWINE ITN Consortium (https://entwine-itn.eu).

The purpose of this interview is to understand how eHealth innovations and technologies to support Informal Care are successfully implemented in practice. Think about how implementation was handled within your organization, what was needed for the implementation of your innovation, what stage of implementation does your innovation find itself in, who are your key stakeholders, how the technology was conceived and how does your context operate. We are interested in your professional opinion and findings, therefore there are no right or wrong answers. In connection with the duration of this assignment, we also wanted to ask if you are available for a short follow up (via email). The interview will last approximately 45 minutes, but you have the right to stop the interview at any time and without giving any explanation.

For the sake of processing this interview, we want to record the meeting. If you are not comfortable with video recordings, you can turn off your camera at any point. With those recording(s) we can transcribe and quote the interview. All names, places and dates will be made anonymous. The recordings are stored securely according to the UT data management system for transcription of the interview. After the transcriptions, the recording will be destroyed. Some of the information or experience you wish to share may be confidential and you do not want it to be used for research purposes. If you do not want us to share certain information you can let us know so that we can handle it discreetly. The anonymized transcript will be shared with you once completed and you can also indicate that we cannot use certain information later.

This research project has been reviewed and approved by the BMS Ethics Committee and no specific risks are envisioned with the participation to this study. Ethical procedures for scientific research, conducted by the Ethics Committee of the Faculty of Behavioral, Management and Social Sciences (BMS) of the University of Twente, require that the interviewees explicitly agree to the interview and how the information will be used in their interviews. This content form is necessary for us to ensure that you understand the purpose of your involvement and that you agree to the terms of your participation.

Therefore, please read the attached consent form and then sign this form to confirm that you agree to the following

UNIVERSITY OF TWENTE.

Consent Form for Successfully implemented technologies to support informal care: multiple case study

YOU WILL BE GIVEN A COPY OF THIS INFORMED CONSENT FORM

Please tick the appropriate boxes

Taking part in the study	Yes	No
I have read and understood the study information dated [DD/MM/YYYY], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	O	O
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time without having to provide a reason.	O	O
I understand that taking part in the study involves participating to a video recorded online interview for the duration of 45 minutes approximately and a short follow up in the form of email exchange. The recordings will be transcribed and deleted right after. I will receive the transcription and will have the possibility to retract any information that I am not comfortable with sharing.	O	O

Use of the information in the study		
I understand that information I provide will be used for scientific publication purposes. The interview(s) will be analysed, and the result will be reported to describe the implementation of eHealth solutions to support informal care. Furthermore, the publication will be part of the researchers' doctoral dissertation. No other use is envisioned for the data.	O	O
I understand that personal information collected about me that can identify me, such as [e.g., my name or where I live], will not be shared beyond the study team.	O	O
I agree that my information can be quoted in research outputs.	O	O
I agree that my company name can be used for quotes.	O	O
	O	O

Future use and reuse of the information by others

	Yes	No
I give the researchers permission to keep my contact information and to contact me for future research projects.	O	O

Signatures

_____   _____   _____

Name of participant [printed]

               Signature   Date

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

_____   _____   _____

Researcher name [printed]   Signature   Date

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Study contact details for further information: Sofia Bastoni, University of Twente Drienerlolaan 5, 7522 NB, Enschede, The Netherlands. Email: s.bastoni@utwente.nl Phone: +31 53 489 5284)

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the Secretary of the Ethics Committee of the Faculty of Behavioural, Management and Social Sciences at the University of Twente by ethicscommittee-bms@utwente.nl

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